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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 435, 436, 438, 440, 447, and 457

Office of the Secretary

45 CFR Parts 155 and 156

[CMS-2334-F]

RIN 0938-AR04

Medicaid and Children's Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements provisions of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act). This final rule finalizes new Medicaid eligibility provisions; finalizes changes related to electronic Medicaid and the Children's Health Insurance Program (CHIP) eligibility notices and delegation of appeals; modernizes and streamlines existing Medicaid eligibility rules; revises CHIP rules relating to the substitution of coverage to improve the coordination of CHIP coverage with other coverage; and amends requirements for benchmark and benchmark-equivalent benefit packages consistent with sections 1937 of the Social Security Act (which we refer to as "alternative benefit plans") to ensure that these benefit packages include essential health benefits and meet certain other minimum standards. This rule also implements specific provisions including those related to authorized representatives, notices, and verification of eligibility for qualifying coverage in an eligible employer-sponsored

plan for Affordable Insurance Exchanges. This rule also updates and simplifies the complex Medicaid premium and cost sharing requirements, to promote the most effective use of services, and to assist states in identifying cost sharing flexibilities. It includes transition policies for 2014 as applicable.

DATES: The effective date for the additions of 42 CFR 435.118, 435.603, 435.911, 435.949, 435.956, 435.1200, 457.315, 457.330 and 457.348; amendments to 42 CFR 431.10, 431.11, 435.110, 435.116, 435.119, 435.907, 435.916, 435.940, 435.945, 435.948, 435.952, 457.340 and 457.350; the removal of 42 CFR 435.953 and 435.955; and the redesignation of 42 CFR 435.911 through 435.914 as 42 CFR 435.912 through 435.915 in CMS-2349 (FR Doc. 2012-6560) published on March 23, 2012, which were to become effective in January 1, 2014 are now effective October 1, 2013.

Other provisions of this final rule that are codified in title 42 of the Code of Federal Regulations are effective January 1, 2014 with the exception of amendments to the following which are effective on October 1, 2013: 42 CFR 431.10, 431.11, 431.201, 431.205, 431.206, 431.211, 431.213, 431.230, 431.231, 431.240, 435.119, 435.603, 435.907, 435.918, 435.1200, 457.110, 457.348, and 457.350; and the addition of 42 CFR 435.1205 and 457.370, which are effective on October 1, 2013. .

Regulations in this final rule that are codified in title 45 of Code of Federal Regulations are effective on [OFR—insert date 60 days from publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

Sarah deLone, (410) 786-0615, or Stephanie Kaminsky, (410) 786-4653, for provisions related to revisions to eligibility notice and fair hearing appeal processes and additional eligibility changes for Medicaid and CHIP.

Melissa Harris, (410)786-3397, for provisions related to essential health benefits.

Leigha Basini, (301) 492-4307, for provisions related to Affordable Insurance Exchanges.

SUPPLEMENTARY INFORMATION:

Executive Summary

This final rule implements provisions of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act). This rule reflects new statutory eligibility provisions, implements changes related to Medicaid and the Children's Health Insurance Program (CHIP) eligibility notices, delegation of appeals, and other related administrative procedures with similar procedures used by other health coverage programs authorized under the Affordable Care Act. This final rule also modernizes and streamlines existing rules.

This final rule amends the requirements applicable to Medicaid benefit packages that provide benchmark or benchmark-equivalent coverage, to include requirements to meet new minimum standards, including the provision of essential health benefits, as required by the Affordable Care Act. In an effort to bring consistency and clarity to part 440, we are removing the terms "benchmark and benchmark-equivalent plan" where they appear together and are replacing these terms with "Alternative Benefit Plan" (ABP).

Beginning in calendar year 2014, individuals and small businesses will be able to purchase private health insurance through competitive marketplaces called Affordable Insurance Exchanges, or "Exchanges." This final rule: (1) specifies standards related to authorized representatives, (2) outlines criteria related to the verification of enrollment in and eligibility for minimum essential coverage through an eligible employer-sponsored plan, and (3) further specifies or amends other eligibility and enrollment provisions. This final rule does not address proposed provisions regarding Exchange eligibility appeals, to provide additional time for the

careful development of standards that can be effectively implemented, particularly for those regarding coordination with Medicaid and CHIP. Additionally, this final rule does not address proposed provisions regarding the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), certified application counselors in an Exchange and SHOP coordination with individual market Exchanges. We intend to address these provisions in a future issuance. The intent of this final rule is to afford each state substantial discretion in the design and operation of the Exchange established by the state, with greater standardization provided where directed by the statute or where there are compelling practical, efficiency or consumer protection reasons.

This final rule also updates and simplifies the complex Medicaid premium and cost sharing requirements to promote the most effective use of services and to assist states in identifying cost sharing flexibilities.

Finally, this final rule provides notice that we are considering, for purposes of the initial open enrollment period for enrollment in a Qualified Health Plan through the Exchange, whether various provisions of the Medicaid and CHIP regulations should be effective October 1, 2013, or whether a later effective date is appropriate.

In this final rule, we do not address all of the proposed regulatory changes to 42 CFR parts 431, 435 and 457. We are focusing on those changes that are most needed to implement the changes made by the Affordable Care Act starting in 2014. We intend to address certain of the other provisions in future rulemaking.

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Acronyms and Terms

Because of the many organizations and terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

[the] Act Social Security Act

Affordable Care Act - The Affordable Care Act of 2010 (which is the collective term for the

Patient Protection and Affordable Care Act (Pub. L. 111-148) and the Health Care

	and Education Reconciliation Act (Pub. L. 111-152))
AFDC	Aid to Families with Dependent Children
BBA	Balanced Budget Act of 1997
BHP	Basic Health Program
CHIP	Children's Health Insurance Program
CHIPRA	Children's Health Insurance Program Reauthorization Act of 2009
CMS	Centers for Medicare & Medicaid Services
[the] Code	Internal Revenue Code of 1986
DHS	Department of Homeland Security
DOL	U.S. Department of Labor
DRA	Deficit Reduction Act of 2005
EITC	Earned Income Tax Credit
EPSDT	Early and periodic screening, diagnosis, and treatment
FEHBP	Federal Employees Health Benefits Program (5 U.S.C 8901, <u>et seq.</u>)
FFE	Federally-facilitated Exchange
FFP	Federal financial participation
FMAP	Federal medical assistance percentage
FPL	Federal poverty level
HCERA	Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152, enacted March 30, 2010)
HHS	[U.S. Department of] Health and Human Services
IHS	Indian Health Service
INA	Immigration and Nationality Act
IRA	Individual Retirement Account

IRC	Internal Revenue Code of 1986
IRS	Internal Revenue Service
MAGI	Modified adjusted gross income
MEC	Minimum Essential Coverage
MMEA	Medicare & Medicaid Extenders Act of 2010 (Pub. L. 111–309, enacted December 15, 2010)
OMB	Office of Management and Budget
OPM	U.S. Office of Personnel Management
PHS Act	Public Health Service Act
PRA	Paperwork Reduction Act of 1995
PRWORA	Personal Responsibility and Work Opportunity Reconciliation Act of 1996
QHP	Qualified Health Plan
Secretary	Secretary of HHS
SEP	Special enrollment period
SHOP	Small Business Health Options Program
SMD	State Medicaid Director
SNAP	Supplemental Nutrition Assistance Program
SPA	State Plan Amendment
SSA	Social Security Administration
SSI	Supplemental Security Income
SSN	Social Security number
TANF	Temporary Assistance for Needy Families

I. Background

A. Medicaid Eligibility Final Rule Part II

The Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010), was amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted on March 30, 2010). These laws are collectively referred to as the Affordable Care Act. In addition, section 205 of the Medicare & Medicaid Extenders Act of 2010 (Pub. L. 111–309, enacted December 15, 2010) (MMEA) and the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96, enacted February 22, 2012) made additional amendments to the Social Security Act (the Act) provisions affected by the Affordable Care Act.

The Affordable Care Act extends and simplifies Medicaid eligibility, and on March 23, 2012, we issued a final rule (referred to as the “Medicaid Eligibility final rule”) addressing certain key Medicaid and CHIP eligibility, enrollment, and renewal issues.

This final rule provides states with additional flexibility and guidance for delegation of appeals and implementation of electronic notices, and modernizes administrative procedures to further promote coordination across multiple health coverage programs, including enrollment in a qualified health plan through the Exchange with advance payments of the premium tax credits and cost-sharing reductions, as authorized by the Affordable Care Act, Medicaid and the Children’s Health Insurance Program (CHIP). These coverage programs are collectively referred to as “insurance affordability programs.” For more information on the legislative overview, please refer to the Medicaid, CHIP, and Exchanges proposed rule (78 FR 4594).

B. Essential Health Benefits in Alternative Benefit Plans

For plan, policy, or coverage years (as applicable) beginning in 2014, most health insurance coverage¹ in the individual and small group markets, Medicaid benchmark and benchmark-equivalent plans (now also known as Alternative Benefit Plans (ABPs)), and Basic

¹ For more information on status as a grandfathered health plans under the Affordable Care Act, please see Interim Final Rule, “Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan

Health Programs (if applicable) will be required to cover essential health benefits (EHBs), consistent with the definition under section 1302 of the Affordable Care Act and implementing regulations at 45 CFR Parts 147, 155, and 156, Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; Final Rule. Under that definition, EHBs include items and services in 10 statutory benefit categories, such as hospitalization, prescription drugs, and maternity and newborn care, and are equal in scope of benefits to a typical employer plan, which will constitute minimum coverage in an ABP.

C. Exchanges: Eligibility and Enrollment

1. Legislative Overview

Section 1311(b) and section 1321(b) of the Affordable Care Act provide that each state has the opportunity to establish an Exchange that: (1) facilitates the purchase of insurance coverage by qualified individuals through qualified health plans (QHPs); (2) assists qualified employers with the enrollment of their employees in QHPs; and (3) meets other standards specified in the Affordable Care Act. Section 1311(k) of the Affordable Care Act specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations promulgated by the Secretary under subtitle D of title I of the Affordable Care Act. Section 1311(d) of the Affordable Care Act describes the minimum functions of an Exchange, including the certification of QHPs.

Section 1321 of the Affordable Care Act discusses state flexibility in the operation and enforcement of Exchanges and related requirements. Section 1321(c)(1) directs the Secretary to establish and operate an Exchange within each state that either: (1) does not elect to establish an Exchange, or (2) as determined by the Secretary on or before January 1, 2013, will not have an Exchange operational by January 1, 2014. Section 1321(a) also provides broad authority for the

Secretary to issue regulations setting standards to implement the statutory requirements related to Exchanges, QHPs, and other standards under title I of the Affordable Care Act.

Section 1401 of the Affordable Care Act creates new section 36B of the Internal Revenue Code of 1986 (the Code), which provides for a premium tax credit for eligible individuals who enroll in a QHP through an Exchange. Section 1402 of the Affordable Care Act establishes requirements for reducing the cost-sharing obligations of eligible individuals who enroll in a QHP through an Exchange, including special cost-sharing rules for certain Indians.

Under section 1411 of the Affordable Care Act, the Secretary is directed to establish a program for determining whether an individual meets the eligibility standards for enrollment in QHPs through the Exchange, advance payments of the premium tax credit, cost-sharing reductions, and exemptions from the shared responsibility payment under section 5000A of the Code.

Sections 1412 and 1413 of the Affordable Care Act and section 1943 of the Social Security Act (the Act), as added by section 2201 of the Affordable Care Act, contain additional provisions regarding eligibility for advance payments of the premium tax credit and cost-sharing reductions, as well as provisions regarding simplification and coordination of eligibility determinations and enrollment with other insurance affordability programs.

This final rule supplements and amends provisions originally published as the March 27, 2012 rule titled “Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers” (hereafter referred to as “Exchange Final Rule”) (77 FR 18310) which encompasses key functions of Exchanges related to eligibility and enrollment.

Unless otherwise specified, the provisions in this final rule related to the establishment of minimum functions of an Exchange are based on the general authority of the Secretary under section 1321(a)(1) of the Affordable Care Act.

2. Stakeholder Consultation and Input

HHS has consulted with interested stakeholders on policies related to the eligibility provisions and Exchange functions. HHS held a number of listening sessions with consumers, providers, employers, health plans, and state representatives to gather public input, and released several documents for public review and comment. HHS also released a bulletin that outlined our intended regulatory approach to verifying access to employer-sponsored coverage and sought public comment on the specific approaches.

Finally, HHS consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with states through the Exchange grant process, consultation with Medicaid directors, and meetings with tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties.

We considered input from these stakeholder meetings and in response to the bulletin on verifying access to employer-sponsored coverage, as well as comments provided in response to the proposed rule as we developed the policies in this final rule.

3. Structure of the Final Rule

The regulations related to Exchanges and QHPs outlined in this final rule are codified at 45 CFR parts 155 and 156. Part 155 outlines the standards related to eligibility for insurance affordability programs to facilitate a streamlined process for eligibility for enrollment in a QHP through the Exchange and in insurance affordability programs. Part 156 outlines the standards for health insurance issuers for participation in an Exchange. This final rule:

- Revises existing definitions and finalizes new definitions to 45 CFR part 155 subpart A.
- Provides a technical correction to 45 CFR part 155 subpart B.
- Finalizes standards related to authorized representatives under 45 CFR part 155 subpart C.
- Finalizes standards related to eligibility determinations for enrollment in a QHP and for insurance affordability programs under 45 CFR part 155 subpart D.
- Finalizes standards related to enrollment-related transactions, special enrollment periods, and terminations under 45 CFR part 155 subpart E.
- Finalizes standards related to termination of coverage under 45 CFR part 156 subpart C.

4. Alignment with Related Rules and Published Information

As noted above, on March 27, 2012, we published the Exchange final rule. This final rule revises and supplements the Exchange final rule, including by finalizing Exchange and Medicaid provisions associated with the eligibility changes under the Affordable Care Act of 2010.

D. Medicaid Premiums and Cost Sharing

Section 1916 of the Act describes long-standing limitations and requirements applicable in states that elect to provide for premiums and other cost sharing under Medicaid. Under section 1916 of the Act, certain individuals are protected from premiums and cost sharing, and cost sharing cannot be imposed on certain services. Permissible cost sharing under section 1916 of the Act is limited to “nominal” amounts (except in some circumstances for non-emergency use of a hospital emergency room). Section 1916 of the Act also establishes authority for states to impose premiums on medically needy beneficiaries and specific groups of individuals with

family incomes above 150 percent of the federal poverty level (FPL). The Deficit Reduction Act of 2005 (DRA) established a new section 1916A of the Act, which gives states additional flexibility, allowing for alternative premiums and cost sharing beyond what is permitted under section 1916 of the Act for somewhat higher income beneficiaries. Such alternative cost-sharing approaches may be targeted to specific groups of individuals and payment may be required as a condition of providing services. All premiums and cost sharing imposed under sections 1916 and 1916A of the Act cannot exceed 5 percent of a family's income. For more background information on the streamlined and expanded flexibility regarding premiums and cost sharing, please refer to (78 FR 4657 and 78 FR 4658).

We initially implemented the DRA authorities through regulations that mirrored the dual statutory provisions by adding a set of additional regulations on alternative cost sharing under section 1916A of the Act to existing regulations setting forth the framework for cost sharing under section 1916 of the Act. We believe states found this duality confusing and, in this final rule, we have integrated the two statutory authorities for premiums and cost sharing (sections 1916 and 1916A of the Act) into a unified framework.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

A. Medicaid Eligibility Part II Final Rule

In the January 22, 2013 **Federal Register** (78 FR 4594), we published the proposed rule entitled “Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing.”

We received a total of 741 timely comments from individuals, state Medicaid and CHIP agencies, advocacy groups, tribes and tribal organizations, policy and research organizations,

health care providers, employers, insurers, and health care associations. The comments ranged from general support or opposition to the proposed provisions to very specific questions or comments regarding the proposed changes.

In this final rule, we are only addressing some of the provisions of the proposed rule. We are reserving action on other provisions and intend to address those provisions in a subsequent final rule. We discuss below only those public comments associated with provisions addressed in this final rule.

We have revised some of the proposed regulations after careful consideration of the comments received. Some comments were outside the scope of the proposed rule, and therefore, are not addressed in this final rule. In some instances, commenters raised policy or operational issues that will be addressed through forthcoming regulatory and subregulatory guidance to be provided subsequent to this final rule; therefore, some, but not all comments are addressed in the preamble to this final rule.

Brief summaries of the proposed provisions that are being finalized in this rule, a summary of the public comments we received on those provisions (except specific comments on the paperwork burden or the economic impact analysis), and our responses to the comments are as follows. Comments related to the paperwork burden and the impact analyses are addressed in the “Collection of Information Requirements” and “Regulatory Impact Analysis” sections in this final rule.

The following sections summarize comments about the rule in general, as well as specific comments about certain policies. . It should be noted that the summarized comments are structured to explain the provisions being finalized and do not necessarily follow the order of the regulation text:

1. Responses to General Comments

Generally, commenters were supportive of the policies in the proposed rule to continue the process of streamlining Medicaid and CHIP eligibility rules, policies and procedures; to support a consumer friendly approach, and provide increased flexibility for states.

Comment: Several commenters were concerned about the complexity of the proposed rules and the significance of the changes that need to be made to fully implement the provisions of the Affordable Care Act. Many commenters were concerned about the short timeframes for implementation and about states' ability to make needed changes to policy, operations, and information technology systems.

Response: We recognize that the timing of this final rule may result in implementation challenges, especially from a systems perspective. As such, we have evaluated the provisions of the January proposed rule and are finalizing in this rule only those provisions that we believe states are already in the process of implementing or must be finalized to meet statutory deadlines. The remaining provisions of the proposed rule will be addressed at a later date.

We will continue to work with states to support their implementation efforts, ensure successful partnerships between states and the federal government. We will also continue to offer intensive technical assistance and support to states, and facilitate sharing of experience and knowledge across states. Consistent with one commenter's recommendation, we will also utilize other tools, including subregulatory guidance and the State Operations and Technical Assistance (SOTA) initiative to address additional state questions that arise.

2. Appeals - Delegation of Authority to Conduct Medicaid Fair Hearings

We proposed to implement sections 1413 and 2201 of the Affordable Care Act in part through procedures to coordinate Medicaid fair hearings under section 1902(a)(3) of the Act concerning eligibility for populations whose income is determined using modified adjusted gross income (MAGI)-based methodologies of the Act with appeals of eligibility determinations that

are made using MAGI-based methodologies by Exchanges for advance payment of premium tax credits and cost-sharing reductions under section 1411(f) of the Affordable Care Act. Consistent with the requirements to streamline and coordinate eligibility determinations, under section 1943(b)(3) of the Act, as added by section 2201 of the Affordable Care Act, we proposed to provide states with an option to delegate the authority to conduct appeals to an Exchange or Exchange appeals entity. The option is similar to the option states have to delegate Medicaid eligibility determinations to an Exchange under §431.10. We also proposed changes to existing regulations at part 431 subpart E to support further modernization and streamlining of the Medicaid fair hearing process.

In this final rule, we are finalizing the provisions of our proposed rule related to delegation of authority to conduct Medicaid fair hearings to an Exchange and an Exchange appeals entity at sections §§431.10, 431.205(b), 431.206(d) and (e), 431.240 and the proposed rule related to reinstatement of an application at §§435.907(h) and 457.340(a). As discussed in section II.A.3. of this final rule (relating to notices), we also are adopting proposed revisions to the current regulations at sections §§431.211, 431.213, 431.230, and 431.231, related to modernizing the process of providing notices to applicants and beneficiaries of their fair hearing rights and decisions. In addition to providing substantive comments on the proposed regulations related to coordination of appeals across the Exchange, Medicaid and CHIP, a number of commenters requested delayed implementation of those provisions. To provide states with additional time to consider and effectuate implementation of such coordination, as well as to provide us with additional time to consider the comments received, we are not addressing proposed provisions at §§431.200, 431, 201, 431.205(e), 431.206(b), (c)(2), (e) as it relates to accessibility under §435.905(b), 431.210, 431.220, 431.221, 431.224, 431.232, 431.241, 431.242, or 431.244. Further, we are not addressing the definitions related to appeals proposed

in 435.4, nor the provisions related to coordination of appeals in §435.1200. We expect to address these proposed provisions in a subsequent rulemaking. Until final regulations are released, current rules in part 431, subpart E continue to apply. We note that while we are not finalizing our proposed rules relating to accessibility in the fair hearing process or as it relates appeals and notices at §431.205(e) and §431.206(e) at this time, fair hearing processes and notices must continue to be provided in an accessible manner in accordance with relevant federal statutes, including the Americans with Disabilities Act and Title VI of the Civil Rights Act of 1964, as well as any applicable state laws.

We received the following comments regarding the proposed regulations related to delegation of fair hearings and reinstatement of applications in certain circumstances, which we are addressing in this rulemaking:

Comment: Many commenters supported our approach to permit delegation of fair hearings to an Exchange or Exchange appeals entity so that an integrated hearing could be conducted to address Medicaid and Exchange-related eligibility issues together. We also received comments supporting the proposals to streamline and simplify our current fair hearings rules. While not providing specific recommendations, the commenters asked that we consider additional measures to coordinate Medicaid and Exchange eligibility appeals even more effectively. A few commenters requested that the final rule maintain state flexibility for states to retain the Medicaid appeals function within the Medicaid agency.

Several commenters were concerned that our proposed rules require duplicative processes because states must maintain the infrastructure and capacity to hear MAGI-based appeals, even if the state delegates the authority to conduct fair hearings to an Exchange. One commenter requested that we eliminate the requirement at proposed §431.10(c)(1)(ii) and §431.205(b)(1)(ii) that an individual be provided an opportunity to request a fair hearing before

the Medicaid agency when the state has otherwise delegated authority to conduct the individual's fair hearing to the Exchange, and instead make this provision a state option. The commenter believed that this requirement would undermine the efficiencies achieved through delegation. Another commenter recommended that only one hearing opportunity be made available to individuals, instead of requiring a hearing if determined ineligible for Medicaid and a hearing related to the eligibility for advance payment of premium tax credits and cost-sharing reductions.

Response: We appreciate the support for the proposal to permit states to delegate MAGI-based eligibility appeals to an Exchange or Exchange appeals entity. We note that such delegation is at state option. States are not required to delegate such authority, but may continue to have the Medicaid agency conduct all Medicaid fair hearings.

We understand commenters' concern about duplication of effort in requiring that Medicaid agencies retain an infrastructure independent of the Exchange appeals process to conduct MAGI-based Medicaid eligibility appeals when the state has delegated authority for MAGI-based eligibility appeals to an Exchange. There are two key reasons why the Medicaid agency must maintain its own appeals infrastructure. First, an individual whose application for Medicaid is denied or not acted upon with reasonable promptness has a right under section 1902(a)(3) of the Act to an opportunity for a fair hearing before the Medicaid agency. We do not anticipate that individuals will necessarily prefer to have their appeal heard by the Medicaid agency, but the statute requires that the option be provided in such delegation through our regulations. Second, in a state where the Federally-facilitated Exchange (FFE) is operating, the HHS appeals entity will only conduct appeals related to MAGI-based eligibility determinations made by the FFE. Thus, in states where the FFE is operating, the Medicaid agency will need to conduct all Medicaid fair hearings related to MAGI-based eligibility determinations made by the Medicaid agency. For these reasons, we are finalizing the requirement as proposed.

States have options to streamline the appeals infrastructure and reduce the number of appeals that will come before the Medicaid agency, in addition to the options to delegate Medicaid appeals authority under this final rule as discussed above. In a state that has established a state-based Exchange, the state Medicaid agency may delegate authority to conduct fair hearings of MAGI-based determinations to the state-based Exchange by requesting a waiver under the Intergovernmental Cooperation Act of 1968 (ICA), as long as the state-based Exchange is a state agency and the state can assure sufficient oversight of the delegated fair hearing process. As we noted in the preamble to the proposed rule, when a state has an ICA waiver permitting delegation of fair hearings to another state agency, the state is not required to offer individuals an option to have their hearing conducted by the Medicaid agency.

In states where the FFE is operating, a state Medicaid agency that allows the FFE to make a Medicaid eligibility determination delegating such authority under §431.10(c)(1)(i) has appeal delegation options not available to a State that proceeds with the assessment model. If the Medicaid agency authorizes the FFE to make MAGI-based eligibility determinations, the agency may also delegate authority to the HHS appeals entity to conduct fair hearings related to determinations of Medicaid ineligibility made by the FFE, establishing an integrated appeals process with simultaneous appeals related to a determination of advance payments of the premium tax credits or cost-sharing reductions. The Medicaid agency would still need to maintain the ability to conduct fair hearings for eligibility determinations and denials made by the Medicaid agency, as well as when delegations are made under these regulations for individuals who opt out of a coordinated appeal before the Exchange or Exchange appeals entity, and specifically request a hearing before the Medicaid agency. States will also need to continue to conduct fair hearings related to non-MAGI based eligibility determinations, as well as fair

hearings related to termination, suspension, or reduction of covered benefits and other adverse determinations.

Finally, with respect to the recommendation that a right to only one hearing be made available, we note that there are two separate statutory authorities for appeals related to Medicaid and enrollment in a QHP and eligibility for APTC and cost sharing reductions, at section 1902(a)(3) of the Act and section 1411(f) of the Affordable Care Act, respectively. While we permit states to integrate these hearings and processes as much as possible, both state Medicaid agencies and the Exchange have distinct responsibilities to provide for such hearings, and we do not have authority to eliminate individuals' statutory rights, or a Medicaid agency's or Exchange's statutory responsibility. We note that we are not addressing in this final rule the proposed requirements relating to coordination of notices. Those proposed rules will be addressed in future rulemaking.

Comment: Several commenters requested clarification of our proposals on delegation of Medicaid appeals to the FFE, a state-based Exchange, or a state with a partnership with the FFE. In addition, commenters sought clarification regarding when an individual's appeals rights are triggered in states which have delegated authority to make Medicaid eligibility determinations to the Exchange versus states in which the Exchange will make only an assessment of potential Medicaid eligibility. A few commenters requested clarification about whether a delegation of authority to conduct Medicaid fair hearings to a state-based Exchange would extend to an appeal to the HHS appeals entity. The commenters were concerned that appeals could not be coordinated at the HHS appeals entity, rendering meaningless any efforts to achieve coordination at the state level.

Response: States may choose to delegate authority to conduct Medicaid fair hearings for MAGI-based eligibility determinations to the Exchange operating in the state regardless of

whether the Exchange is the FFE, the state-based Exchange or a partnership between the state and the FFE in accordance with the final rules at §431.10(c) and (d). There is no difference in the delegation authority under the regulations, as proposed or as finalized, based on the type of Exchange. In accordance with such delegation, the Exchange or Exchange appeals entity may provide a fair hearing on Medicaid issues, but individuals must have the option to have their Medicaid fair hearing heard directly before the single state agency. As discussed below, states with state-based Exchanges that are state governmental agencies also have an additional way to coordinate appeals, beyond delegation under our rules, through a waiver granted under the Intergovernmental Cooperation Act. Under such a waiver, individuals would not have a right to have their Medicaid appeal heard by the single state agency.

In a state that has delegated authority to the Exchange to make Medicaid eligibility determinations based on MAGI, individuals have the right to request a fair hearing when the Exchange has determined the individual ineligible for Medicaid based on MAGI. Thus, the determination of ineligibility by the Exchange will trigger the individual's appeal rights. If the state has delegated authority to the Exchange to conduct fair hearings under these regulations, such an individual found ineligible for Medicaid by the Exchange could request a fair hearing at the Exchange or Exchange appeals entity so that there would be one integrated hearing conducting the Exchange-related and Medicaid appeals at the same time, or the individual may instead request his or her Medicaid issue be heard at the Medicaid agency. If, an individual who is found by the Exchange to be not eligible for Medicaid based on MAGI seeks a determination based on non-MAGI criteria, the individual's electronic account is transferred to the Medicaid agency for a full evaluation by the agency in accordance with §155.345(b) or (c) of the March 2012 Exchange eligibility final rule. If the Medicaid agency still determines the individual

ineligible, he or she would be able to appeal that decision using the Medicaid agency's fair hearing process.

In states in which the Exchange will make an assessment of Medicaid eligibility, and will not make final Medicaid eligibility determinations or denials, an assessment of ineligibility for Medicaid based on MAGI will not trigger Medicaid appeal rights. This is because an assessment is not a final Medicaid eligibility determination. As indicated in §155.302(b)(4) of the March 2012 Exchange rule, as revised in this rulemaking, applicants assessed by the Exchange as not potentially eligible for Medicaid based on MAGI but as potentially eligible for Medicaid on another basis will be transferred to the Medicaid agency for a full Medicaid determination; for these applicants, Medicaid appeal rights will be triggered when the Medicaid agency makes a final eligibility determination. Under §155.302(b)(4), applicants assessed as not potentially eligible for Medicaid on any basis will have a choice whether to withdraw their Medicaid application or obtain a full determination by the Medicaid agency. If the applicant withdraws his or her Medicaid application, a final determination or denial of Medicaid will not be made, and therefore no appeal rights arise at that point. (The applicant will have the ability to reinstate their Medicaid application in certain circumstances, discussed more fully below). When an applicant obtains a formal determination by the Medicaid agency, the Medicaid agency's determination will trigger appeal rights, if applicable.

Finally, if a state agency delegates authority to conduct MAGI-based eligibility appeals to an Exchange, including a state-based Exchange, in accordance with §431.10(c) and (d) of this final rule, such a delegation would extend to any government agency adjudicating an Exchange appeal, including the HHS appeals entity. We note, however, that if a state delegates authority to conduct fair hearings through an ICA waiver to another state agency, including a state-based Exchange or state-based Exchange appeals entity, Medicaid decisions made by that entity could

not be appealed to the HHS appeals entity. The ICA waiver is a waiver of single state agency requirements that permits alternative arrangements of state agency functions to another state agency. Once such an agency has issued a decision after a Medicaid fair hearing, that Medicaid decision would be the final decision of the Medicaid agency and thus no further right of appeal would be available to the individual. If the individual decided to appeal his or her advance payment of premium tax credit, cost-sharing reduction or Exchange eligibility decision to the HHS appeals entity, that entity would need to adhere to the Medicaid appeals entity decision under §155.302(b)(5), as revised in this final rule, and §155.345(h) which will prevent inconsistent decisions between the HHS appeals entity and the state-based Exchange or Exchange appeals entity.

Comment: Many commenters requested clarification on the scope of fair hearings that may be delegated from a Medicaid agency to an Exchange or Exchange appeals entity. Commenters specifically requested clarification regarding whether fair hearings of eligibility determinations on bases other than MAGI may be delegated to an Exchange or Exchange appeals entity, and whether findings other than MAGI-based income determinations may be delegated to an Exchange or Exchange appeals entity.

Response: The term “MAGI-based determinations” is used to refer to determinations in which financial eligibility is determined using the MAGI-based methods described in §435.603 of the March 2012 final Medicaid eligibility rule. However, in accordance with §435.911(c) of the March 2012 final Medicaid eligibility rule, a determination of eligibility based on MAGI also entails a determination that an individual meets the non-financial conditions of eligibility, including state residency and citizenship or satisfactory immigration status, and the denial of eligibility for an individual considered for coverage under a MAGI-based eligibility group may be based on failure to meet any of the financial or non-financial conditions of eligibility. A

delegation of fair hearing authority under §431.10(c)(1)(ii) to an Exchange or Exchange appeals entity regarding a denial of MAGI-based eligibility will need to address any or all of the bases of denial, just as a fair hearing conducted by the Medicaid agency would. We note that we have made some technical modifications to the regulation text at §431.10(c)(1)(ii) to help clarify this point. As also noted in the preamble to the proposed rule, we remind states that while all appeals for an individual with a MAGI-based eligibility determination may be delegated to an Exchange or Exchange appeals entity under the regulation at §431.10(c)(1)(ii), the FFE will only accept a delegation of appeals involving determinations rendered by the FFE.

The permissible scope of delegation under §431.10(c)(1)(ii) to an Exchange or Exchange appeals entity is limited to appeals of MAGI-based eligibility determinations. Appeals related to denials of eligibility for individuals excepted from application of MAGI-based methodologies (for example, eligibility based on disability) may not be delegated under the regulation. As discussed above, states may delegate such appeals to another state agency, including a state-based Exchange, by requesting an ICA waiver.

Comment: One commenter asked whether there is a timeframe under which the individual must request a fair hearing before the Medicaid agency to effectuate the requirement under §431.10(c)(1)(ii) that the state agency must provide an individual an option to have his or her Medicaid appeal conducted at the Medicaid agency when delegating authority to conduct fair hearings to an Exchange or Exchange appeals entity.

Response: An individual must be provided the opportunity to opt to have his or her Medicaid appeal adjudicated at a hearing conducted at the Medicaid agency, instead of having his or her appeal for both enrollment in a QHP and eligibility for APTC and CSR and eligibility for Medicaid addressed at an integrated hearing at the Exchange or Exchange appeals entity. Section 431.206(d) specifies that the individual must be informed of how to exercise this right.

We note that we clarify our proposed regulation at §431.206(d) to require that individuals must be informed of this option in writing. We are revising the regulation text at §431.10(c)(1)(ii) to clarify that the request for a hearing before the Medicaid agency would need to be requested instead of the Exchange hearing. While we are not specifying a specific timeframe, we would expect that if an individual was opting for a hearing before the Medicaid agency, that request would be made at the time that the individual is requesting a hearing. Thus, we finalize these proposed regulations with these minor modifications.

Comment: Many commenters believed that delegation of fair hearing authority under the regulation should be permitted. Some of the commenters emphasized the need to permit delegation only in the simplest manner reducing burden to the consumer, and without any duplication of appeals processes. A few commenters suggested we permit delegation under the regulation only to an independent state agency employing Administrative Law Judges, and that delegation to any other state agency still require an ICA waiver to ensure transparency and opportunity for stakeholder input. A few commenters asked for clarification of the conditions and process required when requesting an ICA waiver. One commenter opposed delegation of authority to conduct fair hearings to any other state or Exchange entity stating that any delegation is duplicative, as state agencies still will be required to conduct Medicaid MAGI-based hearings.

Response: Under proposed §431.10(c)(1)(ii), states would be able to delegate authority to conduct MAGI-based fair hearings to an Exchange or Exchange appeals entity, but to delegate Medicaid fair hearings to another state agency, states would need to request an ICA waiver. We sought comment on whether states also should be permitted to delegate authority to conduct fair hearings to another state agency under the regulation.

The purpose of the proposed rule is to promote coordination of appeals and simplification of the appeals process by permitting delegation of Medicaid appeals to the Exchange or Exchange appeals entity. Because coordination between insurance affordability programs is a key goal of the Affordable Care Act, we are finalizing, with minor modifications, the proposed regulations at §431.10(c)(1)(ii) and at §431.205(b)(1)(ii) to permit delegation of authority to conduct Medicaid fair hearings for denials of MAGI-based eligibility to the Exchange or Exchange appeals entity, including the FFE, state-based Exchange or HHS or state-based Exchange appeals entity, provided these entities are government agencies or public authorities that maintain personnel standards on a merit basis. After consideration of the comments, we have determined not to extend authority to delegate Medicaid fair hearings to state agencies other than a state-based Exchange or an Exchange appeals entity under the regulations because it is already allowed through an ICA waiver. We note that the main goal and justification for the delegation of fair hearings under the regulation is to achieve coordination across insurance affordability programs, something which would not be served by delegation to another state agency. Furthermore, Medicaid agencies already can delegate conduct of fair hearings to other state agencies through an ICA waiver, and there is nothing additional that states would be able to accomplish through delegation under the regulation as opposed to an ICA waiver. Indeed, the flexibility available to states under an ICA waiver is greater than that which is available under the regulation since delegation of fair hearings under an ICA waiver does not require that states provide individuals a right to opt for a hearing before the Medicaid agency, nor would the delegation be limited to MAGI-related appeals.

We have and will continue to apply similar conditions to the delegation of fair hearings under an ICA waiver as those we require under §431.10(c) and (d). As explained in the proposed rule, an ICA waiver may be requested through a straightforward process using a state

plan amendment (SPA), and CMS staff is available to provide technical assistance to states in completing that process. We note that our rules relating to hearing officers do not require that hearing officers be Administrative Law Judges or set any particular qualifications for hearing officers other than impartiality. States have flexibility to set such requirements in implementing fair hearings as they see appropriate. Thus, we do not set standards regarding the qualifications of hearing officers for states that delegate authority to conduct fair hearings or specify rules if the state agency employs Administrative Law Judges in this final rule.

Comment: One commenter expressed concern that the proposal to remove §431.10(e)(2) and (e)(3) weakens the single state agency authority when delegating authority to conduct appeals to another agency. Other commenters supported the removal of those paragraphs because they are inconsistent with the goals of delegation of authority of appeals.

Response: We are finalizing our proposal to remove paragraphs §431.10(e)(2) and (e)(3) as they are inconsistent with the option to delegate the authority to conduct fair hearings to an Exchange. We believe that the proposed language in §431.10(e), which we are finalizing without modification, clearly provides that only the Medicaid agency may develop and issue rules and policy related to the Medicaid program.

Comment: Several commenters requested clarification of the kinds of conclusions of law that could be subject to review by the agency under §431.10(c)(3)(iii). They also asked how the agency review process a state may establish to decisions made by an Exchange or Exchange appeals entity conducting Medicaid fair hearings under this provision relates to the “trumping rule” at §155.302(b)(5), which provides that if an appeals decision rendered by the Exchange or Exchange appeals entity conflicts with a fair hearing decision concerning the same individual rendered by the Medicaid agency, the Exchange must adhere to the Medicaid fair hearing decision. A number of commenters supported the limitation of the agency review process to

conclusions of law. One commenter requested that the option be extended to findings of fact. Others recommend that the option be eliminated altogether. These commenters discussed that any review by the state agency of a hearing officer's legal or factual conclusions would violate the due process protections afforded under Goldberg v. Kelly to have the appeal decided by a neutral arbiter. One commenter suggested that the regulation at §431.10(c) specify the timeframe in which the Exchange or Exchange appeals entity be required to issue a decision for the state agency to complete its review within the time limits set forth in §431.244.

Response: We are finalizing this provision as proposed with minor revisions to clarify the scope of the review process. We note the provision at §431.10(c)(3)(iii) is a state option for Medicaid agencies to establish a process that permits a limited review of the decisions made by the Exchange or Exchange appeals entity to ensure Medicaid fair hearings are made with the proper application of federal and state Medicaid law and regulations, including subregulatory guidance and written interpretive policies. The proposed regulation text is being revised to clarify the scope of what the agency may review would be limited to the legal conclusions made during the fair hearing to ensure that they appropriately apply federal and state Medicaid law and regulations, including subregulatory guidance and written interpretive policies properly and that the review process be conducted by an impartial official who was not directly involved in the initial determination.

By way of example, suppose that the Exchange hearing officer finds that an individual has \$800 in wages and \$200 in child support income each month and, based on these amounts, concludes that the individual's MAGI-based household income is \$1,000 per month. Suppose also that the applicable income standard for the applicable household size for this individual is \$900 per month, and that the hearing officer upholds the initial denial of eligibility. The findings of \$800 in wages and \$200 of child support per month would be factual findings, which the

Medicaid agency could not review under the option provided at §431.10(c)(3)(iii). However, the hearing officer's inclusion of the wages and child support income in total MAGI-based household income involves an application of MAGI-based methodologies, described in §435.603 of the March 2012 Medicaid eligibility final rule, as implemented by the state, which would be reviewable as a conclusion of law. In this case, the inclusion of wages would be correct, but the inclusion of child support income would be incorrect, and the agency upon finding such an erroneous application of state or federal rules could reverse the hearing officer's decision to conclude that, based on household income of \$800, the individual is Medicaid eligible.

Because of the important role that an impartial hearing officer plays in evaluating evidence and weighing credibility in making findings of fact, we are not extending the option at §431.10(c)(3)(iii) to include agency review of findings of fact. We note that fair hearings conducted under a delegation of authority in accordance with §431.10(c)(1)(ii) must be conducted in accordance with §431.10(d)(1), which requires that the delegation agreement between the agency and the Exchange or Exchange appeals entity must set forth the responsibilities of each party to effectuate the provisions of part 431 subpart E of the regulations. Section 431.205(d) provides that the fair hearing process under subpart E must meet the due process standards set forth in Goldberg v. Kelly, 397 U.S. 254 (1970), which requires that any review process be conducted by an impartial official, and be based solely on the information and evidence in the record. We have made a minor modification to §431.205(b)(1)(ii) to clarify that the hearing process provided through delegation of authority to conduct a fair hearing to an Exchange or Exchange appeals entity would include the review by the agency of the Exchange or Exchange appeal entity's application of federal and state Medicaid law and regulations, if such review is elected by the state under §431.10(c)(3)(iii) and

conducted by an impartial official who was not directly involved in the initial determination. We note also that the state's election under §435.10(c)(3)(iii) to conduct this limited review does not create a right for the individual to request or receive a de novo hearing before the agency.

The review process that can be established under §431.10(c)(3)(iii) functions completely independently from the “trumping rule” at §155.302(b)(5) of the Exchange proposed rule. The former comes into play when an individual's fair hearing has been delegated to, and is heard by, the Exchange or Exchange appeals entity. The “trumping rule” at §155.302(b)(5) as modified by this rulemaking and at §155.345(h) is invoked when the Medicaid agency has conducted the Medicaid fair hearing relating to the appeal of a denial of Medicaid eligibility and the Exchange or Exchange appeals entity also has conducted a hearing related to an appeal of an award of advance payments of premium tax credits. Similar to the “trumping rule” at §155.302(b)(5) of the March 2012 Exchange final rule relating to initial eligibility determinations, if the Medicaid agency's fair hearing decision conflicts with the Exchange appeals decision, the Exchange must adhere to the Medicaid agency or fair hearing decision for Medicaid eligibility under §155.302(b)(5) and §155.345(h).

Finally, we do not believe it is necessary to require in the Medicaid regulations specified timeframes within which an Exchange, in conducting a delegated fair hearing, must transmit a decision to the Medicaid agency. Instead, as part of the agreement required under §431.10(d), in delegating the fair hearing authority to the Exchange or Exchange appeals entity, the parties will need to stipulate each party's responsibilities to ensure that the time frames established under §431.244(f) are met.

Comment: One commenter sought clarification of whether the review process of appeal decisions made by the Exchange which the commenter expressed as “required” at

§431.10(c)(3)(iii) is considered in the agency's quality assurance Payment Error Rate Measurement (PERM) sampling.

Response: The regulation at §431.10(c)(3)(iii) does not set a requirement, but provides states an option to establish a review process of appeal decisions as a part of its oversight of the delegation of authority to conduct fair hearings to an Exchange or Exchange appeals entity. We note the agency has other means to oversee its delegation of authority to conduct hearings. Implications for PERM are beyond the scope of this regulation; we intend to issue additional guidance on PERM.

Comment: Many commenters supported the reinstatement of an individual's Medicaid application at §435.907(h) when the individual had withdrawn his or her application after an assessment of Medicaid ineligibility by the Exchange, appealed the level of APTC and CSR awarded by the Exchange, and the Exchange or Exchange appeals entity reversed the initial assessment and found the individual to be potentially eligible for Medicaid. A few commenters sought clarification regarding the retroactive nature of the reinstatement effective as of the date the individual submitted the application to the Exchange. Another commenter asked how this provision relates to the timeliness requirements for Medicaid agencies to process an application under §435.912 of the March 2012 Medicaid eligibility final rule. A few commenters raised a concern that if an Exchange appeals entity hearing officer upholds the finding of eligibility for advance payment for premium tax credit, the reinstatement would not take effect. These commenters recommended that the Medicaid application be reinstated whenever an individual files an appeal with the Exchange or Exchange appeals entity to capture a broader set of individuals who may be eligible for Medicaid or CHIP.

Response: We appreciate the support for the provision at §435.907(h) to reinstate the Medicaid application of an individual who has withdrawn his or her Medicaid application upon

initial assessment of Medicaid ineligibility by the Exchange, but who is subsequently assessed as potentially Medicaid eligible following an appeal related to an award of advance payments of the premium tax credits or cost sharing reductions. We are finalizing this provision as proposed, except to clarify that the 45-day or 90-day timeliness standards do not apply to these reinstated applications. By the time the Exchange appeal decision is rendered, 45 or 90 days from the date of application may already have elapsed, making compliance by the Medicaid agency unrealistic. Instead we clarify that the timeliness standards required under §435.912 of the March 2012 Medicaid eligibility final rule apply based on the date the application is reinstated. However, we note that the 45 and 90 days prescribed in the regulation represent the outer limit for all applications. In the case of a reinstated application which has been the subject of an Exchange appeal, we would expect that the individual's electronic account would be comprehensive, and that considerably less time would be needed for the Medicaid agency to act on the case. We would expect states to take this into account in establishing timeliness standards for prompt determinations on reinstated applications under §435.911(c) and §435.912 of the March 2012 Medicaid eligibility final rule. The reinstated application must be made effective retroactive to the date the individual submitted his or her application to the Exchange (not the date the application is reinstated) to protect the effective date of coverage required under §435.914 of the current regulations (redesignated at §435.915 in the March 2012 Medicaid eligibility final rule). We also proposed a similar application reinstatement provision for CHIP at §457.340(a), which we are finalizing as proposed with a minor modification to remove the reference to §435.909 which was inadvertently inserted in the proposed rule and has no relationship to CHIP. We note that states also will need to develop reasonable timeliness standards for such reinstated applications in accordance with §457.340(d) of the March 2012 Medicaid eligibility final rule.

We have not modified the proposed regulation text to reinstate the Medicaid or CHIP application of every individual who has withdrawn his or her Medicaid or CHIP application in accordance with §155.302(b)(4) of the March 2012 Exchange final eligibility rule and who then subsequently appeals the determination of eligibility for advance payments of the premium tax credits or cost-sharing reductions at §435.907(h) and §457.340(a). We believe that the interests of individuals filing an Exchange appeal who should have been assessed as potentially Medicaid eligible by the Exchange, but who nonetheless withdrew their Medicaid application following the Exchange's assessment, will be protected through the Exchange appeals process because the Medicaid application for those assessed potentially Medicaid eligible will be reinstated, and their account transferred to the Medicaid agency for a full determination. On the other hand, to reinstate the Medicaid application of every applicant for whom the Exchange appeals processes ultimately confirms the initial assessment of Medicaid ineligibility made by the Exchange – regardless of how high above the Medicaid income standard the individual's income may be – would create confusion for individuals and impose, we believe, unnecessary administrative burden on state Medicaid agencies. We expect to work closely with Exchanges to ensure accurate assessments of Medicaid and CHIP eligibility in accordance with federal regulations.

Comment: One commenter sought clarification of when Medicaid agencies will have to decide whether or not to delegate eligibility determinations or fair hearings to the Exchange, and whether there will be additional requirements if the agency chooses not to delegate such responsibility.

Response: There is no deadline to elect to delegate eligibility determinations or appeals to an Exchange or Exchange appeals entity. As discussed in section II.A.6. of preamble, the regulation permitting delegation of eligibility and fair hearings goes into effect on October 1, 2013. Once a state decides to delegate authority to conduct eligibility or appeals, it must

indicate such an election through the state plan, establish a written agreement with the Exchange or Exchange appeals entity, and otherwise comply with the provisions set forth in the regulation. A state may revoke its delegation at a later time through the same process. Whether or not a state chooses to delegate authority, it must comply with the provisions of §435.1200, §457.348 and §457.350, issued in the March 2012 Medicaid eligibility final rule, to ensure coordination across all insurance affordability programs and a seamless consumer experience. We proposed revisions to these provisions in the January 2013 proposed rule to address the agencies' responsibilities to coordinate notices and appeals, but are not finalizing them in this final rule.

Comment: One commenter questioned whether a state might be able to obtain the enhanced matching funds for systems enhancement at a 90/10 match for enhancement of their appeals systems. Another commenter asked for clarification as to whether federal financial participation (FFP) would be available for appeals delegated to an Exchange.

Response: The enhanced FFP match rate of 90/10 for the design, development, and installation of eligibility systems is available only for components of the Medicaid Management Information System (MMIS), including eligibility and enrollment systems through the end of 2015, subject to meeting the seven conditions and standards outlined in the April 19, 2011 final rule at 74 FR 21950. A 75/25 match rate is available for operations and maintenance of these systems. Appeals systems do not qualify for enhanced funding under these rules. Instead, FFP at a 50/50 rate is available. For more details on 75/25 match rate discussion, see http://www.medicaid.gov/State-Resource-Center/FAQ-Medicaid-and-CHIP-Affordable-Care-Act-ACA-Implementation/Downloads/Affordable-Care-Act_-Newest-Version.pdf. The availability of FFP and responsibility for funding subject to cost allocation rules applies to administration of fair hearings in the same manner as any other context and is not affected by the state's delegation decision.

Comment: A few commenters suggested that we revise §431.240 to require that hearing officers who adjudicate Medicaid fair hearings abide by specific ethical standards, either the National Association of Hearing Officials' Model Code of Ethics or the National Association of Administrative Law Judiciary's Model Code of Judicial Conduct for State Administrative Law Judges. We did not receive any comments related to our proposed modification of §431.240 related to access to information.

Response: As discussed above, existing regulation at §431.240 require hearing officers to be impartial. Additionally, existing regulations at §431.205 require hearing systems to comport with due process standards of Goldberg v. Kelly, 397 U.S. 254 (1970). Current regulations do not require hearing officers to belong to a particular profession, and we did not propose to modify this policy in the proposed rule. Therefore, we are not making any changes to §431.240 in response to this comment. However, as noted above, we are addressing this comment, in part, by including that an impartial decision-maker must be used if a state is electing to establish a review process of legal conclusions made by hearing officers operating under delegated fair hearing authority. We also encourage states to examine this issue further and to ensure that the requirement to utilize impartial hearing officers at §431.240 are adhered to when conducting fair hearings. We finalize §431.240(c) without modification.

3. Notices

a. Electronic Notices (§435.918)

Current notice regulations require paper-based, written notices. To establish a more timely and effective notification process, proposed §435.918 would direct states to provide individuals with the option to receive notices through a secure, electronic format in lieu of written notice by regular mail. Consumer safeguards were proposed to ensure that individuals make a conscious choice to receive notices in electronic format, and would be able to opt-in and

opt-out of their election. We solicited comments regarding the proposed consumer safeguards. In addition, we requested comments on whether other types of communications, in addition to eligibility notices, should be offered in electronic format. We are finalizing §431.206(e), to permit beneficiaries to receive notices regarding fair hearings electronically, consistent with proposed §435.918. We note that we are not addressing in this final rule comments related to accessibility of fair hearing notices. We will consider these comments and this portion of §431.206(e) when we finalize our rules related to accessibility for individuals who are limited English proficient and individuals with disabilities in a future rulemaking. We also proposed modifications to §§431.211, 431.213, 431.230, and 431.231 to update and modernize the language in the regulation to remove the term “mail” and instead use “send,” to reflect the option for beneficiaries to receive notices electronically, consistent with the consumer protections in proposed §435.918. We proposed in §457.110(a)(1) the same consumer option and protections for electronic notices in CHIP, and we are making technical changes in the final rule to better align the provisions. A modification was also proposed to paragraph (a) in §457.110 regarding the accessibility of information for individuals who are limited English proficient and individuals with disabilities. However, we will finalize this provision in future rulemaking.

We received many comments regarding the requirement to provide individuals with the option to receive notices electronically, the majority of which supported this option as an important part of modernizing the notification process provided that strong consumer protections are in place.

Comment: We received many comments regarding proposed §435.918(a)(1), which would require the agency to confirm by regular mail the individual’s election to receive notices electronically. Some commenters recommended, instead, allowing electronic confirmation for individuals applying on-line. One commenter suggested that in states with a FFE, the FFE

should be responsible for issuing all mailed confirmations. Also, several commenters were concerned that the proposed written confirmation actually required individuals to choose receipt of electronic notices twice, and that this would be confusing and burdensome for the agency and these consumers. Many other commenters encouraged CMS to maintain the requirement to confirm an individual's election through regular mail to ensure that individuals have made an informed decision, and to provide them with an opportunity to change their election. One commenter suggested that the mailed confirmation include a list of the types of notices that the agency will send in electronic format.

Response: Proposed section §435.918(a)(1), redesignated §435.918(b)(1) in our final rule, requires the agency to send, via regular mail, written confirmation that an individual has elected to receive electronic notices and that forthcoming notices will be delivered electronically. This communication must also instruct the individual on how to change this election if the individual made the initial choice inadvertently or wishes to change his or her mind. The purpose of the mailed communication is to affirm the individual's choice and allow the individual an early opportunity to opt-out of receiving notices in electronic format. The individual does not have to respond to this written notice to complete his or her election to receive electronic notices; he or she need only respond if he or she wanted to change the initial election. Therefore, there will not be any need for individuals to request electronic notices twice, as some commenters thought. We are clarifying at §435.918(b)(1) of the final regulation that it is the agency's responsibility to ensure that the individual's election to receive notices electronically is confirmed by regular mail, since the individual will receive all future communication from the Medicaid agency including information on how to establish an electronic account with the state, if he or she has not already done so. If a different arrangement makes more sense in a given state, the Medicaid agency and Exchange can delegate this

responsibility to the other agency in the agreement entered into under §435.1200(b)(3). We are not requiring that this communication specify which types of notices will be delivered in electronic format, but suggest that states take this under consideration as it would enable individuals to better anticipate the type of notices that will be posted to an electronic account. We anticipate, based on one state's experience piloting electronic notices, few individuals will revert back to paper notices. However, given that electronic notification will be a new approach for many individuals, we believe this is an important consumer protection to ensure that individuals make a deliberate choice regarding the format in which they receive information. In future years, when electronic notices are more prevalent, we will revisit whether written confirmation of the individuals choice to receive notices in electronic format is still a relevant consumer protection.

Comment: Several commenters requested that electronic notices be the default method for notice delivery such that if an individual fails to indicate whether he or she prefers an electronic or paper format for notices, notices would automatically be provided electronically. One commenter suggested that electronic notices should be the default for specific populations, such as those individuals determined eligible through an Exchange website.

Response: We maintain that electronic notices should be provided only if the individual affirmatively opts for such notices. The default approach makes an assumption that the individual has the technology to regularly retrieve notices posted to his or her electronic account. Even if an individual applies through an Exchange website, the individual may not have regular access to technology to enable ongoing retrieval of electronic notices. Consequently, we do not believe this change is appropriate at this time as it could pose a barrier to applicants and beneficiaries with limited access to technology.

Comment: Several commenters recommended that Medicaid and CHIP eligibility notices be provided in both electronic and in paper format until an individual indicates in writing that they no longer wish to receive such notices by regular mail. Some commenters also recommended that all notices regarding adverse actions always be sent in paper format via regular mail to allow for additional protection against delivery error. One commenter recommended that hearing scheduling notices should always be sent via regular mail to ensure adequate hearing slot availability.

Response: We are concerned that requiring agencies to provide dual electronic and paper notices may pose an administrative burden for some states. While we require that agencies provide individuals with a choice to receive notices in electronic format in lieu of paper format, at state option, all notices or a subset of notices, such as those relating to adverse actions, could be provided in dual formats. We appreciate the concern expressed for ensuring consumer protections against delivery error. In §435.918(a)(4), the agency is required to send an email or other electronic communication alerting the individual that a notice has been posted to his or her account. To guard against delivery error, if the required alert is returned as undeliverable, the agency must send such notice by regular mail within three business days of the date of the failed electronic communication. This requirement has been further clarified by a revision to §435.918(a)(5). We believe that electronic notices are likely to increase receipt of important eligibility information, as individuals will have greater flexibility to access notices regardless of changes to their postal address.

Comment: We received a few comments that recommended we amend §435.918 to include specific language noting the importance of ensuring that the notice must be accessible to persons who are limited English proficient and individuals with disabilities.

Response: We agree that all eligibility notices must be accessible to persons who are limited English proficient and individuals with disabilities, and we will be addressing such rules in future rulemaking.

Comment: One commenter requested clarification on what constitutes an “undeliverable” communication in §435.918(a)(5).

Response: “Non-delivery reports” are system messages that report the delivery status to the sender. We expect that if the agency receives a non-delivery report, this constitutes an undeliverable communication.

Comment: One commenter requested clarification regarding how to date a paper version of an electronic notice. When an electronic communication is undeliverable, indicating an individual may not be aware of an electronic notice posted to his or her account, §435.918(a)(5) requires that the agency send a paper version of the electronic notice within three business days. The commenter, noting the ability to send the paper version of the electronic notice within 24 hours, supported maintaining the same date on both notices.

Response: It is important for the date of the paper notice to reflect the date it is sent, not the date of the undelivered electronic notice. We anticipate that while some states may be able to issue a paper version of the electronic notice within 24 hours, other states may take up to the required limit of 3 days. Individuals are given a limited time to take action, such as requesting a date for a hearing, and this is based on the date the notice is sent to the individual.

Comment: One commenter requested clarification as to whether agencies are required to monitor an individual’s account to determine if a notice was accessed.

Response: We are not requiring that agencies monitor accounts to determine whether notices are accessed. If the electronic alert is not undeliverable, the agency should assume an individual is able to access his or her notice.

Comment: One commenter recommended that we include a requirement that allows the agency to limit the number of times an individual can request that an electronic notice be provided in paper format.

Response: We believe that it is an important consumer protection to allow individuals to request notices in a paper format. Some individuals may not have the technology available to readily print notices from an electronic account.

Comment: A number of commenters supported offering additional types of communications through an electronic format. In addition to eligibility notices and information specified in subpart E of part 431, there are other communications that occur between an individual and the Medicaid or CHIP agency. Some of these communications include requests for additional information, annual renewal forms and reminders, premium payment information, and information on covered services.

Response: We do not believe it is necessary to amend §435.918(a) to include other types of communications. In §435.918(a), we specify that eligibility notices and information in part 435, and notices and information required under subpart E of part 431, be provided in electronic format. For example, information on covered services must be available electronically in addition to paper format, as required by §435.905(a). Annual renewal forms must also be offered in electronic format in accordance with §435.916. We do not think it is appropriate or operationally feasible to require other types of communications to be provided electronically. We encourage states with the capacity to provide additional communications electronically, and with beneficiaries preferring that mode of communication, to do so, as long as in compliance with any existing regulations that govern the type of communication.

Comment: One commenter asked whether proposed §435.918(b), which asserts that the agency may only provide electronic notices if the individual elected to receive electronic notices

and must be permitted to change such election at any time, is duplicative of paragraph §435.918(a).

Response: We agree with the commenter, and the provision has been amended by removing redundant language in §435.918(b)(1) and §435.918(b)(2).

Comment: A number of commenters requested a later effective date for implementing electronic notices.

Response: We recognize that states are at different places in the development of their eligibility and enrollment systems, and that the technology needs to be in place to offer beneficiaries and applicants the option to receive notices electronically. We have amended §435.918(a) to delay the requirement to provide notices electronically until January 1, 2015, but permit states to implement October 1, 2013 if their systems are ready.

Comment: One commenter suggested that we clarify whether “send” in §431.230 means send by mail or in electronic format consistent with §435.918.

Response: Under proposed §431.206(e), all information required under subpart E of part 431 must be provided in electronic format in accordance with §435.918, if an individual elects to receive such information in electronic format. To further clarify, we have added to §431.201, that the definition of “send” means deliver by mail or in electronic format consistent with §435.918.

Comment: One commenter requested clarification regarding §431.231(c)(2), which provides beneficiaries 10 days to request a hearing from receipt of the notice of action. The date on which the notice is received is considered to be 5 days after the date on the notice, unless the beneficiary shows that he or she did not receive the notice within the 5-day period. The commenter specifically requested clarification regarding how an individual might show proof that they did not receive an electronic notice within the 5-day time period.

Response: We understand the concern expressed by the commenter, but do not believe that this issue is specific to the receipt of electronic notices, but receipt of notices in general. It is challenging for an individual to provide proof of a negative, however, it is important to provide individuals with the opportunity to demonstrate that they did not receive notices. One example of how an individual might demonstrate that he did not receive an electronic eligibility notice is by providing documentation that he closed the email account on record with the agency. If an individual cannot receive the emailed alert that a notice is posted to the electronic account, the individual is not in receipt of the notice.

Comment: A few commenters requested that we define whether the “5 days” §431.231(c)(2) refers to calendar days or business days.

Response: We are not defining whether the “5 days” refers to calendar days or business days, but allow states the flexibility to define this in their operating procedures.

b. Coordinated Notices (§435.1200)

For individuals whose electronic account is transferred to the Medicaid agency for a determination of eligibility from another insurance affordability program, §435.1200(d)(6) of the March 2012 Medicaid eligibility final rule directs that the Medicaid agency notify such other program of its final determination of eligibility or ineligibility only for individuals who have enrolled in the other program pending completion of the agency’s final determination. We proposed to redesignate and modify this requirement at §435.1200 (d)(5) to require that the Medicaid agency notify the other program of the final determination of Medicaid eligibility or ineligibility for all individuals whose electronic account was transferred from another insurance affordability program. The same requirement was proposed for CHIP at §457.348(d)(5). No comments were received regarding these specific provisions. We also proposed a number of other changes to §435.1200 and §457.348 relating to coordination of notices and appeals. In this

final rule, we are codifying §435.1200(d)(5) of the proposed rule at paragraph §435.1200(d)(6). Other proposed changes to §435.1200 of the March 2012 Medicaid final eligibility rule, including the redesignation of paragraph (d)(6), as appropriate, will be addressed in subsequent rulemaking. We are also finalizing proposed §457.348(d)(5) as §457.348(c)(6), but other proposed changes to §457.348 will be addressed in subsequent rulemaking.

4. Medicaid Enrollment Changes Under the Affordable Care Act Needed to Achieve Coordination with the Exchange

a. Certified Application Counselors (§435.908 and §457.340)

Many state Medicaid and CHIP agencies have a long history of supporting providers and other organizations to assist individuals in applying for and maintaining coverage. Commonly referred to as “application assisters” and referred to in this rulemaking as “certified application counselors,” these organizations and individuals provide direct assistance to individuals seeking coverage, and can play a key role in promoting enrollment among low-income individuals. The proposed regulations at §435.908(c) sought to ensure that certified application counselors, whom we expect to continue to play an important role in facilitating enrollment in the expanded coverage options available under the Affordable Care Act, will have the training and skills necessary to provide reliable, effective assistance to consumers. We proposed basic standards for states to certify application counselors, which we believe are consistent with the practice in many states today. These standards include proposed procedures to ensure that these trained certified application counselors have clear authority to access and protect confidential information about individuals they serve, and with that authority have a special relationship with the Medicaid agency that enables the counselors to track and monitor applications. The proposed regulations at §435.908(c), as finalized in this rulemaking, are applicable to CHIP, as well under §457.340(a) of the March 2012 Medicaid eligibility final rule; no revisions are

needed or made to §457.340(a). We received the following comments concerning the proposed certified application counselor provisions:

Comment: We received a few comments expressing support for the proposed requirement that states have a designated web portal for use by certified application counselors that has a secure mechanism for granting rights for only those activities the certified application counselor is certified to perform. Commenters stated that such a portal will increase the proportion of applications that are submitted electronically, thereby providing more applicants with access to electronic verification and real-time eligibility while increasing the state's administrative efficiency. Other commenters also recommended a clarification that states may use the same portal for Navigators and non-Navigator assistance personnel authorized under 45 CFR 155.205(d) and (e) with proper assignment of rights and functionality.

Response: We appreciate the support for the establishment of a designated web portal for use only by properly trained and certified application counselors. However, given the systems challenges states face in preparing for the initial open enrollment period and starting up the new system of insurance affordability programs, we are concerned that requiring such a portal could disrupt well-functioning application counselor programs that exist today. Therefore, while we encourage states to consider such portals as an effective vehicle for administering and overseeing certified application counselor programs, we are removing from the final rule the requirement that such portals be established as proposed at §435.908(c)(3)(i). Although not required, states may elect to develop these portals to support the work of certified application counselors.

Comment: One commenter requested that we issue guidance on the availability of federal funding to help support grants or payments to certified application counselors – in

particular information about how Medicaid administrative claiming can be used to match community-based investments in application assistance.

Response: FFP is available for state expenditures to certify and support certified application counselors, but, since community-based application counselors are not state or local employees, FFP is not available for salaries or other direct costs of certified application counselors.

Comment: Many commenters requested that we require that certified application counselors be trained to provide culturally and linguistically competent services. They believed that it is not sufficient to remind Medicaid and CHIP agencies of their responsibility to ensure access to individuals with limited English proficiency and those living with disabilities, and urged us to provide states with specific guidance and examples of how to fulfill this responsibility. Some commenters recommended that to be certified, application counselors must be trained in providing culturally and linguistically appropriate services. Some commenters recommended that we require training for application counselors include accommodating the health care needs of specific populations, such as children.

Response: Consistent with title VI of the Civil Rights Act of 1964, the Americans with Disabilities Act, and other civil rights laws, state Medicaid and CHIP agencies must ensure that their programs are accessible to individuals with limited English proficiency and individuals with disabilities. This responsibility is codified, in part, at §435.905(b), §435.907(g), §435.908(a), and §457.330 (incorporating by reference the requirements of §435.907) of the March 2012 Medicaid eligibility final rule, and is also contained in non-Medicaid specific regulations implementing the Americans with Disabilities Act and other civil rights laws. Note that clarifying changes were proposed in the January 2013 proposed rule to the accessibility standard in §435.905(b); those proposed changes are not addressed in this final rule, but we

intend to address them in subsequent rulemaking. State agencies can use certified application counselors as a tool in meeting their responsibilities to make their programs accessible to individuals with limited English proficiency and individuals with disabilities. But, while some organizations providing application assistance to individuals applying for coverage under an insurance affordability program may be subject to civil rights laws independent of the fact that they are serving as a certified application assistor (for example, as a condition of accepting federal funding), we do not believe it appropriate to hold them responsible for meeting the accessibility standards established for state Medicaid and CHIP agencies under our regulations.

Moreover, to require a community organization or provider with a mission to provide targeted assistance to one segment of the population to also be able to provide assistance to all others, would threaten the participation of valuable state partners in maximizing enrollment across the state's entire population.

Comment: Some commenters supported the option provided to states to certify application counselors. These commenters pointed to existing programs in which states work with community organizations to expand enrollment, and that state flexibility to continue current, successful programs is important. Other commenters recommended that certification of application counselors be required for all Medicaid and CHIP agencies. These commenters discussed that there will be organizations providing application assistance in every state, that these organizations need to be trained, and that consumers need to know who is available to provide competent assistance.

Response: We agree that a network of application counselors can be a valuable asset and can support states' outreach and enrollment efforts. We urge all states to consider working with interested organizations and providers in creating an application counselor program. However,

we believe states are best able to determine the need for such a program, and we do not believe it is necessary to require that state Medicaid programs create such programs.

Comment: We received a number of comments on certified application counselors and requirements related to conflicts of interest. Some commenters stated that in addition to receiving training on conflict of interests, certified application counselors should be contractually required to serve in the best interests of clients and to disclose any existing relationships with qualified health plans or insurance affordability programs to consumers. Some commenters recommended that health insurance issuers, their subsidiaries and licensed insurance brokers and agents be explicitly excluded from being certified as certified application counselors given their inherent financial conflict of interest.

Response: We are clarifying the language in §435.908(c)(1)(iii) to make clear that certified application counselors must adhere to all rules prohibiting conflicts of interest. States may not certify any organization or individual who does not meet this standard, or who may be motivated to act in a manner contrary to best interest of the individual being helped. Thus, any organization that the state finds to have an inherent conflict could not, under the proposed regulation, be certified as an application counselor. We do not believe it necessary or appropriate to identify specific types of organizations as categorically barred from serving as application counselors and are finalizing this regulation as proposed.

Comment: A few commenters requested that we require states to maintain a current list of certified application counselors on the agency website, and the list should include any limitations on services that they are certified to provide. Commenters suggested that it will be important for consumers to not only be informed of the functions and responsibilities of certified application assisters, as required in §435.908(c)(3)(i), but to also know who is certified and

whether there are any limitations on the services each certified application counselor is certified to provide.

Response: We encourage states to adopt the practice recommended by the commenter, as an effective mechanism to connect consumers with needed assistance. However, utilization of certified application counselors is at state option, and while we believe such a mechanism will enhance consumers' ability to identify resources available to help with applications we do not think it appropriate to require states to post a current list of counselors on their website. We note that such a requirement could deter some states from creating or expanding their application counselor program if they do not have the resources to create and maintain such a list.

Comment: A commenter asked CMS to clarify that states can meet their outstationing requirements under §435.904 with application counselors at the appropriate locations. They suggested that given the overlap of functions described it would seem inefficient to maintain separate systems of assistance.

Response: States may be able to use certified application counselors to help meet the outstationing requirements set forth in current regulations at §435.904, under which state Medicaid agencies are required to provide pregnant women and children an opportunity to apply for coverage at designated "outstation locations." Section 435.904(e) requires that, except for outstation locations that are infrequently used by the pregnant women and children targeted under the regulation, the state agency must have staff available at each outstation location. Under paragraph (e)(3) of that section, properly trained provider or contractor staff or volunteers – which could include organizations, staff and volunteers certified as application counselors – may be used in lieu of, or as a supplement to, agency staff to meet this requirement, subject to certain conditions set forth in the regulation.

Comment: Commenters asked for clarification on the overlap of functions and certification requirements between certified application counselors in Medicaid and application counselors as proposed for the Exchange at §155.225.

Response: Although the exact language of the Exchange application counselor regulation at proposed 45 CFR 155.225 (which is not being finalized in this rulemaking) and that of the Medicaid regulation at §435.908(c) differ, the policies reflected are consistent. The main substantive difference is that the Exchange regulation at proposed 45 CFR 155.225 would not permit certified application counselors to limit the activities that they agree to perform, but instead would require them to perform all assistance activities identified in the regulation, whereas states can permit Medicaid and CHIP application counselors to elect to limit the activities which they will perform for applicants.

As noted in the preamble to the proposed rule, we remind the commenters that state Medicaid and CHIP agencies and the Exchange are charged under §435.1200 and §457.348 of the Medicaid eligibility final rule and proposed §155.345 of the Exchange rule to enter into agreements with each other to create a seamless and coordinated application and enrollment process across all insurance affordability programs, and the state agencies and the Exchange should consider such coordination in developing their application counselor programs. States could elect, for example, to create a single certification process for all insurance affordability programs, or each program could accept application counselors certified by another program. To the extent to which an application counselor is certified by one program but not the other, the counselor would assist the individual in submitting the single streamlined application for all insurance affordability programs to the entity by which they are certified. It is important to note that regardless of the entity to which the application counselor submits the application, the application will be evaluated for eligibility in QHPs and all insurance affordability programs.

Comment: One commenter requested more information about the development and review of training materials for certified application counselors. This commenter stated that although the regulations provide that any individual providing customer service must be trained in a host of areas related to the insurance affordability programs, no specificity is provided about the development and review of the materials, and they requested clarification on whether states will have the opportunity to review and comment on materials prior to their use. We also received comments that recommended we require certified application counselors to apply for recertification annually or biannually to ensure that they are qualified and up to date on changes in policy and procedures.

Response: Under §435.908(c)(1)(ii) and (iii), states must ensure that application counselors are properly trained prior to certification, and we expect states will need to develop training and any training materials to be used to satisfy this requirement. We note that materials will be developed by HHS for use by certified application counselors registered with an FFE, including State Partnership Exchanges, and state Medicaid and CHIP agencies may adapt such materials to support their training efforts. FFP is available for costs to the state of conducting training or testing of certified application counselors, including any costs to the state for preparation and assembly of training materials. Being effectively trained in the rules and regulations of the different insurance affordability programs in accordance with §435.908(c)(1)(ii) necessarily requires keeping abreast of any pertinent changes in those rules, and under these regulations states will need to ensure that application counselors are kept up-to-date. However, there are different ways to accomplish this goal – annual or periodic recertification is one-way, refresher trainings or written communications may be another – and we believe states should have flexibility in determining the process that best works in each state.

Comment: A few commenters recommended that applicants and enrollees be able to opt to designate their certified application counselor to receive copies of notices, or to access electronic notices in the client account.

Response: As discussed in the preamble of the proposed rule, the certified application counselor program is not designed to provide the level of personal assistance to applicants and beneficiaries that is provided by an authorized representative, discussed in the next section in the preamble. However, there is nothing to prevent an applicant or beneficiary from designating a certified application counselor to also serve as his or her authorized representative, and for such counselor to assume that function, in accordance with §435.923, as finalized in this rulemaking.

Comment: One commenter suggested that regulations governing application assistance are not necessary. The commenter believed that, absent any evidence that application counselors currently working in states to help individuals apply for Medicaid do not have the training and skills necessary to provide reliable, effective assistance to consumers, or would not meet confidentiality requirements, there is no reason to regulate state practices in this area.

Response: We recognize the successful development of application assistor, or application counselor, programs by many states without the existence of federal regulations, and have aimed to develop regulations that will not disrupt existing, successful programs and practice. However, given the significant changes to the availability of and access to affordable health coverage created under the Affordable Care Act – including the advent of coverage in a QHP through the Exchange, with premium tax credits and cost sharing reductions available to qualifying individuals, the coordinated eligibility and enrollment process required across all insurance affordability programs, and the expansion in use of online applications, with the possibility confidential information being returned to consumers in real time through an electronic interface – we believe that establishment of baseline federal standards, to be applied

consistently across states and programs, is important to safeguarding consumer interests and ensuring the integrity of the assistance provided.

b. Authorized Representatives (§435.923)

We proposed regulations intended to be consistent with current state policy and practice, regarding the definition, designation, and responsibilities of “authorized representatives” to act on behalf of applicants and beneficiaries in applying for and maintaining coverage. Authorized representatives have historically provided valuable support to individuals needing help navigating the application and enrollment process, as well as ongoing communications with the agency, particularly to seniors and individuals with disabilities, and we expect their role to continue. We proposed to define the term “authorized representative” as an individual or organization that acts responsibly on behalf of an applicant or beneficiary in assisting with the individual’s application and renewal of eligibility and other ongoing communications with the Medicaid or CHIP agency. Under current regulations at §435.907, retained in the March 2012 Medicaid eligibility final rule, states must accept applications from authorized representatives acting on behalf of an applicant. We received the following comments concerning proposed provisions relating to authorized representatives:

Comment: One commenter requested clarification on whether states may enforce additional requirements not specifically listed in the federal regulations on authorized representatives. An example of this would be state specific regulations governing who may serve as an authorized representative for individuals who are not medically or legally competent.

Response: Under proposed §435.923(a), legal documentation of authority to act on behalf of an applicant or beneficiary under state law, such as a court order establishing legal guardianship or power of attorney may serve in place of a written designation from the applicant

or beneficiary, signed and submitted in accordance with §435.923(f). Under the regulation, however, states may not limit authorized representatives to individuals identified in such a legal document or granted authorization under operation of state law or otherwise impose requirements other than those listed in §435.923 on other individuals whom an applicant or beneficiary wishes to have serve as his or her authorized representative. We have separated the regulation text as proposed at §435.923(a) at §435.923(a)(1) and §435.923(a)(2).

Comment: We received a number of comments regarding who may serve as an authorized representative. One commenter recommended that organizations should not be permitted to be designated as authorized representatives. Another commenter recommended that we allow states to decide whether to permit organizations to be authorized representatives. The commenter suggested that by permitting only individuals to serve as authorized representatives, states will be better able to ensure transparency and accountability of the authorized representative. Another commenter recommended that we add a definition of organization to §435.923(e) to clarify what types of organizations may act as authorized representatives, for example, only non-profit organizations.

Response: We believe that there are situations in which an individual may need an organization to serve as his or her authorized representative and it is appropriate for an organization to serve in this capacity, such as for individuals residing in a nursing home who do not have family available to assist them. We are finalizing the regulation as proposed in this regard. Protections at proposed §435.923(e), finalized in this rulemaking, are designed to ensure that organizations serving as an authorized representative adhere to laws and regulations relating to conflicts of interest and act in the best interest of the individual.

Comment: We received a number of comments related to the timeframe for designation of authorized representatives. One commenter recommended that states be given options or

flexibility in this area, explaining that states may wish to make the designation of the authorized representative last for 12 months by default, for example, unless the applicant or beneficiary designates otherwise. Another commenter recommended that we add that the authorization is valid until the application is denied or benefits are terminated and the appeal process is completed.

Response: Our regulations clearly state that applicants and beneficiaries are able to change authorized representatives at any time. States may not make a designation automatically expire such that an individual would need to redesignate an authorized representative after a given period of time. However, they are allowed to provide beneficiaries with the opportunity to change their authorized representative at the renewal point. For example, states can indicate that a beneficiary has an authorized representative and remind the individual that they may keep or change the representative on the renewal document.

Comment: One commenter asked for clarification on whether the scope of the authorization is defined by the beneficiary or applicant, or whether, once invoked, the representative assumes all of the duties named in the regulations, including “all other matters” with either agency.

Response: We clarify that the scope of the authorization is defined by the Medicaid applicant or beneficiary.

Comment: We received a number of comments on §435.923(c), specifically related to the fact that the designation of an authorized representative can only be revoked in writing. Commenters suggested that it would be more appropriate and efficient to allow the designation to be revoked by all of the modalities by which it can be made in the first place.

Response: We agree with the commenter’s suggestion and have revised the regulation text accordingly.

Comment: One commenter requested clarification on whether the permissions given the authorized representative may be granted in part, for example in tiers, if an applicant so chooses. The commenter suggested that an applicant may wish to authorize someone to sign his or her application, but not to receive his or her notices, for example.

Response: We are clarifying that the permissions given to the authorized representative may be granted in part. The proposed regulation allows applicants and beneficiaries to designate an individual or organization to act on their behalf and that the scope of authorization is defined by the applicant or beneficiary.

Comment: One commenter asked us to confirm that the definition provided for authorized representatives is the same definition that the Social Security Administration uses.

Response: We clarify that the definition is not the same.

Comment: A few commenters requested additional clarification regarding situations in which an individual is unable to personally elect an authorized representative due to medical incapacity. One commenter agreed that written designation by the individual or legal documentation should be obtained in most instances, but the proposed rule may be overly restrictive in that it could result in unreasonable delay in determining some individuals' eligibility for Medicaid. The commenter recommends that states be given the authority to waive this regulation in instances when obtaining legal documentation to allow individuals or organizations to act as authorized representatives would be difficult. Another commenter suggested that legal documentation of authority to act on behalf of an application or beneficiary under state law, such as court order establishing legal guardianship or a power of attorney, should serve in place of written authorizations by the applicant or beneficiary.

Response: Under section §435.923(a), legal documentation of authority to act on behalf of an applicant or beneficiary under state law, such as a court order establishing legal

guardianship or power of attorney may serve in place of the applicant or beneficiary's designation. The option to submit such documentation is intended to enable applicants who do not have the capacity to provide a signature to authorize representation.

5. Medicaid Eligibility Requirements and Coverage Options Established by Other Federal Statutes

a. Presumptive Eligibility for Children (§435.1102)

We proposed to revise existing regulations to align with the adoption of MAGI-based methodologies.

Comment: One commenter suggested that presumptive eligibility could be better streamlined by using only a gross income standard for eligibility determinations.

Response: Current regulations allow states to use either gross income or to have qualified entities make a closer approximation of the countable family income, which would be used for a regular determination by the state agency, by applying simple disregards. We believe it is appropriate to retain this flexibility for states once MAGI-based methodologies are in place. Therefore, we are codifying the flexibility of states in §435.1102(a), as proposed, to direct qualified entities to use either gross income or to apply simplified methods, as prescribed by the state, to better approximate MAGI-based household income, as defined in §435.603 of the March 2012 final rule.

Comment: Many commenters objected to the state option to obtain an attestation of citizenship or satisfactory immigration status, or state residency as part of a presumptive eligibility determination. They suggested that requiring an attestation of immigration status would likely deter some potentially eligible individuals who often need urgent access to health care services from receiving care. Further the commenters suggested that the rules on immigration status are detailed and complex, and qualified entities cannot reasonably be

expected to understand or explain them to individuals being asked to attest their status. Some commenters stated that states should have the option to request self-attestation of citizenship.

Response: We clarify that our proposed rule gave states the option to require qualified entities or qualified hospitals to request this information but did not require it. We believe that this option is important in the context of extending the ability to conduct presumptive eligibility determinations to hospitals because it limits the possibility that individuals who are not citizens or qualified immigrants or residents of the state are found eligible on a presumptive basis, receive expensive services, only ultimately to be determined ineligible for Medicaid. Therefore, we are retaining the language as proposed and maintain this provision as a state option.

Comment: One commenter requested that we add current foster care children as a presumptive eligibility group in our final regulation.

Response: We clarify that former foster children are already a population that is eligible to be determined presumptively eligible. We do not currently have the authority to add current foster care children as a presumptive eligibility group, but this is unnecessary because current foster children are automatically eligible for Medicaid and do not need to be determined presumptively eligible.

b. Presumptive Eligibility for Other Individuals (§435.1103)

Comment: Some commenters stated that states should have the option to elect how many presumptive eligibility periods should be allowed for each pregnancy. Others supported our proposed rule to permit only one presumptive eligibility period per pregnancy.

Response: We believe that providing pregnant women with one presumptive eligibility period per pregnancy is reasonable in accordance with section 1920 of the Act, under which pregnant women may receive ambulatory prenatal care during a presumptive eligibility period, defined as continuing through the date a full Medicaid determination is made under the State

plan, or, if a woman does not submit a regular application through the end of the month following the month during which the presumptive eligibility determination was made.

Therefore, we are finalizing the regulation as proposed to provide one presumptive eligibility period for pregnant women per pregnancy.

c. Presumptive Eligibility Determined by Hospitals (§435.1110)

We proposed to add §435.1110 to implement section 1902(a)(47)(B) of the Act, added by the Affordable Care Act, to give hospitals the option to determine presumptive eligibility for Medicaid. The statute provides hospitals participating in Medicaid with this option whether or not the state has elected to permit qualified entities of the state's selection to make presumptive eligibility determinations for children, pregnant women or other specific populations under other sections of the statute.

We received the following comments concerning the hospital presumptive eligibility provisions:

Comment: We received many comments related to the establishment of standards under proposed §435.1110(d)(1) for hospitals that opt to make presumptive eligibility determinations. Some commenters encouraged CMS to provide states with maximum flexibility to implement presumptive eligibility standards for hospitals, while other commenters stated that the Secretary should establish federal standards applicable to hospitals making presumptive eligibility determinations in all states. Other commenters supported the flexibility given to state agencies to establish standards, and some stated that states should have even broader authority to establish clear criteria and qualifications which hospitals would have to meet to make presumptive eligibility determinations. Some believe that the Secretary should establish minimum federal standards and qualifications, with the state option to impose additional standards. Commenters generally requested additional guidance to states on how they must work with hospitals that elect

to make presumptive eligibility determinations. Finally, some commenters stated that the Secretary should establish federal standards for hospitals that opt to make presumptive eligibility determinations under §435.1110 of the regulations, related to the proportion of individuals determined presumptively eligible by the hospital that submits a regular application and the percent of such individuals who are ultimately determined eligible by the agency. Commenters suggested that states should use the federal standards to determine which hospitals are capable of making presumptive eligibility determinations.

Response: We are finalizing §435.1110(d)(1) as proposed. Oversight of qualified entities making presumptive eligibility determinations, including qualified hospitals under §435.1110, is a state responsibility. Under §435.1110(d)(1), states may establish state-specific standards for qualified hospitals that conduct presumptive eligibility determinations related to the success of assisting individuals determined presumptively eligible who submit a regular application and/or are approved for eligibility by the agency. We believe this is an area more appropriate for state flexibility, than for imposition of a uniform federal standard for all participating hospitals across all states. Therefore, we are finalizing §435.1110(d), as proposed. We will monitor implementation and consider whether further guidance is warranted.

Per §435.1110(d)(2), which we also are finalizing as proposed, state agencies are required to take appropriate correction action for any hospital that does not meet the standards established by the state or which the state otherwise determines is not making, or is not capable or making, presumptive eligibility determinations in accordance with state policies and procedures. In fulfilling their responsibility under §435.1110(d)(2), states may develop other proficiency standards, training and audits, with which hospitals would need to comply, to be authorized to make presumptive eligibility determinations in the state.

Comment: We received many comments on the populations for which hospitals can make presumptive eligibility determinations. Some commenters stated that hospitals should be allowed to make presumptive eligibility determinations for all of the patient populations they serve. Some commenters recommended that states be given the option to elect and limit the populations that may be determined presumptively eligible by hospitals. Some commenters stated that the preamble did not align with the regulation text relating to this issue in the proposed rule. Many commenters requested additional clarification on the populations for which hospitals may make presumptive eligibility determinations.

Response: We intended to propose that qualified hospitals must be permitted to make presumptive eligibility determinations based on income for all of the populations for which presumptive eligibility may be available in accordance with §435.1102 and §435.1103. The specific reference to children, pregnant women, parents and caretaker relatives, and other adults in proposed §435.1110(c)(1) was not intended to eliminate presumptive eligibility determinations by hospitals for other populations included in §435.1103 (that is, former foster care recipients or women with breast or cervical cancer or individuals seeking coverage of family planning services). We are revising the regulation text at §435.1110(c)(1) to clarify that states electing to limit the presumptive eligibility determinations which hospitals can make must permit the hospitals to make presumptive eligibility determinations based on income for all of the populations included in §435.1102 and §435.1103. Under §435.1110(c)(2), which we finalize as proposed in this rulemaking, states may also permit hospitals to make presumptive eligibility determinations for populations for which income is not the only factor of eligibility (for example, for individuals who may be eligible under an eligibility group based on disability, or individuals eligible under a demonstration project approved under section 1115 of the Act).

Comment: A commenter expressed that hospitals wishing to make presumptive eligibility determinations should be required to attend training on policies and procedures established by the states. The commenter suggested that this was important to maximize the likelihood that eligible individuals complete the full Medicaid eligibility process. They supported the proposed rule that states may require hospitals electing to make presumptive eligibility determinations to assist individuals in completing and submitting the full application and understanding any documentation requirements.

Response: In accordance with §435.1110(a) of the proposed rule, finalized as proposed in this rulemaking, states are required to provide Medicaid during a presumptive eligibility period, to individuals who are determined to be presumptively eligible by a qualified hospital, subject to the same requirements as apply to the State options under §§435.1102 and 435.1103 regardless of whether the state otherwise has opted to provide Medicaid during a presumptive eligibility period under either of those sections. While not necessarily requiring establishment of a formal training program, current regulations at §435.1102(b) require states to provide qualified entities with information on relevant state policies and procedures and how to fulfill their responsibilities in making presumptive eligibility determinations. This requirement is unchanged in this rulemaking and will apply in the case of hospitals electing to be a qualified hospital under §435.1110. If a hospital does not follow state policies and procedures, or is not successful in helping individuals to submit regular applications in accordance with standards established by the state, proposed §435.1110(d)(2) would require states to institute appropriate corrective action, including (but not requiring) termination of the hospital as a qualified hospital. We are revising proposed §435.1110 (d) by adding paragraph (d)(3) to provide that the agency may disqualify a hospital as a qualified hospital only after it has first provided the hospital with additional training or taken other reasonable corrective action measures.

Comment: A few commenters requested that states should be able to receive 100 percent FMAP for any recoupments or disallowances CMS may seek related to an improper eligibility determination by a hospital. One commenter questioned whether a state can make a qualified hospital liable when a presumptive eligibility determination results in a denial for a full Medicaid category.

Response: Under existing regulations, there is no recoupment for Medicaid provided during a presumptive eligibility period resulting from erroneous determinations made by qualified entities. Payment for services is guaranteed during a presumptive eligibility period; without such a guarantee, providers could not rely on the determination. Under this provision, states will not be permitted to recoup money from the hospital (and CMS will not recoup FFP from the state). However, under §425.1110(d)(2), a state may disqualify a hospital from conducting presumptive eligibility determinations if the state finds that the hospital is not making, or is not capable of making, accurate presumptive eligibility determinations in accordance with applicable state policies and procedures. Such a disqualification is permitted only after the state has provided additional training or taken reasonable corrective action measures to address the issue. Finally, we clarify that states may not make a qualified hospital liable when an individual who was found presumptively eligible by the hospital submits a full application and is subsequently denied Medicaid eligibility.

Comment: Some commenters requested that for individuals determined presumptively eligible by a hospital for the adult group under §435.119 of the March 2012 Medicaid final eligibility rule, a state should receive 100 percent federal funding for services provided unless and until the individual completes the eligibility process and is determined not “newly eligible” or eligible for coverage under the adult group. Commenters suggested that enhanced federal funding is necessary because there will not be sufficient information available to determine

whether the presumptively eligible individual should be claimed at 100 percent federal funding or the state's regular FMAP at the time of the initial presumptive eligibility determination.

Response: While we understand the commenters' concerns, there is no basis to provide the 100 percent FMAP during a presumptive eligibility period. The state would receive the increased FMAP provided under the Affordable Care Act only for individuals who the state determines actually (not presumptively) qualify for Medicaid under the adult group and are determined to be "newly eligible." The methodology for such claims is set forth in the final FMAP regulation (78 FR 19918). However, states may retroactively adjust claiming to receive the enhanced matching rate for individuals determined presumptively eligible who subsequently complete a regular application, are determined by the state to be eligible for Medicaid under the adult group and are found to be "newly eligible." Such retroactive adjustment may extend back to the first month of the month in which the regular application was filed or up to 3 months prior to the month of application in accordance with §435.914 of the regulations (redesignated at §435.915 in the March 2012 Medicaid final eligibility rule).

Comment: One commenter requested that we confirm that §435.1110(b)(2) of the proposed rule gives states the option to require that to participate as a qualified hospital, a hospital must assist individuals in completing and submitting the full application and help individuals understand any documentation requirements. The commenter suggested that this function is the same as that of an application counselor and requests clarification on whether a state could also require that a hospital that performs presumptive eligibility determinations must follow regulations in §435.908 relating to certified application counselors.

Response: Although we are not requiring hospitals that perform presumptive eligibility determinations to also furnish services of certified application counselors, states may impose specific requirements on hospitals to ensure that they fulfill their role in assisting individuals

with completing and submitting the full application. At a minimum, states have a responsibility to ensure that an individual determined presumptively eligible by qualified hospitals is informed about how to apply and can obtain an application.

Comment: We received several comments on the viability of presumptive eligibility determinations with the advent of real-time eligibility determinations. One commenter recommended that states should have the latitude to require hospitals to use the state's online application system and determine presumptive eligibility only if a real-time full eligibility determination cannot be made. Another commenter suggested that if eligibility can be determined in real-time, then there is no need for presumptive eligibility, and asked us to clarify whether the state could terminate use of presumptive eligibility without violating the Affordable Care Act's Maintenance of Medicaid Eligibility requirements, as added by section 2001(b) of the Affordable Care Act (codified at sections 1902(a)(74) and 1902(gg) of the Social Security Act (the Act)).

Response: We agree that the promise of real-time eligibility determinations makes the role of presumptive eligibility different than it has been in the past. In situations in which the individual files a regular application right away, the presumptive eligibility period would likely be considerably shorter – and eliminated altogether, as a practical matter, if a real-time determination is made. However, even with the most modernized systems, there inevitably will be individuals for whom a real-time eligibility determination will not be possible. There also will be individuals who will not be comfortable with the online application, and will instead opt to use the paper application. In such situations and for such individuals, presumptive eligibility remains a useful tool to facilitate prompt coverage and enrollment in the program. States have flexibility to minimize the length of presumptive eligibility periods by requiring that hospitals and other qualified entities assist individuals in submitting the single streamlined

application online. States may not terminate use of presumptive eligibility for pregnant women or individuals with breast or cervical cancer prior to 2014 or for children prior to October 1, 2019 without violating maintenance of effort.

Comment: One commenter requested clarification on how hospital presumptive eligibility will interact with eligibility in breast and cervical cancer groups.

Response: If a state has elected to provide presumptive eligibility for individuals with breast or cervical cancer under §435.1103(c)(2), it can limit qualified entities under that section to providers which conduct screenings for breast and cervical cancer under the state's Centers for Disease Control and Prevention (CDC) breast and cervical cancer early detection program (BCCEDP), and if it has done so, the state may limit hospitals which may determine presumptive eligibility for individuals with breast or cervical cancer on that basis to hospitals that conduct screenings under the state's BCCEDP. In states that do not opt to provide presumptive eligibility for individuals with Breast or Cervical Cancer under §435.1103(c), states similarly may limit hospitals' ability to determine presumptive eligibility for individuals with breast or cervical cancer under §435.1110 to those that conduct screenings under the state's BCCEDP.

6. Coordinated Medicaid/CHIP Open Enrollment Process (§435.1205 and §457.370)

We proposed to implement section 1943 of the Act and section 1413 of the Affordable Care Act to require that Medicaid and CHIP agencies begin accepting the single streamlined application during the initial open enrollment period to ensure a coordinated transition to new coverage that will become available in Medicaid and through the Exchange in 2014. Our proposed rule seeks to ensure that no matter where applicants submit the single, streamlined application during the initial open enrollment period, they will receive an eligibility

determination for all insurance affordability programs and be able to enroll in appropriate coverage for 2014, if eligible, without delay.

Comment: Many commenters supported the proposal in §435.1205(c)(1) that Medicaid and CHIP agencies to begin accepting the single streamlined application and MAGI determinations from the Exchange and to process MAGI eligibility starting in October 2013. Commenters believe this is necessary to ensure coordination with the Exchange, and to facilitate a seamless transition to the new coverage that will become available in Medicaid and through the Exchanges in 2014. Many commenters acknowledged that the public will be hearing about new coverage options throughout the summer and fall of 2013, and expressed concern that it would result in confusion if, when people went to apply for coverage and were found eligible for Medicaid (or their children eligible for Medicaid or CHIP), they were told to return several months later and submit a new application.

Response: We agree with the commenters that acceptance of the single streamlined application by state Medicaid and CHIP agencies starting in October 2013 is needed to ensure coordination with the Exchange, and in facilitating new coverage that will be available to Medicaid-eligible individuals in January 2014. Therefore, we are finalizing the rule as proposed and confirm that individuals may not be required to return in January to reapply.

Comment: Some commenters expressed concern that it is unreasonable to require states to comply with the prescribed time frames for coordinated enrollment with the Exchange in the proposed rule. They noted that states must make major policy, operations, and systems changes to implement federal requirements, which will impact agency eligibility staff, vendors, clients, and other stakeholders. Pending final and complete federal guidance, it is a significant challenge for states to develop policies, design efficient business processes, build systems and new interfaces, and effectively communicate changes to clients and stakeholders by the proposed

federal implementation dates. One commenter noted that its state legacy system cannot process or transfer electronic accounts, which means that the proposed rule has effectively shortened the timeframe to implement its new eligibility system by 3 months. Another commenter noted that Medicaid eligibility systems, policies and staff are not structured to operate in a time-limited open enrollment environment or to apply competing eligibility criteria concurrently, and cannot be changed to do so with only a few months' notice.

Commenters recommended that Medicaid agencies not be required to begin accepting streamlined applications or determinations from the Exchange prior to January 1, 2014. Instead, during the initial open enrollment from October 1, 2013 to December 31, 2013, commenters requested that at state option, individuals may be required to apply separately to the Medicaid agency and to the Exchange and to have their eligibility determined by the corresponding agency. One state suggested, as an alternative, the information exchanged will be limited to only the Medicaid-specific information that is included in the single streamlined application.

Response: We appreciate the operational challenges states face in preparing for implementation of the Affordable Care Act, but we believe that these effective dates are central to the success of open enrollment and we have consistently targeted the October 1 date as we have worked with states to finance and develop their IT systems. We have identified a set of seven critical success factors that states must meet by October 1 in an attempt to prioritize what must be accomplished within this timeframe. We have regularly shared these with states via webinars, on the CALT at <https://calt.cms.gov/sf/go/doc16369?nav=1>, through State Operational Technical Assistance (SOTA) calls and in IT gate reviews. These include the following: (1) ability to accept application data, (2) MAGI rules engine in eligibility system, (3) MAGI Conversion, (4) Submission of state income thresholds and flexibilities, (5) Connection to

Federally Facilitated Exchange (or establishment of State Based Exchange), (6) Connection to Federal Data Services Hub, and (7) Ability to confirm Minimum Essential Coverage.

We recognize the efforts that states are making across a broad range of areas, and have released regulations, information technology (IT) guidance, funding opportunities, business process models and other tools to assist states as they design, develop, implement, and operate new systems. We will continue to help states fully comply with all relevant eligibility and enrollment changes, as well as achieve the necessary degree of interoperability between IT components in the federal and state entities that work together to provide health insurance coverage through Medicaid and CHIP, and Exchanges. We are finalizing the regulation as proposed.

Comment: Several commenters expressed concern that, in the states which are relying on the FFE and will not be ready to implement the single, streamlined application by October 2013, there is a significant risk that people who apply for coverage through the FFE will be told that they are likely eligible for Medicaid or CHIP, and be sent away without any real opportunity to enroll in coverage or complete the application process. These commenters recommended that HHS strengthen this provision by setting forth a specific timeframe and set of procedures that states must follow to ensure that they are ready to implement the single, streamlined application when open enrollment begins in October 2013. Specifically, they recommended modifying the final rule to require states relying on the FFE to submit information, by September 1, 2013, on whether they intend to: (1) accept the FFE's determinations of Medicaid/CHIP eligibility; or (2) to treat the FFE's finding as an assessment and complete the eligibility determination themselves. In addition, they recommend including a provision to clearly outline that before a state can elect the option to treat the FFE's findings as an assessment, the state must demonstrate that it is (or will be by October 2013) capable of acting upon such assessments in full accordance

with federal law.

Response: We have a process in place for working with states on implementation, including the adoption of mitigation strategies where necessary. We do not believe that a change in the regulations is needed to effectuate these strategies.

Comment: Many commenters believe that it would be time-consuming and impractical to require states to evaluate all cases for eligibility effective in 2013, but that there is a subset of cases that states should be required to evaluate. Specifically, parents whose MAGI-based income falls very close to the state's current income eligibility threshold for parents should be evaluated based on 2013 eligibility rules. Commenters suggested HHS provide guidance to states on the appropriate MAGI income threshold to use for determining whether an individual appears to be potentially eligible under 2013 rules and should be assessed for eligibility using those rules. Some commenters also believe that states should be required to inform people when it appears that their children qualify for coverage under 2013 Medicaid and CHIP rules because families are more likely to pursue applications if they believe that their children will be found eligible for coverage. Finally, a few commenters believed states should be given the option to notify a subset of applicants about the process to apply for coverage with an effective date in 2013 (for example, only those applicants who appear to be potentially eligible under 2013 rules based on the available information provided on the single streamlined application).

Some commenters stated that they are already planning for an October 2013 implementation date of MAGI eligibility and requested that states be given this option without need for a waiver. These commenters recommend states have flexibility in handling applications based on 2013 rules for assessing 2014 coverage. States should be allowed to request applicants submit supplemental form that includes additional information to make MAGI determination, or

to redirect applicants to new application; or, states should have flexibility to process applications using 2013 rules and determine eligibility based on MAGI proxy when possible.

Response: We recognize the challenge of appropriately evaluating all applications submitted during the open enrollment period under both the MAGI-based rules effective January 1, 2014 and under rule in effect in 2013. However, all applicants must have the opportunity to have their Medicaid eligibility assessed based on existing Medicaid rules for 2013 as well as for prospective enrollment effective January 2014. At a minimum under the regulation at §435.1205(c)(4)(ii), states must inform individuals who submit the single streamlined application during October – December 2013 that coverage may be available in 2013, but that a different application will need to be completed for consideration of such coverage, and how the individual can obtain and submit such application. Alternatively, under §435.1205(c)(4)(i), states can use the information on the single streamlined application submitted to make a determination of eligibility effective in 2013, based on 2013 rules, following up with the individual to obtain additional information if needed through additional questions or use of a supplemental form, if needed. States also can pursue a combination of these strategies – using the process outlined in §435.1205(c)(4)(i) for targeted individuals more likely to be found eligible under 2013 rules (for example, parents and caretaker relatives with MAGI-based income within a threshold margin of the applicable income standard and individuals indicating potential disability on the single streamlined application), while directing those not seen as likely-eligible under the 2013 rules to submit a separate application in accordance §435.1205(c)(4)(ii).

States may wish to avoid having to operate two sets of rules for children, parents and caretaker relatives, pregnant women and other non-disabled, non-elderly adults that may be eligible for Medicaid enrollment during this period. To address this, we are offering states the opportunity to begin using the new MAGI-based methodology for these populations effective

October 1, 2013, to coincide with the start of the open enrollment period. See State Health Official Letter #13-003: Facilitating Medicaid and CHIP Enrollment and Renewal in 2014 at <http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/SHO-13-003.pdf>.

Comment: One commenter stated that requiring post-eligibility data matching to ensure continued eligibility as of January 1, 2014 for individuals determined not eligible in October-December but eligible in January, creates an enormous burden during a time when new systems are being implemented and states will be experiencing the largest influx of newly eligible individuals into their system. The commenter noted this would create duplication of efforts when an individual who was determined eligible prior to January is already notified of their reporting requirements and states should be allowed to rely on recipients reporting rather than handling the same cases twice in a 3-4 month timeframe.

Response: Post-eligibility data matching is an option for states to ensure continued eligibility as of January 1, 2014 and/or through the first regularly-scheduled renewal. It is not required. The agency also has the option to schedule the first renewal for individuals who apply during the open enrollment period, and determined eligible effective January 1, 2014, to occur anytime between 12 months from the date of application and January 1, 2015. Consistent with §435.916, beneficiaries are required to report any change in circumstances that may impact their eligibility. In the absence of any reported change that could affect eligibility, no post-eligibility data matching is required.

Comment: One commenter requested that CMS clarify §435.1205(c)(3)(ii) that this state option [to schedule the first renewal under §435.916 to occur anytime between 12 months from the date of application and January 1, 2015] authorizes less than annual periods of coverage/eligibility before renewal in instances where renewal date is set before January 1, 2015.

Response: This option does allow for less than 1 year of coverage for a limited time. For example, if someone applies on November 1, 2013, and is determined eligible for coverage to begin January 1, the state may schedule renewal on November 1, 2014. This would result in less than a year of coverage. This one-time option is intended to provide for ease of administration in the renewal of coverage for a large number of individuals whose coverage begins on January 1, 2014 and would otherwise need to be renewed at the same time.

Comment: We sought comments in the proposed rule on which sections of both this rulemaking as well as the March 2012 Medicaid eligibility final regulation need to be effective October 1, 2013 (as opposed to January 1, 2014) to enable states to meet their responsibilities under §435.1205 and §457.370 of this rulemaking. We received no comments in response to this request.

Response: In the absence of any comments regarding this question, we have determined that the following provisions of the March 2012 Medicaid eligibility final rule are effective October 1, 2013 for purposes of effectuating §435.1205 and §457.370 of this final regulation during the initial open enrollment period beginning October 1, 2013:

- Sections 435.603, 435.911, 435.1200, 457.315, 457.330 and 457.348;
- Amendments to §§431.10, 431.11, 435.110, 435.116, 435.119, 435.907, 435.916, 435.940 – 435.956, 457.340 and 457.350, and the redesignation of §435.911 through §435.914 as §435.912 through §435.915.

In addition, the following provisions of this final rule are effective October 1, 2013: §§435.918, 435.1205, 457.370, and revisions to §§431.10, 431.11, 431.201, 431.205, 431.206, 431.211, 431.213, 431.230, 431.231, 431.240, 435.119, 435.603, 435.907, 435.1200, 457.110(a)(1), 457.348, and 457.350.

Although effective for purposes of codification in the Code of Federal Regulations October 1, 2013 for application during the initial October 1 – December 31 open enrollment period, absent a waiver under §1115 of the Social Security Act approved by the Secretary, financial eligibility based on MAGI-based methodologies codified at §435.603 and §457.315 and eligibility for adults under §435.119 are not effective under the Affordable Care Act until January 1, 2014. Technical revisions to §435.119 to retain the applicability date of January 1, 2014, even as the effective date of that section is moved to October 1, 2013, are made in this rulemaking. No revisions to §435.603 or §457.315 are required, as those sections, as published in the March 2012 Medicaid final eligibility rule, already provide for the January 1 applicability date.

7. Children's Health Insurance Program Changes

a. CHIP Waiting Periods (§457.340 , §457.350, §457.805 and §457.810)

We proposed revisions to existing regulations regarding prevention of substitution of coverage at §457.805 to limit the use of CHIP waiting periods to a maximum of 90 days. This policy aligns with section 1201 of the Affordable Care Act, which amended section 2708 of the Public Health Service Act to prohibit waiting periods exceeding 90 days for health plans and health insurance issuers offering group or individual coverage. This standard, though not directly applicable to CHIP, is currently exceeded in roughly half of the states that impose CHIP waiting periods today. We also proposed to require several exemptions to waiting periods, consistent with policies that many states have in place today, such as for individuals working for employers that stopped offering coverage of dependents. We received the following comments on our proposed waiting period policy as described below.

Comment: Many commenters urged CMS to eliminate waiting periods on January 1, 2014, rather than permit states to continue to impose waiting periods of any length of time for

children. A few commenters encouraged CMS to retain its current policy of providing states with the discretion to maintain waiting periods and establish their own procedures to minimize displacement of private insurance, and some states expressed their intent to eliminate waiting periods in their CHIP programs in 2014. One commenter suggested that waiting periods be applied only to children with family incomes above 200 percent of the FPL. Commenters' concerns with the proposed 90-day waiting period were related to the administrative burden of waiting periods for state CHIP agencies and Exchanges, potential hindrances to streamlined and coordinated enrollment, disruptions in continuity of care for children and a lack of evidence of substitution.

Response: While we acknowledge the commenters' concerns related to the continuation of waiting periods for children in 2014, we also see a need to permit states flexibility to determine an appropriate substitution prevention strategy, with a full range of options from monitoring to imposition of waiting periods up to 90 days. Some states have already eliminated their CHIP waiting periods and we encourage other states to consider taking this step. Nothing in this final rule precludes a state from doing so. States may also elect to eliminate waiting periods specifically for children at lower income levels and/or identify additional exemptions to the waiting period beyond those required in this rule. Therefore, to maintain states' flexibility in identifying substitution strategies while also limiting the period of time a child may not be eligible for CHIP due to a waiting period, we are finalizing the provisions at §457.350, §457.805 and §457.810 as proposed to permit states to impose a waiting period of no more than 90 days, with certain specified exemptions. We note that this policy is consistent with the 90-day maximum waiting period described in Section 1201 of the Affordable Care Act.

Comment: Many commenters were concerned that the proposed policy for a maximum 90-day waiting period would require states and Exchanges to set up administratively complicated

processes to temporarily enroll children in QHPs and to receive APTCs and CSRs while awaiting CHIP eligibility during the waiting period. Several commenters expressed concerns with the administrative complexity of the interactions that must occur between the Exchange and the CHIP agency if a waiting period is in place, including the requirement at §457.350 for the CHIP agency to send the electronic record back to the Exchange for enrollment in a QHP if the child is determined not eligible for CHIP. These commenters also expressed concern that these potential complications do not align with the streamlined eligibility and enrollment process envisioned by the Affordable Care Act. Many commenters stated that requiring the change to a 90-day maximum waiting period policy would be administratively burdensome and costly to states at a time when information technology systems are already overburdened in preparation for significant eligibility changes in 2014. Some commenters highlighted that it is likely that some state systems will not have the capacity to track children who are locked out of CHIP during a waiting period and others expressed concern as to whether states or the Federal government have the capacity to smoothly implement waiting periods in the manner suggested in the proposed rule without a disruption in coverage for children. Some commenters also indicated that if waiting periods were to exist in 2014, state CHIP agencies would need to both track when these children would become eligible for CHIP and also initiate action to enroll children in the program.

Response: For states that opt to apply a waiting period in 2014, we agree that transitioning a child from one insurance affordability program to another upon the conclusion of a 90-day waiting period may present operational challenges. States must take into consideration their system capabilities and weigh the perceived benefits of opting to have a waiting period against any additional administrative or system requirements needed to effectuate a seamless transition of such children from coverage in the Exchange and APTC to the state's

CHIP at the conclusion of the 90 day period. We agree that CHIP agencies will need to track when these children become eligible for CHIP as required at §457.350. In addition, we have further clarified at §457.340(d)(4), that without requiring new applications or information previously provided, CHIP agencies must implement processes to ensure a smooth transition for children from coverage through the Exchange to CHIP at the end of a waiting period, as well as facilitate the enrollment of otherwise CHIP-eligible children who have satisfied the waiting period, but who were not covered in the Exchange. For example, a state could automatically enroll a previously determined CHIP-eligible child at the end of the waiting period without requesting any additional information from the family. Another option would be for a state to suspend applications for all children subject to a waiting period. Once these children have completed the waiting period, the state would then reactivate the application and determine whether the child is eligible for CHIP based on the information previously provided on the application. There is nothing in the above options that precludes a state from checking data sources for updated information or processing a change in circumstances reported by the family.

Comment: Many commenters stressed that waiting periods of any length could negatively impact children's access to continuous and coordinated health coverage. For example, commenters expressed concern that the proposed rule permitting CHIP-eligible children to enroll in qualified health plans (QHPs) in the Exchange during a waiting period, and subsequently enroll in CHIP at the end of a waiting period, will stimulate churning between QHPs and CHIP. These commenters emphasized that disruptions in coverage will impact the health status of children who are left uninsured and/or may have to change plans or providers. Some commenters stated that movement between plans and programs will inhibit the QHPs' ability to measure the quality of care provided to children, and makes it difficult to hold plans accountable for improvements in quality outcomes for children over time.

Response: We acknowledge that the use of waiting periods may create delays in eligibility for CHIP and increase the likelihood of churning between the Exchange and CHIP, which could result in disruptions in coverage that could negatively impact the health status of children. Therefore, this final rule confirms states' ability to eliminate waiting periods to accommodate these concerns. In addition, the final rule codifies the limitation of waiting periods to a maximum of 90 days, to be consistent with waiting periods under section 1201 of the Affordable Care Act. We encourage states to examine the costs and benefits of imposing a waiting period in the context of the Affordable Care Act. To make the transition from Exchange coverage to CHIP as smooth as possible for children, states that do choose to maintain waiting periods will need to meet the requirements at §457.350(i), including providing notification to the appropriate insurance affordability program (for example, the Exchange) promptly and without undue delay of the date on which the waiting period will end and the child will be eligible to enroll in CHIP. We will provide states with technical assistance in this area.

Comment: Several commenters indicated that while there were initial concerns upon implementation of CHIP in the late 1990s that the incentives for substitution of public coverage for private coverage would be significant, states and researchers have had ample opportunity to examine this issue over the last 15 years. These commenters stated that numerous studies have shown that substitution is difficult to measure, there continues to be much conjecture regarding the degree to which substitution occurs, and that there is no evidence that procedures like waiting periods actually prevent substitution. These commenters also noted that there is evidence that uninsured children, including children in waiting periods, frequently forego medical services due to high out-of-pocket costs.

One state reported that during an almost 15-year period, there has been no evidence that crowd out is a concern, including for children at higher income levels. The commenter reported

that the percentage of children in families who dropped their employer sponsored coverage and substituted it for CHIP has been consistently below 2 percent since the inception of CHIP. This commenter recommended that we permit monitoring of crowd out at all income levels rather than continuing to require a substitution strategy, such as a waiting period, for higher income children. Another commenter stated that in their experience in operating CHIP, nearly all families with former employer-sponsored insurance meet at least one of the exemptions to waiting periods included in its CHIP state plan.

Response: We recognize that there is a robust but inconclusive evidence base in the literature calling into question the prevalence of substitution. And, we are therefore, revising our existing regulations to provide states with flexibility to determine how best to operate their CHIP programs. The preamble of the existing regulation (66 FR 2490, January 11, 2001) required that states that provide CHIP coverage to children at or below 200 percent of the Federal poverty level (FPL) must have procedures for monitoring the rate of substitution of coverage, between 200 and 250 percent of the FPL must monitor substitution and identify specific strategies to limit substitution if levels become unacceptable, and for coverage above 250 percent of the FPL states must describe how substitution is monitored and implement specific strategies to prevent substitution. We clarify in this final rule that effective January 1, 2014, monitoring of substitution is a sufficient approach for addressing substitution at all income levels. We expect that if this monitoring demonstrates a high rate of substitution, a state will consider strategies such as improving public outreach about the range of health coverage options that are available in that state.

Comment: Some commenters requested that CMS provide clarity regarding the criteria for specific exemptions (for example, children with special health care needs), and suggested additional types of mandatory exemptions at the Federal level (for example, employees that have

employers that have changed health plans or products). Some commenters noted that states have previously implemented many of the proposed required exemptions and that the majority of applicants already qualify for state-identified exemptions to the waiting period.

Response: As noted by some commenters, many of the mandatory exemptions in the proposed rule have previously been instituted by states on a voluntary basis and have been effective. Therefore, we are adopting in our final rule the proposed exemptions at §457.805. In addition, and as discussed in the preamble of our proposed rule, we are adding an affordability exemption at §457.805(a)(i) for cases when a child's parent is determined eligible for APTC for enrollment in a QHP through the Exchange because the employer-sponsored insurance (ESI) in which the family was enrolled is determined unaffordable in accordance with 26 CFR 1.36B-2(c)(3)(v). We consider this exemption to be essential to preventing families from having to choose between continuing ESI that has been determined to be unaffordable for the parent, and thereby forgoing premium tax credits and cost-sharing reductions for enrollment in an QHP, or dropping the ESI and allowing their child to go without coverage for a period of time to qualify for CHIP. We note that states continue to have the flexibility to provide additional exemptions beyond those specified in this final rule, but other than the affordability exemption at §457.805(a)(i), there will be no additional exemptions added in this final rule. We note that we intend to issue further sub-regulatory guidance related to criteria for required waiting period exemptions.

Comment: One commenter requested that CMS delay the effective date of this provision to give states adequate time to make the necessary changes related to its waiting period policy, such as a change in state law and/or budget.

Response: This provision will be effective on January 1, 2014 unless a change in state law is needed for a state to comply with this provision. Specifically, for states with annual

legislative sessions, the effective date for the application of the 90-day maximum waiting period and required exemptions must be no later than the first day of the next fiscal year beginning after the close of the first regular session of the 2014 state legislature. For states that have a 2-year legislative session, each year of the session is considered a separate regular session for this purpose.

b. Limiting CHIP Premium Lock-Out Periods (§457.570)

We proposed to define a CHIP premium lock-out as a period not exceeding 90 days when, at state option, a CHIP eligible child may not be permitted to reenroll in coverage if they have unpaid premiums or enrollment fees. Following a premium lock-out period, we proposed that the child must be permitted to enroll without regard to past due premiums. We proposed at §457.570 to permit states to impose premium lock-out periods only for families that have not paid outstanding premiums or enrollment fees, and only up to a 90-day period. We also specified that a premium lock-out period must end once a family has paid the premium or enrollment fee. We also invited comments on any alternative late payment policies to encourage families to make their CHIP premium payments in a timely manner to avoid gaps in coverage. We received the following comments concerning the proposed lock-out period provision.

Comment: The majority of commenters supported the proposed rule requiring reasonable notice of non-payment, limiting the use of lock-outs only for non-payment of premiums (and only as long as the non-payment continues, and subject to a 90-day maximum), and disallowing states from requiring payment of outstanding premiums at the end of the lock-out period before re-enrollment. In particular, commenters strongly supported that the CHIP agency must review the family's circumstances (§435.570(b)) to determine if their income has declined, making the child eligible for Medicaid or a lower cost-sharing category. Some commenters also strongly opposed the imposition of lock-out periods for any length of time for a CHIP child, and urged

CMS to modify §457.570 to ban lock-out periods. These commenters indicated that lock-outs are contrary to the goals of a reformed health system, as well as the health of children. Some commenters stressed that a quarter of a year without health insurance can have a significant impact on a child's healthy development, a child should not be subject to penalties for a failure to pay by another family member, and the Affordable Care Act recognizes that children should connect with their medical home eight times in the first year of life alone. One commenter also stated that lock-out periods in CHIP create disruptions in care, burdens on families, unnecessarily increase administrative costs, and that the elimination of lock-out periods is an important consumer protection.

A few commenters asked whether the process of premium collection and debt forgiveness will be aligned with the premium collection regulations for the Exchange.

Response: In response to the support of our proposed rule by the majority of commenters, and comments received by states related to the need to continue to have non-payment of premium policies in place to manage program costs (as described below), we are adopting in our final rule the proposed provisions that authorized states to institute a maximum 90 day lock-out period for non-payment of premiums. Lock-outs are permitted for non-payment of premiums, but only as long as the non-payment continues and subject to a 90-day maximum. We also want to clarify that requirements related to reasonable notice of nonpayment, and review of the family's circumstances to determine if their income has declined (for example, making the child eligible for Medicaid or a lower cost-sharing category), are existing regulatory provisions that we have not modified by this rulemaking.

We appreciate the concerns expressed by some commenters with regard to the potential impact of any lock-out period on children, and for these reasons, we also adopted in the final rule the proposed restriction that lock-out periods may only apply to families who have not paid their

premiums, and must end if a family pays its past due premium. We have also maintained the requirement that children must be permitted to enroll in CHIP subsequent to a 90 day lock-out period regardless of whether the family continues to owe past due premiums. In addition, we are also including requirements for non-payment of premium that are intended to align CHIP policies with policies applicable in the Exchange, to the extent possible. In CHIP and for those individuals with APTC in the Exchange, individuals are provided with a premium payment grace period, may be disenrolled for non-payment of premiums, and will not be required to pay past due premiums to reenroll in coverage. Exchange eligible individuals will have a longer grace period (90 days as opposed to 30 days) than CHIP, but will not be permitted to enroll in coverage until the next open enrollment period. Therefore, the amount of time an individual may have to wait before reenrollment in a Qualified Health Plan will vary, depending on when the premiums are missed in relation to the next scheduled open enrollment period, but will be no longer than 90 days for a child in CHIP .

We note that neither CHIP nor the Exchange have explicit rules governing debt forgiveness policies. More information on the Exchange rules related to non-payment of premiums is available at <http://www.gpo.gov/fdsys/pkg/FR-2012-03-27/pdf/2012-6125.pdf>.

Comment: A few commenters requested clarification on policies governing non-payment of premiums. They requested clarification on policies related to “forgiving” past due premiums and enrollment fees, as well as whether a state can continue to try to obtain the outstanding premium amount without affecting eligibility. One commenter indicated that funds should be recoverable using a debt collection process. The same commenter also asked how many cycles of premium forgiveness would be allowed for an individual. Another commenter asked CMS to generally clarify what steps states and health plans would be permitted to take in situations in which a CHIP enrollee re-enrolls after a lock-out period and again does not pay premiums.

Response: We believe that disenrolling a child from coverage and potentially requiring a child to go without coverage up to 90 days (assuming the family has not paid the premium or enrollment fee), is a significant deterrence to prevent a family from establishing a pattern of non-payment of premiums and re-enrollment. Therefore, this rule does not place a limit/cap on the number of times an individual may be re-enrolled after non-payment of their premiums. Nothing in this rule precludes a state from electing to establish policies for collecting debt from families that have not made their premium payments. Nor does this rule preclude states and health plans from offering incentives to encourage timely payment of premiums.

Comment: Some commenters recommended that states only be permitted to terminate coverage during a continuous eligibility period for failure to pay premiums as proposed at §457.342(b) after complying with the disenrollment protections at §457.570. Several commenters stressed that the proposed rule should be strengthened to capture the intent noted in the preamble that “prohibiting a child from enrollment after the family pays the unpaid premium or enrollment fee is counter to promoting enrollment in and continual coverage.” Some commenters also recommended that the final rule specify that if a family pays its outstanding premium between the end of their payment grace period and before the end of the lock-out period, the child be reinstated back to the effective end date with no gap in coverage and no loss of 12-month continuous eligibility (if applicable).

Response: We agree that coverage terminations occurring during a continuous eligibility period for failure to pay premiums can be implemented only after complying with the disenrollment protections at §457.570, and we have modified §457.342(b) to clarify this requirement. In addition to the preamble language describing that families that pay their premiums or enrollment fees prior to the end of a lock-out period must be re-enrolled in CHIP, we have also specified this requirement at §457.570(c)(2) under this final rule. Section

2103(e)(3) of the Act describes a statutory premium grace period during which CHIP enrollees may pay their monthly premiums before being disenrolled. This provision requires States to grant individuals enrolled in separate child health programs a 30-day grace period, from the beginning of a new coverage period, to pay any required premium before enrollment may be terminated. The new coverage period begins the month following the last period for which a premium was paid. Aside from these requirements, states have, and will continue to have, flexibility to determine when coverage can be reinstated. As specified in our proposed rule at §457.342(b), continuous eligibility may be terminated for failure to pay required premiums or enrollment fees.

Comment: Some commenters expressed concerns for potential unintended consequences of the proposed policies. One commenter stated that the proposed rule creates an incentive for individuals who are otherwise able to pay their premium to cycle through CHIP eligibility every other three month period and encourages gaps in access to medical services for children, who may subsequently present to the CHIP with higher acuity levels and higher cost needs. The commenter also stated that the proposed rule increases costs for states and the federal government, and diminishes health outcomes for children. The commenter encouraged CMS to continue to require member accountability in the CHIP program by allowing the collection of outstanding premiums in the presence of a 90-day grace period. Another commenter objected to the proposed rule to limit lock-out periods to 90 days and allow an individual to re-enroll upon payment of past due premiums, regardless of whether the lock-out period has expired. The commenter stated that this approach creates adverse selection, in that families may stop paying their premium when they may not have immediate health care needs, and then again pay their premiums only when they are in need of health care. Additionally, this commenter stated individuals should be required to pay any past due premiums as a condition of retaining

eligibility for CHIP, even after a lock-out period has been satisfied. This commenter also stated that the proposed rule discards the plain statutory authority of title XXI that delegates this policy to states. Another commenter noted that CHIP is a “stepping stone” between Medicaid and employer-sponsored insurance or Exchange coverage, and that premiums in its current CHIP are minimal in comparison to employer-based coverage and private coverage. The commenter requested that premiums not be waived in states with requirement to repay outstanding premiums and no lock-out period. The commenter stated that waiving premiums does not promote responsibility, intrinsic value, or the effective management of program costs for states.

Response: The goal of allowing coverage for families that make current payments must be balanced with the concern that families will game the system to try to obtain coverage without paying premiums. We agree that there may be situations where families either elect, or are unable to pay their premiums multiple times during a given year. However, we are not aware of any evidence that these situations represent a significant number of cases. And, as stated in our response to the comment above, as long as states adhere to regulations at §457.570, nothing in this rule precludes a state from continuing to establish policies for collecting debt from families that have not made their premium payments. We also encourage states to continue implementing approaches for simplifying premium payment arrangements and coping with administrative concerns families may have, and we continue to encourage states in this area to minimize the number of families that are disenrolled for non-payment of premiums.

Comment: One commenter stated that if CHIP lock-out periods are allowed in 2014, CMS should prohibit states that use this option from requiring children subject to a lock-out period to reapply for coverage and that a child returning to coverage following a lock-out period should be handled in the same manner as a renewal. The commenter believes that because such children were eligible for CHIP apart from non-payment of premiums or enrollment fees, the

state agency should be able to reassess eligibility based on available electronic data sources and families should only be asked for additional information if what has already been provided and currently available electronic data are not sufficient to establish eligibility.

Response: While we encourage states to consider the potential administrative cost savings and reduced burden on families that could result from assigning a pending eligibility status to a child for non-payment of premiums rather than requiring a new application, we will continue to permit states to have the flexibility to make this decision.

Comment: One commenter requested clarification on whether a child can receive APTC or CSR during a premium lock-out period.

Response: We anticipate that this issue will be addressed in further guidance from the Department of Treasury.

Comment: The preamble to our proposed rule specified that a state may not require the collection of past due premiums or enrollment fees as a condition of eligibility for reenrollment once the lock-out period has expired, regardless of the length of the lock-out period. One commenter recommended that this policy also be specified in §457.570(c)(2).

Response: Section 457.570(c)(2) clearly specifies that “a state may not require the collection of past due premiums or enrollment fees as a condition of eligibility for reenrollment once the State-defined lock out period has expired, regardless of the length of the lock-out period.” We have not made any modifications to this section.

Comment: Some commenters indicated that providing multiple ways to pay premiums and sending multiple, non-threatening payment due reminders are helpful in encouraging payment. These commenters suggested that CMS consider future sub-regulatory guidance to states to promote best practices in premium payments.

Response: Most CHIPs report efforts to facilitate payment of premiums and enrollment fees, easing the process for families, and the majority of states also send multiple payment due reminders and allow a variety of payment methods (such as allowing families to make payments at multiple locations). We will consider issuing further sub-regulatory guidance in this area.

8. Premium Assistance (§435.1015)

We proposed to codify the last sentence of section 1905(a) of the Act that authorizes payment of “other insurance premiums for medical or any other type of remedial care or the cost thereof” to support enrollment of individuals eligible for Medicaid in plans in the individual market, including enrollment in QHPs doing business on the Exchange. Premium assistance is one mechanism for facilitating the coordinated system of coverage between Medicaid, CHIP, and the Exchange in 2014. It provides an option for states to assist families who wish to enroll in the same health plan when some family members are eligible for either Medicaid or CHIP while other family members obtain coverage in the Exchange with advance payments of the premium tax credit, and it can provide a way to minimize the extent to which individuals have to change plans when their circumstances change such that their eligibility for an affordable health insurance plan changes. The proposed rule reflected longstanding statutory provisions in light of the new coverage options available in 2014. We received the following comments to proposed premium assistance provisions:

Comment: Many commenters were supportive of states’ ability to use premium assistance authority to purchase private insurance coverage for health plans in the individual market, including QHPs doing business on the Exchange. At the same time, however, they emphasized the importance of ensuring that Medicaid and CHIP-eligible individuals receive the full scope of services to which they are guaranteed in Medicaid and CHIP, such as the full range of pediatric services provided in Medicaid and CHIP. Commenters urged CMS to take steps to

ensure that states provide families and individuals with all of the information they need regarding the benefits to which they are entitled. They noted that the information states track to ensure cost-effectiveness should also be used to assess whether children and adults are receiving the full package of Medicaid or CHIP services. One commenter suggested that states should be required to ensure that beneficiaries experience a seamless enrollment process and that they have a single insurance card and point of contact for all benefits.

Response: Under all premium assistance arrangements, Medicaid and CHIP-eligible individuals remain Medicaid or CHIP beneficiaries and continue to be entitled to all Medicaid/CHIP benefits and cost sharing protections. Thus, we require at §435.1015(a)(2) and (a)(3) that the state agency furnish all benefits covered under the state plan that are not available through the individual health plan and also that the individual does not incur any cost sharing in excess of that allowed in Medicaid. We expect states to have mechanisms in place to ensure that beneficiaries understand their available choices of either direct state plan coverage or coverage through premium assistance for an individual health plan, including a QHP in the Exchange, under the premium assistance option, as well as how to access any additional benefits or cost sharing assistance. Therefore, we have revised §435.1015(b) to include provisions requiring informed choice and information on the process for accessing additional benefits and help with cost sharing, if the individual elects to receive coverage through the premium assistance option. We do not believe, however, that it is appropriate to direct through rulemaking the specific procedures states must employ to provide any necessary “wraparound” benefits or cost sharing; under the state plan option, states have the flexibility to determine how best to meet these cost sharing and benefit responsibilities. We have also clarified in §435.1015(b) that states must require that individuals who have elected to receive premium assistance must obtain covered items and services through the individual health plan to the extent that the insurer is

contractually or otherwise responsible to pay for such benefits.

Comment: Some commenters expressed specific concerns about cost sharing policies and urged CMS to consider putting additional beneficiary protections in place specific to premium assistance to ensure that people understand the cost sharing differences between Medicaid and CHIP and QHPs. They recommended that we create requirements for coordination between Medicaid and the QHP issuer to ensure that people do not exceed permissible cost sharing and asked CMS to provide guidance on how to monitor cost sharing.

Response: We expect states to have mechanisms in place to provide benefits that wrap around health plan coverage to the extent that the health plan offers fewer benefits, or has greater cost sharing requirements than in Medicaid or CHIP. These mechanisms will need to be coordinated with the health plan to successfully implement a premium assistance program. As noted above, we are requiring at §435.1015(b) that states inform individuals how to access additional benefits not provided by the insurer, and also inform individuals how to receive cost sharing assistance. We are not proposing any specific requirements about the way in which such coordination can be effectuated, however, because we believe that states should have flexibility to develop effective coordination procedures consistent with state systems and procedures, including variation in state health care delivery systems.

Comment: Many commenters requested clarification of the cost-effectiveness test for premium assistance. They stressed the importance of a strong cost-effectiveness test to ensure that taxpayer dollars are spent wisely and also that beneficiaries do not lose important benefits and cost sharing protections. They were concerned that the proposed rule could be interpreted to include only the cost of premiums to purchase coverage and not to include in the test the costs associated with paying copayments, deductibles, and other cost sharing requirements. They believe that this should be clarified in the final rule to explicitly include cost sharing. Other

commenters stated that this cost-effective analysis should be performed on an annual basis to ensure that the premium assistance program remains cost-effective even if Medicaid and the individual market experience different rates of cost growth.

Response: Consistent with our approach to cost-effectiveness in all premium assistance authorities, we intend for states to consider the cost sharing requirements of the private health plan (and therefore the cost of providing the cost sharing protections) when determining whether premium assistance is a cost-effective option, and we agree that this should be clarified. Therefore, we are revising §435.1015(a)(4) accordingly. States implementing premium assistance must describe their cost-effectiveness methodology, and to the extent that such a methodology relies on annual per person costs, we would expect states to be re-running the analysis at least annually, as new cost data is available.

Comment: Many commenters requested additional detail on how the option would be operationalized by state Medicaid agencies, Exchanges, and QHPs. One noted that successful premium assistance programs require robust data sharing, data mining, automated calculations using cost-effective algorithms, and strong relationships with private insurers. Some commenters requested that CMS provide states with a template or other tools to simplify the implementation of premium assistance.

Response: We will continue to provide technical assistance to states on the operational aspects of pursuing this premium assistance approach, relying on the experience states have had over the years implementing premium assistance.

Comment: Some commenters stated that families should have the choice of either premium assistance or direct Medicaid state plan coverage, even when premium assistance is cost-effective for the state, and they supported the proposed rule's provision that states may not require enrollment in premium assistance as a condition of Medicaid eligibility. Other

commenters requested that CMS remove the voluntary participation requirement either entirely, or if this requirement is retained, they asked that states be allowed to make participation in premium assistance mandatory for certain Medicaid enrollees, such as adults up to 138 percent of the FPL who would be part of the state's Medicaid expansion population, or for pregnant women with incomes above 133 percent of the FPL.

Response: Consistent with the statute, we are retaining the provision at §435.1015(b) that states may not require a Medicaid-eligible individual, as a condition of receiving Medicaid benefits, to enroll in a health plan in the individual market through a premium assistance arrangement. Enrollment in individual market coverage is not a statutory condition for eligibility. We are also clarifying in §435.1015(b) that states must require that individuals who have elected to receive premium assistance must obtain covered items and services through the individual health plan to the extent that the insurer is contractually or otherwise responsible to pay for such benefits. This is consistent with the provision in section 1902(a)(17) of the Act that, in determining the amount of medical assistance, states may consider available resources, and the provision in section 1902(a)(25) of the Act that requires that states ensure that liable third parties pay primary to Medicaid. We address the issue of requiring enrollment in premium assistance for certain populations in the last response in this section.

Comment: Several commenters expressed concern that permitting state Medicaid programs to establish premium assistance programs could affect premiums in the Exchange. Some commenters recommended that CMS revise the proposed §435.1015(a)(4) to require that premium assistance not increase federal costs and not increase premiums in the individual market.

Response: Medicaid beneficiaries enrolled in a QHP would be included in the individual market single risk pool of the health insurance issuer of the plan in which they are enrolled, just

as any other individual obtaining coverage through such plans. §435.1015(a)(4) requires the cost of premium assistance to be “comparable” to the cost of providing direct coverage under the state plan. We do not use a more restrictive word to allow flexibility because the amount, duration, and scope of the QHP coverage, or the nature of the QHP service delivery system, might be different from direct coverage under the state plan.

Comment: Some commenters stated that CMS must take additional steps to ensure that states do not steer family members of Medicaid-eligible individuals into less expensive plans to accommodate a premium assistance model and also to ensure that any enrollees who will be using premium tax credits have sufficient choice in QHPs. The commenters stated that regulations should require states to remain impartial in providing all available information on all QHPs so the family can choose the best plan or plans for the entire family, and also that Navigators, application assisters, and application counselors must be trained on the premium assistance program and provide impartial assistance to families.

Response: As noted above (and at §435.1015(b)), when a state implements the state plan premium assistance option, the beneficiary’s participation must be voluntary. We also expect states to ensure that application assisters and certified application counselors comply with the requirements in §435.908 of this part and §457.340 under subpart C of part 457, which include requirements that they be effectively trained in the eligibility and benefits rules and regulations governing enrollment in a QHP through the Exchange and all insurance affordability programs operated in the state. In addition, the Exchange regulations at 45 CFR 155.210 require that Exchange Navigators provide impartial information and assistance. A Medicaid or CHIP enrollee who is receiving benefits in whole or in part through a premium assistance arrangement with a QHP will not be eligible for a premium tax credit under section 36B of the Internal Revenue Code because such credits are not available to individuals who, for the coverage month,

are eligible for minimum essential coverage through Medicaid or CHIP.

Comment: A few commenters questioned whether section 1905(a)(29) of the Act creates the authority for premium assistance in the individual market. Many commenters recommended that CMS eliminate the proposed policy to allow premium assistance for plans in the individual market, or otherwise tightly circumscribe it, citing cost concerns, as well as concerns about the operational complexity and potential consumer confusion for consumers created by the “wrap” requirement.

Response: As we stated in the preamble of the proposed rule (78 FR 4624 and 4625), in section 1905(a)(29) of the Act, “medical assistance” is defined to include payment of part or all of the cost of “other insurance premiums for medical or any other type of remedial care or the cost thereof.” We have interpreted this provision to permit payment of FFP for premiums for health plans for Medicaid-eligible individuals, provided the state determines it cost-effective to do so. CMS has approved state premium assistance programs under this authority prior to the enactment of the Affordable Care Act. The Affordable Care Act provided for new rules regulating the operation of the individual and small group insurance markets, and expanded access to insurance coverage through QHPs participating in the Exchange. This results in new opportunities for states to deliver Medicaid coverage through the purchase of private health insurance in the individual market. Our goal is to work with states to ensure that their premium assistance approaches result in a cost-effective, seamless, and coordinated system of health care for beneficiaries.

Comment: Several commenters recommended delaying implementation of premium assistance until rates are determined for QHPs in the Exchange, and the individual market has settled from the changes it will experience in 2014, and states have experience implementing the Medicaid expansion.

Response: As we noted above, premium assistance is an option available under current law. Some states have already expressed interest in using the premium assistance model to deliver benefits to their Medicaid expansion beneficiaries through QHPs doing business on the Exchange. In addition, beginning in 2014, some low-income children will be covered by Medicaid or CHIP while their parents obtain coverage in the Exchange with advance payments of the premium tax credit, and premium assistance provides an opportunity for state Medicaid and CHIP programs to offer coverage to such families through the same plan, even if supported by different payers. It also provides opportunities for continuity of care by increasing the likelihood that individuals could remain in the same health plan when moving back and forth between Medicaid and Exchange coverage due to fluctuations in income or other changes in circumstances. We are not establishing new authority but rather ensuring that the existing authority reflects the new coverage options in the individual and small group markets established by the Affordable Care Act.

Comment: Many commenters supported the retention of the proposed regulation text that makes FFP available for payment of health plan premiums for “individuals” eligible for Medicaid. They believe that this language supports the enrollment of Medicaid-eligible individuals in individual market plans, including plans offering family coverage, while not incorporating limiting definitions of “family” that would unnecessarily limit the benefits of the rule to individuals in families that do not comprise a taxpayer household. One commenter asked for CMS to clarify the meaning of “family” as used in the premium assistance section of the preamble of the proposed rule. The commenter also questioned whether this option is limited to Medicaid and CHIP-eligible individuals who have family members enrolled in an individual health plan, and if so, asked if we proposed to limit this option to members of the same tax household, MAGI assistance group, or to immediate family members.

Response: We have not proposed a definition of “family” that is unique to premium assistance. Regulations at §435.603 of this part (and at §457.301 and §457.315 under subpart C of part 457 for CHIP) contain definitions and requirements related to family size, household, and MAGI-based income for the purposes of Medicaid and CHIP eligibility determinations.

The premium assistance option permits Medicaid or CHIP funds to be used to deliver coverage to Medicaid or CHIP-eligible individuals through the purchase of private health insurance, and it is not limited to Medicaid or CHIP-eligible individuals who have family members enrolled in a QHP. In some cases, the Medicaid or CHIP beneficiary could be enrolled in a health plan that provides individual coverage only, while in other situations, the Medicaid or CHIP beneficiary would be enrolled in a health plan that provides family coverage, depending on the categories of family coverage offered in the Exchange.

Comment: Some commenters, who were in favor of the continued authorization of premium assistance programs, stated that states should be allowed to determine how to make the concept work and urged CMS to allow complete state flexibility in designing and implementing benefit structures and cost sharing requirements.

Response: Individuals receiving coverage through premium assistance are Medicaid beneficiaries and are entitled to the full range of protections, including benefits and cost sharing, available under the law. States have flexibility under the state plan option to design how they will effectuate the coverage that is required while meeting applicable statutory and regulatory requirements. To the extent a state needs additional flexibility, the state may wish to explore demonstration options under section 1115 of the Act.

Comment: Several commenters recommended that premium assistance programs might require, or best be operated under, a Medicaid section 1115 demonstration.

Response: States have the flexibility to adopt premium assistance as an option under the

state plan if it is voluntary for beneficiaries and adheres to all applicable statutory and regulatory provisions. Enrollment in individual market coverage is not a statutory condition of eligibility. Some states have expressed interest in submitting proposals for section 1115 demonstrations to require enrollment in premium assistance and to allow for consideration of a broader range of factors when cost-effectiveness is assessed. In response to these inquiries, we will consider approving a limited number of premium assistance demonstrations that are determined to further the objectives of the Medicaid program and which will test these new arrangements and inform policy. For states that implement premium assistance through a section 1115 demonstration, which could include mandatory enrollment into premium assistance, we will only consider demonstrations under which states make arrangements with the health plan to provide wraparound benefits and cost sharing assistance. For further information on the section 1115 option, including guidelines for proposals, please refer to Premium Assistance Frequently Asked Questions (FAQs) that CMS issued on March 29, 2013, available at <http://medicaid.gov/State-Resource-Center/FAQ-Medicaid-and-CHIP-Affordable-Care-Act-ACA-Implementation/Downloads/FAQ-03-29-13-Premium-Assistance.pdf>

9. Changes to Modified Adjusted Gross Income and MAGI Screen

We proposed to implement sections 1902(e)(14) and 1943 of the Act, and section 1413 of the Affordable Care Act as they pertain to the definition of “modified adjusted gross income” (MAGI) and “household income” in section 36B(d)(2) of the Internal Revenue Code of 1986 (“36B definitions”). We also proposed a modification to previously issued regulations implementing section 1902(e)(14)(I) of the Act. The proposed rule applied the 5 percent disregard established by the Act for purposes of determining the income eligibility of an individual for medical assistance whose eligibility is determined based on MAGI, provided the determination was for the eligibility group with the highest income standard under which the

individual could be determined eligible using MAGI-based methodologies. The proposed changes are discussed in more detail in the January 22, 2013 Medicaid Eligibility proposed rule (78 FR 4625 through 4627). We received the following comments concerning the proposed changes to MAGI provisions:

Comment: Some commenters supported the proposal to apply the 5 percent disregard only to the highest income threshold under a MAGI-group available for the individual and the related impact on the number of individuals for whom states will be able to claim the “newly eligible” enhanced match rate.

Response: The Affordable Care Act established a 5 percentage point of the FPL disregard “for the purposes of determining income eligibility” for individuals whose eligibility is based on MAGI. The objective of the proposal is to balance giving beneficiaries the benefit of the disregard for eligibility purposes, with the intent to give states the opportunity to claim enhanced match for all newly eligible individuals if the state chooses to extend coverage to the new adult group. We propose doing so by ensuring that the disregard is applied to the income calculation of individuals for whom the disregard matters for a determination of eligibility for Medicaid under MAGI-based rules—that is, those for whom the application of the disregard means the difference between being eligible for Medicaid and being ineligible. These individuals are those whose income is within 5 FPL percentage points of the highest net income standard for which they can obtain Medicaid eligibility under MAGI-based income rules. The disregard would not be applied for a determination of eligibility for a particular eligibility group, but rather for eligibility for Medicaid.

Comment: One commenter questioned whether the proposed policy is consistent with federal law, which the commenter views as entitling all applicants to the 5 percent disregard. The commenter stated that our proposed policy could affect beneficiaries’ cost sharing or

benefits because it could result in a change in their eligibility groups. Some commenters noted that, for example, some parents could receive ABP coverage instead of the traditional Medicaid benefit package. The commenters noted, however, that this concern should be minimal since newly eligible adults who are medically frail and likely to need additional services covered under the regular Medicaid benefit package would have a choice of benefit package, between what is offered through an ABP that is based on section 1937 requirements, inclusive of EHB's, and ABP coverage that is not subject to section 1937 requirements, and includes the services approved in the state's Medicaid plan. Other commenters cited concerns about pregnant women and categories that offer only limited pregnancy-related services.

Response: The proposal to apply the 5 percent disregard to determine Medicaid eligibility rather than eligibility for a particular category is consistent with section 1902(e)(14)(I) of the Act. It is not necessarily the case that not applying the 5 percent disregard for purposes of determining eligibility category would result in moving individuals into a different eligibility group with different benefit and possibly cost-sharing rules because if the 5 percent disregard were applied as a general disregard, states would set income eligibility standards at levels that would compensate for that impact. For example, if the 5 percent disregard was applied generally, states might set the income eligibility standard for parents at a level 5 percent less than they would otherwise. Moreover, any adverse impact of a shift of beneficiaries from the parent group to the new adult group with coverage through an ABP will be minimized by the medically frail exception to benchmark coverage limitations. For pregnant women with income at the border between full benefits and pregnancy-related benefits, although the absence of the disregard may result in a pregnancy-related benefit package instead of full benefits, our March 2012 rule revised §435.116(d)(3) to clarify that a State's coverage of pregnancy-related services must be consistent with §440.210(a)(2) and §440.250(p), which allows States to provide

additional services related to pregnancy to pregnant women (see 77 FR 17149).

Comment: Several commenters recommended that CMS not revise the MAGI disregard rules. They raised concerns that there is too little time for states to make the systems and business process updates required to comply with the October 1, 2013 open enrollment period. They noted that the proposed rule requires more complex programming compared to simply adding 5 percent to all MAGI-based categories and that this policy could impact a state's ability to implement the MAGI requirements timely. In addition, they noted that although the 90/10 matching funds are available to make such systems-related changes, states must still finance 10 percent of the cost of these changes despite experiencing severe budgetary issues.

Response: We understand that many states relied up on the March 2012 final eligibility rule when planning their eligibility system builds for 2014. We appreciate that it may be difficult at this point in time to make programming changes for eligibility systems and have those changes take effect by January 1, 2014. In light of this challenge, we are finalizing our proposal, but we will not take any compliance actions for states whose systems cannot accommodate this eligibility determination requirement. We will approve eligibility determination systems even if as of January 1, 2014, the system applies the 5 percent disregard across the board to all individuals whose eligibility is determined using MAGI-based rules, based on a state's assurance that by January 1, 2015 the state will update the system to apply the disregard only for a determination of eligibility for Medicaid under MAGI-based rules.

Comment: Some commenters requested that states that are not expanding to cover the new adult group—and thus not claiming enhanced FMAP--should have the option to use the new calculation and continue to apply the 5 percent across- the-board disregard. Others requested that all states be given the option to apply the 5 percent disregard only to the highest income threshold under MAGI as proposed in our proposed rule.

Response: We believe that applying the 5 percent FPL disregard to determine eligibility based on overall eligibility rather than eligibility group is the best interpretation of section 1902(e)(14)(I) of the Act. Therefore, we are adopting our proposed policy as final, subject to the flexibility in implementation schedules discussed above.

Comment: One commenter asked whether the 5 percent MAGI income disregard would be applicable to only eligibility for the coverage group or whether it would also be applicable to cost-sharing or premium determinations --within the coverage group.

Response: Under this final rule, the 5 percent disregard under section 1902(e)(14)(I) of the Act applies to income determinations relative to Medicaid eligibility. It does not apply to determine into which eligibility group an individual should be placed. Nor is it intended to be applied to determine income for premium or cost-sharing payments.

Comment: One commenter requested clarification about whether, in a state that implements the eligibility expansion under section 2001 of the Affordable Care Act (that is, adopts the adult group), the state would need to apply the 5 percent disregard to a parent or caretaker relative age 65 or older that was not eligible for the expansion group.

Response: The 5 percent disregard is not applied based on an eligibility group, but based on whether the disregard would affect MAGI-based income eligibility for Medicaid as stated above. In the case of a parent or caretaker relative age 65 or older, the 5 percent disregard would be applied in determining MAGI-based income if the individual would otherwise be ineligible based on income. For example, if the parent/caretaker eligibility standard in a state was 80 percent of FPL and the individual's income before application of the disregard put them over the 80 percent standard, the 5 percent disregard would be applied and the individual would be eligible if the disregard brought their countable income below 80 percent of the FPL.

Comment: Another commenter asked for clarification of whether the 5 percent is only

applied when an individual would not be eligible in another group or if it would apply to all individuals being determined for eligibility in the group. The commenter specifically asked about whether the 5 percent disregard would be applied to keep family coverage in the Transitional Medical Assistance (TMA) group.

Response: TMA is beyond the scope of this rulemaking. TMA will be addressed in future guidance.

Comment: Several commenters questioned whether applying the 5 percent disregard to the MAGI income standards equivalent being produced through the process generally referred to as ‘MAGI conversion’ creates a double counting of the disregard. Other commenters asked whether states are being required to expand their income levels for pregnant women and children by 5 percent due to application of the disregard.

Response: We considered carefully the requirements in section 1902(e)(14)(A) of the Act in our December 2012 guidance to states on the establishment of converted MAGI-based income standards equivalent to levels used at the enactment of the Affordable Care Act (“MAGI conversion”). See <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO12003.pdf>. Under this guidance, converted MAGI-based income standards are set without regard to the 5 percent disregard, since the MAGI income conversion requirements in section 1902(e)(14)(A) of the Act are independent of the 5 percent disregard at section 1902(e)(14)(I) of the Act. MAGI-equivalent income standards are established taking into account disregards that are currently in effect but which will no longer be in effect under MAGI. As a result, there is no double-counting of the 5 percent disregard. The 5 percent disregard would apply once when calculating an individual’s MAGI-based income if the individual would otherwise be ineligible.

Comment: Several commenters requested clarification regarding how the 5 percent

disregard under MAGI applies to applicants under a separate CHIP program. Similarly, commenters asked how the 5 percent disregard is applied to individuals at the boundary between Medicaid and CHIP eligibility.

Response: The 5 percent disregard should be applied to individuals who may be eligible for the highest income standard under the applicable Title of the Act (for example, Title XIX or Title XXI) for which the individual may be determined eligible using MAGI-based methodologies. Therefore, in states that have separate CHIP programs, the income disregard should be applied both for the highest Title XIX eligibility group available to the child, as well as to the separate CHIP program to cover similarly situated children at a higher income standard. The result would be that children with a MAGI in the 5 percent band above the Medicaid income standard at issue would be determined eligible for Medicaid. To clarify, we are modifying the language in the final rule at §435.603(d)(4) to specify that the 5 percent disregard should be applied to the highest income standard in the applicable Title of the Act under which the individual may be determined eligible using MAGI-based methodologies. We do not believe this will impact the children for whom the state can claim enhanced match, because the state can claim enhanced match for any child whose income is greater than the upper income threshold under Medicaid on March 31, 1997, whether that child is covered under Title XIX or Title XXI.

Comment: One commenter asked whether there is any reason it would not be permissible for a state to program its eligibility system to build in the 5 percent disregard and effectively set the income limit at 5 percent higher than the state's established limit for MAGI related eligibility groups.

Response: Because the disregard is applied at the individual level, increasing the eligibility income standard for a group would not be the best way to program an eligibility system. Furthermore, doing so would be inconsistent with the statutory purpose of developing a

uniform income determination methodology applicable in all states, which could be applied by the Exchange as well as the State Medicaid or CHIP agency. Therefore, this would not be permissible. Instead if the eligibility system cascades sequentially through possible eligibility options, it should apply the 5 percent as one last eligibility step, only when the system has returned a determination of ineligibility because the individual is over scale for income.

10. Single State Agency – Delegation of Eligibility Determinations to Exchanges (§431.10 and §431.11)

We proposed to revert to the policy proposed in the Medicaid eligibility proposed rule published on August 17, 2011 (76 FR 51148), that single state Medicaid agencies will be limited to delegating eligibility determinations to Exchanges that are government agencies maintaining personnel standards on a merit basis. We retained many of the provisions strengthening the control and oversight responsibilities of the single state agency including the authority to issue policies, rules and regulations on program matters and to exercise discretion in the administration or supervision of the plan. We also proposed to make changes to §431.11 regarding state organization. We received the following comments concerning the proposed changes to the single state agency provisions:

Comment: The majority of commenters strongly support the decision to revert to the policy originally proposed in the August 2011 Medicaid eligibility rule that delegation of the authority to determine eligibility for Medicaid is limited to Exchanges that are government agencies maintaining personnel standards on a merit basis. One state specifically commented that it supports this change as it allows states to maintain program integrity. Several other commenters noted that this construct has been a consistent legal interpretation for many decades. Other commenters noted that many state Medicaid employees are trained social workers who have the knowledge and experience to help our country's most vulnerable citizens, ensuring

consistency and accessibility to benefits.

Response: We appreciate commenters support for our proposed policy, and therefore, we are adopting in this final rule the policy that delegation of the authority to determine eligibility for Medicaid is limited to Exchanges that are government agencies maintaining personnel standards on a merit basis. This is the policy that we originally proposed in our August 2011 proposed rule and that was re-proposed in the January 2013 proposed rule. We believe that under the best read of the statute, determining Medicaid eligibility is an inherently governmental function that must be performed by governmental agencies.

For purposes of delegation, we are treating a quasi-governmental entity or public authority running an Exchange and employing merit system protection principles as a government agency such that delegation to it would be permitted. Although we were explicit in the proposed regulation at §431.10(c)(1)(i)(B), §431.10(c)(2) and §431.10(c)(3)(i) regarding authority to delegate to public authorities, we are deleting these references to public authorities in the final rule to conform with the Exchange regulation which only explicitly requires at §155.20 that Exchanges be governmental agencies or non-profit entities established by a state.

Comment: Some commenters wrote that they especially appreciate the recognition that Medicaid agencies would not be parties to contractual relationships between the Exchange and an entity engaged by the Exchange to determine eligibility, which would make it impossible for the Medicaid agency to provide appropriate oversight. They support maintaining the requirement that the Medicaid agency provide oversight when responsibility for the eligibility determination is delegated to another agency, because monitoring and oversight is necessary regardless of whether the delegation is to a government or non-government agency. They recommended that such oversight should include review of a sample of eligibility decisions made by the Exchange, scrutiny of the “logic” used in information technology systems to ensure

that Medicaid policy is being applied in an accurate manner, regular observations of the processes used by the Exchange in making eligibility determinations, participation by Medicaid agency staff in training of Exchange staff, and monitoring of complaints and appeals. Many commenters suggested more specific requirements in regulation that should be added to §431.10(d), specifying the oversight and monitoring required in the agreement between the Medicaid agency and Exchange or Exchange appeals entity include training for the Exchange or Exchange appeals entity, as well as monitoring of the systems being built.

Response: We agree that the single state agency should be required to provide oversight when responsibility for the eligibility determination is delegated to another agency and are finalizing our proposal requiring this. We appreciate the commenter's various suggestions regarding quality control and oversight by the Medicaid agency and believe they are within the ambit of what is intended by §431.10(c)(3)(ii), requiring the Medicaid agency to exercise appropriate oversight over the eligibility determinations and appeals decisions made by such agencies to ensure compliance with paragraphs (c)(2) and (c)(3)(i) of this section and institute corrective action as needed. We believe §431.10(c)(3)(ii) can be exercised in various ways including those suggested by the commenters. We also agree that participation by Medicaid agency staff in training of Exchange staff would be valuable. We believe that the requirements in §431.10(d) which specify the requirements for the agreement between the Medicaid agency and the Exchange or Exchange appeals entity include the requisite quality control and oversight language.

Comment: Many commenters recommended ways to ensure a coordinated system by engaging non-profits and private contractors in the process of supporting the Medicaid and CHIP eligibility determination, while not allowing them to determine eligibility. Recommendations included providing assistance to consumers with the application and enrollment process as

certified application counselors and operating call centers, providing basic information to potential applicants. One commenter suggested that any contract over the amount of \$1 million entered into by the State for services which support eligibility determination, such as data-matching or application/eligibility screening, be submitted to the Department of Health and Human Services for review.

Response: We agree that certified application counselors and call center administration are ways to engage non-profits and private contractors in the Medicaid eligibility process while assuring all final eligibility determinations are made by governmental entities. However, we do not believe it necessary to subject state contracts for support services related to eligibility determinations to special oversight rules. We believe that the single state agency's responsibility for determining and/or overseeing eligibility determinations includes oversight of such support functions.

Comment: One commenter noted that, while there is value in continuing the role of public employees in Medicaid eligibility determinations, this decision can be expected to have the inadvertent effect of requiring "hand offs" in some states between privatized Exchanges and Medicaid agencies. Specifically, in states operating a privatized Exchange, the Exchange will now be unable to conduct a full Medicaid determination, which means that an individual who applies for coverage via an Exchange and is found likely eligible for Medicaid will be "bounced" to the Medicaid agency for a final determination. Families with children, in particular, are likely to be "bounced" because they are eligible for Medicaid or CHIP at far higher income levels than adults in all states. As a result the commenter recommended that §435.1200(d) include a new subpart requiring states to report to HHS and to make publicly available data on the share of applicants who are determined potentially eligible for Medicaid or CHIP by an Exchange who are eventually enrolled. Moreover, they recommended that procedures should be outlined for

HHS to evaluate the data and take corrective action if data revealed that significant numbers of people are “falling through the cracks” because they must navigate multiple agencies when trying to secure coverage for themselves or their children.

Response: States will be required to establish performance standards in their state plans in accordance with §435.912. To further this work, earlier this year, we issued a request for information (RFI) regarding performance indicators for Medicaid and CHIP business functions. The RFI explained that CMS intends to begin collecting and reporting on information including data regarding individual (applicant and beneficiary) experience with eligibility and enrollment. One of the indicators proposed under the eligibility and enrollment domain was “accurate eligibility determinations,” including a proposed “accurate transfer rate”. The accurate transfer rate would be measured by the percent of individuals transferred to Medicaid, CHIP, or the Exchange, as applicable, who are determined eligible by that agency. We are currently reviewing the comments received and finalizing our proposal for implementation of performance reporting. For further information about the RFI, see our website at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Data-and-Systems/Downloads/RFI-Performance-Indicators-1-24-13.pdf>.

Comment: One commenter requested that we provide public access to agreements between the Medicaid agency and other entities conducting determinations. Some commenters also requested that we require public posting of the agreements on internet websites.

Response: We have provided in §431.10(d) that agreements with federal, state or local entities making eligibility determinations or appeals decisions be available to the Secretary upon request. To the extent that the Secretary requests and obtains a copy of an agreement under §431.10(d), the public can request a copy of the agreement through the Freedom of Information Act, 5 U.S.C. 552. These agreements may also be obtained at the state level under state freedom

of information act laws.

Comment: Some commenters opposed this policy reversal from the previous Medicaid eligibility rule, and noted that, since that rule was issued, several states have relied on it to inform their decisions on establishing a State-Based Exchange, as well as to plan for Exchange and Medicaid systems and operations in future years. They believe these decisions and activities cannot easily be amended or changed in a short timeframe, and this policy change could have a major impact on the work states have completed, as well as their future plans. They requested that CMS revoke the proposed change.

Response: We appreciate the challenges facing states, which is why we signaled nearly a year ago on May 16, 2012, in guidance titled “General Guidance on Federally-facilitated Exchanges” our intent, in light of public comments received on the final Medicaid and Exchange eligibility regulations, to propose further comment regarding ways that States could ensure coordinated systems when engaging non-profits and private contractors in the process of making Medicaid eligibility evaluations, while having government agencies make eligibility determinations. See

http://cciio.cms.gov/resources/files/ffe_guidance_final_version_051612.pdf. We have also shared our intent to propose revised rules in webinars with states on the eligibility rules and in individual state meetings.

11. Conversion of Federal Minimum Income Standards for Section 1931 of the Act (§435.110 and §435.116)

We proposed to require conversion of the federal minimum income standard for section 1931 of the Act to comport with the new rules regarding modified adjusted gross income (MAGI) that will take effect on January 1, 2014. Sections 1902(e)(14)(A) and (E) of the Act ensure that, in the aggregate, individuals who would have been eligible under Medicaid rules in

effect prior to the Affordable Care Act remain eligible once the new MAGI-based methodologies go into effect. Our proposal to direct conversion of the federal minimum standard for section 1931 implements the conversion requirements in the statute more consistently, which is particularly important in light of the Supreme Court's decision in National Federation of Independent Business v. Sebelius, ____ U.S. ____; 132 S. Ct. 2566; 183 L.Ed. 2d 450 (2012). The proposed changes are discussed in more detail in the January 22, 2013 proposed rule (78 FR 4628 and 4629).

We received no comments on our proposed policy to convert the federal minimum standard for section 1931 of the Act, and therefore, are finalizing our proposal in §435.110. This policy relates to the coverage levels for parents and caretaker relatives in states that do not implement the eligibility expansion in section 2001 of the Affordable Care Act to provide coverage for the low-income adult group. In addition, because pregnancy benefits for pregnant women under §435.116(d)(4)(i) are tied to the same May 1, 1988 AFDC income standard for the applicable family size, we are finalizing our proposal in §435.116 that this income limit should also be converted.

B. Essential Health Benefits in Alternative Benefit Plans

Section 1937 of the Act provides states with the flexibility to amend their Medicaid state plans to provide for the use of benefit packages other than the standard Medicaid state plan benefit package offered in that state, for certain populations defined by the state. These ABPs are based on benchmark or benchmark-equivalent packages. There are four benchmark packages described in section 1937 of the Act:

- The benefit package provided by the Federal Employees Health Benefit plan (FEHB) Standard Blue Cross/Blue Shield Preferred Provider Option;

- State employee health coverage that is offered and generally available to state employees;
- The health insurance plan offered through the Health Maintenance Organization (HMO) with the largest insured commercial non-Medicaid enrollment in the state; and
- Secretary-approved coverage, which is a benefit package the Secretary has determined to provide coverage appropriate to meet the needs of the population provided that coverage.

Benchmark-equivalent coverage is provided when the aggregate actuarial value of the proposed benefit package is at least actuarially equivalent to the coverage provided by one of the benefit packages described above, for the identified Medicaid population to which it will be offered. Section 1937 of the Act further provides that certain categories of benefits must be provided in any benchmark-equivalent plan, and other categories of benefits must include “substantial actuarial value” compared to the benchmark package.

That said, we appreciate that it may be difficult at this point to make changes to the ABP that take effect by January 1, 2014. In light of this challenge, we will partner with states to work as quickly as possible to come into full compliance with these provisions. We do not intend to pursue compliance actions on these issues to the extent that states are working toward but have not completed a transition to the new ABPs on January 1, 2014.

Conforming Changes to Medicaid to Align with Essential Health Benefits

We proposed to implement section 2001(c) of the Affordable Care Act that modifies the benefit provisions of section 1937 of the Act. Specifically, section 2001(c) of the Affordable Care Act added mental health benefits and prescription drug coverage to the list of benefits that must be included in benchmark-equivalent coverage; required the provision of Essential Health Benefits (EHBs) beginning in 2014; and directed that section 1937 benefit plans that include medical/surgical benefits and mental health and/or substance use disorder benefits comply with

the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).

In addition, we proposed to implement section 1902(k)(1) of the Act, which requires that medical assistance for the new eligibility adult group for low-income adults under section 1902(a)(10)(A)(i)(VIII) of the Act must receive medical assistance provided through an ABP (which must include coverage of EHBs as of the same date).

We also proposed to implement section 1937(a)(2)(B)(viii) of the Act, which provides that individuals in the new mandatory eligibility group for former foster care children under age 26 are exempt from mandatory enrollment in an ABP.

We proposed to implement section 1937(b)(7) of the Act, which provides that medical assistance to individuals described in section 1905(a)(4)(C) of the Act (individuals of child bearing age) through enrollment in an ABP shall include family planning services and supplies.

We proposed to codify in §440.345(e) the process to determine how often states would need to update ABPs after December 31, 2015.

We also proposed to add a new §440.347 to incorporate section 2001(c)(5) of the Affordable Care Act.

Furthermore, anti-discrimination provisions found at section 1302(b)(4) of the Affordable Care Act were proposed to be codified §440.347(e).

1. General Comments

Comment: One commenter stated they support the structure for implementing EHBs as proposed.

Response: CMS appreciates the support.

2. Alignment with Essential Health Benefits Provisions

a. Scope of Alternative Benefit Plans (§440.305)

We proposed to add the new adult eligibility group as an eligibility group that must receive benefits consistent with section 1937 of the Act. We also proposed that groups provided ABP coverage under section 1937 of the Act may be identified based on individual characteristics and not by the amount or level of FMAP funding.

Comment: Many commenters commended the addition of language prohibiting states from targeting Medicaid expansion populations solely on the basis of applicable matching rate. In addition, many commenters applauded language proposing to codify the flexibility HHS has given to states to use the Secretary-approved option in section 1937 of the Act to extend comprehensive Medicaid coverage to the newly-eligible expansion population. The commenters further urged CMS to partner with states to ensure that this population's full range of mental health and substance use needs and other health needs will be met.

Response: We thank the commenters for their support.

Comment: One commenter questioned the inclusion of the sentence which states, "Enrollment in ABPs must be based on the characteristics of the individual rather than the amount or level of federal matching funds." The commenter stated this to be an unnecessary statement since eligibility for FMAP is based on eligibility category. It is unclear why enrollment in a benchmark plan would impact FMAP.

Response: People who qualify for eligibility under the new adult eligibility group will be determined to be either newly eligible or already eligible. For Medicaid coverage provided to the newly eligible population, the state will receive 100 percent FMAP in 2014 and for those who are determined to be eligible under December 2009 state rules, the state will receive its otherwise applicable FMAP. We included this language to clarify that states may not design different benefit packages based on the level of FFP they will receive, but rather the benefit package should be designed based on the medical needs of the population being served

Comment: One commenter believed that the use of ABPs will assist states with expanding coverage in a meaningful way. However, the new adult population may have unique health care needs, including a high incidence of behavioral health and social issues. The commenter believed that the use of the ABPs would be most beneficial if they are used to tailor the scope of services and alignment of benefits to ensure adequate delivery systems for high need populations.

Response: Section 1937 of the Act offers flexibility for states to provide medical assistance by designing different benefit packages plan for different groups of eligible individuals. We agree with the commenter that ABPs can be successfully designed to meet the needs of the new adult population, including those with varying health care needs. As long as each benefit package contains all of the EHBs, much flexibility exists for states to meet the needs of beneficiaries.

Comment: One commenter was concerned that individuals age 50 to 64 may not be provided EHBs that are at least equal to those available to high-income individuals who purchase coverage on the commercial markets.

Response: We understand that there could be some variation in EHBs as defined for the individual market and for Medicaid based on the selection of different benchmark plans to define EHBs. But the flexibility to select different benchmark plans to define EHBs for Medicaid ABPs will allow states to address the unique needs of each circumstance and promote administrative simplicity, while still providing a floor for coverage. As long as that floor is met, Medicaid beneficiaries in the new adult group can also receive benefits from the selected coverage options under section 1937 of the Act or through substitution of benefits.

Comment: One commenter stated it is important that all individuals obtaining Medicaid coverage under the Affordable Care Act receive health coverage appropriate for their needs,

including strong coverage for mental health and substance use disorders. The commenter also wrote it is important that traditionally Medicaid eligible populations that may be enrolled in ABPs are guaranteed adequate coverage.

Response: ABP flexibility is an option that states can choose to use in redesigning their current Medicaid benefit program. The requirement that ABPs include EHBs and comply with mental health parity requirements ensures a minimum level of sufficiency of the coverage.

Comment: One commenter requested that HHS require or give states the option to provide EPSDT coverage to 19- and 20-year olds who qualify for the new adult group.

Response: The existing provisions of §440.345 require states to make available EPSDT services as defined in section 1905(r) of the Act that are medically necessary for those individuals under age 21 who are covered under the State plan. We did not propose to change this requirement. To the extent that any medically necessary EPSDT services are not covered through the ABP plan, states must supplement the ABP plan to ensure access to these services. EPSDT provisions apply to 19- and 20-year olds who qualify for the new adult group.

Comment: One commenter believed that the Affordable Care Act provided an unprecedented opportunity to improve access to somatic and behavioral health treatment for the “jail-involved” population. The commenter noted that up to 6 million incarcerated individuals have income below 133 percent which would make them newly eligible for Medicaid under the Affordable Care Act. These individuals could represent up to 1/3 of the newly eligible population, underscoring the importance of considering the particular circumstances of incarcerated individuals in implementation of the Affordable Care Act.

Response: Paragraph (A) following section 1905(a)(29) of the Act and implementing regulations at §435.1009, specify that Medicaid is prohibited from making payments for care or services for any individual who is an inmate of a public institution, except as an inpatient in a

medical institution. We read this prohibition to apply generally to medical assistance, whether provided through the regular coverage plan or through an ABP. Regular coverage or regular Medicaid benefit package is defined as Medicaid state plan services including services defined in section 1905(a), 1915(i), 1915(j) and 1945 authorities. Thus, while we agree with the commenter that incarcerated individuals may be eligible for Medicaid, they would not be entitled to ABP benefits inconsistent with the payment exclusion. We note that this is consistent with the exclusion of incarcerated individuals from eligibility to enroll in coverage through the Exchanges. It is also consistent with the responsibility under the Eighth Amendment of the United States Constitution of governmental entities to provide necessary medical care to individuals who they are holding as inmates, which effectively creates a liable third party for such care.

States should suspend, rather than terminate, the Medicaid eligibility of individuals who are enrolled in Medicaid when entering a public institution, so as to ensure ease of reinstatement of coverage post-release. Additionally, if an individual is not already enrolled in Medicaid, states can enroll eligible individuals prior to their release so that the individual can receive Medicaid covered services in a timely manner upon discharge.

Comment: One commenter believed that the new eligibility category is likely to attract younger and healthier populations than traditional Medicaid. The commenter believed that a percentage of those who are newly eligible will acquire a condition or disability after they are enrolled in an ABP. The commenter recommended that HHS standardize an effective process for ensuring that beneficiaries whose health status changes have the opportunity to access in a timely manner other ABP or traditional state Medicaid plans which meet their needs. The following standards were suggested: a process for participants to request and receive clinically appropriate benefits not routinely covered by the plan; a process for participants to request and

receive coverage for benefits beyond the limits set by the plan where extraordinary circumstances exist; and a process for participants to request and receive coverage of specialty care not routinely covered by the plan when medically necessary and appropriate.

Response: As noted, states have the flexibility to define different benefit packages to meet the needs of disparate populations. In addition, individuals in the new adult group meeting the exemption criterion found in section 1937 of the Act have the ability to choose between ABP benchmark coverage designed by the state using the rules of section 1937 of the Act including EHBs as a minimum level of coverage, or ABP benchmark coverage defined as the state's approved regular state plan benefit package, which is not subject to the requirements of section 1937 of the Act.

Comment: One commenter supported providing states with flexibility to add state plan benefits and services found in base-benchmark plans to benchmark-equivalent benefits. The commenter also believed it would be helpful to clarify that adding such benefits would be possible and appropriate for individuals in the Medicaid expansion group.

Response: We appreciate the commenter's support, and clarify here that individuals in the new adult group can receive benchmark-equivalent coverage or Secretary-approved coverage which can include a broader range of services than in public employee or commercial benchmark coverage options.

Comment: One commenter interpreted the proposed rule to say that individuals who are newly eligible adults – and not deemed medically frail – do not qualify for additional services above and beyond what is required under section 1937 of the Act and the EHB. Based on that interpretation, if a state wanted to provide wrap around services for a particular population, in which some of the newly eligible would fall under, it would not be allowable unless the state created a Secretary-approved plan that incorporates the benefits into the underlying plan. The

commenter requested that CMS clarify and/or confirm the interpretation of this provision.

Response: We confirm that the individual's interpretation is correct. Section 1902(k)(1) of the Act provides that individuals in the new adult group receive benchmark or benchmark-equivalent coverage subject to the requirements of section 1937 of the Act (except that individuals who would otherwise be exempt may choose to receive benchmark or benchmark-equivalent coverage that is not limited by section 1937 of the Act, and thus have the option of benchmark or benchmark-equivalent coverage that is equal to the Medicaid benefit package otherwise available). Such coverage can be in the form of Secretary-approved coverage, which may, at state option, include a broader range of services than public employee or commercial benchmark options.

Comment: Many commenters requested CMS clarify that the federal matching rate is based on the individual and not the services provided. A few commenters requested clarification that services provided through the Secretary-approved ABP process for Medicaid expansion individuals will be covered at the enhanced rate and that Medicaid expansion individuals who are exempted into traditional Medicaid coverage will also be covered at the enhanced rate.

Response: We clarify that the enhanced FMAP rate for newly eligible individuals is available for all services they receive. The matching rate is based on the individual, not on the services provided to them.

Comment: One commenter urged HHS to clarify the flexibility that states will have to design multiple ABPs targeting specific populations. The commenter understands this provision will allow states to put in place ABPs for sub-populations within the newly eligible group (that is, people living with chronic viral hepatitis or other chronic conditions) and urges CMS to clarify that this is an appropriate use of the ABP flexibility.

Response: Section 1937 of the Act provides states with significant flexibility to design

Medicaid benefit coverage under the State plan. There are many options in selecting an ABP, and states may offer different ABPs to different targeted populations (except that, as discussed elsewhere, targeting cannot be based on the amount or level of federal matching funding).

Section 1937 of the Act provides states with the statutory construct to provide an ABP without regard to requirements at sections 1902(a)(1) (related to state-wideness) and 1902(a)(10)(B) (related to comparability) of the Act. This flexibility is provided at §440.376 and §440.380, respectively.

Comment: One commenter was unclear why the term ABP is being used. The Affordable Care Act references ABPs specifically for evaluation of the ABPs as required under the Class Independence Advisory Council. Other sections reference alternative benefits or programs specifically under section 1937 of the Act or the establishment of Basic Health Plans. The commenter believed the use of the term is confusing and unnecessary since benchmark plans are not alternative plans or programs as originally identified in the law. Another commenter found §440.305 confusing as paragraph (a) refers to “benchmark and benchmark-equivalent” however paragraph (b) refers to ABP. The commenter suggested revising paragraph (a) by replacing benchmark and benchmark-equivalent with ABP.

Response: The Deficit Reduction Act of 2005 amended the Act by adding a new section 1937 of the Act to provide for the use of benefit packages other than the standard benefit package, namely benchmark and benchmark-equivalent packages. The Affordable Care Act made statutory changes to section 1937 of the Act, one of which is the requirement that section 1937 coverage packages include EHBs. We issued regulations outlining how the precise parameters of EHBs will be established in the non-grandfathered plans in the individual and small group markets and, to some degree, how they will be implemented in section 1937 coverage plans. In that regulation, the term “base-benchmark” was used to refer to the base plan

used by states to determine EHBs for coverage plans in the non-grandfathered plans in the individual and small group markets. That base-benchmark plan becomes the EHB-benchmark plan after it is supplemented with any missing categories of EHBs. In an effort to prevent confusion between the term “benchmark” used for the non-grandfathered plans in the individual and small group markets, and the use of “benchmark” by section 1937 coverage plans, we chose from the statutory construct of section 1937 of the Act the term “Alternative Benefit Plan” (ABP) to hereafter refer to Medicaid benchmark and benchmark-equivalent plans as ABP.

Comment: One commenter indicated that there was no adult group under section 1902(a)(10)(A)(i)(VIII) of the Act on or before February 8, 2006 so the exception in subsection (b) does not appear to fit.

Response: Section 6044 of the Deficit Reduction Act of 2005 amended Title XIX by adding a new section 1937 of the Act that allows States to amend their Medicaid State plan to provide for ABPs and limits application of this provision to individuals whose eligibility is based on an eligibility category under section 1905(a) of the Act that could have been covered under the State’s plan on or before February 8, 2006. In 2010, section 2001(a)(1) of the Affordable Care Act amended Title XIX to establish a new optional adult eligibility group for low-income adults age 19 to 64. Effective January 1, 2014, States that implement this new eligibility group must provide medical assistance for that group through an ABP. As specified, all provisions of section 1937 of the Act apply to the new adult eligibility group except that those individuals in the new adult group who meet the exemption criteria will have a choice between ABP benchmark benefits as defined by the state under the rules of section 1937 of the Act and ABP benchmark benefits defined as the state’s approved Medicaid state plan, without regards to the rules of section 1937 of the Act.

Comment: A few commenters believed the final rule should clarify that an ABP

designed for individuals within the new adult eligibility group can align with traditional Medicaid coverage through the process of designing of a Secretary-approved plan.

Response: We understand the importance of this issue, and reiterate guidance here. Secretary-approved coverage, which can include the full regular Medicaid state plan benefit package, is one of the four statutorily specified coverage benchmarks available under section 1937 of the Act. States can choose to use Secretary-approved coverage to significantly align the benefits offered to the new adult eligibility group with the regular state Medicaid package. Like with the other three statutorily specified coverage benchmarks, the Secretary-approved coverage must include EHBs as described in section 1302(b) of the Affordable Care Act and applicable regulations. In all cases, EHBs are first defined as the benefits from the base benchmark plan and supplemented with benefits from other base benchmark plans as necessary. CMS is clarifying in this rule that substitution of benefits as defined at §156.115(b) is applicable to EHBs in ABPs. We believe that states will appreciate this added flexibility. Substitution of benefits can occur benefit by benefit. The benefits must fit into the same EHB category and the benefits being interchanged must be actuarially equivalent. Benefits do not have to be similar in nature, they must only be in the same EHB category and actuarially equivalent. Furthermore, states may substitute more than one benefit that when combined are actuarially equivalent to a single benefit. States may use their Medicaid state plan benefits for substitution if the state plan benefit is actuarially equivalent and in the same EHB category of benefit that will be replaced. ,-

Comment: Consistent with the provisions of sections 1902(k)(1) and 1903(i)(36) of the Act, the commenter requested that CMS confirm that the coverage for individuals eligible only through section 1902(a)(10)(A)(i)(VIII) of the Act is limited to benchmark or benchmark-equivalent coverage.

Response: That is correct. This still leaves states with significant flexibility to design coverage using the options of benchmark coverage, which includes Secretary-approved coverage, and benchmark equivalent coverage. Section 1937 of the Act must also provide EHBs, which through selection of a base-benchmark plan, supplementation and substitution, will be used to define the EHBs. EHBs are then incorporated with the section 1937 benchmark coverage to lead to a complete benefit package.

Comment: Several commenters stated that the option to offer specialized benefit packages, in the form of more than one ABP, to different target populations creates an administrative burden and confusion for families. The option to offer specialized benefit packages might require more than one design process and public notice; additional actuarial analyses of the different benefit packages for rate setting; an extra process for tracking individuals; and a state's contracted MCOs would have to manage different benefit packages.

Response: The flexibility to provide specialized benefit packages to one or more targeted populations is at the option of the state. Each state will determine whether it is appropriate or administratively feasible to design and offer different benefit packages for different groups of beneficiaries.

Comment: One commenter was concerned with the disparities in coverage that the proposed EHB policy would create. That is, the guidance suggests that the policy only mandatorily applies to the newly eligible category of adults. In states that wish to take up the new expansion option this creates a situation in which the higher income expansion population will receive a more generous benefit package than the existing population would receive.

Response: We understand the commenter's concern, and it is true that the benefit package may be different because of the requirement that ABPs provide EHBs. However, it is not clear that the ABP benefit package provided to the new adult eligibility group will be more

generous than the existing Medicaid benefit package. In addition, we remind readers that the EHB requirements apply to all individuals receiving services through an ABP, not just those in the new adult group.

Summary: We did not make any changes to proposed regulation text as a result of comments in this section.

b. Exempt individuals (Former foster care children) (§440.315)

We proposed to implement section 1937(a)(2)(B)(viii) of the Act, added by section 2004 of the Affordable Care Act, as amended by section 10201(a) of the Affordable Care Act, by providing that individuals eligible under section 1902(a)(10)(A)(i)(IX) of the Act will be exempt from mandatory enrollment in an ABP. .

Comment: Many commenters commended HHS for confirming that the new former foster care children group is exempt from mandatory enrollment. Many other commenters expressed support for affirming at §440.315(h) that former foster care children are statutorily exempt from mandatory enrollment in an ABP, and therefore, can access the full Medicaid benefit, including EPSDT services, up to age 21.

Response: We appreciate commenter support. Individuals under age 21 receive EPSDT either through the ABP or as additional coverage that supplements the ABP.

Comment: One commenter wrote that while the proposed rule clarifies that former foster care youth up to age 26 are eligible for full Medicaid benefits, may not be mandated into an ABP, and will have access to full EPSDT services up to age 21, after age 21, former foster care youth will no longer have access to EPSDT benefits and requested clarification as to the meaning of “full Medicaid benefits.” According to the commenter, the American Academy of Pediatrics recently reported that children in foster care experience significantly higher rates of medical and mental health challenges, and therefore, believes that youth aging out of foster care

require comprehensive health coverage that recognizes their unique needs. Once a youth turns 21 they lose EPSDT coverage but continue to have the same health needs. The commenter therefore requested that CMS define “full Medicaid benefits” to include benefits akin to EPSDT, including dental coverage, mental health services and physical health care.

One commenter stated she appreciates the clarification that former foster care children are exempt from mandatory enrollment in an ABP and that they will receive full Medicaid benefits. However, it is not clear whether this means they can receive EPSDT. The commenter urged CMS to consider mandating, or at a minimum, allowing states to provide EPSDT benefits for this at risk population because in a majority of states oral health is not part of the adult Medicaid benefit package and evidence suggests that roughly 35 percent of children in foster care have significant oral health problems. Making sure oral health issues are addressed as former foster care youth move into adulthood will have a significant impact.

Response: We acknowledge that children in foster care generally experience significantly higher rates of medical and mental health challenges and that these health challenges often continue after aging out of foster care. For this reason, Congress provided statutory protection for an individual who receives aid or assistance under part B of title IV of the Act for children in foster care or an individual for whom adoption or for whom foster care assistance is made available under part E of title IV of the Act, without regard to age, by exempting these individuals from mandatory enrollment in an ABP.

Under the existing provisions of §440.345, States must make available EPSDT services, as defined in section 1905(r) of the Act, for those individuals under age 21 who are enrolled in an ABP. To the extent that medically necessary EPSDT services are not otherwise covered through the ABP for individuals under 21, states are required to supplement the ABP to ensure access to these services. However, there is no statutory authority to require states to provide

EPSDT services beyond age 21. We note that states have the flexibility to design an ABP targeted to former foster care children that provides a more comprehensive array of health coverage than is provided through the regular state plan and to offer voluntary enrollment in such a plan. Through the ABP option, states can provide this population with oral health and other services not otherwise available to adults through State plan coverage.

Summary: We have not changed proposed regulation text as a result of comments received in this section.

c. Benchmark-equivalent health benefits coverage (Prescription drugs and mental health benefits) (§440.335)

We proposed to implement section 2001(c) of the Affordable Care Act that added mental health benefits and prescription drug coverage to the list of benefits that must be included in benchmark-equivalent coverage.

Comment: Many commenters were supportive of paragraphs (b)(7) and (b)(8) implementing the statutory requirements for benchmark-equivalent coverage to include prescription drugs and mental health benefits. A few commenters commended the broad list of services included in the proposed rule.

Response: We agree that the inclusion of prescription drugs and mental health benefits as defined within ABPs are important and necessary and we appreciate the support of commenters regarding the coverage of the benchmark-equivalent health benefits.

Comment: A few commenters were pleased that HHS listed services that can be vital to people with disabilities and chronic health conditions as allowable in benchmark-equivalent and Secretary-approved coverage.

Response: We acknowledge the special medical needs of individuals with chronic health conditions. The final rule provides a clear path to coverage for chronic disease management

under §440.347.

Comment: A number of commenters requested that CMS clarify paragraph (c)(1). The commenters believed that CMS is suggesting it will use a similar policy for benchmark-equivalent coverage as it does for Secretary-approved coverage and, thus, allow addition of benefits through the benchmark-equivalent coverage process. The commenters believed there is no legal impediment to this approach and supported it. The commenters urged CMS to confirm this interpretation.

Response: We confirm this interpretation. The rule provides states the flexibility to include coverage for benefits beyond the required coverage and allows for states to create benchmark-equivalent coverage that can include benefits not available through the benchmark options.

Comment: Numerous commenters were confused by the language in §440.335(c)(1) allowing addition of services available in “2 or more” benchmark options, as opposed to the language of “1 or more” which appears in §440.330 and in current regulation. The commenters believed this may be a clerical error and recommended the “1 or more” language to maximize state flexibility.

Response: A clerical error was made in §440.335(c)(1). The regulation has been corrected to read, “...for any additional benefits of the type which are covered in 1 or more of the standard benchmark...”

Comment: One commenter was concerned that only provision §440.335(c)(1) was being amended leaving (c)(2) and (c)(3) intact. The commenter believed this will result in conflict with newly added §440.335(b)(7) and (8) as these provisions provided that four benefits (prescription drugs, mental health, vision and hearing services) must represent 75 percent of the actuarial value and are not required to be covered.

Response: We disagree that the existing provision §440.335(c)(2) will conflict with §440.335(b)(7) and (b)(8). The actuarial value of the coverage for prescription drugs, mental health services; vision services; and hearing services must still be at least 75 percent of the actuarial value of the coverage for that category of service in the benchmark plan used for comparison by the state.

However, provision §440.335(c)(3) is in conflict with §440.335(b)(7) and (b)(8). The state will, by default, meet the conditions of (c)(3) because prescription drugs and mental health services are now required benchmark-equivalent coverage and states will not have an option to provide such coverage as regulation currently allows. States also have the ability to add vision and hearing services through new requirements for additional coverage at §440.335(c), for individuals not in the new adult group. Individuals in the new adult group can receive these vision and hearing services, at state option, through the use of Secretary-approved coverage. Therefore, we have stricken §440.335(c)(3) from the final rule.

Summary: As a result of comments received in response to the proposed regulation, CMS has deleted §440.335(c)(3) from the final rule. Additionally, an error was made in §440.335(c)(1). The regulation has been corrected to read, "...for any additional benefits of the type which are covered in 1 or more of the standard benchmark coverage packages described in §440.330(a) through (c) of this part or State plan benefits ..." Otherwise, CMS has not made any changes to this section.

d. EPSDT and other required benefits (family planning services and supplies) (§440.345)

We proposed to codify section 2303(c) of the Affordable Care Act by adding paragraph (b) to §440.345 to provide that ABP coverage provided to individuals described in section 1905(a)(4)(C) of the Act (individuals of child bearing age), include family planning services and supplies.

Comment: Many commenters thanked CMS for codifying the important provision requiring that ABP coverage provided to individuals of child-bearing age include family planning services and supplies. This will help insure that Medicaid beneficiaries can access essential family planning services and supplies regardless of the type of Medicaid plan in which they are enrolled.

Response: We thank the commenters for their support.

Comment: One commenter requested further clarification as to the specific services and supplies that fall into this category. Clarification was also requested on which services are covered for individuals of child bearing age, including minors who can be considered to be sexually active, who are eligible under the state plan, and who want such services required under section 1905(a)(4)(C) of the Act. Because family planning services are not clearly defined in federal law or regulation, the commenter urged CMS to clarify in this rule that family planning services and supplies include but are not be limited to: examination and treatment by medical professionals; medically appropriate laboratory examinations and tests; counseling services and patient education; medically approved methods; procedures, pharmaceutical supplies; and devices to prevent contraception and infertility services, including sterilization reversal.

Several recommended HHS clarify family planning to specify coverage of section 1905(a)(4)(C) of the Act services and supplies and require states to assure compliance with section 1902(a)(23) of the Act freedom of choice for family planning services and supplies, since it is likely that many states will contract with managed care organizations, some of which may have no Medicaid experience. They believe that explicitly requiring freedom of choice will increase the likelihood that all plans will comply with the freedom of choice requirement.

Response: Family planning services and supplies are described in section 1905(a)(4)(C) of the Act. We have chosen not to use this rule as the vehicle for issuing additional guidance on

family planning services, as such guidance would need to have broader implications than this rule provides. In addition, we do not believe it is necessary to address issues relating to beneficiary choice of family planning provider in this provision, since this provision deals only with coverage issues under an ABP, and not with issues such as freedom of choice of provider. That issue is separately addressed in our regulations at §431.51 and §441.20.

Comment: One commenter addressed section 2(B)(1) of the preamble, specifically the statement “Consistent with the current law, states have the flexibility within those statutory and regulatory constructs to adopt prior authorization and other utilization control measures, as well as policies that promote the use of generic drugs.” The commenter is concerned that the interpretation of this statement could provide too much flexibility for states in the use of utilization control measures, creating a barrier to necessary family planning supplies for Medicaid enrollees, as women need access to the full range of contraceptive methods to utilize the method most effective for them. The commenter requested HHS to issue sub-regulatory guidance that prohibits barriers to the full range of FDA-approved contraceptive methods guaranteed under the Affordable Care Act.

Response: Prior authorization and utilization control measures are common practices used within regular Medicaid, public employee, and commercial insurance products. Benefit packages designed within ABPs also have this flexibility. These approaches should not be used as a barrier to needed services. This proposed rule and final rule added the Affordable Care Act requirement that all ABPs must include coverage of family planning services and supplies. Nothing in the final rule authorizes deviation from the protection of beneficiary free choice of family planning provider, consistent with section 1902(a)(23) of the Act and §431.51, or an exception to the requirement at §441.20 that the state plan provide that beneficiaries are protected from coercion or mental pressure and are free to choose the method of family planning

to be used.

Comment: One commenter wrote that discrimination in benefit plan design is a persistent practice in the insurance industry and the exclusion of treatment for infertility is one example. Infertility affects an estimated 12 percent of women of child bearing age and infertility treatments are more commonly prescribed for women than for men. Another commenter recommended that the list of required categories of services for benchmark-equivalent coverage incorporate each of the benefits including family planning services and supplies required under EHB as specified in §440.347(a) for consistency and clarity and to ensure consumer protections.

Response: Coverage of infertility services is generally at the option of the state. However, coverage of infertility services becomes part of the ABP benefit package either: (1) if the state selects a coverage plan under section 1937 of the Act that includes such coverage or chooses to include such coverage as part of a benchmark-equivalent coverage plan; or, (2) if the base-benchmark plan chosen by the State to define EHBs covers infertility treatment in an EHB category, unless the state elects the option set forth in 45 CFR 156.115(b) to substitute actuarially equivalent benefits in defining EHBs. We are reiterating here that CMS is clarifying in this rule that substitution of benefits as defined at 45 CFR 156.115(b) is applicable to EHBs in ABPs. We believe that states will appreciate this added flexibility. Under 45 CFR 156.115(b)(1), substitution of benefits can occur benefit by benefit. The benefits must fit into the same EHB category and the benefits being interchanged must be actuarially equivalent. Furthermore, states may substitute more than one benefit that when combined are actuarially equivalent to a single benefit. States may use their Medicaid state plan benefits for substitution if the state plan benefit is actuarially equivalent and in the same category of benefit that will be replaced. We do believe it is necessary to explicitly list the EHB categories in the regulation text for benchmark-equivalent coverage, as section 1937 of the Act was amended to require both

benchmark and benchmark-equivalent coverage to include all EHBs. States will identify substituted benefits in the ABP SPA when submitted to CMS.

Summary: We will not be making changes to proposed regulation text as a result of comments received.

e. EPSDT and other required benefits (Mental health parity) (§440.345))

Section 2001 (c) of the Affordable Care Act directed that benefit plans under section 1937 of the Act that include medical and surgical benefits and mental health and/or substance use disorder benefits comply with MHPAEA and we codified this at §440.345(c) in the proposed rule.

Comment: Almost all commenters expressed support for the requirement in §440.345(c) requiring that mental health or substance abuse benefits must be provided by ABPs and must comply with MHPAEA. Many also commended CMS for clarifying that ABPs must include mental health parity as this will lead to the provision of necessary services to millions of individuals. A number of commenters wrote about how extremely important it is that all individuals gaining Medicaid eligibility under the Affordable Care Act receive coverage appropriate for their needs including strong coverage of mental health and substance use disorders. Many expressed their appreciation for CMS's strong support for this provision. Many stated that they appreciated the proposed rule's explicit recognition of the Affordable Care Act requirement that ABPs must provide the EHBs, including mental health and substance use disorder (MH/SUD) services.

Response: CMS thanks the commenters for their support on the language in the regulation.

Comment: Some commenters asked CMS to provide additional detail on how the requirements of MHPAEA apply to ABPs including details on how to supplement benchmark or

benchmark-equivalent coverage to bring it into compliance with parity and how to identify violations in parity compliance. Commenters requested clarification that MHPAEA requires ABPs to offer the same scope of MH/SUD services as medical services, including adequate prescription drug coverage.

Response: On January 16, 2013, CMS released a State Health Official Letter regarding the application of MHPAEA to Medicaid MCOs, CHIP, and ABPs. This guidance specifically states that all Medicaid ABPs (including Secretary-approved coverage) must meet the parity requirements, regardless of whether services are delivered in managed care or non-managed care arrangements. This includes ABPs for individuals in the new low-income Medicaid expansion group, effective January 1, 2014.

Comment: Many commenters wrote that more than just requiring compliance was needed in this final rule because of the documented disparity between coverage of medical surgical benefits and coverage of MH/SUD services in commercial and employer health coverage. With about one quarter of adults suffering from a diagnosed mental health disorder, disparity in services and cost sharing has wide ranging impact. Some stated that studies and literature indicate deficits in employer coverage of mental health benefits and that limits on MH/SUD services were lower than those for medical surgical benefits. Some commenters stated that in clarifying the application of mental health parity CMS should make clear that if psychiatric rehabilitation services are provided, so must psychiatric habilitation be required, and that CMS should assure that a robust package of mental health coverage is part of ABPs. Commenters indicated that supplementation, substitution, parity and other protections are the best approaches for EHBs to meet the complex health needs of the low-income adults who will gain Medicaid eligibility under expansion. The commenters encouraged CMS to do whatever is within its authority to encourage all plans to expand their mental health and substance use

disorder treatment to provide better care by providing the full range of MH/SUD services and to ultimately reduce costs and unnecessary loss of productivity and life.

Response: States must offer services in all ten EHB categories, including MH/SUD services, and must provide such MH/SUD services in a manner that complies with the parity requirements of MHPAEA. We do not intend to require or request states to include specific services within EHB categories offered by their ABP. As states determine their ABP service package, states must use all of the EHB services from the base-benchmark plan selected by the state to define EHBs for Medicaid, substituting or supplementing as necessary. We believe this will allay concerns expressed by commenters, as commercial plans must also adhere to mental health parity requirements.

Comment: One commenter wrote that final MHPAEA regulations are not yet released, and therefore, CMS should provide a detailed framework for determining and enforcing parity compliance in this final rule. The commenter recommended that HHS establish a clear process for how states can modify a plan to ensure parity compliance if it is not compliant; clarify that the term “treatment limitation” includes both quantitative and non-quantitative treatment limitations and includes limits on scope of service and duration of treatment; require full disclosure of benefit and medical management criteria from states and plans to ensure MHPAEA compliance in ABPs; ensure that ABPs may not apply a financial requirement or treatment limitation, as specified in MHPAEA; include examples of parity violations and detailed information on how to supplement coverage that falls short of the parity requirements; and review all ABPs to ensure compliance with MHPAEA.

Response: The January 16, 2013 CMS State Health Officials Letter provided a framework for States to apply MHPAEA to ABPs. Since the release of this State Health Officials Letter, we have also provided technical assistance to states regarding the application of

MHPAEA to ABPs prior to submission of the ABP state plan amendments.

Comment: A commenter requested that we clarify the applicability of mental health parity to Medicaid managed care organizations that provide benchmark or benchmark-equivalent coverage. The commenter wanted to know if states would be required to provide services (for example; rehabilitation, habilitation, substance abuse services, etc.) that are optional services for Medicaid programs if they are not currently covered.

Response: The January 16, 2013 State Health Official Letter specifically states that all Medicaid ABPs (including Secretary-approved coverage) must meet the parity requirements, regardless of whether services are delivered in managed care or non-managed care arrangements. In addition, under §440.347, ABPs must include MH/SUD services regardless of whether they are currently covered in the state's Medicaid plan.

Comment: One commenter requested that CMS clarify the guidelines concerning ABP benefit substitutions that involve mental health benefits. One wrote that substitutions should not be allowed if they would diminish the value of the mental health coverage provided by the EHB-benchmark plan on which ABP benefits are based. The commenter recommended that this issue be carefully monitored; if possible, CMS should develop an easily applied, objective test to evaluate whether a proposed benefit substitution would reduce the value of mental health coverage compared to the mental health coverage provided by the EHB benchmark plan. Additionally, some commenters stated there still is confusion about how to apply the parity requirements. Commenters encouraged CMS to issue explicit guidance on whether benchmark plans will be evaluated for compliance with parity requirements as necessary before they are approved by CMS as ABPs.

Response: As discussed above and below in the summary, substitution will be allowed according to provisions at 45 CFR 156.115(b) except that states will perform substitution rather

than issuers. We will review all ABP state plan amendment requests from states against applicable federal laws and regulations, including MHPAEA.

Comment: Some commenters wrote that because they are not specifically enumerated in MHPAEA, inpatient mental health substance abuse disorder (MH/SUD) services are often not covered. Many commenters stated that the definition of “inpatient” in the Interim Final Rules implementing MHPAEA leaves the definition up to the state and insurance companies. This is important and unfortunate because it allows for avoidance of MHPAEA and invites litigation. A number of commenters stated that HHS can easily rectify this deficiency by explicitly mandating residential coverage as an “inpatient service which must be offered on par with medical/surgical coverage.” Some urged CMS to explicitly restate the requirement that all Medicaid ABPs must cover MH/SUD services. A number of comments stated that inpatient services must be defined as including residential services, including Institutions for Mental Diseases (IMDs). HHS can improve the interpretation of relevant definitions by incorporating by reference those definitions as set forth by the American Psychiatric Association in its Diagnostic and Statistical Manual of Mental Disorders. By offering a federal floor of required services states can take comfort that they have met the mandated requirement. One commenter wrote that IMD restrictions present an access barrier for the expansion population and the Affordable Care Act is clear that ABPs should include the EHB hospitalization and mental health services that are included in commercial coverage that must cover EHB. Another commenter wrote that HHS should prohibit ABPs from including mental health benefits that are subject to higher limitations on amount, scope, and duration than benefits intended for physical/medical conditions, or narrowly specifying that mental health services cannot be a component of other EHB categories, such as the mental health rehabilitation needs that are required following a traumatic medical event.

Response: States must offer services in all ABPs that reflect the ten EHB categories,

including MH/SUD services. We do not intend to require states to include specific services within EHB categories offered through an ABP. Nor are we specifically requiring coverage of any particular residential mental health services as part of “inpatient services,” provided that the coverage complies with MHPAEA. States may, however, be required to provide residential mental health services that are included in the section 1937 coverage plan that is the basis for the ABP, or that is included in the base-benchmark plan selected by states to define EHBs for Medicaid.

We clarify, however, that the IMD payment exclusion does apply to all medical assistance, even medical assistance furnished through an ABP. This means that FFP is not available for any services, including services provided through an ABP, furnished to an individual under age 65 who resides in an IMD, except for inpatient psychiatric hospital services furnished to individuals under age 21. Finally, we clarify that the requirement that all ABPs comply with MHPAEA includes compliance with MHPAEA requirements regarding treatment limits.

Comment: A commenter wrote that under the traditional Medicaid program, the term “medical assistance” does not include care or services for any individual who is a patient in an institution for mental disease, but benchmark coverage does not have an express exclusion of care and services for such individuals. The commenter asserted that for benchmark coverage, which includes coverage for EHBs, exclusion of these same services for patients residing in an IMD would directly conflict with the plain language of the law because section 1937 of the Act provides for no exception for individuals between ages of 21 and 65 residing in an IMD, but does contain an exemption from other provisions of Title XIX (to which the IMD exclusion applies). The commenter states that just as an ABP is exempt from complying with the requirements related to state-wideness and comparability in the Medicaid statute because they

conflict with the benchmark authority, so too is the plan exempt from complying with the IMD exclusion which cannot be applied in a consistent manner with the EHB requirements. The commenter also added that, just as application of the IMD exclusion to an ABP would be “directly contrary” to a state’s ability to offer EHBs, the exclusion is also contrary to any of the benchmark/benchmark-equivalent coverage described in the statute. Another commenter argued the same points and also stated that the IMD exclusion is not consistent with the definition of an ABP to include, among a selection of plans, the health insurance plan offered through the HMO that has the largest insured commercial non-Medicaid enrollment in the state. As such coverage would necessarily be available on par to individuals residing inside and outside of an IMD, the commenter asserted that Congress never intended the IMD exclusion to apply to Medicaid beneficiaries enrolled in an ABP.

Response: We do not agree with the commenters’ statements that the IMD exclusion does not apply to medical assistance furnished through an ABP. The IMD exclusion is not a service or benefit exclusion. It is a payment exclusion that applies to all Medicaid services provided to an individual residing in an IMD, not solely a payment exclusion for services provided in or by an IMD. The statute excludes services furnished to residents of an IMD from the term “medical assistance,” and we read this exclusion to apply whether medical assistance is furnished through regular coverage or through an ABP. (Above we clarify that we have a parallel reading of the similar payment exclusion for inmates of a public institution.) Thus, we clarify that the IMD payment exclusion applies to coverage offered through ABPs. Benefits furnished through ABPs can be structured so that individuals have inpatient options for mental health treatment outside of IMDs, but to the extent that an individual resides in an IMD, the IMD exclusion would apply. We are not aware of any contrary congressional intent, and this position is consistent with the express statutory exclusion from the definition of medical assistance.

Comment: A few commenters stated that MH/SUD services are sometimes provided in facilities that are considered an institution of mental disease for which FFP is excluded and requested that CMS reconcile the requirement that these services must be provided as an EHB .

Response: For the reasons discussed above, we are clarifying that the IMD payment exclusion does apply to medical assistance furnished through ABPs. We expect that ABPs will ensure that coverage for MH/SUD services is available consistent with MHPAEA and the final regulations that govern EHBs under Medicaid. There may be options for inpatient services other than inpatient services in IMDs that states may wish to consider to meet MHPAEA obligations under ABPs.

Comment: One commenter stated that exclusions for otherwise-covered benefits such as mental health services that treat eating disorders and gender disorders should not be permitted, as these exclusions carve out coverage explicitly on the basis of health condition and are discriminatory.

Response: We will review ABP state plan amendments to ensure their compliance with applicable federal statutes and regulations, including MHPAEA, and EHB anti-discrimination provisions.

Comment: One commenter stated that healthcare providers who provide MH/SUD treatment services were encouraged by the passage of MHPAEA but many states and insurance companies are “stonewalling” implementation and inclusion of MH/SUD treatment as a mandate. EHB requirements will not correct this problem unless HHS rules provide better clarity regarding implementation of parity, in particular inclusion of inpatient services.

Response: MHPAEA does not require the provision of specific MH/SUD services. Rather, it requires these services to be provided in parity with medical/surgical services, when benefit packages include both sets of services. The release of the January 13, 2013 State Health

Official Letter has provided initial guidance to states and managed care plans regarding the application of MHPAEA to the Medicaid program. We believe that guidance provides useful information to states regarding their efforts to apply MHPAEA to their Medicaid ABPs. In addition, CMS is reminding commenters that inpatient hospitalization is a required EHB for ABPs.

Comment: One commenter stated that Medicaid regulations should employ the same disorder carve-outs for the expansion population as used for existing populations and remain in compliance with federal parity laws. Further, states should not be required to provide different or additional MH/SUD benefits to the expansion populations than what is furnished to existing beneficiaries.

Response: This regulation does not prohibit states from using their current delivery systems or designing new delivery systems to offer EHBs, including MH/SUD services. States are required to offer MH/SUD services consistent with the process set forth in this regulation regarding the development of ABPs and MHPAEA. Because of the need to select a public employee or commercial plan to define EHBs for Medicaid, there could be differences between the ABP benefit package and the services otherwise offered in the regular Medicaid coverage package..

Comment: Many commenters strongly urged CMS to release final MHPAEA regulations as soon as possible and to include how to apply parity to EHBs and ABPs and to give examples of violations. A commenter stated that without the final rule on MHPAEA, effective compliance will not be possible. Another commenter requested prompt release of additional guidance referenced in the January 13, 2013 State Health Official Letter, concerning any requirements to apply parity principles across multiple managed care delivery systems and urged a flexible approach to measuring parity in carve-out setting in promotion of continuity for existing

arrangements and authorities.

Response: A response on the timing of a final MHPAEA regulation is beyond the scope of this regulation.

Comment: One commenter wrote that insurance companies have sought to avoid implementation of MHPAEA and states that do not currently require mental health parity may be concerned that compliance will result in the state incurring the costs associated with the expansion of state mandates. Two commenters stated that there are lingering concerns with some of the parity language in the proposed regulation, which states in §440.345 that ABPs that provide both medical and surgical benefits, and mental health or substance use disorder benefits, must comply with MHPAEA. CMS should revise this language to make it clearer and more accurate. The commenters asserted that MHPAEA does not apply to coverage under section 1937 of the Act that is delivered in a non-managed care arrangement; rather the Affordable Care Act extended the protections of MHPAEA to this coverage without amending MHPAEA. Specifically, regarding coverage under section 1937 of the Act, the Affordable Care Act requires that “the financial requirements and treatment limitations applicable to such mental health or substance use disorder benefits comply with the requirements of section 2705(a) of the PHS Act (MHPAEA) in the same manner as such requirements apply to a group health plan” and the final rule should include similar language.

Response: It is unclear exactly what the commenter is asking, in terms of incurring expenses associated with state benefit requirements. Therefore, we will not be able to respond to this comment at this time. We disagree with the commenters’ assertion that mental health parity requirements do not apply to ABPs using non-managed care delivery systems. Parity requirements apply to all ABPs, regardless of the use of managed care.

Comment: One commenter wrote that because of changes in the income eligibility

standards we expect Medicaid expansion is more likely to enroll individuals who are working but have no insurance and who need this coverage to access treatment to maintain employment. People with addictions enter treatment at different phases and will use different parts of the continuum, and elimination of any part of the continuum would violate MHPAEA and cost human lives. The commenter urged CMS to adopt the same standards set forth in the proposed rule for the Affordable Care Act standards related to EHB, Actuarial Value, and Accreditation for purposes of Medicaid ABPs. Additionally, the commenter stated that MHPAEA holds out the promise that everyone will be able to get help but strong enforcement of MHPAEA is necessary.

Response: It is unclear exactly what the commenter is asking. Therefore, we will not be able to respond to this comment at this time.

Comment: A commenter wrote that this rule as proposed rule fails to link MHPAEA compliance to adherence to the Interim Final Rule which operationalizes MHPAEA. The previously issued Proposed Rule for Standards Related to Essential Health Benefits, which addressed the design of EHBs for commercial market insurance beneficiaries, made specific reference to the Interim Final Rule effectuating MHPAEA. The proposed rule simply says the EHBs of ABPs must comply with MHPAEA. The commenter questioned whether this lack of direct reference to the existing law mean Medicaid ABPs need not comply with all provisions of the Interim Rule. The commenter strongly urges CMS to clarify whether or not these ABPs must comply with all provisions of the Interim Final Rule and what if any law, in whole, or in part, it will use to assess ABP compliance with MHPAEA.

Response: On January 16, 2013, CMS released a State Health Official Letter regarding the application of MHPAEA to Medicaid MCOs, CHIP, and ABPs. This guidance specifically states that all Medicaid ABPs, including Secretary-approved coverage, must meet the parity

requirements, regardless of whether services are delivered in managed care or non-managed care arrangements.

Comment: Several commenters wrote that exclusions of mental health, substance use disorders and behavioral health treatments that fail to meet the parity standards required by MHPAEA are discriminatory. Despite existing parity requirements state implementation and enforcement of MHPAEA has varied widely and patients seeking mental health services are frequently subjected to excessive and inappropriate non-quantitative limitations. Another commenter stated that CMS should identify a standard to determine whether the coverage provided complies with non-discrimination provisions of the Affordable Care Act.

Response: As stated in the January 13th State Health Official Letter, ABPs must comply with MHPAEA.

Comment: One commenter suggested that the goal of Affordable Care Act coverage was to include the 10 EHBs including mental health and substance use disorder services.

Response: We agree with the commenter that one goal of Affordable Care Act coverage was to include coverage of the 10 EHB categories, including mental health and substance use disorder services in ABPs. We support providing a floor of coverage to Medicaid beneficiaries. As mental health parity also applies, this will lead to parity among mental health and substance use services and other medical and surgical services.

Summary: We will not be making changes to proposed regulation text as a result of these comments. However, we are clarifying that the payment exclusion for services provided to individuals residing in an institute of mental disease (IMD) continues to apply to all individuals participating in ABPs. This is important because many commercial products offer coverage of residential services in settings that for Medicaid purposes are considered IMDs, and federal matching funds will not be available for medical assistance for individuals who reside in such

settings.

f. EPSDT and other required benefits (ABPs include EHBs and all updates and modifications) (§440.345)

We proposed at §440.345(d) the requirement that ABPs provide EHBs and include all updates and modifications thereafter by the Secretary to the definition of EHBs.

Comment: Several commenters wrote that the revisions make Federally Qualified Health Center (FQHC) requirements within ABPs less clear. The EHBs are the floor of ABP coverage and that the requirement to provide EHBs within ABP does not circumvent existing requirements within section 1937 of the Act, which includes coverage of FQHCs. The commenter stated to identify that the regulation as drafted is confusing as subsections (a) describing the requirement that at least the ten categories of EHBs be included in section 1937 of the Act and (b) describing the requirements to include the benefits covered in one of the state selected benchmark plans and subsection (a) does not indicate that it is a floor. The commenters requested that CMS reiterate or clarify revisions to the regulation to reaffirm this.

Response: There are several benefits specified by section 1937 of the Act that are required in addition to EHBs. We did not change §440.365, which reflects section 1937(b)(4) of the Act, providing that states must assure access to these services through the benchmark or benchmark-equivalent coverage or otherwise, to rural health clinic services and FQHC services, even if the state does not contract with an FQHC or rural health clinic and that payment for these services must be made in accordance with the payment provisions of section 1902(bb) of the Act. The inclusion of EHBs within section 1937 of the Act establishes a minimum level for benefits, to which other benefits required as part of section 1937 of the Act are added.

Comment: Many commenters were supportive of the Affordable Care Act's application of EHB requirements to ABPs and providing a floor of benefits. Some commenters also

supported inclusion of updates and modifications made thereafter. Some commenters went further to support the inclusion of mental health and substance use disorder benefits as consistent with the MHPAEA.

One commenter generally supported implementing EHBs in ABPs to provide a stable set of core services for people receiving benefits in the ABP, and to help align the rules for patients and providers to ensure continuity of care. This is important for people who will churn between Medicaid, the commercial markets and potentially a state basic health plan.

Response: CMS appreciates the support of commenters.

Comment: A few commenters identified that EHB definitions will affect how individuals maintain access to health care, services and drugs and biologicals that they need.

Response: We agree with these commenters. The new coverage will likely be different from the coverage that beneficiaries receive today. States will have discretion regarding how to define EHBs using the process outlined in this regulation, namely selecting the base-benchmark plan to define EHBs. For Medicaid, we remind readers that EHBs are only the floor for coverage, and states have options for offering coverage that exceeds this floor. States can also add additional coverage for beneficiaries receiving ABPs who are not eligible for the new adult group.

Comment: One commenter suggested that home care services should be included in the Medicaid ABP to the same extent that they are included in the existing regular Medicaid program.

Response: The rules for establishing coverage are different between the regular state Medicaid program and flexibility provided within section 1937 of the Act. States must provide home health services as a mandatory benefit in the regular Medicaid state plan. This is not a minimum requirement for coverage under of section 1937 of the Act and is not required as an

element of EHBs.

Comment: One commenter requested clarification that the Affordable Care Act established a floor of coverage using EHBs. Benefits should not be limited solely to EHBs as no ceiling was established. The Affordable Care Act only restricts costs for state mandated benefits from being passed onto the federal government via the EHBs.

Response: Yes, EHBs are considered a minimum level of coverage. ABPs are not limited solely to EHB benefits; ABPs are constructed based on the coverage plan under section 1937 of the Act selected by the state, including EHBs based on the state selected base benchmark plan, supplemented as necessary and subject to substitution of actuarially equivalent benefits as permitted under 45 CFR 156.115(b). The section 1937 coverage plan selected by the state can include a Secretary-approved coverage plan that may include benefits that are not available under other section 1937 coverage options. Furthermore, ABPs are required to cover certain benefits including rural health clinics, FQHCs, and family planning services and supplies. EPSDT services for individuals below age 21 also apply within section 1937 of the Act. MHPAEA also applies to the provision of MH/SUD services.

Comment: One commenter requested that CMS consider adding an EHB requirement for hospitals and pediatricians to conduct risk assessments of all newborns for severe respiratory syncytial virus (RSV) disease.

Response: These services can be covered if states select coverage options that cover such services. Furthermore, children must receive all EPSDT services as part of the ABP, and states may consider such risk assessments to be part of the required EPSDT screening services. For the new adult group, only 19- and 20-year olds will be covered by EPSDT. There are both requirements and flexibility for states in both selecting plans and constructing EHBs and section 1937 coverage options. Please refer to the summary at the end of this section for further

discussion of these steps and flexibilities.

Summary: We have not made any changes to regulation text, based on public comments received.

g. EPSDT and other required benefits (Process for updating EHBs) (§440.345)

In §440.345(e), we proposed that the ABPs that include EHBs will remain effective through December 31, 2015 without a need for updating. We also proposed that we will consult with states and stakeholders and evaluate the process to determine updates to the ABPs after that date.

Comment: Several commenters offered support of the intent of our proposed policy concerning the updating of ABPs that have been determined to include EHBs as of January 1, 2014. One commenter supported the Department's intent to issue future guidance for updating EHB benefits for 2016 and subsequent years. Similarly, another commenter indicated support of the alignment of the transition period for updating ABPs with the transition period designated for updating EHBs in 45 CFR Part 156.

Response: We appreciate the support.

Comment: A few commenters indicated concern that imposing a requirement to update section 1937 benchmark plans would add significant new workload for states. One commenter believed that there is currently no statutory requirement to make updates to section 1937 plans, and suggested that the Secretary allow for grandfathering of currently offered section 1937 benchmark benefit plans. Many commenters also recommended that HHS reserve some authority to resolve significant problems with the benefits package during this time period by revising the proposed provision to add that states with approved ABPs as of January 1, 2014 do not have to update benefits until December 31, 2015, “unless the Secretary determines that there are exceptional circumstances to update a plan.” Several commenters urged the Department to

set up a formal mechanism to ensure that adequate data is collected for ABPs in 2014 and 2015 to inform updating benefits in 2016 through a transparent process in which consumers help guide any necessary changes. Similarly, several other commenters urged the Department to consider a more robust stakeholder engagement in all aspects of processes used to assess the current EHB approach and whether to adopt a new approach in 2016.

Response: CMS has been working with states to submit state plan amendments using a standardized template that includes the information needed for approval from CMS. The CMS review process allows for resolution of issues identified within the ABP prior to approval. We aligned the timeframes with CMS policy to allow for implementation efficiencies. As we develop the process, we will take into account balancing potential workload of the state and CMS and the need for information to keep the ABP current with changing commercial market products. It is important for ABPs to stay current with changes in the base-benchmark as well as with public employee or commercial plans that may have been selected as section 1937 coverage options. Commercial plans are usually updated annually. All ABP SPAs are required to have public notice and approved SPAs will be placed on a CMS website. We are also updating the Medicaid Statistical Information System (MSIS) to improve the quality, accuracy, and timeliness of data submitted to CMS by states. That said, we appreciate that it may be difficult at this point to make changes to the ABP that take effect by January 1, 2014. In light of this challenge, we will partner with states to work as quickly as possible to come into full compliance with these provisions. We do not intend to pursue compliance actions on these issues to the extent that states are working toward but have not completed a transition to the new ABPs on January 1, 2014.

Comment: One commenter indicated that the applicability of the proposed provision was unclear when applied to states that choose not to expand coverage as of January 1, 2014, but

might choose to offer a benchmark benefit plan prior to December 31, 2015.

Response: These provisions apply to all existing and new ABPs that have an effective date of January 1, 2014 or later.

Summary: We will not be making changes to proposed regulation text as a result of comments received.

h. Essential health benefits (§440.347)

We proposed to add EHBs within section 1937 of the Act and that individuals in the new adult group who meet the criteria for exemption from mandatory enrollment will receive a choice of benchmark coverage defined as the benefit package using section 1937 rules or the state's approved Medicaid state plan that is not subject to the section 1937 rules. We proposed a process for establishing EHBs within an ABP that is consistent with the general provisions for established EHBs in the individual and small group market, but reflects the particular circumstances of Medicaid. In particular, the process reflects the fact that the state establishes coverage rather than an insurance issuer, and that the coverage is consistent with the requirements of section 1937 of the Act. We also proposed that, while EHBs will be defined by the state using a selected base benchmark from the list of those plans that can be chosen to define EHBs in the individual and small group market, the base benchmark plan for defining EHBs for Medicaid can be different than the base benchmark plan chosen for the commercial market. We further proposed that there could be more than one base benchmark plan for defining EHBs for Medicaid ABPs.

Comment: One commenter stated they support the structure for implementing Essential Health Benefits as proposed.

Response: CMS appreciates the support.

Comment: One commenter supported §440.347, which allows states to have more than

one ABP to reflect the health care needs of a targeted population and use a different base benchmark plan for each ABP. A few commenters supported HHS implementing the statutory requirements to at a minimum include EHBs. One commenter supported the general approach to coverage of EHBs. Another commenter supported states having broad flexibility to choose a benchmark plan, including the same options available in the commercial market and the ability to use a different plan from the one that was selected for the state's commercial plans. This commenter also recommended that the state's Medicaid State Plan be considered for Secretary-approved coverage for the ABPs. They requested clarification of the timeframe for approval of Secretary-approved plans.

Response: We appreciate the support of our policy to allow states the flexibility to use different base benchmarks in Medicaid from those used for the non-grandfathered plans in the individual and small group markets.

We confirm that Secretary-approved coverage is part of the ABP template, and can include the full coverage otherwise available under the approved state plan, as long as all requirements of this regulation are met. The entire template is considered a state plan amendment to be completed and submitted by the state to CMS for approval. The timing of action on state plan amendments is addressed in our regulations at §430.16, which include one 90-day review period, the option for CMS to request additional information, and an additional 90-day review period.

Comment: One commenter requested that HHS clarify that states can design ABPs for subpopulations within the newly eligible group.

Response: We confirm that states can offer different ABPs to subpopulations within the newly eligible group. Under section 1937(a)(1)(A) of the Act, coverage through an ABP can be offered to "groups specified by the State" without regard to the comparability or statewideness

requirements at section 1902(a)(10)(B) of the Act and §440.240. (Other requirements, such as civil rights protections, still apply and may affect the nature of the groups that a state may specify.) As a result, states may offer ABPs that are appropriate for the unique characteristics of subgroups of the new adult group; for example, states may offer different ABPs to individuals in different geographic regions, or to individuals who have particular medical, service or support needs.

Comment: The flexibility for states to select EHBs at §440.347(b) and (c) to achieve targeting of populations causes more harm than good according to some commenters. The commenters believe that states already have significant flexibility to target ABPs through the Secretary-approved process and the targeting flexibility adds little but creates confusion. CMS would be better served in terms of administrative simplicity, oversight, and consumer understanding if one EHB standard was applicable in the commercial markets and ABPs. These commenters recommend that HHS require states to use the state-selected base benchmark plan that applies for the commercial markets for ABPs as well. Another commenter believes that EHBs should establish a minimum floor of coverage and that all plans should be required to use the state-selected base-benchmark plan that applies for the commercial markets for purposes of section 1937 of the Act as well. This will reduce administrative burden and better align standards between EHB in the commercial markets and in Medicaid.

Response: The flexibility provided at §440.347(b) and (c) permits states to design different benefit packages that at a minimum include EHBs. Alternatively, one benefit package could be used for multiple populations. States also have the choice to use the same base benchmark in ABPs and the commercial markets, which would result in aligning standards for EHB in coverage under ABPs and the commercial markets. We have adopted policies that would maximize state flexibility while ensuring sufficient coverage for beneficiaries.

Comment: One commenter is seeking clarification of the phrase set forth in §440.347 “consistent with the requirements set forth in 45 CFR [part] 156”, particularly if it adds obligations to the requirement to select a benchmark plan that includes benefits in each of the ten EHB categories. A few commenters request clarification of the specific provisions of 45 CFR Part 156 related to EHB that apply.

Response: This regulation is consistent with the EHB requirements under 45 CFR Part 156, but specifically addresses the application of those requirements for purposes of compliance with section 1937 of the Act as amended by section 2001(c) of the Affordable Care Act. The base-benchmark plans for defining EHBs include the same choices in both Medicaid and the non-grandfathered plans in the individual and small group markets. States may choose a different base benchmark plan for Medicaid than for the individual and small group markets. But, recognizing that Medicaid coverage is provided in a different context than coverage in the individual and small group markets, we provide that states may choose a different base benchmark plan for Medicaid than the individual and small group markets, and may choose more than one base benchmark plan for Medicaid. We also provide that states exercise the options available in the individual and small group market to insurance issuers. This regulation identifies those aspects of 45 CFR part 156 that are modified within Medicaid under the section of the preamble entitled “Modifications in Applying the Provisions of This Proposed Rule to Medicaid.”

Comment: Several commenters suggested that the list of required categories of services for benchmark-equivalent coverage include the EHBs as specified in §440.347(a) for consistency and clarity as ABP coverage must include at least the EHBs. Another commenter suggested that CMS should pursue parity between Medicaid state plan benefits and the new ABP for newly eligible adults to assist with “churn” between Medicaid and the commercial markets.

Response: Section 1302 of the Affordable Care Act establishes EHBs that must be provided as part of benchmark benefit coverage. A benchmark-equivalent benefit package must be actuarially equivalent to the benchmark plan that is chosen. We do not believe it is necessary to specifically add the EHB categories to benchmark-equivalent coverage because we are instead setting out procedures to ensure that coverage includes EHBs that govern both benchmark and benchmark-equivalent coverage.

Comment: Section 440.347(c) allows states to select more than one EHB option for ABPs. A few commenters urged CMS to limit states to choosing a single EHB option for Medicaid to provide a floor of benefits. They asserted that Congress intended consistency among ABPs by applying EHB requirements to them. Some commenters asserted that allowing for selection of multiple options will create unnecessary administrative burdens on state Medicaid programs and this commenter suggests that there should be only one EHB benchmark option for ABPs. But other commenters agreed with our proposed rule that, because ABPs serve a different population than private health plans, the single EHB benchmark does not need to be the same as the one chosen for the state's individual and small group market. Another commenter asked that CMS clarify that states do not have the flexibility to vary amount, duration, and scope of benefits within populations on a plan-by-plan basis as currently allowed, which would only increase complexity. This commenter also requested clarification related to whether the limited authority provided through the DRA and now expanded through this rule can be superseded by section 1115 authority. This commenter also responded that a state may try to combine flexibilities for EHB, ABP, premium assistance, and amount, duration, and scope to shift to a model that has not been adequately explored for unintended consequences.

Response: While it is true that coverage of EHBs will be required for non-grandfathered plans offered in both the individual and small group markets and Medicaid, we think it is

important to provide states flexibility to define EHBs as appropriate in each context. In the non-grandfathered plans offered in the individual and small group markets, states have some flexibility to define EHBs through selection of a base benchmark plan. For Medicaid coverage, we believe that additional flexibility will enable states to tailor coverage to the needs of the Medicaid population. While states can, for simplicity, choose one standard to determine EHB in both the individual and group markets and in Medicaid, they are not required to do so. We are permitting states flexibility to choose a single standard or multiple standards for EHB in Medicaid to ensure a full range of coverage options. States must determine whether multiple standards would result in administrative burdens. We are reminding states that the floor of coverage is EHBs defined by the benefits, including limitations on amount, duration, and scope, from the selected base benchmark plan (but states may be required to, or may have options to, cover benefits above that floor consistent with section 1937 of the Act). Please refer to the summary at the end of this section for further discussion of these steps and flexibilities.

Comment: Several commenters recommend that the Department ensure that Secretary-approved coverage is actuarially equivalent to the other benchmark coverage options. These commenters support the clarification that Secretary-approved coverage must provide robust benefits. However, these commenters indicate that it is important for Secretary-approved coverage to provide the same level of coverage as other benchmark plan options to prevent newly eligible people from receiving lesser coverage.

Response: This rule is not intended to change the assessment of Secretary-approved coverage, except to the extent that it must include EHBs. The standard that we apply for assuring the sufficiency of the benefit package established using Secretary-approved coverage is whether the benefits are appropriate to meet the needs of the population provided that coverage, as outlined in §440.330(d). EHBs establish a floor of benefits for ABP populations and must be

provided with Secretary-approved coverage as with any ABP. Secretary-approved coverage permits states flexibility to design a benefit plan that might differ from the other options available under section 1937 of the Act. As mentioned previously, in all cases a state must first select a base benchmark to define EHBs. The EHBs in the base benchmark plan serve as the minimum floor of coverage that is supplemented for any missing EHBs. Using substitution, states may achieve a benefit package that includes benefits from the regular state plan.

Comment: One commenter believed that extending full Medicaid benefits to the newly-eligible expansion population, supplemented as needed to comply with the EHB, parity, and other protections in the law, is the best approach for meeting the complex health needs of low-income adults who will gain Medicaid eligibility under the expansion. The commenter urged CMS to work with States to ensure that this population's full range of substance use disorders and mental health needs and other health needs will be met. The commenter further suggested that CMS include language in the final rule that explicitly restates the requirement that all Medicaid ABPs must cover mental health services and substance use disorder services for all enrollees.

Response: States have much flexibility, but are not required to use benefits from their regular Medicaid benefit package for the new adult coverage group, as long as EHBs are assured. The statute and regulation direct that mental health parity requirements and EHB requirements, including the provision of mental health and substance use services, be met. In some circumstances, we anticipate that the coverage furnished to the new adult coverage group may include certain benefits, such as certain substance abuse treatment services, that the state has elected not to cover under the state's regular Medicaid benefit package.

Comment: The commenter stated general agreement with the approach that CMS has recommended for the ABP to be offered to certain populations under the expansion of Medicaid.

The commenter requested clarification that the state would choose an ABP from four benchmark packages and would compare that choice to the private market EHB, supplementing coverage of the ABP if necessary to ensure that all EHB categories are included.

Response: There are both requirements and flexibility for states in constructing EHBs and section 1937 coverage options. Please refer to the summary at the end of this section for further discussion of these steps and flexibilities.

Comment: One commenter would like to underscore the importance of promoting seamless coverage among low-income individuals. Many of the individuals newly eligible for Medicaid in 2014 are likely to have fluctuations in income, and therefore are likely to “churn” between Medicaid and subsidized Exchange insurance coverage. This churn could result in treatment disruptions among patients and create administrative complexity for Exchanges, plans, and providers. Thus, promoting seamless coverage for this population and ensuring coordination of care during coverage transitions will be critical.

Response: We appreciate the circumstances that the commenter identified for individuals that may have fluctuations in income. States have options for minimizing treatment disruptions and CMS will work with states to promote continuity of care.

Comment: One commenter urges CMS to consider revising certain sections of the proposed rule to allow states the greatest opportunity to develop ABPs that are reflective of the population that they serve and ensure the long-term financial sustainability of this category of eligibility. This commenter believes that the proposed regulations create a cumbersome and confusing process and appear to strongly incentivize states to essentially mirror state plan benefits. This commenter wants maximum creativity to define the benefit package that will be provided to the newly eligible population, and encourages CMS to use this opportunity to allow for greater innovation at the state level by allowing design of benefit packages that simply take

pieces of both Medicaid and the commercial market while also covering all EHBs. This approach will lead states to compare Medicaid to private and commercial market benefits and potentially add benefits to the Medicaid state plan.

Response: We believe that the regulations offer significant flexibility for states to create benefit packages for all or for different groups of its newly eligible population. Appropriate benefit package design for the population's needs may contribute to long-term financial stability.

Comment: A few commenters were concerned with disparities in coverage as the guidance suggests that the policy only mandatorily applies to the newly eligible category of adults. In states that expand their Medicaid programs to include these new categories of eligibility, they note that a higher income expansion population will receive a more generous package than existing populations. This will create a churn in Medicaid where states will likely have to expand coverage for all adult populations within Medicaid to prevent churn. They assert that this would result in significant financial cost to states to expand benefits to all adults as new benefits for the existing population are ineligible for the enhanced match offered under the Affordable Care Act for the newly eligible expansion population.

Response: The Medicaid statute provides that coverage may be different for those people who receive coverage through an ABP established under section 1937 and those who receive regular Medicaid coverage. People in the new adult group must receive benchmark or benchmark-equivalent benefits, including EHBs. Consistent with the statute, the rules promulgated in this regulation will apply to all ABPs, not just for those people in the new adult group. As long as ABP (including EHB) requirements are met, states have significant flexibility in designing benefit package options that approximate regular state plan benefits.

Comment: Many commenters recommended that ABPs provide appropriate coverage to

meet the needs of the population in all ten EHB categories as per the general requirements of §440.330. These commenters suggest that the lack of a minimum standard in each of the ten categories is a flaw in the Exchange EHB standard that gets further magnified in Medicaid. For women's health, this is particularly important in terms of preventive services, prescription drugs, and maternity care. Several commenters support the EHB requirement as a strong floor for ABPs and indicate that states should have ample flexibility to add to the floor. These commenters also provided recommended regulatory language for §440.347(a) through (c).

Response: EHBs are a floor to coverage and states have flexibility to design an ABP that includes coverage above the minimum level of EHBs. Section 1302(b)(2) of the Affordable Care Act directs the Secretary to determine EHBs by reference to benefits typically offered in the group market, which is the same standard that we are applying in Medicaid by requiring that states determine EHBs by selecting a base benchmark from among the regulatory options described in §156.100. All benefits within the base benchmark that defines EHBs will need to be incorporated into the ABP, supplemented as necessary and subject to substitution of actuarially equivalent benefits as permitted under 45 CFR 156.115(b). But the ABP can include other benefits based on the state choice of coverage option.

For groups other than those in the new adult group, states can also offer additional benefits to supplement the benchmark or benchmark equivalent coverage that includes EHB and other required services. Sections 1902(k)(1) and 1903(i)(26) clarify that individuals in the new adult group receive benchmark or benchmark-equivalent coverage (that includes EHB and other required services and, as we explain below, for individuals who would otherwise be exempt from enrollment in an ABP, the option to receive an ABP that consists of regular Medicaid coverage). We intend to issue an ABP state plan amendment template and corresponding implementation guides for the states to use when submitting ABP state plan amendments.

Comment: One commenter supports requiring coverage of all ten EHBs, as this will go a long way toward ensuring that Medicaid participants have adequate health care coverage. They request that HHS define the scope and services within each of the ten benefit categories to ensure that the covered services are at a minimum the same and provide a level of guaranteed coverage. This is necessary to ensure that there is adequate coverage within categories and balance between categories, and necessary to determine if ABPs are equivalent to the EHB package and comply with Affordable Care Act.

Response: We thank the commenter for the support.

Comment: One commenter indicated that ABPs should include an array of home care services that exist in traditional Medicaid benefit programs to comply with the American with Disabilities Act and Supreme Court Olmstead decision. To the extent that EHBs include institutional care or inpatient settings, a state must offer a choice of “the least restrictive environment.” Similarly, states that choose to provide services to individuals enrolled in ABPs that involve care in an institution should be required to include home and community-based care as well.

Response: Section 1902(k)(1) of the Act provides that medical assistance for the new adult eligibility group is limited to benchmark and benchmark-equivalent coverage. Section 1902(k)(1) of the Act also provides an exception to the requirements of section 1937 of the Act for individuals who would be described in the exemptions at section 1937(a)(2) of the Act. This means that individuals in the new adult eligibility group that otherwise meet the exemption criteria are required to be enrolled in benchmark or benchmark-equivalent coverage, but their benchmark or benchmark-equivalent coverage is not limited by the requirements of section 1937 of the Act. Therefore, these individuals must have a choice to receive ABP benefits as defined by the state applying the requirements of section 1937 of the Act using benchmark or

benchmark-equivalent coverage (including EHBs and other required coverage) or ABP benefits defined without regard to the requirements of section 1937 of the Act, which consists of regular Medicaid coverage under the state plan. Home care is not a standardized term in Medicaid, so clarification would be needed to determine which Medicaid benefit category is actually applicable.

We agree that states are obligated to comply with the Americans with Disabilities Act and the Olmstead decision.

Comment: One commenter requests that crisis services be included in the mental health and substance abuse services category in the EHB package. This commenter requests that it be offered by qualified health plans and in new Medicaid expansion benefits in each state. These are important services to the safety net and for 24/7 crisis care, suicide prevention and access to emergency health care services, especially in communities where emergency mental health clinics or mobile health services are unavailable.

Response: CMS is not requiring specific services to be included in any of the EHB categories, but all ABPs must include all EHBs defined through the process described in our regulations.

Comment: Several commenters suggest that EHBs should comply with a consistent standard across ABPs as they are concerned that the proposed rule allows for states to select more than one option for establishing EHB to implement multiple ABPs for targeted populations. These commenters also recognize the need for states to target populations to address specific health care needs.

Response: We are providing flexibility for states to select base benchmark plans in Medicaid that are different than the one selected for the individual and small group market, and to select multiple base benchmark plans, to maximize the ability for states to define ABPs that

serve the unique needs of Medicaid populations and subpopulations.

Comment: One commenter requested CMS include autism coverage in the EHB package to correct the omission. Lack of coverage can create significant financial burden on families and discourages autism professionals from practice. Families also may decide to not pursue treatment.

Response: States have choices in determining in the benefit package that will be covered in their state within federal guidelines, but all ABPs must provide for coverage of EPSDT services for individuals under the age of 21. We expect that services to treat autism may be covered through a variety of coverage categories and many would be included in a state's ABP either because the services are within the section 1937 coverage option or included as part of EHBs.

Comment: One commenter applauds HHS for including coverage of the full package of EHBs, as it includes coverage of screening and brief counseling for domestic and interpersonal violence, in the Medicaid ABPs.

Response: We thank the commenter for the support. While it is not certain that every ABP will include counseling for domestic and interpersonal violence, such services will be provided if they are part of the EHBs.

Comment: One commenter believes that strong and comprehensive oversight and enforcement of EHBs and nondiscrimination standards at the state and federal level will help ensure consistent coverage of transplant benefits and eliminate discriminatory insurance practices. Therefore, the commenter asserted, ABPs must cover all EHB categories without discrimination for people who have or will acquire health conditions that lead to end stage organ failure. The commenter stated that a wide range of medical services are required during the transplant process and fall under the categories of ambulatory services, hospitalization, chronic

disease management, mental health services, rehabilitative services, and prescription drugs. The commenter urged that all of these treatments must be covered under ABPs.

Response: If transplant services are covered as part of the coverage option chosen by the state, or the benefits under the selected base benchmark plan, as supplemented (and subject to permissible substitution of benefits), then they will be covered as part of the ABP.

Comment: According to one commenter, the Affordable Care Act specifies that entities covered under section 340B(a)(4) of the Public Health Services Act, which includes federally recognized Hemophilia Treatment Centers, be designated as essential community providers and that designation requires that qualified health plan networks to include Hemophilia Treatment Centers. This commenter requests that state Medicaid programs be encouraged or required to include essential community providers in their networks.

Response: Coverage through an ABP remains subject to requirements under the state plan to provide for beneficiary free choice of provider, and provider payment rates that are consistent with efficiency, economy, and quality of care and assure sufficient access to services. States have options to limit free choice of provider in some circumstances, for example, managed care service delivery consistent with section 1932 of the Act, or through selective contracting arrangements authorized under a waiver under either section 1915 of the Act or section 1115(a) of the Act. In any of these cases, states must assure sufficient beneficiary access to services.

Comment: Several commenters suggested that the review of EHB, in the private insurance market and Medicaid, consider whether limits in coverage and changes in medical evidence or scientific advancement affect whether enrollees have difficulty accessing services. The EHB should be based on the most recent and reliable clinical evidence available and a process should be developed to inform and shape EHBs based on these factors over time. If not

available, there should be an allowance for some physician discretion.

Response: Consistent with the provisions of section 1302(b) of the Affordable Care Act, CMS has in the regulations at 45 CFR part 156 defined EHBs by reference to coverage plans available in the commercial market.

Comment: Several commenters also requested that review of EHBs be disaggregated to include demographic categories. HHS should require states to report enrollees' race, ethnicity, language, sex, and disability status data uniformly, as well as data on other demographic areas such as sexual orientation and gender identity, as described in section 4302 of the Affordable Care Act.

Response: This information does not appear to be related to the review of EHBs. We note, however, that we are developing a Transformed Medicaid Statistical Information System that will include expanded data elements regarding beneficiaries, claims and providers per Affordable Care Act.

Comment: One commenter supports inclusion of all ten EHB to reflect appropriate balance in each category and requested that anesthesia and pain management services be included in the ten categories of benefits covered by the ABPs. This commenter also requested that CRNAs and other non-physician providers who bill for Medicare Part B be included in Medicaid ABPs.

Response: The coverage of particular services will depend upon the coverage option selected by the state, and the EHBs that are determined based on the state-selected base benchmark plan, as supplemented (and subject to substitution of actuarially equivalent benefits) consistent with the process described in 45 CFR part 156. This rule will not affect the ability of states to set provider qualifications for covered services.

Comment: One commenter requested that dollar limits on a specific category of benefits

and targeted use of utilization management techniques be prohibited.

Response: Annual dollar limits are prohibited in the public employee or commercial plans that are the basis for coverage options and the base benchmark options according to section 2711 of the Public Health Service Act. Utilization management techniques are common practice for benefit management and will continue to be allowed in Medicaid. We expect that these practices will be non-discriminatory and not impede access to needed, covered services.

Comment: One commenter indicated that HHS should specify in the final rule that to meet the health care needs of diverse segments of the population, an ABP must provide a process for participants to request and receive: clinically appropriate benefits not routinely covered by the plan, especially when the ABP is less costly than the covered benefit; coverage for benefits beyond limits set by the plan; coverage of specialty care not routinely covered by the plan when medically necessary and appropriate.

Response: We are specifying in the final rule that, if an individual in the new adult group meets the criteria for exemption from mandatory enrollment in an ABP that would otherwise be applicable, then the individual would have a choice of an ABP that includes at least the EHBs, and is subject to the requirements of section 1937 of the Act, or benchmark or benchmark-equivalent coverage that is not subject to the requirements of section 1937 of the Act, and thus, includes all regular Medicaid state plan benefits. Other individuals do not have that choice but this rule does not affect their right to appeal denials of coverage through the state's fair hearing system.

Comment: Commenters requested clarification and further guidance on the supplementation process established in both the proposed rule for the EHBs in the commercial market and the proposed rule for EHBs in Medicaid ABPs. Many commenters requested that CMS clarify what benefits would constitute coverage in each category and identify a threshold to

trigger supplementation of a benefit category. It appears that a single service could be determined to be sufficient to define an EHB in Medicaid and therefore would not achieve MHPAEA compliance. A few commenters also stated that a single service would not meet non-discrimination requirements in addition to the balance requirement, which requires a much stronger minimum set of benefits in each category. One commenter requested clarification of the Medicaid EHB supplementation process including the extent to which the scope of services in one EHB category must be consistent with services offered other health service categories. Several commenters believe that additional provisions need to be added to ensure that the level of benefits in each EHB category are meaningful and adequate to meet the needs of the population. Several commenters also requested that CMS clarify what benefits would constitute coverage in each category and explain how CMS would enforce the non-discrimination and balance requirements.

Response: Supplementation occurs when a base-benchmark plan does not include items or services within one or more of the categories of EHB. Benefits from the base benchmark that are determined to be EHBs must be included as an EHB, unless substituted by the state. While the rules at §156.115(b) indicates that the “issuer” may substitute benefits, in Medicaid, the state functions as the issuer and we thus provide that the state can exercise the option to substitute benefits. We indicated that requirements at §156.110 apply unless we specifically modified the approach in Medicaid. Section 156.110(e) that specifies balance requirements also apply to EHBs established in Medicaid. All benefits within the section 1937 coverage option must also be provided. CMS will conduct a review of all ABP SPAs to determine appropriateness for approval.

There are both requirements and flexibility for states in constructing EHBs and section 1937 coverage options. Please refer to the summary at the end of this section for further

discussion of these steps and flexibilities.

Comment: The HHS February 17, 2012 Bulletin allows for substitution of services within the rehabilitative and habilitative benefit, allowing the plan to facilitate substitution of services at the provider level based on patient need not predetermined by the issuer, according to one commenter. The November 20, 2012 Patient Protection and Affordable Care Act; Standards related to Essential Health Benefits, Actuarial Value, and Accreditation proposed rule indicated that the issuer would create a substituted benefit plan, which would leave providers with no choice but to provide services in the benefit package and potentially lead to an individual choosing a plan that does not cover the services that they need.

Response: States, not issuers, define benefits within section 1937 of the Act. Section 156.115(b) outlines the substitution policy that will also be applicable to Medicaid except that, in Medicaid, states have the role of issuers and will indicate the substituted benefits. Substitution requires that benefits be in the same EHB category and that they are actuarially equivalent. This means that a state for example, could substitute a personal care benefit for an in vitro fertilization benefit in the EHB Ambulatory Services category, as long as they were actuarially equivalent. Within the rehabilitative and habilitative services and devices EHB, benefits can be substituted as long as the resulting benefits still provide for coverage of both rehabilitative and habilitative services. We expect that the benefit design will result in clinically appropriate services based on medical necessity. The resulting ABP, which includes EHBs that have been supplemented if necessary, individual benefits that have at state option been substituted, and benefits from the section 1937 coverage option, must be approved by CMS. Once approved, a description of the benefits included in the final ABP should be publicly available so that beneficiaries are knowledgeable of the benefits to which they are entitled. That said, we appreciate that it may be difficult at this point to make changes to the ABP that take effect by January 1, 2014. In light of

this challenge, we will partner with states to work as quickly as possible to come into full compliance with these provisions. We do not intend to pursue compliance actions on these issues to the extent that states are working toward but have not completed a transition to the new ABPs on January 1, 2014.Comment: Many commenters are concerned that there is no requirement regarding adequacy of benefits. These commenters specifically requested that HHS provide a cross-reference to §440.230(b) and state explicitly that the requirement that every service offered through the Medicaid state plan “be sufficient in amount, duration, and scope to reasonably achieve its purpose” also applies to EHBs in the ABPs. A few commenters recommended that the regulations be revised to require states to supplement the benefits in a benchmark plan if any service in the EHB category is not sufficient in amount, duration, or scope to reasonably achieve its purpose.

Response: Under section 1937 of the Act, states are authorized to offer ABPs that include benefits derived from public employee or commercial market products, essential health benefits and certain other required benefits. Sufficiency standards applicable to the traditional Medicaid benefit package generally do not apply to ABPs. If Secretary-approved coverage is chosen as the section 1937 coverage option, however, then we would require that the benefit package must “provide appropriate coverage to meet the needs of the population provided that coverage” under §440.330(d). Sufficiency standards at §440.230 will be applied in our review of proposed Secretary-approved coverage.

Comment: Many commenters requested that CMS reconsider the proposed approach and define comprehensive federal EHBs for section 1937 coverage that all states would be required to use to supplement their chosen benchmark or benchmark-equivalent coverage. They urged that CMS should go further and require states to cover comprehensive benefits in each of the EHB categories and work with states to ensure that minimum coverage is met. One commenter

went further to suggest that CMS and HHS adopt a comprehensive, national EHB in 2016, when the trial period for the current approach is complete.

Response: EHBs in Medicaid will generally be defined in the same fashion as they are defined in the individual and small group market, except for certain EHB categories discussed in the proposed rule and this final rule. This approach allows the public employee or commercial market plan selected by the state to define EHBs for Medicaid to set the floor for EHB coverage (with supplementation as needed and substituted as desired). States then have the authority to offer other services (including through Secretary-approved coverage for the new adult group).

Comment: One commenter requested that HHS clarify that the requirement for balance among EHB categories ensures robust coverage in each category and cannot be used to lower other categories if one or more categories lacks robust coverage.

Response: Consistent with the requirements of 45 CFR 156.110, EHB categories must be appropriately balanced to ensure that benefits are not unduly weighted toward any category. Any benefits that are determined to be EHBs from the base benchmark plan must be provided. Section 1937 of the Act also has an “equal to” standard that indicates that all benefits from a section 1937 coverage option must be provided. When Secretary-approved coverage is used, benefits must meet Medicaid sufficiency standards as well as the requirement that the benefit package be appropriate to meet the needs of the population.

Comment: Many commenters reiterated concerns regarding the EHB proposed rule and EHB benchmark plan standards. This concern remains for ABPs as the Department does not sufficiently define the scope of coverage in any statutorily required category specifically maternity care. The base benchmark plans may include coverage of maternity services, but the plan documents do not specify which services define maternity coverage or provide details on coverage including limits. The lack of clear definitions further complicates the substitution and

supplementation methodology. Several commenters want the Department to establish clear standards for what must be covered as required by sections 1302(b)(1) and 1302(b)(4)(C) of the Affordable Care Act to ensure a comprehensive standard. The adoption of coverage should not result in a discriminatory benchmark.

One commenter expressed concerns related to the ambiguously defined EHB categories and encouraged HHS to definitively confirm the extent to which cost effective, clinically effective nutrition care services such as medical nutrition therapy are included as EHBs within Medicaid benchmark and benchmark-equivalent plans. This commenter requests adequate federal oversight and approval of benchmark plan selection by HHS to reflect the vital and unique role that nutrition plays in improving and maintaining health for all Americans, but also recognizes the need to define EHBs flexibly. This commenter seeks clarification in the final rule on the metrics and bases upon which HHS will determine whether a benchmark or benchmark-equivalent plan meets the EHBs mandated by Affordable Care Act.

Response: Section 1937 of the Act permits states to offer coverage through an ABP without regard to sufficiency requirements that are applicable to regular state plan benefits, except that we would apply sufficiency standards in our review of proposed Secretary-approved coverage as the section 1937 coverage option. Substitution is allowed in section 1937 of the Act using requirements found at 45 CFR 156.115(b) except that the state will be exercising the option for substitution rather than an individual market issuer.

Comment: Commenters requested that CMS provide clear regulatory guidance to states to ensure that the process for supplementing coverage to meet the additional requirements of Affordable Care Act is clear. This is especially important given that EHBs are not universally covered well by state Medicaid programs such as mental health and substance use services. Furthermore, for states that choose to use benchmark-equivalent coverage, this commenter

requests that CMS establish clear limits on states' ability to use benchmark-equivalent coverage to undermine the EHB protections as it appears that under the proposed rule that they can reduce the value of EHBs under the benchmark-equivalent option to anything short of elimination.

These commenters request that CMS ensure the comprehensiveness of the benefits for all beneficiaries covered by section 1937 of the Act regardless of the ABP chosen by the state.

Response: Benchmark-equivalent benefit packages must be at least actuarially equivalent to one of the section 1937 benchmark coverage options and must include benefits within certain categories of basic services. In addition, the Affordable Care Act amended section 1937 of the Act to require the provision of EHBs in benchmark equivalent coverage, so we do not believe that use of this section 1937 coverage authority will undermine the EHB protections. The process for supplementation is found at 45 CFR 156.110(b)(1) through (4) and substitution requirements are at §156.110(b). All benchmark-equivalent coverage packages must adhere to section 1937 requirements, and must not violate the EHB anti-discrimination principles.

Comment: One commenter recommended that HHS specify in the final rule that ABPs must include benefits routinely covered by the benchmark plan, regardless of whether those benefits are listed in the data collection template used to report base benchmark benefits to HHS. Furthermore, all benefits within categories of care that list more than one benefit must be covered. For example, an ABP should be required to cover as three distinct benefits rehabilitative services, habilitative services, and rehabilitative and habilitative devices as opposed to only covering one of them.

Response: We intend to develop a template for states to use to define the ABP in Medicaid that will result in the submission of a state plan amendment. This is a different process than the one used for states to submit the base benchmark benefits for the individual and small group market. A state can select a different base benchmark plan for the individual and small

group market than it does for Medicaid purposes. We anticipate issuing further guidance on these operational issues.

Comment: One commenter strongly encourages CMS to provide further guidance on alignment issues during the plan comparison and supplementation process. This commenter encourages CMS to clarify that during supplementation, states must create the most comprehensive benefit package possible, drawing from services covered in either the section 1937 coverage option or the comparison base benchmark plan, which could include drawing across categories if necessary to create a robust set of services that will result in adequate coverage of EHBs.

Response: To clarify, the ABP must include as a floor the EHBs covered by the base benchmark plan selected by the state to define EHBs for Medicaid, supplemented as necessary and subject to substitution of actuarially equivalent benefits as permitted under 45 CFR 156.115(b). Balance requirements of 45 CFR 156.110(e) also apply. In addition, the ABP must include any benefits from the section 1937 coverage option that are not in the base benchmark plan, whether they are EHBs or not. If the section 1937 coverage option that is one of the three public employee or commercial products provides a service in a greater amount, duration, or scope than the EHB provided in the base benchmark plan, the state must utilize that section 1937 standard for that service. If the section 1937 coverage option is Secretary-approved coverage, then the state may choose which benefit to use.

Comment: One commenter requests that HHS specify that appropriate balance of EHB coverage includes coverage of benefits across the care continuum, prohibits substitution between categories of EHB (for example, prohibit coverage of rehab therapy but include drug coverage) and between benefits (cover wheelchairs instead of rehabilitative hospital care to restore a person's ability to walk), cover all EHBs within the settings and by specialists which provide the

current standard of care, and protect patients' access to appropriate and medically necessary care as provided by skilled medical professionals.

Response: Substitution of benefits can be achieved when defining the EHBs according to 45 CFR 156.115(b). Benefits must be in the same EHB category and actuarially equivalent. Balance requirements at 45 CFR 156.110(e) apply, as CMS did not indicate that they do not apply in Medicaid. CMS will be reviewing each state plan submission. As with all Medicaid services, states will establish medical necessity criteria for the receipt of ABP services. .

Comment: A commenter indicated understanding that benefit substitution among EHB categories would be prohibited for ABPs as it is prohibited for Exchange plans. However, this commenter believes that substitution even within benefit categories could be extremely problematic for children's and pregnant women's access to needed services. Commenters urged HHS to prohibit substitutions or at a minimum give states the flexibility to disallow substitutions. If benefit substitution within categories is retained, this commenter recommends that a more restrictive standard than an actuarial equivalence test on the value of the benefits compared to the EHB benchmark plan be implemented.

Response: Substitution of benefits within EHB categories will be at state option, according to parameters described in 45 CFR 156.115(b). This process will be the same for Exchange plans and ABPs, except that states will be in the role of the health insurance issuer for purposes of substitution.

Comment: Commenters note that in some states the EHB benchmark covers services beyond those included in the Medicaid state plan. They argue that requiring states to supplement coverage to make it comparable to the EHB benchmark is not a workable solution for states, particularly for states that wish to expand in 2014. They further assert that some of the immediate operational challenges include the need to enroll new providers, set reimbursement

rates, design claims and payment rules, and incorporate those rules into systems, and if managed care is used, new capitation rates will need to be designed, which will result in a large administrative burden.

Response: It is true that ABPs under section 1937 of the Act will contain different benefits than those offered in regular Medicaid, based on the coverage options and EHBs that a state elects. These differences are inherent in the statutory design. While EHBs will establish a minimum level of benefits, that level may result in greater or lesser benefits than are available under regular Medicaid. ABPs require that benefits that are based on commercial insurance products include the benefit, the benefit description and limitations on amount, duration, and scope as the minimum standard. States have been working with CMS toward defining EHBs and ABPs and as part of that process states may need to undertake contracting activities and system changes to offer and administer the ABP.

Comment: In the proposed rule concerning EHBs, requirements could be different in different states according to one commenter. Since two of the four benchmarks are tied to what is available to state employees in the state and what is available from the largest HMO in the state, employers may have confusion about the requirements in a particular state. This commenter requests identification of who oversees an employer that has employees with a principle place of employment in multiple states, and wonders whether it would be the Department of Labor.

Response: The standards discussed in this regulation relate to the implementation of EHBs for Medicaid. Employers do not offer Medicaid as part of their offerings to employees and therefore, this question is outside the scope of this regulation.

Comment: One commenter asked if, given the requirement that states must supplement the benchmark package if EHBs are not covered, states would be required to add these benefits

to the state plan under the Secretary-approved coverage option that is based on state plan coverage. The commenter asserted that it is unclear if the state must supplement services that are covered in the base-benchmark selection for the Exchange, and that it is unclear if supplementation is only for the benchmark plans provided to newly eligible individuals or if states that are seeking to provide a Secretary-approved benchmark plan to newly eligible individuals will be required to amend the state plan to add the new EHB services not otherwise covered. The commenter also asked whether states would now be required to add services that are not currently covered and categorized as optional, and also wondered if EHB supplementation only applies to benefits for newly eligible people or must the state meet this requirement for all benchmarks offered regardless of population.

Response: States are required as part of the ABP to cover all EHBs. While most of the EHBs are also included under regular Medicaid coverage, there may be exceptions. For example, substance abuse services and habilitative services may not be part of a State's regular Medicaid benefit. The EHB requirement applies to any ABP offered by the state, including those based on Secretary-approved coverage.

Comment: One commenter indicated that the regulatory language fails to specify that states must supplement missing categories. This commenter recommends that the Department clarify that states must follow the process established in 45 CFR part 156 to ensure that any missing categories are supplemented in the final rule. The Department should also ensure that benefit design in ABPs does not result in less comprehensive benefits than the private insurance market, and therefore, ABPs should be required to include benefits at least as robust as those in the state's full EHB package.

Response: EHBs establish a floor of benefits for ABPs offered under section 1937 of the Act and are based on commercial market products, which means at a minimum EHBs will

include benefits at least as robust as those in the base benchmark chosen by the state. The supplementation process in section 1937 of the Act will follow 45 CFR 156.110(b).

Comment: Several commenters generally supported the proposed process to designing the Medicaid ABP. However, HHS must establish transparent, minimum standards for states using “Secretary-approved” coverage. It will be critical to ensure that the state cannot develop an ABP based on the weakest benefit level available at each step of the process. The commenters expressed concern that the rule offers very little guidance about what the ABP must cover to meet the ten categories of EHBs required by Affordable Care Act and the scope of required coverage. They indicated that this lack of clarity may lead to people in the Medicaid expansion group not receiving the full range of services available to people at higher income levels accessing private market or Exchange coverage in their state. An additional commenter expressed that the youngest and most vulnerable citizens, the birth to three population, need to have access to all necessary high quality, comprehensive physical, developmental, mental health and medical care to ensure positive growth and development.

Response: Current and proposed regulation at §440.335(d) states that Secretary-approved coverage must be appropriate to meet the needs of the population being served. CMS will review proposed Secretary-approved coverage against that standard. And CMS will apply the sufficiency standards of §440.230 in evaluating benefits included in Secretary-approved coverage. In addition, all ABPs, including Secretary-approved, must include the full range of EPSDT services for individuals under age 21, which ensures that they will have access to comprehensive screening and necessary medical care.

Comment: Several commenters expressed concern regarding the process proposed by CMS to demonstrate compliance with EHB, saying it is too burdensome and applying the EHB definition that was created for small group health plans for commercial products in the private

market needlessly complicates section 1937 of the Act. They asserted that requiring that states begin by using one of the ten commercial benchmark plans as the EHB base is not useful for states that want to use the full Medicaid benefit set under Secretary-approved coverage. They argued that using the full Medicaid benefit set allows all Medicaid clients to receive the same benefit set and states would not have to operationalize a post-eligibility review process to screen people for opting out of the ABP for the traditional state plan. Their position was that, given the number of changes that states must implement in 2014, maintaining a single benefit set reduces administrative burden and confusion for clients and minimizes the number of required system changes. According to one commenter, it is essential that the new adult group have the same benefit set as the full state Medicaid benefit set. Furthermore, the commenter asserted that the mandatory Medicaid benefit set should be an option to serve as the basis for demonstrating EHB compliance under the Secretary-approved option without supplementation. A few commenters recommend that HHS create a second definition of EHB compliance that would be based on the Medicaid mandatory benefit set, limit that definition to the ABP in Medicaid programs, and allow states to use this benefit set as the basis to build a coverage option for Secretary-approved coverage.

Response: Section 2001(c) inserted new paragraph (b)(5) into section 1937 of the Act. This amendment requires that benchmark and benchmark-equivalent benefit packages must provide EHBs described in section 1302(b) of the Affordable Care Act, beginning January 1, 2014. The same process to define EHBs applies to both commercial plans and Medicaid, with adjustments only to reflect the unique nature of Medicaid. Thus, EHBs must be established within section 1937 using one of the state options for base benchmark plans as set forth in 45 CFR part 156. States may still elect to offer Medicaid state plan benefits in their section 1937 coverage option using Secretary-approved coverage, as long as all requirements of this

regulation are met.

Comment: Many commenters indicated that states electing state plan benefits using the Secretary-approved option should not be required to supplement with additional EHB services. Although they acknowledged that section 1937 of the Act requires inclusion of EHBs as defined under section 1302(b) of the Affordable Care Act, they asserted that this does not mandate importation of entire segments of coverage from private plans nor does it require a wholesale matching of these offerings in Medicaid. They asserted that implementing EHBs in section 1937 of the Act in this way is onerous and could result in the relatively less vulnerable, higher income expansion group as compared with Medicaid beneficiaries receiving more generous benefits such as substance use disorder services. They further asserted that Congress certainly could not have intended for the new enrollees to end up receiving more robust coverage than the categorically needy base. They stated that this also creates administrative complexity for states and a situation where incoming beneficiaries who may be disabled must choose between disparate benefit schedules. The commenters believed that the only way to mitigate disparate benefit schedules is for states to expand all benefits for existing and new eligible beneficiaries, something states are not in a fiscal position to do. They further asserted that the Affordable Care Act did not authorize a departure from long standing state discretion under Title XIX to develop appropriately balanced benefits and suggested that, if states must expand all benefits for existing and newly eligible beneficiaries, then states must receive 100 percent FFP for these benefits.

Response: We believe that our response to the question above also responds to this question; the statute requires that all ABPs, even Secretary-approved coverage, include EHBs. There are both requirements and flexibilities for states in constructing EHBs and section 1937 coverage options. The process for defining and including EHBs is the process used under section 1302(b) of the Affordable Care Act, adapted to the unique circumstances of the Medicaid

program.

Comment: One commenter indicated that the intersection of §440.345(d) and §440.347(a) is confusing, and recommends that CMS clarify in regulation that EHBs form a floor for the ABPs and do not supplant any preexisting requirements under section 1937 of the Act and 42 CFR part 440, subpart C. Regulations would be clearer if §440.347 were worded as a definition of EHB rather than a restatement of the mandate to include EHB in an ABP and for clarity should simply reference relevant provisions in 45 CFR part 156.

Response: Section 440.345(d) is intended to establish the universe of benefits required within the ABPs. In addition, state must assure access to RHC and FQHC services and transportation to and from medically necessary services as set forth at §440.365 and §440.390 respectively. Section 440.347 is intended to specify the categories of EHBs and the process by which those EHBs are established within the ABP. Both sections should be read in conjunction to the other.

Summary: We are adopting the following approach for treatment of individuals in the new adult group who meet the exemption criteria from mandatory enrollment in benchmark or benchmark-equivalent coverage in the final rule. If an individual in the new adult population meets the criteria for exemption, then they have a choice of the ABP based on benchmark or benchmark-equivalent coverage including at least the EHBs, or an ABP with coverage defined as the state's approved Medicaid traditional state plan, which is not subject to any other requirement of section 1937 of the Act, including EHB requirements. We are not making any changes as a result of these comments.

i. Essential health benefits (Non-discrimination policy) (§440.347)

Section 1302(b)(4) of the Affordable Care Act provides that benefit design cannot discriminate and CMS codified this section of the Affordable Care Act at §440.347(e). Benefit

design discrimination policies do not prevent states from using targeting criteria to group people together to receive specific benefit packages.

Comment: One commenter expressed support for the inclusion of the new provision clarifying that individuals cannot be discriminated against based on their “age, expected length of life, or an individual’s present or predicted disability, degree of medical dependency, or quality of life or other health conditions.” The commenter seeks age-appropriate care and benefits for children, whether through family or child-only coverage.

Response: We appreciate the support.

Comment: Several commenters indicated that while they understand that section 1937 of the Act allows states the flexibility to amend Medicaid state plans to provide certain populations (as defined by the state) with benefits packages other than those offered in the standard Medicaid state plan, HHS must closely monitor this and ensure there is no discrimination in benefit design for certain populations.

Response: Benefit design should not discriminate against individuals who receive a benefit package under section 1937 of the Act based on age, disability, life expectancy or condition but may include benefits designed to meet the special medical needs of segments of the covered population. Benefit packages designed in section 1937 of the Act include the same oversight as the regular Medicaid state plan. Aside from the EHB anti-discrimination requirements, §440.230(c) indicates that state Medicaid agencies cannot arbitrarily deny or reduce the amount, duration, or scope of a required service to an otherwise eligible recipient based solely on diagnosis, type of illness or condition.

Comment: Several commenters expressed support of the requirement that EHB benefit design cannot discriminate on the basis of an individual’s age, expected length of life, or an individual’s present or predicted disability, degree of medical dependency, or quality of life or

other health conditions. The commenters believe these non-discrimination provisions will require vigorous monitoring and strong enforcement.

Response: We thank the commenters for their support. We expect states to comply with these provisions and implement benefit packages that do not discriminate. ABPs will be subject to the same monitoring process as currently used in the Medicaid state plan.

Comment: Many commenters expressed support for the inclusion of a non-discrimination provision in §440.347(e). But some commenters pointed out that, while the proposed rule recognized the importance of non-discriminatory plan design §440.347(e) fails to state the full range of nondiscrimination protections applicable to the EHB. Many commenters expressed concern that the preamble only references section 1302(b)(4) of the Act and the requirements proposed in §440.347(e) state only the protections under that statutory provision. Therefore the commenters believe that the requirements in §440.347(e) reflect an incomplete and insufficient standard. The commenters believe that the protections under section 1557 of the Affordable Care Act also apply, and the final rule must expressly state a comprehensive and consistent nondiscrimination standard, explicitly requiring EHB benefit design to comply with section 1557 of the Affordable Care Act. The commenters recommend the final rule be revised to include the language used in the nondiscrimination standard set out in the proposed EHB rule. The commenters believe that without the additional requirements the benefits of both section 1557 and the Affordable Care Act as a whole in ensuring comprehensive coverage for all individuals will be undermined. Lastly, the commenters also requested the regulation prohibit ABPs from including all of the following:

- Participant cost-sharing designs that are more burdensome on some benefits than others.
- Unreasonable and arbitrary visit and dollar limits on a specific category of benefits, so

as to discourage participation by individuals with brain injury.

- Targeted use of utilization management techniques for some benefits, and not to others.
- Defining the benefits in such a way to exclude coverage for those services based upon age, disability, expected length of life, or the willingness or capacity to participate in wellness programs or behavioral incentive programs.

Response: Some of the protections sought by commenters are already contained in laws applicable to state Medicaid programs. Section 430.2, an existing regulation, identifies other regulations applicable to state Medicaid programs including 45 CFR part 80, which requires that programs receiving federal assistance, through the Department of Health and Human Services, include effectuation of Title VI of the Civil Rights Act of 1964 and 45 CFR part 84, which implements Section 504 of the Rehabilitation Act of 1973, prohibiting disability discrimination. In addition, state Medicaid programs are subject to the Age Discrimination Act of 1975. Therefore, these protections are already applicable to Medicaid.

We appreciate commenters pointing out deficiencies in §440.347(e) and have revised it to align with the regulation implementing EHBs in the Exchanges.

Comment: A few commenters indicated appreciation of CMS's work to revise current Medicaid rules such that they incorporate statutory non-discrimination provisions from section 1302(b)(4). The commenters strongly encourage CMS to also codify all statutory non-discrimination provisions applicable to issuers of QHPs that meet EHB requirements. CMS should specify that §156.200 and §156.225 also apply to ABPs. Section 156.200 specifically prohibits discrimination based on factors including but not limited to race, disability, and age. Section 156.225 codifies section 1311(c)(1)(A) of the Affordable Care Act which prohibits marketing practices and benefit designs that result in discrimination against individuals with

significant or high cost health care needs. The commenters believe that all Affordable Care Act non-discrimination provisions applicable to QHPs issuers and EHB standards must similarly apply to ABPs in Medicaid to ensure consistency of standards across all forms of all health care coverage.

Response: The requirements in 45 CFR part 156 apply to QHP issuers and not Medicaid managed care plans. However, there are similar protections in place in the regulations governing Medicaid managed care plans. If ABPs are delivered through a Medicaid managed care plan, those protections, including marketing, appeals and grievances, beneficiary information, and non-discrimination based on health status will apply to the Medicaid managed care plans providing ABP benefits. There are similar protections on many of these issues for Medicaid fee for service delivery systems, requiring fair hearing, free choice of provider, and beneficiary information.

We take this opportunity to clarify that States have the flexibility to use managed care to deliver ABP benefits without regard to statewideness and comparability of services. Further, freedom of choice of provider may also be disregarded to the extent the State can demonstrate that freedom of choice would be contrary to the effective and efficient implementation of an ABP.

Comment: Many commenters also recommended §440.347(e) be amended as follows: EHBs cannot be based on a benefit design or implementation of a benefit design that discriminated on the basis of an individual's race, color, national origin, sex, sexual orientation, gender identity, age expected length of life, or of an individual's present or predicted disability, degree of medical dependency, or quality of life or other health conditions. Other commenters recommended §440.347(e) be amended as follows: (e) EHBs cannot be based on a benefit design or implementation of a benefit design that discriminates on the basis of an individual's age,

expected length of life, an individual's present or predicted disability, degree of medical dependency, or quality of life or other health conditions, race, color, national origin, language, sex, sexual orientation or gender identity.

Response: The suggested change to §440.347(e) is unnecessary because the protections described are already reflected in existing Medicaid regulations.

Comment: Many commenters expressed concern about the lack of guidance under the proposed rule for monitoring and enforcement of the proposed nondiscrimination provisions, and believe that the final rule must better define how individual states will assess, monitor, and enforce the law's nondiscrimination provisions. Moreover, the commenters do not believe it is sufficient to delegate all monitoring and enforcement to states. The commenters recommend the final rule define how CMS will take enforcement action when states are not ensuring compliance with the nondiscrimination standards established under the Affordable Care Act. The commenters also recommend that CMS develop a clear standard for what constitutes a discriminatory benefit design. This standard must address both individual cases of intentional discrimination and benefit designs that are facially neutral but that have the effect of systematically disadvantaging members of protected classes. Ultimately, this standard must make clear that the determination of whether a coverage limitation or exclusion is discriminatory should turn on the degree to which the benefit design is based on sound standards of clinical appropriateness rather than on arbitrary distinctions between health conditions or personal characteristics. To assist federal and state regulators in rectifying discrimination in benefit design, CMS should follow up on the final rule with sub-regulatory guidance explaining how to evaluate products for impermissible discrimination and providing examples of discriminatory benefit designs such as those listed above. In addition, CMS should require trained evaluators in each state to regularly and transparently review coverage available through ABPs for

discriminatory benefit designs and to ensure identified instances of discrimination are remedied in an expedient manner. Where CMS determines that a state Medicaid agency is not fulfilling its responsibilities in this area, CMS should establish a review procedure to focus on ensuring that all services deemed part of the EHBs are available to all eligible individuals for whom they are medically necessary, without arbitrary discrimination on the basis of any protected personal characteristic.

Response: ABPs are Medicaid state plan amendments and are subject to the same monitoring and oversight that occurs in the Medicaid state plan. Under this process, states review applicable requirements and design their program, including ABPs. The proposed design is submitted to CMS for approval, and CMS reviews the proposal for compliance with federal requirements. If approved, CMS may also review state implementation for compliance with federal requirements. In addition, issues can be raised by beneficiaries through the fair hearing process if services are denied. As with any Medicaid service, we recognize the important role that all stakeholders play in making CMS aware of any perceived ABP noncompliance. We will consider issuing further guidance on this topic.

Comment: One commenter is concerned that the proposed rule does not establish sufficiently robust oversight or enforcement framework to provide states with essential guidance to implement such a program. The regulatory text does not expressly require the Exchanges, states or OPM to monitor plans for compliance with the prohibition on discrimination. This commenter urges CMS to adopt an express requirement in the regulatory text of the rule that the Exchanges, states and OPM monitor for non-discrimination.

Response: Medicaid is a federal and state partnership and as such, states have the first line of responsibility to design and implement their program in compliance with federal requirements, including the non-discrimination requirements. Federal oversight is implemented

using the existing state plan process, as well as ongoing monitoring of program operations.

Comment: Several commenters expressed concern that applying the EHB standard to prescription drug coverage in Medicaid would not provide appropriate protections for people with chronic conditions like cancer, diabetes, Parkinson's, HIV/AIDS, schizophrenia, epilepsy, obesity and organ transplant recipients. The commenters believe that focusing on a number of drugs covered, as opposed to ensuring a breadth of drugs are covered, could result in a selection of drugs that meets the minimum requirement but discriminates against potential enrollees.

Response: While we understand the commenters' concerns, the statute permits states a certain amount of flexibility in determining and structuring ABPs that meet the needs of enrollees and are consistent with overall state objectives. We must clarify a statement in the preamble to the proposed rule, indicating that requirements under section 1927 of the Act are applicable to ABPs under section 1937 of the Act. Section 1927 of the Act does not affect the flexibility of states to define ABP benefit packages consistent with a coverage benchmark and including EHBs. The amount, duration, and scope of prescription drug coverage would thus be governed by the requirements of section 1937 of the Act. To the extent that a prescription drug is within the scope of the ABP benefit as a covered outpatient drug, section 1927 of the Act is then applicable. For such covered outpatient drugs, since payment is available under the state plan, all drug rebate obligations under the rebate agreement are required for drug manufacturers under 1927(b) of the Act.

To explain in more detail, the amount, duration, and scope of coverage for an ABP is determined under section 1937 of the Act, which authorizes benchmark or benchmark-equivalent coverage "notwithstanding any other provision that would be directly contrary." But, the drug rebate obligation applies under section 1927 of the Act when payment is made under the Medicaid state plan for covered outpatient drugs as part of the ABP. In addition, to the extent

that covered outpatient drugs are within the scope of ABP coverage, the protections and limitations for such coverage under section 1927 of the Act apply. So, for example, to the extent that coverage under an ABP includes a class of covered outpatient drugs, a state could impose limitations on that coverage only consistent with the provisions of section 1927(d) of the Act. In general the requirements for prescription drug coverage under section 1937 of the Act, through the requirement for coverage of EHBs, will mean that ABPs will meet existing section 1927 requirements for Medicaid payment of covered outpatient drugs, which we believe will address the commenters' concerns. We discuss the interaction between the requirements for prescription drug coverage under section 1937 of the Act with the requirements for covered outpatient drugs under section 1927 of the Act in further detail later in this final rule.

Comment: Some of the commenters are concerned that CMS allows states to place limitations on amount, duration, and scope and adopt prior authorization and other utilization control measures, as well as policies that promote the use of generic drugs. The commenters believe that for people living with chronic conditions, use of utilization management techniques can have a detrimental impact and inhibit people from accessing needed treatments. The commenters also believe that these limitations can violate the non-discrimination requirements in the law.

In particular, commenters indicated that it is imperative that non-discrimination protections found in §440.347 are strictly and clearly applied to the ABP prescription drug benefit. HIV care and treatment standards maintained by Federal agencies recommend a combination of medications for effective management of HIV disease (see <http://www.aidsinfo.nih.gov>). Quantitative limits on the number of drugs covered per month are discriminatory against people with HIV and others whose quality of life and health depend on access to a specific regimen of multiple prescription drugs to treat both HIV and co-occurring

conditions as recommended by their medical provider. The application of the non-discrimination provisions should prohibit states from applying quantitative limits on monthly drug coverage for the expansion population, and the commenters urged that this standard also be applied to the traditional Medicaid population. If monthly drug limits are considered, there must be provisions to allow for a timely override process that does not delay immediate and uninterrupted access to the medications when recommended by a medical provider.

Commenters also requested that CMS adopt a more robust standard for evaluating limitations on amount, duration, and scope and prior authorization and utilization control measures that may be discriminatory by design. These evaluations should be specific to the population and based on sound medical evidence regarding the prescription drugs necessary to provide adequate coverage. Restrictions to prescription drug coverage in Medicaid, such as monthly drug limits, could leave some Medicaid beneficiaries with less comprehensive coverage than that offered to individuals covered in the Exchange because of limitations that are discriminatory based on health care need.

A few commenters also expressed concern that the proposed rule does not discuss the circumstances in which a limitation on drug coverage could violate the non-discrimination requirement. CMS should provide additional guidance about its interpretation of the nondiscrimination rule and its enforcement strategies, particularly for prescription drugs. The commenters believe that this should include oversight functions to actively monitor and test for discriminatory plan design and implementation, and to report such activities to CMS. For instance, the implications of plan substitutions within a category of EHBs or prescription drug cost-sharing designs for high risk enrollees should be considered.

Response: States have considerable flexibility in implementing the provision of Medicaid services through ABPs. While this flexibility permits states in some instances to limit

prescription drug coverage based on the coverage offered under other public employee or commercial plans, it also includes the ability to exceed the amount, duration, and scope of prescription drugs covered by those plans, as long as the services provided are consistent with the Medicaid requirements.

The non-discrimination provisions adopted in this final rule at §440.347 require that states will need to assess whether their ABP benefits, including any limitations placed on the amount, duration and scope of any benefit, discriminate on the basis of the individual's age, expected length of life or any individual's present or predicted disability, degree of medical dependency, or quality of life or other health conditions. We will consider whether additional sub-regulatory guidance on these matters is needed.

Comment: One commenter stated that private market carriers argue that exclusions for services or drugs commonly provided for the treatment of conditions such as HIV/AIDS are not discriminatory because they apply to all plan enrollees, regardless of their specific negative effect on people with these conditions.

Response: Under the law, states must assess whether their ABP benefit designs, including service or drug exclusions that are applied to all beneficiaries, discriminate based on an individual's age, expected length of life, or an individual's present or predicted disability, degree of medical dependency, or quality of life or other health condition contrary to the non-discrimination provisions being adopted in this final rule at §440.347.

Comment: One commenter suggested that in developing an analysis framework to aid in testing for discriminatory plan benefits, CMS must ensure that ABPs refrain from using benefit designs that treat patients in a disparate manner based on age. For example, where FDA approves a drug or biologic for use in patients within a certain population, such as pediatrics, the commenter argued that ABPs should not be permitted to restrict coverage or employ varying

utilization techniques for children of different age ranges within that pediatric population. The commenter requested CMS' vigilant oversight to protect children from being subject to age-based discrimination in accessing FDA-approved products.

Response: The non-discrimination provisions adopted in this final rule at §440.347 require that states will need to assess whether their ABP benefits, including any limitations placed on the amount, duration and scope of any benefit, discriminate on the basis of the individual's age, expected length of life or any individual's present or predicted disability, degree of medical dependency, or quality of life or other health conditions. A limitation on medically necessary care provided to pediatric patients would violate the requirement under section 1937 of the Act that ABPs include the full range of medically necessary EPSDT screening and treatment services. Thus, the issue would not be one of benefit design but of compliance in providing a covered benefit.

Comment: A few commenters stated that CMS should adopt similar guidance and review processes as required under Medicare Part D program in the Medicaid EHB final rule. These proven non-discrimination policies and processes have been critically important in assuring that all Medicare beneficiaries -- from the healthiest beneficiaries to the most vulnerable beneficiaries with serious and chronic illnesses -- can obtain affordable Part D coverage that meets their individual needs. Additionally, CMS' experience assessing Medicare Advantage plans' cost-sharing and benefit designs for discriminatory effects may help point the way.

Response: We appreciate the comments regarding the use of Part D non-discrimination standards and will consider those standards as we evaluate these issues and the need for further guidance.

Comment: Several commenters indicated that meaningful non-discrimination protections will require a thoughtful and thorough review of preferred drug lists (PDLs). They stated that

the following approaches could help ensure meaningful access: (1) PDLs should only be permitted to categorize a drug as non-preferred when there are genuine therapeutic alternatives classified as preferred; (2) PDLs should allow for appropriate access to drugs or drug classes needed for adherence to widely accepted treatment guidelines; (3) The most commonly used medications (or therapeutically similar medications) for conditions with high prevalence in the Medicaid population should be categorized as preferred drugs; and (4) Most importantly, medications used by particularly vulnerable Medicaid beneficiaries, such as those living with HIV/AIDS, cancer or serious mental illness, should be largely available as preferred drugs, given the importance of avoiding medical complications and interruptions in therapy for individuals with those conditions.

Response: For covered outpatient drugs, a PDL is permitted under section 1927 of the Act, as long as it is under a prior authorization program that meets the requirements of section 1927(d)(5) of the Act. Furthermore, as we discuss in the cost sharing sections of this final rule, a PDL may also be established for cost sharing purposes.

Comment: Many commenters expressed concern that the regulation did not provide examples of what would be considered discriminatory benefit design. The commenters request CMS identify a clear standard to determine whether the coverage provided complies with the non-discrimination provisions of the Affordable Care Act. Additionally, the commenters believe that CMS should provide examples to States of what would constitute violations, monitor ABP coverage for compliance with the non-discrimination requirements, and enforce these provisions of the law. Many other commenters added that the rule also did not establish a process to bring discriminatory benefit design or practice into compliance. CMS should consider developing more detail in the final regulation defining these protections. This should include a process for bringing a State's chosen benchmark or benchmark-equivalent option into compliance with the

law.

Response: States will submit Medicaid state plan amendments for federal approval to implement ABPs and receive FFP. The state will assure in that submission that they will comply with non-discriminatory requirements as set forth in §440.347(e). If issues are detected with adherence to these requirements, we will pursue appropriate action with the state to rectify the issues. As always, we appreciate the ongoing input of stakeholders to help inform states and CMS of concerns relating to these matters.

Comment: One commenter indicated that it is unclear how the requirement that EHBs cannot be based on a benefit design or implementation of a benefit design that discriminates on the basis of an individual's age, expected length of life, or of an individual's present or predicted disability, degree of medical dependency, or quality of life or other health condition will be evaluated in the context of benchmark plans for specified population. It is unclear whether targeting permitted under other sections such as section 1915(i) of the Act would be permitted. The commenter wondered whether it would preclude the establishment of specialty plans based on diagnosis.

Response: Section 1937 of the Act does allow for a waiver of comparability at §440.230(c); thus permitting states to identify groups of people, populations, based on certain characteristics such as presence of a chronic condition. States can then design benefit packages that are suitable for the population, but this activity does not permit benefit designs that are inherently discriminatory.

Comment: A few commenters expressed concern that neither earlier rules on EHB nor this proposed rule specifically define "discrimination" in the context of discriminatory benefit design. The commenters urge HHS to develop and promulgate a definition of "discrimination" that will allow states to evaluate health plans uniformly. The proposed rule delegates entirely to

states the task of evaluating EHB for discriminatory design or intent with no further guidance at all. The absence of a definition of discrimination will inevitably lead to a 50-state patchwork of definitions. The commenters strongly believe that the definition of discriminatory benefit design should not vary among states.

Response: Medicaid is a federal and state partnership that allows states to design state-specific programs within broad federal guidelines and, more generally, that allocates responsibilities to both states and the federal government. By identifying states as accountable for determining that benefit design is not discriminatory, we recognize their important role in assuring compliance with this important statutory directive. Such accountability does not negate federal responsibility. As noted, we will consider whether further guidance on discrimination benefit design would be useful.

Comment: One commenter pointed to the Affordable Care Act's provision barring discrimination in EHB as prohibiting disability-based discrimination in making decisions about coverage, reimbursement rates, establishing incentive programs, and designing benefits, and the commenters believe those requirements should apply to Medicaid ABPs. The commenter recommends the Department provide additional guidance concerning applications of the Affordable Care Act EHB non-discrimination mandate to ABPs. The commenter believes the Department should also identify a minimum scope of services that plans must cover to comply with the Affordable Care Act's parity and nondiscrimination requirements and the requirement that EHB take into account the "needs of diverse segments of the population, including . . . persons with disabilities."

Response: The United State Supreme Court decision in Olmstead v. L.C. rendered on June 22, 1999 held that unjustified segregation of people with disabilities constitutes discrimination in violation of Title II of the ADA. Public agencies must provide services to

people in the community when services are appropriate, people do not oppose services in the community, and the community-based services can be reasonably accommodated, taking into account the resources available to the entity and the needs of others who are receiving disability services from the entity. Medicaid beneficiaries must receive services in the most integrated setting appropriate. We agree with the commenter that benefit design, including rate structures, should not create a pathway to institutionalization or segregation. Setting is not an appropriate targeting criterion, because it is potentially discriminatory as different benefits could be designed based on where individuals live and therefore, it would not be acceptable as a waiver of comparability.

Comment: Many commenters recommend CMS use the following data to determine compliance with the non-discrimination requirements:

- Medical necessity requirements for Medicaid must be evaluated and standardized, and HHS should monitor state implementation of medical necessity to ensure that people living with HIV, chronic disabilities and other chronic and complex conditions have unimpeded access to essential care and treatment.
- Utilization management techniques, exclusions, and service limits must be closely monitored to ensure that plans have not put in place barriers to services or excluded or limited certain items or services solely to deny access to care for people with chronic and complex health conditions. The commenters urge HHS to develop a list of practices that amount to discrimination to help guide monitoring and enforcement activities. For instance, requiring step therapy for HIV treatment without a medical override provision is a discriminatory utilization management technique that should be barred. Similarly, a monthly limit on prescription drugs (for example, several states have monthly limits of three or four prescription drugs) is also per-se discriminatory, as applied to people living with HIV and other chronic conditions.

- Physician network size and composition must be evaluated to ensure that Medicaid managed care plan networks include providers that are able to deliver quality care for people living with HIV and other chronic and complex conditions. A plan network that excludes HIV providers violates network adequacy standards outlined in qualified health plan standards and is a discriminatory plan design practice that forecloses access to EHB services. In addition, patient protections (for example, standing out-of-network referrals) will be necessary to ensure a smooth transition to coverage and to support continuity in care. The commenters strongly urge CMS to require Medicaid managed care plans to contract with Essential Community Providers, including Ryan White medical providers.

- For chronic and complex conditions, where the standard of care is rapidly evolving, reference to clinical guidelines is particularly important to ensure that coverage decisions are based on established medically accepted guidelines.

Response: Thank you for your suggestions. We agree that Medicaid managed care provider networks need to be adequate to provide services to all of their members. It is at state discretion to include (or not) standards for managed care providers in the contracts that the state holds with the managed care organizations in the state. Managed care entities can contract with any provider operating within the scope of their license to provide services.

Comment: A few commenters recommend ongoing procedures for states to monitor and share data on how they are meeting their benefit design and anti-discrimination obligations over time, and make this information transparent and readily available in at least an aggregate fashion to HHS, the public, and to health advocates.

Response: We appreciate the comments. We are currently redesigning data collection procedures and standards and will consider these comments.

Comment: One commenter is requesting that any coverage under the Affordable Care

Act, including Medicaid Programs, adequately cover therapies that cancer patients absolutely must take whether or not there is an actuarial equivalent at a lower cost. Coverage of drugs and services related to cancer care should not create cost barriers to patients through cost-sharing schemes such as burdensome co-pays and co-insurance. To do so would be unfairly discriminatory, and could impact a patient's ability to access their care, particularly low-income patients enrolled in Medicaid. The commenter would like to see strong protections and oversight established to prevent discrimination.

Response: We agree that a patient's ability to pay cost sharing imposed for a service can affect a patient's access to care and that low-income patients are particularly sensitive to such costs. Medicaid cost sharing rules at §447.52 generally and §447.53 for drugs apply to ABPs. States design cost sharing for therapies and drugs using those rules, and cost sharing rules may not be implemented in a manner that would be discriminatory. Annual dollar limits on services will not be allowed on benefits in the public employee or commercial plans that are the basis for the base benchmark options used to define EHBs per section 2711 of the Affordable Care Act.

Comment: A few commenters believe that §440.347(e) sets out a strong non-discrimination requirement. However, the commenters also believe that there will be times when individuals are going to need access to legal advocacy to seek redress from discrimination and enforce these due process protections. The commenters recommend that the states be required to assist individuals to use the due process and appeals processes, this would include: (1) information and assistance in pursuing complaints and appeals; (2) negotiation and mediation; (3) case advocacy assistance in interpreting relevant law; (4) reporting on patterns of non-compliance by plans as appropriate; and (5) individual case advocacy in administrative hearings and court proceedings relating to program benefits.

Response: We appreciate these suggestions; however, they are outside the scope of this regulation.

Comment: Many commenters representing the Lesbian Gay Bi-Sexual and Transgender (LGBT) community stated that the final rules must also address gaps in enforcement of this prohibition on discriminatory exclusions by providing clear guidance to state Medicaid agencies on implementation of these nondiscrimination standards. Enforcement is a major concern for these commenters in two areas: (i) instances of discrimination against individual enrollees, and (ii) discriminatory benefit design. The former is very important for LGBT enrollees, and they encourage CMS to work with state Medicaid Directors to ensure that robust and transparent appeals procedures are equally available to all individuals who need them. With regard to discriminatory benefits design, they are particularly concerned about enforcement in the context of potential disagreement as to what kinds of benefit limitations and exclusions constitute impermissible discrimination in benefit design.

Response: We appreciate the concerns expressed by these commenters. We intend to work with states on these matters as well as consider ways in which discrimination for LGBT enrollees may be rooted in benefit limitations and exclusions as well as in appeals processes.

Comment: Several commenters stated that the proposed rule requires that a Medicaid benchmark plan's benefit design cannot be discriminatory, and the final regulation must ensure adequate protections against discrimination. The commenters recommend the regulation require the following non-discrimination standards:

- Processes for review of plan benefits design to avoid discrimination caused by unfair utilization management techniques or other plan design elements.
- Requirements for plans to disclose to all prospective and current members all utilization management techniques as well as all limits on services.

- Final authority at the federal level to approve any state non-discrimination review processes to ensure appropriate measures are in place to guarantee that plans are meeting the requirements of this section.

- Federal monitoring programs to ensure appropriate checks are in place to guarantee that plans are meeting federal requirements.

In addition, the commenters urge CMS to clarify that Medicaid cost-sharing limits apply to the managed care organizations participating in the Medicaid program. For more details on non-discrimination standards, the commenters refer CMS to its proposed regulatory language for a comprehensive set of patient protections

Response: In Medicaid, utilization management processes are at state discretion. States have flexibility to design and implement the Medicaid program in the state according to state policies and procedures. States will assure in the state plan amendment submission that anti-discrimination practices at §440.347(e) are met. We clarify here that Medicaid cost sharing parameters apply to services provided in a managed care delivery system. Furthermore, we have oversight responsibility of state programs to insure that federal rules and requirements are being followed.

Comment: One commenter pointed out that §440.347 deals exclusively with patient non-discrimination. The commenter indicated that there is also provider discrimination within health plans, where sometimes entire classes of healthcare professionals are excluded from providing services under the benefit solely based on their licensure or certification. The commenter believes such discrimination can limit or deny patient choice and access to a range of beneficial, safe and cost-efficient healthcare professionals, impairing competition, patient access to care, and optimal healthcare delivery. The commenter recommends the rule require ABPs offering EHBs to align payment systems to adhere to existing state provider non-discrimination laws as

applicable, and to the federal provider non-discrimination provision in the Patient Protection and Affordable Care Act (Sec. 1201, Subpart 1, creating a new Public Health Service Act Sec. 2706, “Non-Discrimination in Health Care, 42 USC §300gg-5) slated to take effect January 1, 2014.

Response: We require that all providers are operating within the scope of their licensure or certification when providing services to Medicaid beneficiaries.

Summary: We appreciate the comments and suggestions and may consider further guidance. No change in the substance of the regulatory text is needed. However, CMS made grammatical changes to the regulation text at §440.347(e) as a result of comments received in this section.

3. Modifications in applying the provisions of this final rule to Medicaid

We proposed in the implementation of section 1937 of the Act and the provisions in the Affordable Care Act relating to EHBs, a process in Medicaid for designing ABPs. The Affordable Care Act modified section 1937 of the Act to implement two standards for minimum coverage provision; not only must EHBs, as defined by the Secretary, be provided, but all requirements of section 1937 of the Act continue to apply. Furthermore, we outlined expectations for specific EHBs as they are implemented in Medicaid including: habilitative services; pediatric or and vision services; prescription drugs; preventive services as an EHB; and the fact that all other Title XIX provisions apply.

a. Essential health benefits (Rehabilitative and habilitative services and devices) (§440.347)

The proposed rule requested comment on an approach for defining habilitative services in Medicaid and we reserved regulatory text to do so. We received varied comments, and are adopting in this final rule the requirement that services covered by the base benchmark are the floor of EHB coverage, substituted as desired by the state. Under 45 CFR 156.110(f), if no habilitative services and devices are included in the base benchmark, states have the option to

determine generally the required EHB services that are in the category of habilitative services and devices. If the state has done so, the base benchmark, and coverage under the ABP, must reflect that determination. If the state has not made a general determination of the habilitative services that are required for this EHB category, the state must exercise the option set forth in 45 CFR 156.115(a)(5) to determine EHB for the specific ABP. Under that option, habilitative services and devices must be included as EHBs either in an amount, duration, and scope no more restrictive in terms of treatment and benefit limitations than rehabilitative services and devices, or otherwise to an extent determined by the state and reported to HHS. In other words, if the base benchmark does not include habilitative services and devices, ABP coverage must, at a minimum, be based on the general state determination of habilitative services and devices that are included in EHBs, or on a Medicaid-specific determination for the particular ABP.

While we are not prescribing a specific definition of habilitative services and devices for purposes of ABP coverage of EHB, we clarify here that states may choose to adopt service definitions similar to those issued by the National Association of Insurance Commissioners (NAIC), as follows: rehabilitative services and devices are defined as services and devices provided to assist a person to prevent deterioration and regain or maintain a skill or function acquired and then lost or impaired due to illness, injury or disabling conditions. The NAIC also defines habilitative services and devices as services and devices provided for a person to prevent deterioration or attain or maintain a skill or function never learned or acquired due to a disabling condition. CMS will consider the need for future guidance, once experience is gained in implementing these EHB services and devices. We also note that while there is a definition of habilitative services under existing sections 1915(c) and 1915(i) of the Act, this definition is not necessarily applicable and may in fact not be appropriate for the population covered under ABPs.

Comment: A number of commenters believed that by requiring coverage of habilitative services in the ten mandatory EHB categories, Congress clearly indicated its intent to meet the health needs of individuals with functional limitations following illness, injury, disability or due to a chronic condition. The commenters recommended that HHS develop an objective minimum national standard for habilitative services based on “appropriate coverage to meet the needs of the population,” and allow states flexibility to add to this minimum for purposes of innovation.

A few commenters recommended HHS better define this category of services including providing clarity as to how plan definitions and scope of coverage will be assessed to ensure compliance with non-discrimination provisions. A number of commenters requested HHS cover habilitation at parity with rehabilitation, with some comments suggesting this standard also require habilitative services under Medicaid to be at least as generously defined as in the private market.

Many commenters requested that HHS require coverage of habilitative devices without arbitrary restrictions and caps that limit the effectiveness of the benefit.

Several commenters recommended HHS include a set of habilitative services specifying the minimum type of services to be provided and specify that these services are a floor.

Many commenters recommended that habilitation be covered separate and distinct from rehabilitation. For example, the plan cannot substitute rehabilitation for habilitation or apply only a single visit limit to both benefits. Each benefit must have separate and distinct limits which are applied based on medical necessity, not an arbitrary cap.

One commenter requested that HHS recognize that habilitative services are similar in type and scope to rehabilitative services (for example, physical therapy, occupational therapy, speech-language pathology). One commenter believed that habilitation should be covered in the same setting and include the same type of providers and specialists as covered in the

rehabilitation benefit.

A number of commenters believed that setting clear, comprehensive, and uniform standards for habilitative services will prevent non-aligned localized definitions that could create serious problems across programs and states. A few commenters requested formal guidance on what the minimal expectation is for habilitative services.

A few commenters believed that when states adopt the habilitative benefit for ABP, HHS require that they do not impose financial requirements, quantitative treatment limitations, or financial limitations that are more restrictive than the predominant requirements or limitations that apply to all other benefit categories.

Response: We believe the provision of habilitative services is in addition to rehabilitative services and devices as an EHB. As EHBs are based on commercial market products, we are interpreting rehabilitative services as an EHB to more closely align with commercial market definitions, rather than the broader definition of rehabilitation in Medicaid. We therefore, are establishing that the commercial market definition of EHBs is the floor of coverage, subject to substitution flexibilities. If the commercial market coverage is not adequate, states, not issuers, define the benefit. At state discretion, as indicated above, states may offer coverage of habilitative services and devices that is no more restrictive in terms of amount, duration, and scope than rehabilitative services and devices. We expect that the services will be clinically appropriate to meet the needs of individuals based on medical necessity. We have added this flexibility for states to define a minimum standard of coverage if the commercial market benefits are not adequate. We are suggesting, but not requiring, definitions of rehabilitative and habilitative services and devices, as indicated above, and will consider needs for future guidance. We are reiterating that the benefit flexibility under an ABP allows states considerable latitude to define the benefit package for each population and there may be services that are covered in

some settings but not in other settings, or that are covered when furnished by some practitioners but not others. This is flexibility that exists currently in the commercial marketplace, and is extended to state Medicaid programs under section 1937 of the Act.

Comment: One commenter recommended that the coverage and medical necessity determinations for habilitative services and devices should be based on clinical judgment of the effectiveness of the therapy, service, or device to address the deficit. In addition, HHS should make clear that such benefits are to cover maintenance of function not just improvements, to assure that individuals in need have access to care that prevents deterioration of their conditions.

One commenter requested that HHS inform states that habilitative services need to be medically necessary and plans must be clear on how they define and determine medical necessity.

Response: States may require that all services covered under Medicaid be medically necessary. Determining the specific coverage of habilitative services and devices will be done by the state, based on services found in the base benchmark plan selected by the state to define EHBs for Medicaid, and substituted as desired. If a base benchmark plan does not include habilitative services, consistent with 45 CFR 156.110(f) and 156.115(f), States will determine which services are included as EHB in the habilitative services and devices category. We agree with the commenter that habilitative services, generally speaking, cover acquisition and maintenance of skills, while rehabilitative services cover restoration of previously acquired skills, but we are not setting forth a specific definition of these terms at this time.

Comment: One commenter recommended that HHS look to state Medicaid programs as a guide for defining what habilitation services should be covered under the EHB. A number of commenters requested that HHS require states and plans to adopt the definition of habilitative services put forth by the NAIC, which was included in the Department's proposed rule defining

medical and insurance terminology. Many commenters recommend that if the NAIC definition is not used, an alternate definition to consider is provided in Medicaid law under section 1915(c)(5)(A) of the Act.

Response: We appreciate these suggestions and find the definitions of rehabilitative services and devices and habilitative services and devices extremely useful. Habilitative services and devices as described in the base benchmark plan is the floor of coverage, subject to substitution flexibility. If a base benchmark plan does not include habilitative services, consistent with 45 CFR 156.110(f) and 156.115(f), States will determine which services are included as EHB in the habilitative services and devices category. States may choose to offer habilitative services and devices in no more restrictive in terms of amount, duration, and scope of treatment than is applied for rehabilitative services and devices.

Comment: One commenter requested the state-defined habilitative benefit definition, as applied to section 1937 ABP in Medicaid, should not be extended to QHPs on the Exchange. This commenter indicated that in many states, Medicaid takes an expansive view of habilitative services, and there is a risk that if applied to the commercial market, this could raise costs on QHPs in the Exchange. States should have the option to either separately define habilitative services for Medicaid or apply the state-defined habilitative definition for the Exchange to the Medicaid programs, but not apply a broad Medicaid habilitative service definition to QHPs in the Exchange.

Response: This regulation is focused on the parameters of the habilitative services and devices that are EHBs for purposes of section 1937 ABPs under the Medicaid program and, this regulation does not apply to QHPs.

Comment: Many commenters recommended that states should be allowed to define habilitative services for their Medicaid program.

Response: We are adopting the position in this final rule that states will have the ability to define habilitative services and devices. If the base benchmark plan selected by the state to define EHBs, does not include habilitative services and devices, states will define the habilitative services and devices that will be regarded as this EHB category and must be covered in the ABP. In so doing, states can choose to offer habilitative services and devices that are at a minimum no more restrictive in terms of amount, duration, and scope than rehabilitative services and devices.

Comment: One commenter requested that HHS continue to allow states and issuers the flexibility to define habilitative services for the individual and small group markets as proposed in the EHB proposed rule and not be required to follow Medicaid definitions.

Response: We reiterate that this regulation applies only to the Medicaid program, and has no bearing on the provision of habilitative services in the individual and small group markets.

Comment: One commenter requested HHS clarify that states will be deemed to cover habilitation if they provide ABP enrollees with such services through a section 1915(c) waiver program.

Response: The new adult eligibility group is not eligible for enrollment in section 1915(c) waivers. However, states may also add section 1915(i) services to the ABP using Secretary-approved coverage, which may include some habilitative services and devices. But we do not see a reason to “deem” compliance with the habilitative services and devices EHB requirements just because a state may include some habilitative services and devices in those ways. The state must still determine habilitative services and devices that are EHBs in accordance with this regulation.

Comment: A few commenters recommended that if HHS does not use a national standard for Medicaid habilitative service benefits, then states should be required to base their definitions

on documented and evidence-based criteria, such as those endorsed by a relevant national academy of providers or national disease group; and states should not automatically be allowed to use their Exchange habilitative services definitions unless it independently meets the criteria stated above.

Response: We expect that states will consider the efficacy of services, evidence-based criteria, and the needs of the populations being served as they are designing habilitative services, based on the services found in the base benchmark selected by the state to define EHBs for Medicaid, and supplemented and substituted as necessary and desired.

Comment: Many commenters recommended that the state-defined habilitative services for Exchanges should not apply to Medicaid. Instead, some commenters indicated that states should be required to define habilitative services through a public process that establishes minimum standards for coverage, while taking into account unique circumstances of the Medicaid population, including the impact of a restrictive definition on access to critical services in early intervention and special education. One commenter believed that states should have the option to offer parity.

Response: In terms of complying with EHB requirements, the same basic framework applies to both ABPs and plans in the individual and small group markets. But that basic framework includes considerable flexibility that states can exercise in the Medicaid context. While states will ultimately determine coverage of habilitative services we encourage states to do so in recognition of the unique needs of the Medicaid population. As states work to identify coverable habilitative services, they are expected to consider input from the public in making the decisions. ABPs are subject to public notice requirements in §440.386.

Comment: One commenter requested that the final rule ensure that the state's Medicaid definition of habilitation is at least as generous as the definition used for Exchange plans.

Response: While we believe that the procedures we are adopting to determine habilitative services included in EHB for Medicaid will generally be at least as generous as the parallel procedures for the individual and group market, we are not requiring that result. We believe that the procedures for Medicaid will lead to appropriate coverage for Medicaid beneficiaries while recognizing the state's role in designing Medicaid coverage.

Comment: Many commenters recommended against HHS allowing any of the potential flexibility, authorized in the Exchange, for issuers to define the habilitative benefit. Commenters were concerned that issuers would limit the range of services too narrowly.

Response: States will retain flexibility to design services covered within the rehabilitative and habilitative services and devices EHB consistent with the procedures set forth in this final regulation.

Comment: A few commenters recommended HHS require states to establish the same definition of habilitative services for ABP, QHPs, and Exchange, due to the significant amount of churn associated with the population being served. One commenter believed that habilitative services should have a common definition, but that definition should not necessarily determine what is covered by the Exchange or Medicaid. Those habilitative services that are to be covered should be separately established by the Exchange and by Medicaid, since this is a question of affordability and comprehensiveness.

Response: We recognize the possibility for churn between Medicaid and the individual and small group markets. We believe the flexibility reflected in this regulation provides the basis for continuity between the commercial market and Medicaid. We are also allowing states to use provider qualifications from the commercial market plans to help minimize the possibility for provider changes if a person's plan changes.

Comment: One commenter indicated that currently under Medicaid, habilitation services

are defined in statute and provided as an alternative to institutional services such as nursing home care. As noted in the regulation, employers do not cover the service consistent with Medicaid requirements. As a result, if parity is required without consideration of the scope of habilitation services offered, the result could be states exceeding the EHB standard. States should be provided the flexibility to define and provide coverage of habilitation services.

Response: Habilitative services and devices are coverable services under the section 1915(c) waiver program and the waiver program does provide a suggested definition. Section 1915(i) also allows coverage of habilitative services and devices where states define the service. We are giving states flexibility to define habilitative services and devices within the standards finalized in this regulation. In addition, states may offer either habilitative or rehabilitative services in excess of these standards.

Comment: Numerous commenters believed that states should not be allowed to define habilitative services through parity with rehabilitative services since the two service sets have totally distinct purposes and impact different sets of individuals. They asserted that parity is a poor standard because there is no certainty that the rehabilitative services level is itself adequate to begin with.

Response: We appreciate the commenters' concerns. We are establishing that the state may determine the ABP-covered benefit beyond the benefits included in the base benchmark plan,. To the extent that the base benchmark has no habilitative services, the state may elect to include as the EHB category habilitative services and devices coverage that is no more restrictive in amount, duration, and scope than the coverage of rehabilitative services and devices. We acknowledge that this standard does not guarantee provision of any particular habilitative or rehabilitative service. This will be in large part determined by the services offered in the plan selected by the state to define EHBs for Medicaid.

Comment: One commenter requested HHS, at a minimum, afford flexibility to issuers allowing them to either provide parity by covering habilitative services in the same manner as rehabilitative services or report the services it decides to cover to HHS.

Response: The procedures we have adopted recognize that states have the role that issuers have in the individual and small group market. Federal Medicaid works directly with state governments and not issuers. Therefore, we believe that having states define the habilitative services benefit instead of issuers, using the procedures finalized here, is the most appropriate approach.

Comment: One commenter believed that habilitative services complement rehabilitative services and are integral to ensuring that the beneficiary receives comprehensive care that restores him/her to maximum functional levels. This commenter stated that both substitution among and parity between these services could be problematic if the beneficiary's medical condition requires significantly more rehabilitative services than habilitative services and vice versa.

Response: States may implement utilization management processes that allow for individuals who need additional services beyond the limits established in the ABP to receive such services based on medical necessity. States could substitute rehabilitative services for rehabilitative services and habilitative services for habilitative services.

Comment: A number of commenters recommended that HHS remove the requirement that state Medicaid programs cover habilitative services, as this is not a separate mandated category of EHB services. Instead, a Section 1937 plan that covers either rehabilitative or habilitative services should be deemed to cover items and services within the general EHB category for rehabilitative-habilitative services.

Alternatively, a few commenters recommended that HHS clarify that ABPs must cover

all of the benefits within categories of care that list more than one benefit, as is the case for rehabilitative and habilitative services and devices. In particular, a plan should not be considered to meet the requirement of covering all EHBs unless it covers, as three distinct benefits, rehabilitative services, habilitative services, and rehabilitative and habilitative devices, as opposed to covering only one of the many benefits included in this category.

Response: Habilitative services are listed as a required benefit category of EHB at section 1302(b)(1)(G) of the Affordable Care Act. It is part of a category of EHBs, but is distinct from rehabilitative services and devices. Both rehabilitative and habilitative services and devices must be offered in all ABPs.

Comment: A number of commenters supported access to habilitative services and devices including autism services, durable medical equipment, orthotics, prosthetics, low vision aides, hearing aids, augmentative communication devices that aid in speech and hearing, and other assistive technology and supplies that are often critical to ensure individuals are able to function independently in the community.

Response: We appreciate the comment and agree that these types of services could assist people with living in the community. We are not requiring any specific services to be offered within this EHB category.

Comment: A number of commenters requested that HHS require coverage of services without age restrictions. They indicated that a pediatric-only habilitative benefit is inadequate, especially as the new eligibility category is for adults only.

Response: EHBs including rehabilitative and habilitative services and devices apply to all individuals who receive a benefit package in ABPs, regardless of age. For the new adult group, only individuals who are ages 19 and 20 will qualify for EPSDT services.

Comment: A few commenters requested HHS prohibit the exclusion of specific

conditions or diagnoses from accessing the benefit.

Response: ABPs allow for comparability to be waived, which results in allowing for targeting of individuals to specific benefit packages. However, all individuals in the new adult group and other individuals the state either mandates or offers voluntary enrollment into an ABP must receive all EHBs, including habilitative and rehabilitative services and devices.

Comment: A few commenters recommended that states should define habilitation using EPSDT criteria.

Response: Section 1905(a) of the Act does not include a service category for “habilitation services” so it is not useful to look to EPSDT coverage for guidance and EPSDT criteria do not apply under law to adults. For children, however, the EPSDT benefit must provide eligible individuals with any medically necessary service that is coverable under a section 1905(a) service category. Consistent with the law, these regulations extend the EPSDT benefit, which also includes children covered in an ABP. Therefore, children in an ABP should receive any covered section 1905(a) benefits that they require based on medical necessity.

Comment: A few commenters requested that HHS cover habilitation services, which maintain an individual’s functional status, as defined by the HHS Summary of Benefits and Coverage regulations.

Response: The HHS Summary of Benefits and Coverage regulations apply to private insurance markets, which do not include Medicaid.

Comment: A few commenters cautioned against restricting services in EHB plans without allowing for an exception process.

Response: States do have the flexibility to allow for exception processes for utilization management of the benefit; such exceptions must be based on medical need.

Comment: One commenter recommended that the habilitative benefit cover the full array

of health and ancillary service needs of children with special health care needs. The commenter believed that this is especially important for children aging out of foster care, as these children are at greater risk of having a chronic condition requiring habilitative services.

A few commenters indicated that it is inappropriate for any one service to satisfy the requirement for a benchmark plan covering habilitative services. For example, providing only Applied Behavioral Analysis to children under the benchmark plan is inadequate to satisfy the full requirement of coverage of habilitative services. These commenters requested that the benchmark plan utilized be as comprehensive in its coverage as feasible. One commenter recommended defining habilitation and contrasting it with rehabilitation to help clarify the distinction between the two benefits.

Response: We remind readers that states must not only comply with the standards finalized in this regulation, but must also include all habilitative services covered in the public employee or commercial plan selected by the state to define EHBs for Medicaid, supplemented and substituted as necessary and permitted.

Comment: One commenter believed there should be no exclusion for services that may be educationally-relevant, as is the current policy in Medicaid.

Response: Payment for Medicaid services must be for services that are medical or remedial in nature as specified by the particular authority from which the service is derived.

Comment: One commenter requested HHS provide states a description of maintenance programs and clarify at what point services are no longer covered.

Response: The level at which services no longer have clinical value is determined by the state through medical necessity criteria.

Comments: One commenter requested that HHS clarify the clinical settings in which habilitative services may be covered and ensure that there is a prohibition against “school”

exclusions.

Response: Settings in which services are furnished are largely determined by the providers authorized by the state to deliver services. Practitioners within schools can become Medicaid providers if they meet the provider qualifications as established by the state. In ABPs, states may use provider qualifications for the benefit as defined for the commercial market, Medicaid provider qualification rules for the benefit, or a combination of both.

Comment: A few commenters requested information related to the cost of adding habilitative services.

Response: Habilitative services are not included in the benefit package typically included in the Medicaid state plan, and our limited experience does not allow for extrapolation for a nationally required service. States will initially receive 100 percent FMAP starting January 1, 2014 to cover the cost of providing services to individuals who are considered newly eligible in the new adult group, and that funding will decline to 90 percent FMAP in 2020. For individuals who are considered not newly eligible in the new adult group and those who are not in the new adult group, FMAP will be provided at the state's regular FMAP rate.

Comment: Many commenters recommended that HHS prohibit the use of cost-sharing requirements or utilization management tools which target the habilitation benefit and are not applied to other EHB benefits.

Response: We are not accepting this comment because states have the flexibility to impose cost sharing consistent with the exemptions and beneficiary protections set forth in sections 1916 and 1916A of the Act, which we address separately in this final rule. There is no exemption under those provisions for habilitation services. In determining how to exercise the flexibility to impose cost sharing, however, we recognize that states must consider their obligations under the Americans with Disabilities Act and must not implement a discriminatory

benefit design.

Comment: A few commenters were disappointed that HHS has chosen not to provide states any guidance regarding the habilitation benefit in ABP.

Response: In the proposed rule, we solicited public comments on the EHB requirements for rehabilitative and habilitative services, including devices. We received considerable numbers of comments, and considered those comments carefully. We weighed concerns about burden and cost of expansive coverage against the benefits of wider access for beneficiaries to needed care. We also considered the treatment of these benefits in the commercial market. Based on this consideration, we are issuing in this final regulation the policy for coverage of rehabilitative and habilitative services, including devices. We hope that these policies provide the guidance requested by commenters.

Comment: Many commenters requested HHS stipulate in the final regulation an ongoing process for data collection and evaluation related to ABP and Exchange coverage of habilitative services and devices. If this data were compared to the model definition of habilitation, that would give parameters for determining the adequacy of coverage for the first year of ABP and exchange operation.

Response: CMS collects data from states in a variety of ways. The data will be available to help states, CMS and others determine what services are actually being provided, and it will help to inform us for future coverage decisions.

Comment: One commenter indicated that states should be able to include as Medicaid state plan services any habilitative services included in either its Exchange EHB benchmark or ABP.

Response: Habilitative services are only required in the Medicaid program for individuals in an ABP. Many states cover habilitative services under their section 1915(c) waivers. States

interested offering habilitative services in other contexts should initiate conversations with CMS.

Comment: One commenter believed the habilitative benefit proposed to be defined in the November 20, 2012 EHB proposed regulation is wholly inadequate and urged HHS to pursue promulgation of a strong, uniform definition of habilitative services for ABPs, as well as those offered through the Exchange.

Response: The scope of this regulation is related to the definition of habilitation services as EHBs for purposes of Medicaid ABPs under section 1937 of the Act. This regulation does not extend to the definition of habilitation services as EHBs for purposes of the individual and small group markets.

Comment: One commenter recommended that HHS have the authority to amend state defined coverage of habilitative services should evidence show that they provide insufficient coverage for users.

Response: We anticipate that states will provide appropriate coverage of this service but section 1937 of the Act gives states a certain amount of flexibility to define ABPs that include the minimum coverage defined as EHBs.

Comment: One commenter believed that by requiring section 1937 plans to cover habilitative services, CMS is creating a disconnect between the scope of services offered under the state plan and section 1937 coverage, in essence making the section 1937 plans more generous than current Medicaid state plans (which goes against congressional intent).

Response: The Affordable Care Act established habilitative services as part of the EHB category “Rehabilitative and Habilitative Services and Devices.” EHBs are required to be offered as part of ABPs and are not required in other Medicaid state plan benefits for adults. ABP benefit packages will be different from those defined as the Medicaid state plan.

Comment: One commenter believed that requiring habilitative coverage does little to

ensure that appropriate services are available to individuals, as those requiring habilitative services are likely to be considered “medically frail”, exempting them from mandatory enrollment in the benchmark package.

Response: Individuals in the new adult group who meet the criteria to otherwise be determined to be exempt for medical frailty, will have a choice between ABP coverage that is defined in accordance with the requirements of section 1937 of the Act, including the EHB requirements, or ABP coverage that is defined as the coverage available under the state’s approved Medicaid state plan. People who are not in the new adult group and are eligible for voluntary enrollment may be given a choice by the state between the benefit package defined using the ABP or the state’s approved Medicaid state plan. An individual who has such an election may obtain needed habilitation services if the state has elected to provide such coverage under the state plan under section 1915(i) of the Act. If not, such individuals who need habilitative services may wish to voluntarily enroll in an ABP defined under section 1937 of the Act, if the EHB benefit package, inclusive of habilitative services, meets their needs.

Summary: We solicited public comments related to this provision in the proposed rule. We clarify in regulation text that the state will define rehabilitative and habilitative services. Services covered by the base benchmark are the floor of EHB coverage, substituted as desired by the state. Under 45 CFR 156.110(f), if no habilitative services and devices are included in the base benchmark, states have the option to determine generally the required EHB services that are in the category of habilitative services and devices. If the state has done so, the base benchmark, and coverage under the ABP, must reflect that determination. If the state has not made a general determination of the habilitative services that are required as this EHB category, the state must exercise the option set forth in 45 CFR 156.115(a)(5) to determine EHB for the specific ABP. Under that option, habilitative services and devices must be included as EHBs either in an

amount, duration, and scope no more restrictive in terms of treatment and benefit limitations than rehabilitative services and devices, or otherwise to an extent determined by the state and reported to HHS. In other words, if the base benchmark does not include habilitative services and devices, ABP coverage must, at a minimum, be based on the general state determination of habilitative services and devices that are included in EHBs, or on a Medicaid-specific determination for the particular ABP.

b. Pediatric Oral and Vision and EPSDT Services

For Medicaid, medically necessary services, including pediatric oral and vision services, must be provided to eligible individuals under the age of 21 according to requirements of the EPSDT benefit. We clarified in the proposed rule that any limitations relating to pediatric services that may apply in the individual or small group market does not apply to Medicaid. In this final rule, we made no change from the proposed rule.

Comment: Several commenters expressed appreciation for and support of the clarifying language in the preamble that confirmed that medically necessary services provided to eligible beneficiaries under the age of 21 must be provided under the EPSDT program, and that any limitation relating to pediatric services based on benchmarks would not apply to Medicaid for children enrolled in ABPs.

One commenter added that the EPSDT benefit ensures that Medicaid eligible children have access to a complete range of medically necessary services, concluding that this will prove especially important for children with chronic conditions.

A separate commenter believed that the pediatric services category for benchmark plans for all populations must include a comprehensive pediatric services benefit modeled after EPSDT.

Response: We generally agree with these commenters, that the EPSDT benefit is

important in offering increased access and a comprehensive range of medically necessary services for children under the age of 21. For children enrolled in Medicaid, all medically necessary services in general, including pediatric oral and vision services, are covered under the Medicaid EPSDT benefit, which applies to every section 1937 ABP. As a result, EHB supplementation for pediatric services is not necessary in Medicaid.

When assuring access to EPSDT services, a state has the option to offer medically necessary services to eligible children through either benchmark and benchmark-equivalent plan benefits without limitation or, alternatively, a state may meet the ESPDT requirement by providing services in combination with an eligible individual's benchmark or benchmark-equivalent plan as additional benefits. The state Medicaid program must assure that eligible individuals enrolled in ABP coverage receive EPSDT services that can be accessed in the most beneficial and seamless manner for the population being served.

Comment: One commenter believed that subjecting ABP benefit categories to EPSDT requirement, such as preliminary screening, would water down ABP benefit packages and serve as an artificial barrier to care that children need. The commenter believed that a robust pediatric vision services benefit, as envisioned by Congress in the Affordable Care Act, based on coverage typical in the commercial market, should not be interrupted by imposing a harmful screening requirement.

Response: We disagree. The commenter may have a misunderstanding of the EPSDT screening requirements. States are required to adopt EPSDT screenings (that is, preventive visits) for well-child, vision, hearing, and dental services. States may also adopt a national periodicity schedule such as Bright Futures (the Guidelines for health of the American Academy of Pediatrics). Services are provided based on these periodicity schedules and at other intervals as determined medically necessary. The inclusion of screening requirements as part of the

EPSDT mandate should not in any way “water down” benefits provided under ABPs to individuals under the age of 21. It should serve to ensure that children receive the necessary screenings and any additional services and treatments according to appropriate standards of care.

Summary: No changes were made. CMS clarified in regulation text that EPSDT applies to pediatric services including oral and vision care as a result of comments received in this section.

c. Essential health benefits (Prescription drugs) (§440.347)

In the proposed rule, we proposed to add a new paragraph (b)(7) to include benchmark-equivalent health benefits coverage for prescription drugs. We also indicated in the preamble that section 1927 of the Act requirements for covered outpatient drugs also apply to such prescription drug benefits as an EHB. As we previously discussed, we are clarifying in this final rule that this statement may have been over-inclusive, since section 1927 requirements do not apply to ABPs to the extent that they conflict with the flexibility under section 1937 of the Act for states to define the amount, duration, and scope of the benefit for covered outpatient drugs. We received the following comments:

Comment: A few commenters expressed support of paragraph (b)(7) of §440.335, which implements the statutory requirements for benchmark equivalent coverage of prescription drugs.

Response: We appreciate the commenters’ support for the coverage of prescription drugs as required under section 1937 of the Act.

Comment: A few commenters indicated that in the current Medicaid program, states limit the number of drugs and include other utilization control measures that are harmful to patients and deny them the therapies that meet their health needs as prescribed by their physician. Some state Medicaid programs limit patients to two to four brand name drugs per

month. Such limitations clearly do not meet patients' needs and the commenter urges CMS not to allow states to adopt them for the expansion population. Patients should be able to access the medications that they need as prescribed by their physicians. If they are not able to access appropriate medications, patients may become ill, impacting healthcare spending in the long run.

The commenters further seek clarification on what is being proposed in the rule's recommendation regarding prescription drug limits. While the rule proposes that the ABP has to meet the benefits in the state-selected EHB for the private market, the rule separately appears to replace the ABPs EHB drug benefit category with that described in section 1927 of the Act. In the final rule, the commenters ask for clarification on this matter and specifically on whether the ABP drug benefit is trumped by what is outlined in section 1927 of the Act, including with respect to any limitations. Furthermore, they are greatly concerned by the seemingly open ended ability of states to impose limits, and recommend that quantity limitations not apply to the ABP.

Another commenter states that CMS' final rule must clearly specify all the drug access protections that apply to Medicaid ABPs. The commenter believes that these protections are essential in the Medicaid context because Medicaid beneficiaries represent a vulnerable population that tends to have lower health status and fewer resources to obtain needed care.

Response: States have considerable flexibility in designing benefit packages for ABPs, including in the process of ensuring coverage of EHBs. While this flexibility permits states in some instances to limit prescription drug coverage based on the coverage offered under other public employee or commercial plans, it also includes the ability to exceed the amount, duration, and scope of prescription drugs covered under those plans. We also clarify that nothing in the commercial market implementation of EHBs, including prescription drugs, directly prohibits the utilization of monthly quantity limits. In developing ABPs, states must include prescription drug coverage to at least reflect the EHB-benchmark plan standards, including the requirement to

have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not otherwise covered. We believe these requirements will result in coverage that is similar to the coverage otherwise required under regular Medicaid state plan coverage.

Comment: A few commenters stated that they support the rules governing coverage of prescription drugs under Medicaid (section 1927 of the Act) applying to the ABP requiring coverage of nearly all of the drugs produced by manufacturers who participate in the Medicaid drug rebate program. The breadth of coverage offered by the Medicaid drug benefit is important to meet the medication needs of people with HIV who rely on a complex and unique drug regimen to treat HIV infection and manage serious co-occurring conditions, such as heart disease, serious mental illnesses and hepatitis B or C. However, they have serious concerns regarding the flexibility afforded to states to apply quantitative limits on drug coverage, particularly given that these limits are not common practice in the private insurance market. Allowing these types of limits in ABPs threatens access to lifesaving care and treatment and undermines the letter and spirit of the Affordable Care Act's EHB requirements for newly eligible Medicaid beneficiaries. It will also have the effect of undermining the adequacy of prescription drug coverage for those with chronic health needs. The commenters recommend that HHS apply the section 1927 requirement for the range of covered medications, but prohibit additional authority for quantitative limits or other limits except as legally applicable based on the underlying ABP and EHB benchmarks. The commenters further recommend that §440.347 be amended to read: "(e)Prescription drugs. Prescription drugs will be offered at a minimum in accordance with the requirements of section 1927 of the Act and implementing regulations."

Response: While drug rebate obligations under section 1927(b) of the Act are applicable to payment for covered outpatient drugs covered through an ABP, the amount, duration and scope of coverage for an ABP is determined under section 1937 of the Act, which authorizes

benchmark or benchmark-equivalent coverage “notwithstanding any other provisions that would be directly contrary.” This being the case, we do not have the authority to require states, when establishing its benefits under its ABP, to meet the coverage requirements of section 1927 of the Act. Doing so would be directly contrary to flexibility with respect to the amount, duration, and scope of coverage provided under section 1937 of the Act. As for the commenters’ concerns with the limits provided under section 1927 of the Act as they apply to the Medicaid population, especially on disease specific or chronic care populations, we note that states have considerable discretion in the provision of Medicaid services including the ability to define the amount, duration, and scope of prescription drugs covered under ABPs. We also clarify that nothing in the commercial market implementation of EHBs, including prescription drugs, prohibits the utilization of monthly quantity limits.

Comment: One commenter stated that in 2014, the Affordable Care Act requires that ABPs cover at “least essential health benefits, as described in section 1302(b) of Affordable Care Act”. The commenter continues that while CMS proposes that the EHB requirements described in its November 2012 EHB proposed rule apply to ABPs, the Medicaid EHB proposed rule does not spell out the minimum prescription drug coverage requirements that will govern ABPs.

The commenter requests CMS clarify that Medicaid ABPs must cover at least the same number of drugs in a particular United States Pharmacopeia (USP) class that the state-selected benchmark plan pertinent to the ABP covers, consistent with the “Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation” proposed rule. The commenter also requests that CMS consider identifying classes of drugs in which broad access to different drugs within the class is essential to assure that vulnerable patients have prompt access to the right medicine for a serious illness, and bolster the drug coverage requirements for those drug classes accordingly.

Response: As indicated above, states have considerable discretion in the provision of Medicaid services including the ability to define the amount, duration, and scope of prescription drug coverage under an ABP. In developing ABPs, states must include prescription drug coverage consistent with the EHB-benchmark plan standards. These standards are set forth at 45 CFR 156.122 and include the requirement that health plans have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the health plan. We believe such requirements will result in coverage that is similar to the coverage otherwise required under regular Medicaid state plan coverage.

Comment: One commenter is concerned with the adequacy of the EHB prescription drug benefit, which will apply to Medicaid beneficiaries enrolled in ABPs effective January 1, 2014. Medicaid beneficiaries in ABPs including those low-income adults who are newly eligible for Medicaid under Affordable Care Act are entitled to coverage for EHB. The proposed rule codifies this requirement and incorporates the definitions and standards that were specified for EHB coverage in the individual and small group market in the EHB proposed rule that CMS published on November 26, 2012, including CMS' proposed formulary standard for the prescription drug benefit. While the final rule states that USP will be used at least through "the years 2014 and 2015 during the transitional EHB policy" and thus it applies to the Medicaid ABPs during that time, the commenter urges CMS reconsider the use of the USP system as it is currently structured after 2015 given that many significant concerns remain. The commenter lists the following concerns regarding the EHB prescription drug benefit:

- The inadequacy of the USP to represent the full range of categories and classes of drugs needed by the populations covered by the EHB, including Medicaid beneficiaries enrolled in ABPs, because the USP was created as a classification system to be used by Medicare Part D plans;

- The need to incorporate specific protections for vulnerable populations to ensure appropriate access to vital medications;
- The need to expand the USP categories and classes and include more detail to adequately represent the drugs needed by enrollees in plans subject to EHB;
- The inability of USP categories and classes to capture all medical benefit drugs, including physician-administered drugs, and the need for CMS to specify that plans must offer robust coverage of drugs that are included as part of a comprehensive medical benefit, including a wider range of therapies, and should not rely on the USP categories and classes when determining coverage for physician-administered therapies;
- A requirement that new therapies be reviewed and added to plan formularies within 90 to 180 days through a process that mirrors the review process performed by independent Pharmacy and Therapeutic Committees in Medicare Part D to support timely access to new and innovative medications;
- A requirement for specific appeals and exceptions procedures to ensure that patients have access to needed treatments, and the application of these procedures also apply to drugs that are covered as part of a comprehensive medical benefit; and,
- The need for CMS to provide specific guidance about Medicaid ABPs regarding acceptable and unacceptable utilization management techniques, without which there is a real risk that plans could apply utilization management tools in a way that discriminates against individuals with more significant health care needs.

Response: We appreciate the comments submitted regarding the application of the EHB requirements to ABPs, including the commenter's concerns with the use of the USP classification system. As stated above, states have considerable discretion in the provision of Medicaid services including the ability to define the amount, duration, and scope of coverage

under an ABP. We also clarify that nothing in the commercial market implementation of EHBs, including prescription drugs, prohibits the use of utilization management tools. In developing ABPs, states must include prescription drug coverage to reflect the EHB-benchmark plan standards, including the requirements at section 45 CFR 156.122. We believe these requirements will result in coverage that is similar to the coverage otherwise required under regular state plan coverage.

Comment: A few commenters indicated that the preamble to the proposed rule says that all drugs of the companies that participate in the drug rebate program should be included in the ABP; however that language is not included in the language of the proposed regulation. The commenters recommended that the regulatory language be amended to correct that omission. Additionally, commenters agreed with HHS' legal conclusion, stated at 78 FR 4631, that section 1927 of the Act applies to ABPs and believe that this is a critical protection requiring coverage of a range of drugs necessary to meet the needs of the Medicaid population. The commenter recommends that HHS' explicitly state this requirement in the regulation.

Response: As noted earlier, we must clarify a statement in the preamble to the proposed rule, indicating that coverage requirements under section 1927 of the Act are applicable to ABPs under section 1937 of the Act. While drug rebate obligations under the rebate agreement are required for drug manufacturers under section 1927(b) of the Act, the amount, duration and scope of drug coverage under an ABP is determined under section 1937 of the Act. The drug rebate obligation applies because payment is made under the Medicaid state plan for covered outpatient drugs as part of the ABP. The amount, duration, and scope of coverage for an ABP are determined under section 1937 of the Act, which authorizes benchmark or benchmark-equivalent coverage "notwithstanding any other provision that would be directly contrary." That said, to the extent that covered outpatient drugs are within the scope of coverage, the non-

coverage provisions under section 1927(d) of the Act would apply. For example, states will continue to be permitted to apply certain permissible restrictions such as prior authorization. However, when establishing such programs, states must continue to adhere to the requirements that states must respond within 24 hours for pre-authorization requests, except for excluded drugs listed at section 1927(d)(2) of the Act, and that at least a 72-hour supply of a covered outpatient prescription drug must be dispensed in an emergency situation. Further, we are revising §440.345 to add a new paragraph (f) that states that when states pay for covered outpatient drugs under their ABP's prescription drug coverage, they must comply with the requirements of section 1927 of the Act.

Comment: A few commenters believed that ABPs are required by statute to include all outpatient drugs in the Medicaid drug rebate program, as well as meet the requirements for prescription drugs as proposed in the EHB proposed rule for the commercial market. These commenters also believe that in the absence of prescription drug coverage in a particular category or class, the ABP benefit must include at least one drug. They also recommend that the final rule clarify that prescription drug coverage within ABPs must provide the greater of the statutorily required coverage described in section 1927 of the Act, or the required EHB coverage described in the proposed rule issued November 26, 2012. Another commenter recommended that CMS require each ABP's coverage of prescription drugs to be consistent with the state's EHB standard.

Response: As indicated above, states have considerable flexibility in implementing the provision of Medicaid services through ABPs. In developing ABPs, states must include prescription drug coverage to reflect the EHB-benchmark plan standards at section 45 CFR 156.122 for prescription drug coverage. We believe these requirements will result in coverage that is similar to the coverage otherwise required under regular state plan coverage.

Comment: A few commenters indicated that the regulatory text is correct at part 440, but the preamble is not, in that the rebate statute section 1927 of the Act does not apply to ABPs. They reasoned that the benefits under section 1937 of the Act are mandatory benefits, and they explicitly refer to the prescription drugs of the essential health benefits and not to the covered outpatient drugs of the voluntary Medicaid benefit to which section 1927 of the Act applies. Thus, the EHB's prescription drug coverage, which requires the greater of one drug in a class or the number of drugs in the class in the benchmark plan, should apply to ABPs. If it is determined that section 1927 of the Act applies, then all the requirements and protections of section 1927 of the Act should apply to ABPs.

A commenter stated that the rebate statute applies exclusively to covered outpatient drugs; it requires manufacturers to pay rebates on covered outpatient drugs (when they are paid for under a state Medicaid plan); and it limits the restrictions that states can place on access to covered outpatient drugs. The statute defines a "covered outpatient drug" in terms of what is included in the definition and what is excluded. This commenter believes the term "covered outpatient drug" is a well understood term of art meaning those drugs to which the Medicaid rebate statute applies. If Congress had intended the Medicaid rebate statute to apply to Medicaid ABPs, then Congress would have stated this explicitly and described the drugs covered under an ABP as "covered outpatient drugs." When Congress decided to apply the rebate statute to Medicaid managed care organizations, Congress made its decision clear and took the steps necessary to make its decision workable. For example, Congress explicitly revised the rebate statute to provide that covered outpatient drugs for which payment was made under the state Medicaid plan includes "such drugs as dispensed to individuals enrolled with a Medicaid managed care organization if the organization is responsible for coverage of such drugs," among other changes.

By contrast, the commenters assert that Congress took an entirely different approach with Medicaid ABPs. Unlike in the Medicaid MCO case, Congress never mentioned Medicaid rebates in the statutory provision authorizing ABPs, never mentioned ABPs in the Medicaid rebate statute, never established any mechanism for ABPs to report drug utilization data to states and for states to include this data in manufacturers' rebate invoices, and never provided that state payments to ABPs would be premised on the understanding that states would collect Medicaid rebates.

Similarly, the commenters indicate that section 1937 of the Act makes no mention of covered outpatient drugs. Instead, the drug-related provisions in section 1937 of the Act provide only that (1) benchmark-equivalent coverage must include "prescriptions drugs" (among other basic services required in benchmark-equivalent plans) and (2) starting in 2014, all ABPs must provide "at least essential health benefits as described in section 1302(b) of Affordable Care Act, which benefits include prescription drugs." Thus in both of the statutory provisions referencing ABPs' drug coverage, Congress omitted the term denoting those drugs that are subject to the Medicaid rebate statute and instead incorporated different terms with no connection to the rebate statute. And Congress' decision to omit "covered outpatient drug" terminology is consistent with its decisions: (1) not to require to authorize reporting of ABP drug utilization data to states and manufacturers; and (2) not to address any implications of state rebate collection on ABP payments. Congress' decision not to apply the rebate statute also is consistent with the purpose of section 1937 of the Act, which is to give State Medicaid programs more flexibility and allow them to operate more like commercial payers.

Another commenter stated that the prescription drug benefit to be provided to Medicaid beneficiaries under section 1937 of the Act is not the same benefit as the "prescribed drugs" provided under a State plan under section 1905(a)(12) of the Act. Indeed, the coverage for

prescription drugs made available to the Medicaid expansion population is derived from a different statutory authority than the traditional Medicaid option to provide coverage for “prescribed drugs.” The benefit under section 1905(a)(12) of the Act is optional for a State, while the prescription drug provided by an ABP is mandatory in accord with EHB requirements established by Affordable Care Act. Therefore, the commenter contends, and urges CMS to clarify in the final rule, that there is no statutory basis to apply section 1927 of the Act to these ABPs.

In short, the commenters believe the statutory evidence demonstrates that Congress decided not to apply the Medicaid rebate statute to ABPs. When a word or phrase has become a term of art with a specialized meaning, that specialized meaning governs. Likewise, when Congress uses a term of art in one statutory provision but omits it in another (like section 1937 of the Act), then Congress intends a different meaning; “where Congress includes particular language in one section of a statute but omits it in another..., it is generally presumed that Congress acts intentionally and purposefully in disparate inclusion or exclusion.” Accordingly, applying the rebate statute to ABPs would be directly contrary to section 1937 of the Act and thus prohibited.

Response: Drug rebate obligations are required for drug manufacturers under 1927(b) of the Act when payment occurs for covered outpatient drugs covered through an ABP. However, the amount, duration, and scope of drug coverage under an ABP are determined under section 1937 of the Act. That is, the drug rebate obligation applies because payment is made under the Medicaid state plan for covered outpatient drugs provided as part of the ABP prescription drug benefit. The amount, duration, and scope of coverage for an ABP are determined under section 1937 of the Act, which authorizes benchmark or benchmark-equivalent coverage “notwithstanding any other provision that would be directly contrary.” That said, to the extent

that covered outpatient drugs are within the scope of coverage, the non-coverage provisions of section 1927 of the Act would apply.

Comment: A commenter indicated that they anticipate that requiring ABPs to satisfy the requirements of both section 1927 of the Act and the EHB formulary standard may present significant practical challenges for the ABPs. The proposed rule does not explain how these two sets of requirements will fit together or whether and when the requirements of section 1927 of the Act will take precedence over the EHB formulary standard. For example, section 1927 of the Act requires manufacturers and the Secretary to enter into an agreement under which manufacturers must pay rebates to state Medicaid agencies for utilization of the manufacturer's covered outpatient drugs, in return for the state coverage of such drugs, which may be restricted only within the set confines of section 1927(d) of the Act. The proposed EHB prescription drug benefit, by contrast, requires coverage of at least the greater of (1) one drug in every USP category and class; or (2) the same number of drugs in each category and class as the EHB benchmark plan.

Response: As we stated earlier, there is no authority to require states to meet requirements of section 1927 of the Act related to the amount, duration and scope of covered outpatient drugs under an ABP. States have some discretion in the provision of Medicaid services including the ability to define the amount, duration, and scope of coverage under an ABP. In developing ABPs, states must include prescription drug coverage to reflect the standards used to define EHBs for Medicaid. As stated earlier, we believe these requirements at 45 CFR 156.122 will result in coverage that is similar to the coverage otherwise required under regular Medicaid state plan coverage.

Comment: A few commenters indicated that to the extent that CMS nonetheless decides to apply section 1927 to ABPs, it is of the utmost importance that CMS apply and stringently

enforce both the coverage and access requirements of that section. CMS should explicitly indicate that the section 1927 safeguards on coverage and exclusions apply, in addition to the prescription drug benefit requirements of the EHB proposed rule. Any requirements for payment of rebates under section 1927 of the Act without adherence to the coverage and exclusion limitations violates the intent and spirit of that section.

Another commenter indicated that the Medicaid rebate statute requires states that provide payment for drugs to cover all “covered outpatient drugs” of manufacturers that sign a Medicaid rebate agreement, subject to certain limitations on coverage that the statute describes very specifically. The rebate statute explicitly lists the limited circumstances in which a State Medicaid program may exclude or otherwise restrict coverage of a drug manufactured by a company with a Medicaid rebate agreement.

Response: While drug rebate obligations under the rebate agreement with drug manufacturers under section 1927(b) of the Act are applicable to covered outpatient drugs covered through an ABP, the amount, duration, and scope of drug coverage under an ABP are determined under section 1937 of the Act alone. The drug rebate obligation applies when payment is made for covered outpatient drugs in accordance under the Medicaid state plan, including a state’s ABP. The amount, duration, and scope of coverage for an ABP is determined under section 1937 of the Act, which authorizes benchmark or benchmark-equivalent coverage “notwithstanding any other provision that would be directly contrary.”

Comment: One commenter recommended that the prescription drug benefit under ABPs should include all over-the-counter and prescription medications approved by the FDA to treat tobacco cessation. The commenter continues that tobacco cessation medications are currently on the list of “drugs subject to restriction” in section 1927(d) of the Act, and therefore, states are allowed to exclude coverage of these drugs.

Response: Effective January 1, 2014, section 1927(d) of the Act requires states to provide coverage of non-prescription and prescription covered outpatient drugs used to treat tobacco cessation for all Medicaid beneficiaries. Notwithstanding that requirement, we note that there is no authority to require states to meet requirements of section 1927 of the Act related to the amount, duration, and scope of covered outpatient drugs under an ABP. States have considerable discretion in the provision of Medicaid services including the ability to define the amount, duration, and scope of coverage under an ABP. In developing ABPs, states must include prescription drug coverage to reflect the standards for defining EHBs in Medicaid. As stated earlier, we believe these requirements at 45 CFR 156.122 will result in coverage that is similar to the coverage otherwise required under regular Medicaid state plan coverage.

Comment: A few commenters indicated that the agency says that the states have the flexibility to “adopt prior authorization and other utilization control measures, as well as policies that promote use of generic drugs.” The commenters believe there is potential for conflict between the prescription drug coverage of an ABP supplemented by the states’ essential health benefit standard, and a drug benefit that is consistent with the State’s Medicaid program. The commenter urged clarification of the coverage standard accompanied by protections to ensure that patients can appeal utilization controls that might prevent them from receiving necessary medications.

One commenter recommended that CMS monitor the implementation of traditional Medicaid and ABP PDLs and utilization management techniques, and act to stop burdensome limitations that reduce access to care and could impact patient health because of limited access to needed drugs. The commenter also recommends requiring that decisions regarding PDLs take into account evidence-based clinical practice guidelines, and not just of drugs; and that CMS require that states only be permitted to classify a drug as non-preferred when there are genuine

therapeutic alternatives classified as preferred.

Response: Prescription drug coverage under an ABP is still subject to the provisions related to drug rebates, as well as the non-coverage provisions under section 1927(d) of the Act. Therefore, states will continue to be permitted to apply certain permissible restrictions such as prior authorization. However, when establishing such programs, states must continue to adhere to the requirements that states must respond within 24 hours for pre-authorization requests, except for excluded drugs listed at section 1927(d)(2) of the Act, and that at least a 72-hour supply of a covered outpatient prescription drug must be dispensed in an emergency situation.

Furthermore, a state Medicaid agency's Pharmacy and Therapeutics (P&T) Committee typically makes decisions on inclusion of preferred drugs in a therapeutic class when establishing a state's PDL. Specifically, the P&T Committee reviews evidence-based information, along with review of comparative clinical trials to make such decisions regarding a state's PDL. A PDL is permitted under section 1927 of the Act, as long as it is under a prior authorization program that meets the requirements of section 1927(d)(5) of the Act.

Comment: One commenter recommends that individuals have access to the full range of available clotting factors without limitation through restrictive drug formularies, which negatively impacts patient care. Patients and physicians should make the choice of which therapy is appropriate. The commenter also noted that hemophilia patients should have access to a range of specialty pharmacy providers. Several commenters recommend that CMS require states to implement beneficiary protections consistent with Medicare Part D, including consideration of specific drugs, tiering, and utilization management strategies used in each formulary.

Response: As we stated earlier, there is no authority to require states to meet requirements of section 1927 of the Act related to the amount, duration and scope of covered

outpatient drugs under an ABP. States have considerable discretion in the provision of Medicaid services including the ability to define the amount, duration, and scope of coverage under an ABP. In developing ABPs, states must include prescription drug coverage to reflect the standards for defining EHBs in Medicaid. As we have noted in prior responses, we believe these requirements will result in coverage that is similar to the coverage otherwise required under regular Medicaid state plan coverage.

Comment: One commenter stated that section 2001(c) of Affordable Care Act modified the benefit provisions of section 1937 of the Act. Among other things, section 2001(c) of the Affordable Care Act added mental health benefits and prescription drug coverage to the list of benefits that must be included in benchmark equivalent coverage; and directed that ABPs that include medical/surgical benefits and mental health and/or substance use disorder benefits comply with the Mental Health Parity and Addiction Equity Act of 2008.

This being the case, the commenter encourages CMS to clarify and strengthen the guidance on drug formularies in the current parity regulations which make it difficult to determine whether a formulary satisfies the law's parity standards.

Response: While we appreciate the commenter's concern, the Interim Final Regulation regarding the Mental Health Parity and Addiction Equity Act of 2008 is not the subject of this final rule.

Comment: One commenter suggested that CMS provide guidance to states on medication assisted treatment of substance abuse disorder. Specifically, states should be required to cover Methadone, Buprenorphine, Vivitrol, etc., in the EHB and that where needed states should expand the formulary to include all FDA approved medications for the treatment of substance use disorders.

Response: CMS is not providing guidance regarding specific services offered in each of

the ten essential health benefits in this final rule.

Comment: One commenter requests that CMS encourage state Medicaid programs to utilize the 340B drug purchasing program provided by hemophilia treatment centers or HTC so that individuals with hemophilia can receive their pharmacy services from their HTC. HTCs with 340B programs integrate clinical and pharmacy services to provide comprehensive high-quality care to patients and closely monitor drug utilization, allowing for more immediate changes in treatment and better management of treatment costs. Patients benefit from lower cost prescriptions that reduce out-of-pocket spending and accumulation of costs towards caps on health insurance expenditures and ongoing education and support to ensure that they appropriately assess their treatment needs. Medicaid programs will benefit from better management of overall treatment costs through close monitoring of bleeds and factor use to reduce complications.

Response: We appreciate the comments regarding the 340B program and coverage of drugs for hemophilia; however, the State's utilization of the 340B drug purchasing program is outside the scope of this rule.

Comment: CMS should establish clear requirements to assure that utilization data for populations eligible to receive Medicaid rebates is maintained separately from data from other lines of business. That is, the final regulation must provide clear rules to assure that plans maintain data on prescription drug claims appropriately and do not mix data from populations eligible for Medicaid rebates with data for other enrollees not eligible for Medicaid rebates. Because many plans may offer products in the exchanges as well as participate in Medicaid managed care (under either section 1903(m) of the Act, as well as Medicaid ABPs) the potential for confusion is high and clear rules are needed to assure that utilization for rebate-eligible patients is maintained separately from data for other lines of business.

Response: If the state administers its ABP via a Medicaid MCO, the state will need to ensure the MCO distinguishes these claims from its other lines of business for the purpose of claiming Medicaid rebates consistent with the current requirement for such claims under section 1927 of the Act. CMS expects to issue subregulatory guidance on collecting manufacturer rebates for ABPs. Manufacturers are not required under section 1927 of the Act to pay rebates absent a Medicaid payment for the drugs, which would not be present in the case of drugs dispensed to Medicaid beneficiaries that are enrolled in qualified health plans where the only Medicaid payment was premium assistance for the beneficiary.

Summary: Based upon the comments requesting clarification as to whether or not section 1927 of the Act applies to prescription drug coverage provided under a state's ABP, we will be adding paragraph (f) to §440.345 to require that when states pay for covered outpatient drugs under their ABP's prescription drug coverage, states must comply with the requirements under section 1927 of the Act.

4. All Other Title XIX Provisions Apply

We clarified in the proposed rule that all other Title XIX of the Act provisions apply unless, as spelled out in section 1937 of the Act, a state can satisfactorily demonstrate that implementing such other provisions would be directly contrary to their ability to implement ABPs under section 1937 of the Act.

Comment: We received one comment requesting that CMS elaborate on what is meant by the preamble language that all other provisions under title XIX of the Act apply, and whether states are required to cover the current mandatory Medicaid benefits, and ensure non-emergency transportation, when using an ABP for the new adult expansion group.

Response: The Medicaid benchmark and benchmark-equivalent coverage was first authorized by the DRA, which included language stating that “notwithstanding any other

provision of title XIX” states can offer medical assistance to certain Medicaid beneficiaries through benchmark or benchmark-equivalent benefit packages. As a result of CHIPRA changes to the DRA, CMS regulations were revised to implement this change in law. CHIPRA language provides clearly that a state’s benchmark or benchmark-equivalent programs may vary only from statutory requirements explicitly waived in section 1937 of the Act (statewideness and comparability), unless states can demonstrate that other provisions not identified in section 1937 of the Act would be directly contrary to their ability to implement ABP. As such, in the proposed rule, we offered clarifying language in the preamble to reiterate that this current policy continues to apply. Due to statutory requirements, states may not disregard any provisions of title XIX and are therefore required to assure that all populations receiving ABPs, including the new adult expansion group, have access to transportation necessary to obtain Medicaid covered services.

Summary: No changes will be made to the proposed regulation as a result of comments received in this section.

5. Preventive Services as an EHB

The EHB Final rule specified that, to provide EHB, a plan must provide coverage of preventive services. This requires plans to cover a broad range of preventive services including “A” or “B” services recommended by the United States Preventive Services Task Force; Advisory Committee for Immunization Practices recommended vaccines; preventive care and screening of infants, children and adults recommend by HRSA’s Bright Futures program, and additional preventive services for women recommended by the Institute of Medicine. We proposed that Title XIX premium and cost sharing provisions apply to preventive services for adults, but not for children.

Comment: Many commenters commended HHS for including in ABPs the full range of

preventive services required in the EHB, including all of the services specified in section 2713 of the PHS Act. The commenters believed this is a critical provision for vulnerable populations and will help achieve the Affordable Care Act objective of shifting health care emphasis from expensive interventions to cost-effective prevention. The commenters requested that HHS explicitly state this requirement (currently in the preamble at 78 FR 4631) in the regulation itself.

Response: The language in the preamble to the proposed rule, originating in section 2713 of the PHS Act, was included as a reference to the requirement to cover preventive services as part of providing EHB, which has been implemented by regulation codified at 45 CFR 147.130. We do not believe this requires further clarification in this final rule.

Comment: A number of commenters asked CMS to clarify its preamble language, “Title XIX premium and cost sharing provisions apply to preventive services.” Specifically, CMS should clarify whether it intends this to apply to the ABPs for the new expansion population and/or to current state Medicaid plan services.

Response: We agree that this issue needs to be clarified, particularly in light of the issuance of the final rules implementing EHB requirements for the individual and small group markets. In the final regulations issued February 25, 2013 at 78 FR 12835, the provision of EHB was defined at 45 CFR 156.115(a)(4) to “include preventive health services described in [45 CFR] §147.130”. That cross referenced provision describes the requirement for coverage of preventive services without cost sharing. As explained in the preamble to the proposed regulations, at 77 FR 70644, 70651 (Nov. 26, 2012), the intent was to include in the EHB coverage obligation the prohibition on cost sharing for preventive health services. Thus, while Medicaid cost sharing provisions at sections 1916 and 1916A of the Act apply generally to preventive services provided in ABPs, cost sharing may not be applied to preventive services that are within the definition of EHBs (described in 45 CFR 147.130). An ABP may include

preventive services beyond the floor of coverage required as EHBs, and cost sharing may be applied to such preventive services at state option to the extent permissible under sections 1916 and 1916A of the Act.

Comment: One commenter requested clarification on whether the full range of United States Preventive Services Task Force (USPSTF) “A” and “B” services is specific to benchmark benefits offered to individuals that are newly eligible.

Response: These services, along with IOM-recommended women’s preventive services, ACIP-recommended vaccines, and HRSA’s Bright Futures recommendations, comprise the preventive services EHB category that will be provided to all individuals in an ABP, including those in the new adult group. In addition, coverage of USPSTF “A” and “B” preventive services under section 4106 of the Affordable Care Act applies, at state option, to preventive services furnished under the regular state plan. States implementing the preventive services EHB in their ABP without cost sharing will be eligible for the additional 1 percentage point of FMAP (for newly eligible individuals, this increased FMAP will be available once Federal reimbursement of services drops below 100 percent).

Comment: A few commenters were concerned that other preventive screenings recommended by the CDC are not included in the proposed rule. The commenters recommended the inclusion of all CDC hepatitis B and C screening recommendations as required components of Medicaid’s ABPs.

Response: CMS recognizes the importance of CDC recommendations related to preventive services. The proposed rule was not meant to be an exhaustive list of all recommendations made by government agencies such as the USPSTF. States have the option to adopt CDC recommendations as long as they are in line with EHB preventive service statutory and regulatory guidance.

Comment: A few commenters requested that HHS clearly define which tobacco cessation treatments are required to be covered as a preventive service under EHB. The commenters believed this definition should be comprehensive, and include – and require – all tobacco cessation medications approved by the FDA as well as individual, group and phone counseling. The commenters believed it should be based on and reference the most recent version of the Public Health Service Guideline Treating Tobacco Use and Dependence, to ensure that when and if the guideline is updated the benefit will be revised as appropriate.

Response: We appreciate the commenter’s recommendations. Tobacco cessation programs are important preventive services. However, states have been given latitude on how to furnish this service within the bounds of statute, regulation, and sub-regulatory guidance. Tobacco cessation for pregnant women is defined in section 4107 of Affordable Care Act and is located at section 1905(a)(4)(D) of the Act. We also issued a letter to State Medicaid Directors dated June 24, 2011 that clarified policy related to this provision. The only tobacco cessation services required to be furnished in the EHB package are those recommended by the entities designated in section 2713 of the Public Health Service Act.

Comment: Many commenters requested greater definition of the preventive services that states are required to cover to meet the EHB requirement. The commenters found it difficult to determine what preventive health services are covered and what the scope and limits of the coverage may be.

Response: The definition of preventive services as an EHB includes a broad range of preventive services including: “A” or “B” services recommended by the United States Preventive Services Task Force; Advisory Committee for Immunization Practices (ACIP) recommended vaccines; preventive care and screening for infants, children and adults recommended by HRSA’s Bright Futures program/project; and additional preventive services for

women recommended by Institute of Medicine (IOM). Further definition was not provided as these standards were established by experts in the field of prevention.

Comment: A few commenters requested that HHS provide the following guidance:

- Clarify in the language of the final rule that Medicaid ABP must cover all section 2713 services.
- Clarify that section 2713 coverage requirements apply even where there is overlap with EHB categories.
- Create standards to ensure that section 2713 preventive service coverage offers meaningful incentives to providers.
- Encourage states to align traditional Medicaid coverage with the section 2713 preventive services requirement.

Response: We appreciate the commenters' request to include further descriptions within the final rule. The rule, as written, requires states to provide a robust set of preventive services that align with §147.130. The Affordable Care Act established §4106 effective January 1, 2013 within regular Medicaid coverage, which includes a subset of the services implemented in §2713 of the Public Health Service Act (PHSA). A State Medicaid Director Letter on §4106 was released on February 1, 2013 (<http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD-13-002.pdf>).

Comment: One commenter requested clarification regarding the interval after which a preventive service rated with an A or B by the USPSTF must be included in EHBs for Medicaid plans. The commenter encouraged HHS to establish an interval of no later than the 1-year minimum specified in section 2713(b)(1) of the Public Health Service Act, irrespective of any other timetable HHS choose for updating the EHBs more broadly over time.

Response: Section 2713(b)(1) and (2) of the Public Health Service Act set forth the

interval between the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year for which of the requirements described in subsection (a) is effective for the service described in such recommendation or guideline. We believe that such an interval is appropriate for applicable preventive services included in the ABP.

Comment: One commenter requested specificity around the process by which USPSTF recommendations will be incorporated into EHBs over time and the process for determining the frequency and intensity of USPSTF-recommended behavioral interventions.

Response: A broad range of preventive services including all “A” or “B” services recommended by the United States Preventive Services Task Force must be incorporated in the EHB and are required to be implemented according to the effective date of the submitted SPA. If states want an effective date of January 1, 2014 for the entire ABP including these preventive services, then a SPA will need to be submitted by the end of the first calendar quarter of 2014. States are expected to keep abreast of changes to the USPSTF-recommended services to ensure provision of a current array of services.

Comment: One commenter indicated that, to the extent that HHS does not specify the number of covered visits to registered dietitian specialists for medical nutrition therapy, national practice guidelines should determine appropriate coverage.

Response: We encourage states to consult and rely on national practice guidelines, as they design their benefit packages.

Comment: One commenter requested that while HHS may be reluctant to explicitly require coverage of obesity treatment, HHS should clarify whether management of obesity and metabolic disorders are chronic disease management services and are therefore covered services under the “Preventive and Wellness Services and Chronic Disease Management” category of the

EHB package. One commenter believed that beneficiaries affected by severe obesity should have access to bariatric surgery with comprehensive pre- and post-surgery nutrition evaluation and counseling to ensure the efficacy and cost effectiveness of the bariatric surgery benefit over the long term.

Response: “A” or “B” services recommended by the United States Preventive Services Task Force must be incorporated in the EHB. Current USPSTF guidelines provide for the screening and counseling for obesity in both children and adults. Aside from the services specified at section 2713 of the Public Health Service Act, we are not mandating the provision of specific services through the EHB package. We agree that bariatric surgery, complete with appropriate counseling, can be a valuable service, and it will be covered in the ABP if it is included in EHB definitions of the public employee or commercial plan selected by the state to define EHBs for Medicaid, supplemented and substituted as necessary and permitted. States may also choose to add this service to their ABP.

Comment: One commenter asked HHS to clarify whether a state that chooses to use its current state plan as the ABP would need to add services to the state plan for ABP recipients if not all preventive services are included. The commenter also asked whether states would need to amend the state plan and provide these services for all Medicaid recipients of the state plan services.

Response: The regular state plan does not need to be amended to reflect the breadth and depth of required preventive service coverage in an ABP. States will have to comply with the definition of preventive services for the EHB category within the ABP. States using Secretary-approved coverage to implement a benefit package similar to their Medicaid state plan would need to ensure provision of all EHB preventive services through the ABP, even if such services are not available under the state plan. A state plan amendment will be required to implement an

ABP for the new adult group and for any other categorically needy eligibility groups that a state may wish to enroll in an ABP.

Comment: A number of commenters recommended that HHS apply the PHS Act 2713 cost-sharing prohibition for preventive services under section 2713 of the PHS Act to the same preventive services covered by ABPs. The commenters believed these protections are essential to provide meaningful coverage to vulnerable population and avoid the unfair outcome of greater cost-sharing for poorer individuals. The commenters believed cost sharing on preventive services should be prohibited based on the authority of section 2713 of the PHS Act. One commenter believed that cost-sharing for preventive services is prohibited under the definition of EHB in regulations at 45 CFR 156.115, which state that the EHB include “preventive health services described in [45 CFR] §147.30.” The commenter explained that this section lists the services included in the definition of preventive health services and states that insurers “may not impose any cost-sharing requirements (such as copayment, coinsurance, or deductible) for those items or services.” The commenter believed the definition of preventive services in the EHB is unique in that it incorporated a prohibition on cost-sharing in the definition of the benefit. The commenter believed that by requiring EHB in ABPs, Congress intended to carry that prohibition on cost-sharing into Medicaid’s ABPs. A number of commenters believed that prohibiting cost sharing for preventive services is consistent with the provision giving states a percentage point increase in their FMAP under section 4106 of the Affordable Care Act.

Response: We appreciate the concerns commenters raised regarding cost sharing for preventive services and we are adopting their suggested policies in light of the provisions of the recently issued EHB regulations for the individual and group markets at 45 CFR 156.115(a)(4). As stated above, states may not impose cost sharing for preventive services included in ABPs that are within the scope of EHBs, as defined at 45 CFR 147.130, but may impose cost sharing

consistent with sections 1916 and 1916A of the Act on preventive services that go beyond that scope. This is because the definition of preventive services for purposes of the EHBs precludes cost sharing, and Medicaid ABPs must include EHBs. We clarify that the broader prohibitions on cost sharing for preventive services at section 2713 of the PHS Act apply only to group health plans and health insurance issuers providing group or individual health insurance coverage, and do not apply to Medicaid. For preventive health services beyond the scope of EHBs, we note that cost sharing is not allowed for preventive services provided to children under sections 1916 and 1916A (b)(ii) of the Act. We agree with commenters that this preclusion of cost sharing for preventive service EHBs is consistent with the policies set forth in section 4106 of the Affordable Care Act, which added section 1905(b)(5) to the Act, giving states an increase in the federal medical assistance percentage for preventive services if the state did not impose cost sharing on such services.

Comment: A number of commenters believe that cost sharing should not be applied to the EPSDT population.

Response: While we discuss cost sharing issues at greater length in discussing the streamlined cost sharing regulations being issued in this final rule, for EPSDT for individuals enrolled in ABPs, we note that sections 1916 and 1916A (b)(ii) of the Act preclude cost sharing for individuals under age 18 who are mandatorily eligible, and preclude cost sharing for preventive services (such as well baby and well child care and immunizations) provided to children under 18 years of age regardless of family income. Section 1916(b)(2)(a) of the Act further states that cost sharing cannot be imposed under the plan for services furnished to individuals under 18 years of age (and, at the option of the State, individuals under 21, 20, or 19 years of age, or any reasonable category of individuals 18 years of age or over). These provisions also apply to ABPs.

Summary: No changes will be made to the proposed regulation as a result of comments received in this section.

6. Other Changes to Simplify, Modernize, and Clarify Medicaid Benchmark Requirements and Coverage Requirements

We proposed to make certain changes to the regulations to promote simplification and clarification where needed, and provide some additional flexibilities to states regarding benefit options. We received the following comments:

a. Diagnostic, screening, preventive, and rehabilitative services (Preventive services) (§440.130)

We proposed to conform our regulatory definition of preventive services at §440.130(c) with the statute relating to the issue of who can be providers of preventive services. Our current regulation states that preventive services must be provided by a physician or other licensed practitioner. This is not in alignment with the statutory provision at section 1905(a)(13) of the Act that defines “services ... recommended by a physician or other licensed practitioner of healing arts within the scope of their practice under state law.” We proposed to change the rule to make clear that physicians or other licensed practitioners may recommend these services. In our proposed rule, we inadvertently used punctuation that would have had the effect of eliminating the other three prongs of the preventive services definition, and we are restoring those prongs in this final rule.

Comment: Many commenters commended HHS for conforming the regulatory definition relating to who can provide preventive services at section 1905(a)(13) of the Act that defines “services...recommended by a physician or other licensed practitioner of healing arts within the scope of their practice under State law.” Many commenters believed this change will improve access to preventive services, expand access to evidence based practices, and provide greater partnership between providers and advocates. The commenters urged CMS to preserve this

important provision in the final rule.

Response: We agree that the amended regulatory definition of who can provide preventive services will result in improved access to preventive services and facilitate partnership between providers and advocates. This provision has been codified in the final rule.

Comment: A number of commenters believed that the amended regulatory definition will be especially important to low-income people who disproportionately access care through community-based and support services and may experience significant stigma and lower trust levels with other providers.

One commenter believed current Medicaid regulations surrounding §440.130(c) have significantly limited the available care and treatment for Medicaid and CHIP-enrolled children who suffer from chronic diseases.

Response: The amended definition may result in greater access for individuals who suffer from chronic disease as the pool of providers could increase significantly.

Comment: A few commenters commended HHS for making reference to this regulatory change in a February 1, 2013 letter to State Medicaid Director. The letter stated that if the proposed regulatory change is finalized, then preventive services recommended by USPSTF or ACIP, and provided by practitioners other than physicians or other licensed practitioners, are eligible for the 1 percentage point FMAP increase established under the Affordable Care Act.

Response: We attempt to provide as much notice as possible related to rule making and appreciate the commenter's support.

Comment: One commenter believed the proposed language, “(c) Preventive services means services recommended by a physician or other licensed practitioner of the healing arts acting within the scope of authorized practice under state law”, was overly broad.

Response: The regulation is consistent with statutory language in section 1905(a)(13) of

the Act. The final rule increases the number of providers able to furnish services. We are not changing regulation text at §440.130(c)(1) through (c)(3).

Comment: One commenter believed that the proposed new definition in the rule represents a far broader view of the term “preventive services” than Congress contemplated in Affordable Care Act. For purposes of describing what services are included in EHB, “preventive services” are already extensively described at §147.130. The proposed revision in the definition of “preventive services” at §440.130 would not primarily affect the scope of preventive services required to be offered as EHB in the state benchmark plans. Rather, the amendment would greatly expand the scope of the preventive services benefit that may be offered as an optional service under standard state MA plans.

Response: This change is not based on an interpretation of “preventive services” as it is used in the Affordable Care Act for purposes of EHB, but an interpretation of the coverage of preventive services under regular Medicaid under section 1905(a)(13) of the Act. This regulatory change will primarily impact the provision of preventive services under the regular state Medicaid plan. Section 4106 of the Affordable Care Act, ‘Improving Access to Preventive Services for Eligible Adults in Medicaid,’ broadens the section 1905(a)(13) preventive services benefit by providing a 1 percentage point FMAP increase on clinical preventive services that are assigned a grade of A or B by the USPSTF.

Comment: A number of commenters believed the new definition could have a significant fiscal impact on states’ Medicaid programs because, as a part of EPSDT, the expanded scope of services must be offered to recipients under age of 21.

Response: While we acknowledge that this change will result in additional providers being authorized to provide preventive services, it accurately reflects the statutory language for the preventive services benefit. In addition, broadening the scope of providers who can provide

preventive services in the Medicaid program may reduce, rather than increase, program expenditures by making available services in the most efficient and effective settings. Providing broader access to these types of providers and benefits may assist individuals with improved health.

Comment: A number of commenters requested clarification on preventive services. The commenters believed that the definition provided (§440.130) is broad and will be difficult for states to operationalize without more detail. The commenters requested a more precise definition that includes the current procedural terminology codes for each preventive service and that HHS work with states to develop preventive definitions. Without such guidance states and the federal government could end up inappropriately paying for air conditioners, ineffective weight loss programs, or similar services which are simply not appropriate.

Response: States still have the ability to restrict preventive services to direct patient care that is medically necessary and is for the purpose of preventing disease, disability and other health conditions or their progression, prolonging life and promoting physical and mental health and efficiency. The commenters may have been confused because we inadvertently proposed to eliminate these other prongs of the preventive services definition, which we preserve in this final rule. States also have some options in determining coverage of preventive services, and can specify the options, and specific billing codes, for covered preventive services using the state plan amendment process.

Comment: One commenter urged HHS to retain the current regulatory definition which established that the allowable providers of preventive services are physicians or other licensed practitioners. The commenter disagreed that the provider requirements for preventive services under the Affordable Care Act should be aligned with Medicaid provider requirements for the optional benefit category as established under section 1905(a)(13) of the Act. The commenter

stated that the benefits are distinctly different and have different purposes, particularly for children up to the age 21.

Response: We disagree with this position. Both section 1905(a)(13) of the Act and Affordable Care Act provide for a more robust set of preventive services than the current regulations, in allowing a broader pool of providers to deliver such services. In making this change in the final rule, we are aligning our regulation with the statutory coverage provision. States will continue to have some flexibility to determine the scope of covered preventive services in their state by submitting a SPA to do so.

Comment: Many commenters were concerned that this broad language would allow for unlimited services as recommended by health care providers and other providers of the healing arts. These commenters requested that this be clarified to impose reasonable limits on services.

Response: Under existing rules, states can establish limitations on amount, duration, and scope, on the optional preventive services provided the resulting benefit is sufficient to meet the purpose of the benefit. CMS reviews each state plan amendment submitted by states to determine the sufficiency of the benefit.

Comment: One commenter recommended closer integration of community prevention and lifestyle changes into the Medicare and Medicaid programs, as an important opportunity to both effectively and often less expensively treat and prevent chronic disease, such as heart disease and diabetes.

Response: We agree that greater coordination between Medicare and Medicaid will provide efficiencies and health outcomes for individuals with chronic disease as well as other conditions. Medicaid continues to build closer and more integrated community preventive services with Medicare.

Comment: One commenter believed that Registered Dietitians should be designated as

the recognized providers of nutrition services, including medical nutrition therapy and nutrition counseling because of RD's demonstrated competency and effectiveness. This commenter stated that nutrition counseling is medically necessary for chronic disease states in which dietary adjustment has a therapeutic role, when it is prescribed by a physician and furnished by qualified provider.

Response: We believe that Registered Dietitians have an important role in furnishing nutrition services. All preventive services should be furnished by qualified providers within their scope of practice.

Comment: One commenter urged HHS to clarify that §440.130 of the proposed regulation does not dictate who can provide preventive services; it merely dictates what providers can recommend them, consistent with the totality of the statute.

Response: The proposed regulation does not dictate who can provide preventive services; it defines who can recommend such services. States will have discretion to determine which providers will provide the service using the state plan amendment process.

Summary: No changes to the proposed regulation will be made as a result of comments received in this section.

b. Public notice (§440.386)

The proposed rule added a new provision to allow states greater flexibility when required to publish public notice associated with an ABP state plan amendment (SPA). We proposed modifying the public notice requirement for ABPs to require that such notice be given prior to implementing a SPA when the new ABP provides individuals with a benefit package equal to or enhanced beyond the state's approved state plan, or adds additional services to an existing ABP. We proposed the requirement to publish public notice no less than two weeks prior to submitting a SPA that establishes an ABP that provides coverage that is less than the coverage by a state's

approved state plan or includes cost sharing of any type. Based on public comment, we are negating what we proposed, as we do not believe that 2 weeks is a sufficient time period. We will be reverting back to our existing policy of requiring the states to provide “a reasonable opportunity to comment” on all ABP SPAs prior to their submission to CMS.

Comment: Many commenters supported requiring states to give public notice before implementation of a SPA that established an ABP. The commenters also commended HHS for requiring states to provide public notice regarding how they must comply with the requirement that children have access to EPSDT.

Many commenters believed that the proposed public notice requirements at §440.386 are problematic and HHS should not use them as a model for all SPAs. Some commenters believed proposed §440.386 repeats the language of §440.305(d) requiring a “reasonable opportunity” for public comment, but then limits the public comment period to just two weeks for certain ABPs which the state Medicaid agency determines provide less coverage or higher cost sharing than existing benchmark plans, and other commenters believed that two weeks is an inadequate amount of time for meaningful stakeholder consideration and input.

Many commenters believed HHS should require an advance notice and comment period of no less than 30 days as this aligns with other comment periods (such as the state comment period for section 1115 waivers) and is particularly important because of the time and effort required to conduct the benefit-by-benefit comparisons between non-aligned Medicaid state plans, ABP proposals and EHBs which will be necessary to provide meaningful input.

Response: We have considered all of the comments concerning the requirement for public notice and agree with the commenters that two weeks is not sufficient to allow for a meaningful timeframe in which public comments can be solicited and considered. We are therefore revising §440.386 to revert to our existing ABP public notice policy currently found at

§440.305(d). We would also like to clarify that the public notice requirements at §440.386 are applicable only to section 1937 ABPs.

Comment: A number of commenters requested HHS require a mandatory 15-day period (sometimes referred to as a “cool down” period) for states to review comments received and incorporate suggestions into the final ABP submission.

A few commenters believed that §440.386 creates a two tiered process whereby the state’s own evaluation of an ABP determines whether it is subject to public notice and comment. The commenters believed this kind of agency determination defeats the very purpose of transparency and stakeholder input.

Many commenters believed that there is no compliance provision to help ensure meaningful participation by the public, unlike the reporting requirement of §431.412(viii) for section 1115 demonstrations. The commenters requested that any SPAs, including those establishing ABPs, should be subject to the same transparency and public input procedures and reporting requirement modeled upon those governing section 1115 demonstrations to help ensure meaningful participation by the public, and that HHS understands the issues raised at the state level when making the SPA approval decision.

Response: In revising §440.386 to revert to our existing policy, we believe that we have provided a minimum floor that allows sufficient time for stakeholder feedback and state review.

Comment: Numerous commenters requested that at a minimum, SPAs that materially change a state Medicaid program should be subject to increased transparency and stakeholder input requirements.

Response: States will be required to follow existing public notice requirements, which requires that the state must have provided the public with advance notice of the State plan amendment and reasonable opportunity to comment prior to the submission of the SPA.

Comment: A few commenters recommended that states should be required to provide detailed information on the ABP options under consideration.

Response: The state is required to provide information regarding the ABP through the public notice process.

Comment: A number of commenters requested that HHS include specific requirements for adequate public posting of the proposal, including that it be posted on an internet website, as well as a clear description of the process and timeline for comment submission.

Response: We believe that states should have the flexibility to determine how best to provide public notice to the populations in their state.

Comment: One commenter believed that notice and stakeholder engagement requirements should explicitly include HIV/AIDS programs within health departments.

Response: We believe that all stakeholder groups, including HIV/AIDS, will be served by the public notice policy.

Comment: One commenter noted that there were a number of different sources of information for public notice (including 59 FR 49249 (September 27, 1994); §447.205; and new transparency requirements for waiver and waiver renewals (see State Health Official (SHO) Letter #12-001)) and HHS could achieve efficiencies by streamlining notice requirements.

Response: While there are various methods for providing public notice across programs, we believe that each serves its own purpose for that program. The public notice regulations under §440.386 provide the most efficient and effective policy for ABPs.

Comment: One commenter proposed that HHS further define “substantial”, which triggers the “notice and comment” requirement. The commenter requested that HHS adopt a universal definition of “substantial” so that there is no confusion of the word’s meaning.

Response: “Substantial” is used in the ABP public notice requirements. It means that

eligibility, enrollment, benefits, cost sharing, payment methodologies, or delivery systems have changed significantly to affect beneficiaries.

Comment: One commenter believed that requiring public notice for a SPA when an ABP provides a benefit package equal to or enhanced beyond a state's approved state plan was puzzling. The commenter believed it added yet another public notice requirement with questionable return, particularly when this occurs prior to implementation. The commenter agreed that prior public notice should be required when providing a lesser benefit package than the approved State Plan, adding cost sharing or reducing benefits.

Response: We believe, for the purpose of transparency, ABPs should be disseminated to the public. We believe it is important that all beneficiaries are made aware of changes being made to ABPs.

Comment: One commenter requested that when a SPA is submitted providing less coverage the public should have at least 30 days to submit comments and the agency should provide a summary of the comments it receives and how the comments were addressed when it submits the SPA to CMS for approval.

Response: Based on comments related to this section of the regulation, we will be continuing with the existing ABP public notice requirements. Requiring the state to provide a summary of the comments it receives and how the comments were addressed when it submits the SPA to CMS for approval could be too onerous to operationalize depending on the magnitude of comments received. CMS reserves the right to request, when appropriate, specific information on public comments.

Comment: A few commenters requested that HHS publically release all ABPs selected and allow an opportunity for public comment to ensure plan adequacy.

Response: All approved SPAs are public documents. If the commenter would like to comment on a particular SPA they may contact their specific state.

Comment: Many commenters recommended HHS amend §430.12 by adding new paragraph (d) or deleting §440.386 (a) and (b) and replacing them with language that would require a 30 day public comment period and a 15 day review period for the state and outlined the detail to be included in the public notice. These commenters also included requirements for publication of public notice and information to be included in the SPA.

Response: We appreciate the commenters' thorough language recommendations. However, we believe that the current public notice policy sufficiently balances the need for transparency while preventing the impediment of the approval of SPAs in a timely manner.

Comment: One commenter requested that HHS monitor the public information on Medicaid programs and State-Based Exchange, provide and consider issuing guidance on how to communicate benefit packages to enrollees and plan members in a clear and effective way, incorporating low literacy-level principles. The commenter suggested that HHS should consider requiring states to undergo a public stakeholder review process for these materials.

Response: We thank the commenter for these recommendations and will take them under further review however they are beyond the scope of this regulation.

Comment: One commenter requested that HHS require all state plan amendments be made public and subject to comment.

Response: While we agree it is a good practice for states to place SPAs online; requiring states to do so is beyond the scope of this regulation.

Comment: One commenter asked if HHS was going to require additional public notice requirements on anything that is related to cost-sharing.

Response: Cost sharing of any type requires public notice per §440.386.

Comment: One commenter believed there was a technical error made in the Part 440-services. The commenter noted that the general provisions section §440.305 to §440.386 is not mentioned in the description of the changes to either §440.305 or §440.386.

Response: CMS will take this opportunity to delete §440.305(d) as a new §440.386 has been added for public notice.

Summary: CMS will delete §440.305(d), which was the section describing public notice requirements, as a new §440.386 has been added for public notice. We have reverted to our existing public notice requirements based on public comment on this section of the rule.

c. Exempt individuals (Modifying definition of medically frail) (§440.315)

The proposed rule updated the definition of the “medically frail” category of individuals exempted from mandatory enrollment, and solicited comment about whether to add SUD to the definition. The final rule adds individuals with chronic SUDs to the definition of “medically frail”, based on the overwhelming support in public comments.

Comment: Many commenters strongly supported CMS’s definition of exempt individuals and clarification of medically frail. In supporting the definition of medically, many commenters also thanked the Secretary for including in the definition of medically frail, individuals with serious or disabling mental illness, (including children with serious emotional disturbances), and individuals with physical, intellectual or developmental disabilities that significantly impair their ability to perform one or more activities of daily living; many commenters agreed that individuals with a disability determination based on Social Security criteria should be exempted from mandatory enrollment in an ABP.

One commenter stated that medically frail are an identifiable population with unique care and cost characteristics and this definition provides an opportunity for these individuals through practices that may not be included in the products offered through state exchanges.

Response: We are pleased with the overwhelming support for the clarified definition of “medically frail” displayed in the majority of comments.

Comment: Many of the commenters urged CMS to include individuals with substance use disorders in the definition of medically frail because individuals with substance use disorders (SUD) have similar health needs as those with the other complex conditions included in the definition, and ABP coverage may be less likely to provide needed services and supports typically provided by Medicaid.

Many commenters also pointed out that individuals with SUD cannot be considered disabled under Social Security law if SUD is a contributing factor material to the determination that the individual is disabled, regardless of the severity of the SUD. Particular concern was raised about benchmark coverage in states that may choose the weakest available benchmark plan option in an effort to limit perceived financial risk for the state, or to avoid political risk. Concern was also raised that beneficiaries living in states offering fewer benefits “suffer” from placement in clinically inappropriate levels of care resulting in poor outcomes and higher federal costs.

One commenter wrote that SUD should be included in the definition of medically frail because scientific research indicates that addiction is a chronic brain disorder with intrinsic behavioral and social components, similar to other forms of mental illness.

In supporting clarification of the definition of medically frail, a commenter wrote that the definition should include all those with disabling conditions because the reference plans that may serve as the model for benefits in ABPs are employer-sponsored insurance plans and may not be adequate to serve the needs of those who are too medically frail to work.

Another commenter wrote that it supported clarifying the definition of medically frail by including all those with disabling conditions. Medicaid should provide more comprehensive

benefits for individuals and this language will allow it to do so since employer sponsored plans often inadequately cover substance use disorders, therefore the commenter supports adding SUD to the definition of medically frail.

Alternatively, a few commenters recommended that CMS not require that individuals with SUD be considered exempt from mandatory ABP enrollment. This commenter wrote that because states must design their ABPs to include a comprehensive array of mental and behavioral health services, inclusive of substance use treatment at parity with physical health services, it seems unnecessary and overly prescriptive to mandate the exemption of individuals with SUDs.

Response: Since publication, in 2010, of the Final Rule: State Flexibility for Medicaid Benefit Packages, numerous stakeholders have raised concern that individuals with SUD may not be appropriate for enrollment in an ABP because ABPs may not provide the same level of care provided by the standard Medicaid State plan. Individuals with a substance use disorder may have chronic health conditions and need an expanded array of behavioral health and possibly long term services and supports.

Considering the overwhelming support for including SUD in the definition of medically frail, we have modified §440.315(f) to include as medically frail, individuals with chronic SUD. While we recognize that substance use is among the EHBs, we believe that individuals with this condition could be medically frail and should have the choice to elect voluntary enrollment in an ABP or receive full state plan benefits (for individuals in the new adult group, through an ABP that consists of full state plan benefits).

Comment: One commenter wrote that while the definition of “medically frail” appropriately clarifies that individuals with serious mental illnesses and children with serious emotional disturbances are included among “individuals with disabling mental disorders” it

inappropriately excludes people with psychiatric disabilities from another listed group – “individuals with a physical, intellectual or developmental disability that significantly impairs their ability to perform one or more activities of daily living.” People with psychiatric disabilities should continue to be included in that group. Particularly due to the lack of clarity about what may count as a “serious mental illness,” it is important to ensure that people with mental illness have the same opportunity as people with other disabilities to qualify for exemption on the grounds that their disability significantly impairs their ability to perform one or more daily living activities.

Response: We acknowledge that individuals with serious mental illness tend to have significant co-morbid conditions that are going to require a different array of mental health and medical services, and long term services and supports that may not be available through an ABP. However, we do not believe it is necessary to explicitly specify that individuals with psychiatric disorders also qualify for “medically frail” due to deficiencies in activities of daily living. Individuals only need to meet one criterion within this definition to qualify for the exemption to mandatory enrollment. Section 440.315(f) provides states with a minimum standard for identifying individuals who are medically frail and states have the flexibility to expand this definition.

Comment: A commenter wrote that the term medically frail should be replaced with individuals with disabilities.

Response: We are retaining the term medically frail in our regulations because that term is specified in section 1937 of the Act and we believe it would be confusing to use a different term for the exemption.

Comment: One commenter stated that CMS should avoid defining any new categories of medically frail as the concept of medically frail as outlined in the proposed rule is incomplete

and unworkable, and more time and thought needs to be put into this before moving forward with final rules. The commenter believes there are both operational and implementation challenges to the new concept of medically frail contained in the proposed rule and since there is no clear definition of medically frail, or guidance on how a state would go about making that determination, if the rules were implemented as written, the likely result would be a significant disruption of the eligibility process and a large number of appeals.

Response: Section 440.315 provides states with a minimum standard for exempting specified categories of individuals from mandatory enrollment in an ABP. We do not expect these exemptions to mandatory enrollment to be disruptive to the eligibility process as eligibility determination occurs first as a separate process. States will not need to determine whether a beneficiary qualifies as medically frail upfront but will need to have a process for identifying individuals who cannot be mandatorily enrolled into an ABP.

Comment: We received many comments requesting that CMS provide further clarification regarding the operationalization and coverage implications of the proposed revision to the definition of medically frail, as well as clarifying how the revised definition will impact implementation.

One commenter indicated that states have limited experience with ABP coverage under section 1937 of the Act, and it is unclear how exemption from mandatory enrollment in an ABP for individuals defined as medically frail (and other categories of exempt individuals) would be operationalized on a broader scale. Further, it may be operationally challenging to identify the range of individuals included in the proposed definition as medically frail, prior to eligibility determination and plan enrollment, particularly for individuals with SUDs.

Several commenters requested CMS to provide clear, objective standards for defining medically frail, such as the criteria used to determine eligibility for Supplemental Security

Income. One comment also expressed concern that any approach to identifying individuals who could be exempt from mandatory enrollment in an ABP not stigmatize individuals or create unintended barriers to seeking treatment. Several commenters wrote that the definition of medically frail is vague and will be difficult for states to operationalize. Another wrote that the impact of the medically frail definition will be significantly mitigated if CMS clarifies that a state's existing Medicaid benefit package will be deemed to meet the ABP standards under the Secretary-approved coverage option.

One commenter expressed concern that the definition of medically frail is so broad that there could be confusion, inconsistency, and costly implications to having such a broad set of individuals eligible for exemption and recommended that CMS should clearly and carefully define the set of individuals who would be exempt and not include individuals with chemical dependency in the definition.

A number of commenters encouraged HHS to develop a systemic plan for how the medically frail that are enrolled into an ABP, based on the streamlined application collecting minimal information about disability or function, will be identified for exemption and stated HHS must develop requirements and supports for states to identify exemption eligibility.

Several commenters expressed concern that the process of ensuring that all exempt individuals are identified and enrolled in the benefit plan that best service their health care needs (either an ABP or traditional Medicaid) will be very burdensome or difficult for states and asked that CMS provide further guidance on how this can be accomplished. Several of these commenters stated that ABPs are not well aligned with traditional Medicaid and urged CMS to provide further guidance to states on methods and strategies for identifying exempted individuals through the streamlined application process and enrolling them in the appropriate coverage.

Another commenter envisioned situations where it may be beneficial for a medically frail

individual to have access to an ABP rather than traditional Medicaid and urged CMS to design processes that ensure that individuals have the ability to make an informed choice about their Medicaid benefit options.

Another commenter voiced concern that the proposed rule does not require a process to ensure that individuals are appropriately identified as potentially exempt when they apply for coverage. This commenter pointed out that individuals with serious mental illnesses and disabilities may not realize that they may qualify as exempt if they do not receive clear notification concerning (1) the possibility that they may be exempt, (2) the process for determining whether they are exempt, and (3) how to opt out of enrollment in an ABP if they are exempt. The final rule should require this type of notice and process.

Response: CMS acknowledges that many states will not have prior experience with implementation of an ABP, or with identifying individuals who are exempt from mandatory enrollment or who meet the criteria for exemption. We anticipate that for existing eligible individuals the state, if it chooses, will be able to screen beneficiaries it intends to enroll to identify exempt individuals by eligibility category and through the use of historic medical encounter data.

For newly enrolled individuals, who are eligible based on income rather than disability, the state will not initially have information concerning their current health status or historic encounter data. Therefore, the enrollment process could be important to identifying if an individual meets the criteria of the statutory exemptions. One appropriate screening option includes beneficiaries identifying themselves as meeting the exemption criteria. We encourage states to implement a process to screen for exempt individuals using this minimum standard for identifying individuals who are medically frail. Proposed regulations that were not finalized as part of this rule at §435.917(b) and (c) set forth the information that must be provided to an

individual regarding benefits and services and provide that the information must be sufficient to enable the individual to make an informed choice. Sample beneficiary notices will be provided to the states by CMS, incorporating questions posed to beneficiaries to aide in the self-identification process. While the individual is being provided with this information through options counseling, the individual could be initially enrolled in benchmark or benchmark-equivalent coverage that is subject to section 1937 requirements.

Comment: One commenter wrote that the phrase “disabling mental disorders” relies on non-measurable terms. The commenter believes that specific disorders, including SUDs, should be added if they meet a defined disability test. CMS should provide states with the flexibility to define medically frail or provide states with general guidelines that an individual would have to meet to qualify and allow states to set defined criteria.

Response: To ensure appropriate service protection for individuals with disabilities and special medical needs, we have included a basic definition of medically frail that we anticipate will ensure that vulnerable individuals with special medical needs are not mandatorily enrolled in an ABP that may not provide appropriate medical treatment for their individual medical condition. Section 440.315(f) provides states with a minimum standard for defining medically frail populations.

Comment: Several commenters stated that the underlying goal of the exemption from mandatory enrollment of vulnerable populations is to protect access to needed services. There may be instances where amount, duration and scope limitations are more restrictive under the Medicaid state plan rather than under the ABP, highlighting the need for beneficiaries to receive easily understandable information that allows them to compare coverage options.

Response: CMS thanks the commenters’ for acknowledging the underlying purpose for exempting certain populations from mandatory enrollment in an ABP and concurs with this

comment. Beneficiaries need to make individualized determinations of the benefit package (either the ABP or the regular state plan) that best meets their needs.

Comment: Several commenters requested CMS provide further guidance on the enrollment and selection process for medically frail beneficiaries as this will be critical for those who qualify to be able to select the benefit plan that best meets their health care needs. The commenter wants to assure that, depending on the circumstances, medically frail individuals will not be forced into a plan that provides fewer benefits than the traditional Medicaid plan or the ABP.

Response: The purpose of the criteria for the exempt categories is to assure that individuals with special medical needs will be enrolled in a coverage plan that best provides necessary services. The design and implementation of a process to determine medical frailty will likely be specific to each state. However, states will have to follow proposed regulations that were not finalized as part of this rule at §435.917(b) and (c) in that sufficient information must be provided to an individual about benefits and services to enable the individual to make an informed choice.

Comment: One commenter requested that CMS allow states to define the exempt medically frail population using objective measurable criteria.

Response: Section 440.315 provides states with a minimum set of criteria for exempting specified categories of individuals from mandatory enrollment in an ABP or for individuals in the new adult group, a choice between benchmark coverage that is either coverage defined in the ABP or benchmark coverage that is the state's regular approved Medicaid state plan.

Comment: One commenter recommended that the definition of "medically frail" include individuals that meet the Medicaid Health Home eligibility requirements in section 2703 of the Affordable Care Act.

Response: We believe that many enrollees in health homes, as they are individuals with chronic conditions that are serious and complex, will be covered by the existing definition of medically frail. But not all health home enrollees have that level of medical need, and we have determined that the suggested revision would not serve the limited purposes of the exemption.

Comment: One commenter requested that the definition of medically frail include all people with disabilities, because this definition is one of the most essential provisions among all of the proposed rules, and because persons with disabilities would be imperiled as a result of mandatory enrollment in an ABP modeled after a commercial plan.

One commenter stated that inclusion of individuals with SSI appears to broaden the definition of medically fragile for which there is currently no standard definition and historically states have been able to define. As a result, determinations for SSI will likely differ as other considerations are included in the determination.

Response: In defining medically frail, §440.315 (f) covers a wide range of populations that will be determined to be eligible for voluntary enrollment, or in the case of individuals determined eligible for the new adult group, eligible to choose to receive benchmark benefits as defined in the ABP or benchmark benefits that are the state's approved Medicaid state plan, assuring that these individuals will receive care that is appropriate to their medical needs. As proposed, §440.315(f) specifically includes individuals with disabling mental disorders (including children with serious emotional disturbances and adults with serious mental illness), individuals with serious and complex medical conditions, individuals with a physical, intellectual or developmental disability that significantly impairs their ability to perform one or more activities of daily living, and individuals with a disability determination, based on Social Security criteria, or in states that apply more restrictive criteria than the Supplemental Security Income (SSI) program, as the state plan criteria. Sufficient information must be provided to an

individual about benefits and services to enable the individual to make an informed choice according to proposed regulations that were not finalized as part of this rule at §435.917(b) and (c).

Section 440.315(f) provides states with a minimum standard for identifying individuals who are medically frail and states have the flexibility to expand this definition.

Comment: One commenter wrote that, by including in the final rule such a broad description of medically frail, CMS could substantially increase the number of individuals who would be exempt from mandatory enrollment in section 1937 benefit plans. The commenter asserted that this would allow the states less flexibility in creating plans to best meet the needs of these individuals. The commenter wrote that this is particularly true if individuals with SUDs were to be included in the definition and strongly recommended not including people with SUD in the medically frail category as mental health and SUD services are required benefits under the EHB benefits package. The commenter also questioned the reasoning behind including people with SUD in the definition of medically frail.

Response: We do not agree that the definition of medically frail is too expansive and will unduly limit state flexibility. Nor do we think that inclusion of individuals with SUDs will be problematic. We recognize that a broader definition of medically frail individuals will mean that such individuals will only elect to enroll in an ABP if the benefits are designed to meet their needs at least as well as regular state plan coverage.

Comment: One commenter wrote that if newly eligible individuals meet the criteria for exemption and are exempt from section 1937 of the Act, the Federal government needs to clarify if the enhanced funding for this group would be available for all services provided to those individuals.

Response: Yes, enhanced FMAP is available for all services provided to a newly eligible

individual, whether that person chooses the ABP based on a benchmark or benchmark equivalent package that includes the EHBs in compliance with section 1937 of the Act, or chooses an ABP equal to the state's approved regular state plan.

Comment: A number of commenters expressed concern how individuals who are exempt will be identified and requested further guidance on enrollment and selection process for medically frail so that those exempt can select the plan that best meets their needs. Several commenters recommended adding a requirement that the notice provided to individuals who have been found eligible for the expansion group include detailed information regarding how one can qualify for an exemption and the services and supports that would be available to a person who is exempt from mandatory enrollment in an ABP, and should include information regarding how to request and receive an exemption. A commenter suggested that this requirement should be added to §435.917. Another stated that those who may be exempt will need clear, consumer friendly information and decision support to help them understand their choices

Another commenter voiced concern that the proposed rule does not require a process to ensure that individuals are appropriately identified as potentially exempt when they apply for coverage. Individuals with serious mental illnesses and disabilities may not realize that they may qualify as exempt if they do not receive clear notification concerning (1) the possibility that they may be exempt, (2) the process for determining whether they are exempt, and (3) how to opt out of enrollment in an ABP if they are exempt. The final rule should require this type of notice and process.

A commenter expressed concern that the proposed rule does not issue requirements outlining the process states should use to identify people who are exempt and this is particularly pertinent given the ongoing confusion about whether or not states will be able to claim enhanced

federal match for Medicaid expansions individuals who are exempt from ABP enrollment. The commenter fears states will incur high administrative costs managing different federal match rates for different Medicaid expansion individuals, creating an incentive to develop processes that implicitly or explicitly discourage exempt individuals from taking advantage of their right to enroll in traditional Medicaid.

One commenter voiced concern that including in the definition of medically frail individuals with disabling mental disorders, individuals with serious and complex medical conditions, individuals with physical and intellectual or developmental disabilities that significantly impair their ability to perform one or more activities of daily living, or individuals with a disability determination based on Social Security criteria does not appear to be couched entirely within SSA disability criteria and that some individuals with substance use disorders who are not otherwise considered “disabled” under Medicaid may be viewed as medically frail and exempt for ABP. Therefore, individuals with SUDs would be included in a higher-level, comprehensive Medicaid benefit package, thereby increasing costs to the state without the benefit of the higher federal match under the Medicaid expansion to newly eligible adults.

Response: We intend that, as amended, §440.315 may expand the number of individuals who will qualify as exempt beyond the scope of those who are otherwise considered disabled to include other individuals whose medical needs mean that they are medically frail. We also agree that exempt individuals will need clear, consumer friendly information and decision support to help them understand their choices. For Medicaid beneficiaries who are not in the new adult group, existing requirements at §440.320 requires the state to provide each individual considering voluntary enrollment in an ABP a comparison of the ABP option versus the State plan option before the individual chooses to enroll. The comparison must also include information on the cost-sharing obligations of beneficiaries. CMS has proposed requirements that were not

finalized as part of this rule at §435.917(b) and (c) that an individual must receive information based on eligibility regarding benefits and services that are available to them. Information must be sufficient for the individual to make an informed choice. Proposed regulations that were not finalized as part of this rule at §435.917(b) and (c) will apply to all Medicaid beneficiaries including adults in the new eligibility group. Individuals in the new adult group who otherwise meet criteria for exemption from mandatory enrollment may be enrolled in benchmark or benchmark-equivalent coverage subject to section 1937 requirements during the options counseling period to insure coverage during this time.

Comment: Several commenters stated that CMS should further clarify which medical conditions are considered “serious and complex” and urged CMS to specify that chronic conditions such as HIV/AIDS and viral hepatitis, which may have co-morbidities, are serious and complex and individuals with serious and complex conditions should be exempted from mandatory enrollment in an ABP. Many commenters strongly recommended that HHS also include in the definition of medically frail or special medical needs, individuals with chronic health conditions because individuals with chronic illness should not be forced into an ABP package that will not meet their predictable needs, as this may lead to higher long term costs associated with poorly managed chronic conditions.

One commenter indicated it was assumed that chronic kidney disease and end stage renal disease were considered to be chronic diseases and another commenter indicated that individuals with Cystic Fibrosis fall squarely within the medically frail definition.

Another commenter wrote that it was assumed that long term cancer survivors managing complex treatment or a complicated set of late and long-term effects would fit the description of complex medical conditions and therefore could choose the most appropriate benefit plan.

Some commenters also stated that being forced into a health plan that does not meet the

needs of a person with chronic illness may lead to higher long-term costs associated with poorly managed chronic conditions.

One of the commenters urged CMS to specifically include in the definition of medically frail individuals with chronic viral hepatitis.

Response: The exemption categories established by statute and the proposed clarification in §440.315 are intended to provide states with a minimum standard for exempting vulnerable populations. We agree with the commenters that illnesses such as HIV/AIDS, viral hepatitis, cancer and end stage renal disease are all serious chronic medical conditions. It would not be possible for CMS to include an exhaustive list of conditions that should qualify as medically frail, but we believe that the criteria as currently drafted is broad enough to include individuals for whom a choice of service package is most appropriate.

Comment: Several commenters suggested that benchmark exempt populations are vulnerable and best serviced by traditional Medicaid.

Response: We expect the exemptions process or the process designed for individuals in the new adult group will provide these individuals with an informed choice of the benefit package that best meets their needs.

Comment: A commenter wrote that the current exemption definition would create the need for a new frailty determination process for all newly eligible adults for states that implement an ABP that is different from the standard benefit. This is a concern for one state as it becomes an administration burden for the consumer and the state system with considerable fiscal implications and proposes a common benefit for adult populations in Medicaid that would avoid the frailty determination and exemption process.

Response: We acknowledge the writer's concerns, and are not requiring any specific processes for implementing the exemptions criteria for the new adult group. We provided a

minimum standard for identification of individuals who are medically frail and proposed regulations that were not finalized as part of this rule at §435.917(b) and (c) regarding benefits option counseling should be followed. Individuals may receive benchmark or benchmark-equivalent coverage subject to 1937 requirements during the options counseling period to insure coverage during this time.

Comment: Two commenters wrote that some states have Medicaid and other public health care programs that have developed special initiatives designed to meet the needs of enrollees who have substance use disorders. They indicated that these initiatives may include provision of care management services, discouraging drug-seeking behavior by requiring care to be provided by a specified doctor and hospital, etc. The commenters asserted that exempting these individuals from mandatory ABP enrollment would make it far more difficult for Medicaid Programs to meet these individuals' health care needs. While the writers agree with the characterization of a substance use disorder as "medically frail", and thereby exempting them from mandatory enrollment in an ABP, it would make it more difficult for Medicaid Programs to meet these individuals' care needs.

Response: We appreciate the commenters' concern but do not agree that exempting individuals with chronic SUD from mandatory ABP enrollment would make it more difficult for Medicaid programs to meet the individuals' health care needs. Section 1937 of the Act provides states with the flexibility to redesign current Medicaid benefit coverage to provide unique programs for targeted populations and encourages states to be creative in the design of its coverage packages. The exemption of individuals with chronic SUD is not an impediment to providing quality care that meets the specific needs of this population. Conversely, the flexibility provided by ABPs encourages states to design comprehensive benefit packages that would encourage voluntary enrollment.

Comment: One commenter wrote that states should be able to employ traditional Medicaid disability assessments in evaluating medically frail exemption and limit receipt of long term care services and supports to those undergoing asset testing. To ensure long term stability and a fiscally sound expansion, the commenter requested sufficient flexibility to limit receipt of non-EHB services including long term care services, to the non-expansion population via state plan amendment or section 1915(c) waiver and recommended revision to the medically frail exemption to align with the disability assessments already in use within Medicaid.

Response: We disagree with this commenter. We believe the current construct of the medically frail exemption category is in keeping with legislative construct

Comment: A commenter wrote that the proposed revision to the definition of medically frail seems to run against the Affordable Care Act's benefit design for the expansion population, that is, coverage tied to section 1937 of the Act and incorporation of an EHB standard from the individual and small group markets, which excludes coverage from long-term care and supports. The commenter asserted that Affordable Care Act congressional goals to contain the costs of the Medicaid expansion may be jeopardized if states are faced with widespread eligibility for long term care services without the traditional program integrity tools used to filter such services based on objective need. The commenter further asserted that existing ABP rules already exempt a broad range of vulnerable individuals as compared to traditional disability assessment and that within what is likely to be a large exempted class, these beneficiaries will access benefits otherwise excluded from the EHB standard, namely institutional or long term care through the state plan, at sizable cost to states and the federal government. Of particular concern to the commenter is the application of personal care services to a large exempt segment of the new adult group and these long-term care benefits would be accessed in the streamlined MAGI enrollment where asset evaluation would be prohibited.

Response: The Affordable Care Act did not change the categories of individuals exempted from mandatory enrollment, and added the provision at section 1902(k)(1) of the Act, which contemplates that individuals who meet the conditions for exemption would receive ABP coverage that is not subject to the requirements of section 1937 of the Act. There is nothing in the Affordable Care Act that would preclude us from clarifying and amplifying the term “medically frail” to include populations that have high medical needs resulting from disabling mental disorders, substance use disorders, serious and complex medical conditions, or disabilities. We are clarifying in this final rule that the exemptions to benchmark or benchmark-equivalent coverage do not directly apply to the new adult population, but if an individual in the new adult population meets the criteria for exemption, then that individual has a choice of an ABP based on benchmark or benchmark-equivalent coverage including EHBs, or an ABP defined as the state’s approved Medicaid regular state plan, which is not subject to EHB requirements. Please see more detailed response above for additional information related to this provision.

Summary: We changed the proposed regulation language at §440.315(f) by adding “chronic substance use disorders” to the definition of the medically frail exemption category.

d. Benchmark health benefits coverage (Adding benefits to Secretary-approved coverage) (§440.330)

In the proposed rule, we amended §440.330(d) by broadening the benefits available as Secretary-approved coverage from section 1905(a) benefits to benefits of the type that are available under 1 or more of the standard benchmark coverage packages or state plan benefits described in sections 1905(a), 1915(i), 1915(j), 1915(k) or 1945 of the Act, or any other Medicaid state plan benefits enacted under Title XIX, or benefits available under base benchmark plans described in §156.100.

e. Secretary-approved health benefits coverage and §440.330(d) and State plan requirements for providing additional services (Adding benefits to Additional coverage) (§440.335)

Comment: Many commenters offered general support for the flexibility allowed in the proposed rule to include a broader range of selected benefits through a Secretary-approved coverage package.

Some commenters noted that the ability of states to select coverage corresponding to their full traditional Medicaid benefit as their ABP, which would be presented under the Secretary-approved coverage option, offers a clear distinction between the section 1937 benchmark options and the EHB benchmark options set forth in 45 CFR part 156.

Many commenters believed that the proposed language correctly offered states the option to use the Secretary-approved option in section 1937 of the Act to extend comprehensive Medicaid coverage to the new adult expansion group and that extending full Medicaid benefits to this population, supplemented as needed to comply with the EHBs, mental health parity and other protections in the law, is the best approach for meeting the complex health needs of the low-income adults who will gain Medicaid eligibility under the expansion.

Response: The proposed provisions for defining Secretary-approved coverage sought to balance statutory requirements for establishing a minimum coverage standard through ABP with the flexibility that states may need when considering the appropriate range of ABP coverage relative to the medical needs of the population being served. States may also substitute benefits using the state's approved Medicaid state plan benefits as long as the benefits are in the same EHB category and they are actuarially equivalent. We appreciate the commenters' support.

Comment: Some commenters were not clear on which state plan benefits may be included and, thus, urged HHS to clarify that state plan benefits enacted under Title XIX are available for inclusion through the Secretary-approved process irrespective of whether they have

otherwise been implemented in a particular state Medicaid program. As an example, those commenters noted that a state that may conceivably want to design a Medicaid benchmark targeting vulnerable populations, such as individuals with dementia, and include a particularly relevant home support service that is not an otherwise available service in the state's Medicaid program.

Response: We wish to clarify for commenters that any benefits described in sections 1905(a), 1915(i), 1915(j), 1915(j) or 1945 of the Act, and any benefits included in a selected benchmark coverage option may be included in an ABP whether or not those benefits are offered through a particular Medicaid program.

Comment: Many commenters requested that, in addition to the provisions that Secretary-approved coverage must meet the needs of the target population, HHS revise language to require that the final Secretary-approved benefits package be at least actuarially equivalent to one of the first three benchmark options, indicating that this would ensure that states use the Secretary-approved option to provide a benefit that is innovative and comprehensive, and not solely to provide a benefit that is lesser.

Many of the same commenters recommend amending §440.330(d) to read as follows: Any other health benefits coverage that the Secretary determines, upon application by a State, provides appropriate coverage to meet the needs of the population provided that coverage, and is at least actuarially equivalent to one of the benchmark options in paragraphs (a), (b), or (c). Secretarial coverage may include benefits of the type that are available under 1 or more of the standard benchmark coverage packages defined in §440.330(a) through (c) of this chapter, State plan benefits described in sections 1905(a), 1915(i), 1915(j), 1915(k), and 1945 of the Act (whether actually covered in the state plan or not), any other Medicaid State plan benefits enacted under title XIX, or benefits

available under base benchmark plans described in §156.100.

Response: For commenters requesting that we require an actuarial equivalence study for Secretary-approved coverage against one of the three benchmark options at §440.330(a) through (c), the statute defines Secretary-approved coverage as one of the minimum standards for benchmark coverage, and as such, the benchmark options in §440.330(a) through (d) should serve as a reference for states considering the benchmark-equivalent coverage option offered in other regulatory provisions at §440.335. Section 1937 of the Act does not expressly mandate an actuarial study of Secretary-approved coverage. Therefore, we are adopting §440.330(d) as proposed, and we believe that our clarification here will serve to clarify that a state plan benefit need not be offered through the regular state Medicaid program for its inclusion in benchmark coverage, or benchmark-equivalent coverage.

Comment: Many commenters indicated support of the intent to revise §440.335(c)(1) to similarly align policy for benchmark-equivalent coverage as it does for Secretary-approved coverage and, thus, allow addition of benefits through the benchmark-equivalent coverage process. Commenters believed that there are no legal impediments to this approach and urged HHS to finalize the revision.

Similarly, other commenters commended the Secretary for continuing to allow states the option for coverage of additional benefits in excess of the minimum required coverage for benchmark-equivalent plans and for revising the language to include home and community-based services available under state plan options among these potential additional benefits.

Many other commenters applauded HHS's inclusion of various options for LTSS and care coordination support. Commenters generally offered strong support and commended the decision to enable states the flexibility necessary to align ABPs with state-plan options for home

and community-based services, self-directed personal assistance services and attendant services, and other state Medicaid plan benefits described in section 1915(i), (j), (k) and section 1945 of the Act.

One commenter indicated that the flexibility to offer such services may provide states further opportunity to offer home and community-based services to particular populations since the proposed rule retains the section 1937 waiver of comparability that allows states to choose target populations for receipt of specialized benefit packages. The commenter offered an example of a state that could design benefit packages that help support community living, including employment for persons with disabilities.

One commenter was concerned that states may not take advantage of this flexibility, and suggested that CMS consider issuing additional guidance to states regarding the ability to cover services critical to chronic care management for the new adult eligibility group, such as the new health home benefit.

Similarly, another commenter requested that CMS clarify how authorities at sections 1915(i) and 1945 will be used given that individuals that would most likely benefit from these authorities will be exempt from enrollment:

Response: CMS is providing states with additional options to craft benefit packages that most appropriately meet the needs of the population being served. Benefits that can now be included as Secretary-approved coverage may in fact assist people who do not yet qualify as medically frail. For instance, if someone needs assistance with medication administration, they may not yet meet the definition of medically frail, but they may benefit significantly from the service and in fact avoid progression toward that exemption group or meeting the associated criteria. We are in support of melding regular medical/surgical benefits with home- and community-based services that support people living the community and potentially avoiding or

delaying hospitalization or institutionalization.

Comment: One commenter indicated recognition that section 1915(i) of the Act has proven to be a particularly critical tool available to states to expand home and community based services and supports to cover a broad array of services that enable individuals with mental illnesses to succeed in their own homes.

Response: We are in agreement with the commenter that section 1915(i) of the Act can serve as a critical tool available to states to expand an array of services that enable individuals with chronic condition to succeed independently. For this reason, we will finalize regulations to include section 1915(i) of the Act as a viable state plan option that states may consider for inclusion when selecting an ABP.

Comment: A few commenters requested clarification from CMS that states may include section 1915(c) of the Act and other waiver-based services in their ABPs. Commenters stated concern that states may need flexibility to include additional services, such as personal care and other services that enable Medicaid beneficiaries to remain in their homes to their ABPs because section 1915(c) of the Act was not referenced in §440.360.

Similarly, many state Medicaid agencies stated that the regulatory sections should expressly specify that states may provide ABP enrollees with access to section 1915(c) programs. The commenters indicated belief that section 1915(c) services are "state plan benefits enacted under Title XIX" given that section 1915(c) is found in Title XIX and offers services that a state plan may include as "medical assistance under such a plan." The commenters also requested that CMS confirm their reading of §§440.330, 440.360, allowing states the option to provide enrollees with section 1915(c) waiver services either as part of Secretary-approved ABP or as "additional services" available to non-expansion enrollees.

Response: Section 1915(c) of the Act is not a state plan benefit, and therefore, is not

consistent with our general principle that Secretary-approved or additional coverage consists of coverage under one of the benchmark coverage options or regular state plan benefits. Because the same services provided under section 1915(c) of the Act may be provided under section 1915(i) of the Act, which can be offered in an ABP, we do not see any reason to add section 1915(c) benefits as an exception to this general principle.

Summary: No changes to the proposed regulation were made as a result of these comments.

f. Benchmark-equivalent health benefits coverage and §440.360 State plan requirements for providing additional services (Adding benefits to Additional coverage) (§440.335)

In the proposed rule, we amended §440.335(c) and §440.360 by broadening the benefits available as additional coverage from section 1905(a) benefits to benefits of the type that are available under 1 or more of the standard benchmark coverage packages or state plan benefits described in sections 1905(a), 1915(i), 1915(j), 1915(k) or 1945 of the Act, or any other Medicaid state plan benefits enacted under Title XIX, or benefits available under base benchmark plans described in §156.100.

Comment: Many commenters believed that the proposed rule would prohibit states from providing wrap-around or other additional benefits to newly-eligible adults, but would allow states to provide additional benefits for other populations in ABPs.

Many commenters shared the belief that the Affordable Care Act does not appear to prohibit states from providing additional services to the newly-eligible populations and that CMS should allow states flexibility to provide additional services to the newly eligible population without having to go through the additional process required for Secretary-approved coverage. Those commenters believed that if CMS determines that the law prohibits states from providing additional benefits to the newly-eligible population, it should allow states the ability to

simply add these benefits using a streamlined process under the Secretary-approved option or through another mechanism.

Several commenters urged CMS to clarify through the final rule that states may provide additional benefits to ABPs for those eligible through section 1902(a)(10(A)(i)(VIII) of the Act through the Secretary-approved coverage option, so as to not implicate the restriction on additional coverage for the new adult group contained through §440.360. Those commenters believed that the proposed language is misleading and could be interpreted that the expansion population is not able to receive additional benefits in any circumstances, noting that the intent of the proposed rule is that the expansion group is limited to benchmark ABP coverage.

A number of commenters requested that CMS allow states the flexibility to provide additional benefits beyond what is minimally required in the benchmark to any or all populations in ABPs, including the expansion population.

Similarly, another commenter urged CMS to allow states to be as expansive as they want to be in offering health care services to all beneficiaries of ABPs, including the newly eligible Medicaid expansion population, beyond what is minimally required within each state's ABP.

Other commenters noted that states may identify deficiencies and gaps in the commercial benchmark plan options that fall outside parity, non-discrimination, EHB and other requirements. In this situation, commenters believed that a state should be able to add benefits easily for its expansion population and CMS should provide states with all available flexibility to do so.

Response: Section 1902(k)(1) of the Act is very clear that individuals eligible through the new adult expansion group are limited to benchmark or benchmark-equivalent coverage. In addition, there is a payment exclusion under section 1903(i)(26) of the Act for FFP in any additional coverage. "Additional services" authorized under section 1937 fall outside

benchmark and benchmark-equivalent coverage. But we are addressing this concern by allowing states increased flexibility under this final rule to include broader benefits and services that are appropriate for the population being covered and that are similar to the benefit types listed in §440.360, through Secretary-approved coverage or benchmark-equivalent coverage.

Comment: Many commenters indicated strong support for HHS' proposed policy and commended the Department for clarifying the authority for states to provide a wide range of benefits in developing Secretary-approved coverage. In continuing, those commenters noted that many consumer stakeholders have misunderstood the allowance for inclusion of benefits under Secretary-approved coverage due to the general prohibition on adding services to Medicaid benchmarks and requested that the Department clarify that benefits can be added, but only through the Secretary-approved process.

Other commenters urged CMS to consolidate these sections and clarify that, despite the prohibition on adding services to Medicaid benchmarks, states have the flexibility to offer additional and richer benefits to all those enrolled in ABPs, including the expansion group, by choosing the Secretary-approved coverage option. Those commenters also requested clarification that the federal match otherwise available for these populations is available for the additional benefits when they are approved by the Secretary.

Similarly, other commenters requested that CMS clarify and confirm that the interpretation of this provision within the proposed rule is that if a state wanted to provide wrap-around services for a particular population that some of the "newly eligible" population may fall under, it does not appear that would be allowed unless the state creates a Secretary-approved plan that incorporates the benefits into the underlying plan itself.

One commenter indicated that it would be helpful for CMS to clarify that adding additional benefits is possible for individuals in the newly eligible group, and that the prohibition

on additional coverage for the expansion group at §440.360 only applies to benefits that have not been included in the benchmark package selected by the state. The commenter also suggested that both benchmark-equivalent coverage and Secretary-approved coverage provide the state flexibility to include benefits that can be covered through a Medicaid state plan or a base benchmark option available to the state.

Response: We reassert the statutory construct that does not allow the new adult group to received “additional” services. However, the broadening of Secretary-approved coverage to include the same options for services accomplishes the goal of allowing individuals in the new adult group access to that same robust benefit package. We reiterate that services provided under an ABP do not have to be offered under the regular state plan.

Comment: Several commenters recognized that the Secretary's clarification that additional benefits may include those available under base benchmark plans (described in §156.100), in addition to standard benchmark coverage packages or standard state plan benefits. Those commenters were concerned about flexibility for states to model ABPs after any base benchmark, noting that not every base benchmark plan option may provide appropriate benefit levels for the Medicaid population.

One commenter familiar with the needs of underserved and poor populations with chronic conditions was appreciative that the EHB rules builds upon protections already offered through existing rules that allow states to enroll certain populations in Medicaid benchmark plans, and grants states significant flexibility through regulations at §440.360 to develop a more comprehensive benefits package that will better meet the needs of people with HIV and others with chronic conditions.

Response: As mentioned in previous responses, we believe the statute requires states to balance the appropriateness of the ABP package when considering the population being covered.

Therefore, we believe our regulations encourage states to consider other options if their analysis reveals that the base benchmark options elected do not provide an appropriate level of benefits relative to the population being covered.

Comment: A few commenters wished to emphasize that section 1937 of the Act requires states to provide FQHC services to beneficiaries who receive ABP coverage in the same manner as CMS previously stated and conveyed in the agency's April 30, 2010 final rule. The commenters emphasized that for situations where no FQHCs are available to section 1902(a)(10)(A)(i)(VII) of the Act enrollees under their managed care plan, then the state must provide the beneficiary enrolled in ABP coverage with FQHC services on a per-visit basis as required by section 1902(bb) of the Act. Alternatively, if a managed care entity is able to provide FQHC services to any beneficiary receiving ABP coverage, payments for such services must be made on a cost-related prospective payment system basis, with state supplemental payments provided where the PPS payment would exceed the amount provided under the managed care contract.

Commenters indicated concern that because §440.360 is silent on states' obligation to provide FQHC and RHC services as part of benchmark or benchmark-equivalent coverage, the proposed regulation fails to distinguish clearly between required and "additional benefits" for the section 1937 package and that the omission of FQHC services from the list creates the impression that these services are not a required benefit within section 1937 coverage.

Several commenters recommended that CMS clarify the FQHC services requirement by: (a) consolidating §440.365 into §440.345; or (b) independently reference §440.365 in §440.360 by having the first sentence of regulatory provision §440.360 read, "In addition to the requirements of §440.345 and §440.365."

Response: We agree with the commenters that regulations at §440.365 continue to

require that the state must provide that individuals enrolled in an ABP have access, through that coverage or otherwise, to rural health clinic services and FQHC services. Such required services are required as part of §440.365 and a state must assure to CMS that they are providing these services, which is different than adding additional services described at §440.360. FQHCs are considered Essential Community Providers in the commercial market, and we anticipate these entities playing a critical role in Medicaid ABPs as well. When these providers are part of the ABP provider network, reimbursement to them must adhere to statutory requirements.

Summary: Minor grammatical edits to the proposed regulation were made as a result of these comments.

g. Other Comments Received

We received various other comments that did not relate specifically to provisions proposed in the proposed rule.

Comment: One commenter stated that to realize the opportunity presented by the Affordable Care Act, it is essential that individuals who are admitted to jail and are eligible for Medicaid be enrolled in Medicaid either during incarceration or immediately upon release to the community. By law federal Medicaid matching funds are not available for the costs of needed items and services for individuals who are enrolled in Medicaid while they are inmates, unless they are admitted to a medical institution for treatment during the period of incarceration. Nonetheless, the suspension of benefits does not affect the Medicaid eligibility of inmates or their ability to enroll in the program if eligible.

Response: Paragraph (A) following section 1905(a)(29) of the Act and implementing regulations at §435.1009, exclude from the definition of medical assistance care or services for any individual who is an inmate of a public institution, except as an inpatient in a medical institution. We read this exclusion to apply generally to medical assistance, whether provided

through the regular coverage plan or through an ABP. Thus, while we agree with the commenter that incarcerated individuals may be eligible for Medicaid, they would not be entitled to benefits inconsistent with the exclusion. We note that this is consistent with the exclusion of incarcerated individuals from eligibility to enroll in coverage through the Exchange. It is also consistent with the responsibility under the Eight Amendment of the United States Constitution of governmental entities to provide necessary medical care to individuals who they are holding as inmates, which effectively creates a liable third party for such care.

Individuals who are enrolled in Medicaid when entering a public institution should have their eligibility suspended, rather than terminated, as they remain eligible. This also ensures ease of reinstatement of coverage post-release. Additionally, if an individual is not already enrolled in Medicaid, states are encouraged to enroll eligible individuals prior to their release so that the individual can receive Medicaid covered services in a timely manner upon discharge.

Comment: A commenter requested additional guidance as to what type of information CMS will need to approve an ABP state plan amendment and how CMS will determine if mental health parity has been met.

Response: We will be issuing a template for states to use to submit ABPs as a state plan amendment. At this time, mental health parity will be determined to be met with an assurance by the state. We will be developing more specific policy related to this topic in the near future.

Comment: One commenter requested CMS clarify what Medicaid category the EHBs are applicable. The commenter wondered whether EHBs only apply to the expansion population and ABPs or does it also apply to individuals who are currently eligible for Medicaid. The commenter questioned whether, for example, current Medicaid benefits would need to be adjusted to include habilitative services.

Response: EHBs apply only to section 1937 of the Act and were not extended into

regular Medicaid. Therefore, regular Medicaid state plan benefits will not include the EHBs.

Summary: No changes to the proposed regulation were made as a result of these comments.

7. Summary

ABPs are intended to offer states flexibility in designing benefit packages for the Medicaid population that are benchmarked to public employee or commercial plans. To ensure coverage of the kinds of services that will also be assured for those purchasing coverage in the individual and small group market, the law also requires that ABPs cover the ten EHBs specified by law.

Recognizing that states face challenges in administering both their state plan benefits and ABPs, we have sought to provide as much flexibility in aligning those packages as possible. That said, we appreciate that it may be difficult at this point to make changes to the ABP that take effect by January 1, 2014. In light of this challenge, we will partner with states to work as quickly as possible to come into full compliance with these provisions. We do not intend to pursue compliance actions on these issues to the extent that states are working toward but have not completed a transition to the new ABPs on January 1, 2014. To establish its base benchmark for EHBs for Medicaid, the state can select the same or a different plan than the base benchmark used for the Exchanges. Once having selected the base benchmark plan for EHBs, the state maps the benefits to EHB categories, and then can engage in supplementation and/or substitution:

- Through supplementation at 45 CFR 156.110, the state must add EHBs to a base benchmark plan that is missing a required category of EHBs. States can supply the missing EHBs from other base benchmark plans.
- Through substitution at 45 CFR 156.115(b), the state can replace one or more of the

benefits within each category of EHB, as long as it maps appropriately to the category and the services are actuarially equivalent to the services that are being substituted. State Medicaid programs can use this process to substitute Medicaid state plan benefits for public employee or commercial plan benefits, for example, as long as applicable requirements are met. States must provide notification to CMS that they have engaged in substitution and have an actuarial certification and analysis available for inspection.

States must assure, as they evaluate their base benchmark for EHBs and take these steps that they also properly account for special Medicaid considerations discussed in this rule. When states pay for covered outpatient drugs under the ABP prescription drug benefit, they must comply with the requirements under section 1927 of the Act. Habilitative services and devices are defined by what is in the state selected base benchmark plan, substituted as desired. If not defined in the base benchmark, the state will define the benefit. For example, states may offer coverage of habilitative services and devices that is no more restrictive in terms of amount, duration, and scope than the rehabilitative services and devices covered under the applicable benchmark plan. We expect that the services will be clinically appropriate to meet the needs of individuals based on medical necessity. Pediatric oral and vision care must follow requirements of the EPSDT benefit.

The final base benchmark plan for EHBs for Medicaid, after completion of these steps, provides the floor for Medicaid coverage to individuals in the ABP.

States also select a section 1937 coverage option. If the section 1937 coverage option and the plan initially selected as the base benchmark for EHBs are the same, the state will meet all requirements by specifying as the final ABP the final base benchmark, as supplemented and subject to permissible substitution, and further supplemented to the extent necessary to ensure coverage required under section 1937 of the Act, including EPSDT services, family planning

services, and FQHC and RHC services.

If the section 1937 coverage option and the selected base benchmark plan are different (including when the state elects Secretary approved coverage option or benchmark equivalent coverage), states have to take the following steps to construct their final ABP:

- If any other benefits are available in the section 1937 coverage option, add that benefit.
- For any benefits in common from the section 1937 public employee or commercial market plan options, but with one having more robust qualities related to amount, duration, or scope, the benefit with the more robust coverage.
- For any benefits in common from the section 1937 Secretary-approved coverage option, but with one having more robust qualities related to amount, duration, or scope, determine whether to apply the benefit with the more robust coverage.

Alternatively, a state can first determine their ultimate goal in creating their benefit package (for example, wanting to create an ABP that mirrors the state's regular Medicaid state plan benefit package as much as possible), and develop their ABP starting first with the selection of their 1937 coverage option. This would entail comparing the state plan benefit package with the base benchmark benefit package, supplementing the state plan benefit with EHBs as necessary, and applying permissible substitution of benefits consistent with 45 CFR 156.115(b) to better align with state plan benefits.

C. Exchanges: Eligibility and Enrollment

Throughout this proposed rule, we proposed technical corrections to regulation sections in part 155 to replace references to section 36B of the Code with the corresponding sections to the Department of Treasury's final rule, Health Insurance Premium Tax Credit (26 CFR 1.36B-0 et seq.), published in the May 23, 2012 **Federal Register** (77 FR 30377). We are finalizing

these technical corrections as proposed.

1. Definitions (§155.20)

In §155.20, we proposed technical corrections to the definitions of “advance payments of the premium tax credit” and “application filer,” and added a definition of “catastrophic plan” by referencing the appropriate statutory provision within the Affordable Care Act. We did not receive specific comments on these technical corrections, and are thus finalizing them as proposed.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.20 of the proposed rule with a technical correction to the definition of advance payments of the premium tax credit, which we clarify refers to the payment of the tax credit authorized by 26 U.S.C. 36B and its implementing regulations.

2. Approval of a State Exchange (§155.105)

In §155.105, we proposed a technical correction to replace the reference to section 36B of the Code to the applicable Treasury regulation. We did not receive specific comments on this section, and are thus finalizing the provision as proposed.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.105 of the proposed rule without modification.

3. Functions of an Exchange (§155.200)

In §155.200, we proposed to clarify that the Exchange must also perform the minimum functions described in subpart F concerning appeals. The only comments we received supported this clarification.

Summary of Regulatory Changes

We intend to finalize the clarification to paragraph (a) at a future date when subpart F is finalized, and so thus maintain the previous language from the Exchange final rule.

4. Authorized Representatives (§155.227)

We proposed to add §155.227, establishing minimum requirements for the designation of authorized representatives who may act on an applicant's or enrollee's behalf in the individual and small group markets. We noted in the preamble that the proposed rule for authorized representatives for Exchanges closely tracks the proposed rule for authorized representatives for Medicaid.

In paragraph (a), we proposed that the Exchange must permit applicants and enrollees in the individual and small group markets to designate an individual person or organization to act on that applicant or enrollee's behalf. We also proposed that an applicant or enrollee may have such a representative through operation of state law, subject to applicable privacy and security requirements. We also proposed that the Exchange must not restrict the option to designate an authorized representative to only certain groups of applicants or enrollees. We noted that the Exchange should ensure that the authorized representative agrees to maintain, or be legally bound to maintain, the confidentiality of any information regarding the applicant or enrollee provided by the Exchange, and that authorized representatives should adhere to applicable authentication and data security standards. Additionally, we proposed that the Exchange should ensure that the authorized representative is responsible for fulfilling all responsibilities encompassed within the scope of the authorized representation, as described in this section, to the same extent as the person he or she represents.

In paragraph (b), we proposed the situations when the Exchange must permit an applicant or enrollee to designate an authorized representative. We also proposed that the single, streamlined application described in §155.405 will provide applicants the opportunity to

designate an authorized representative and will collect the information necessary for such representative to enter into any associated agreements with the Exchange as part of the application process. We noted that applicants and enrollees who do not designate an authorized representative on their applications will subsequently be able to do so through electronic, paper formats, and other modalities, as described in §155.405(c)(2). We also noted that legal documentation of authority to act on behalf of an applicant or enrollee under state law, such as a court order establishing legal guardianship or a power of attorney, may serve in the place of the applicant or enrollee's designation.

In paragraph (c), we proposed that the Exchange must permit an applicant or enrollee to authorize a representative to -- (1) Sign the application on the individual's behalf; (2) submit an update or respond to a redetermination for the individual; (3) receive copies of the individual's notices and other communications from the Exchange; and (4) act on behalf of the individual in all other matters with the Exchange.

In paragraph (d), we proposed that the Exchange must permit an applicant or enrollee to change or withdraw an authorization at any time. We also noted the authorized representative also may withdraw his or her representation by notifying the Exchange and the applicant or enrollee.

In paragraph (e), we proposed that an authorized representative acting as either a staff member or volunteer of an organization and the organization itself must sign an agreement meeting the requirements proposed in regards to Exchange certified application counselors. We noted that while the protections afforded by such an agreement are important when an authorized representative is a member or volunteer of an organization, we believe that they are not logical in cases where an authorized representative is not acting on behalf of an organization. We sought comments on applying the protections in paragraph (e) to authorized representatives more

broadly.

In paragraph (f), we proposed that the Exchange require authorized representatives to comply with any applicable state and federal laws concerning conflicts of interest and confidentiality of information.

In paragraph (g), we proposed that the designation of an authorized representative must be in writing, including a signature, or through another legally binding format, and be accepted through all of the modalities described in §155.405(c) of this part.

We received the following comments concerning the proposed authorized representative provisions.

Comment: Several commenters recommended that the Exchange be required to make clear the powers and duties authorized representatives may have with respect to the Exchange, as well as all other requirements of §155.227, in a manner that is easily understandable by both the authorized representative and applicant or enrollee.

Response: In the final rule, we added a provision to paragraph (a) specifying that the Exchange must provide information regarding the powers and duties that an authorized representative may have with respect to Exchange activities to both the applicant or enrollee and the authorized representative.

Comment: Several commenters suggested that an authorized representative should have an affirmative duty to notify the Exchange and the applicant or enrollee on whose behalf he or she is acting of any revocation or material change in the authorized representative's legal authority to act on behalf of the applicant or enrollee. These commenters also suggested that such a material change or revocation should result in revocation of the authorized representative's authority to act on behalf of the consumer for Exchange purposes.

Response: We have clarified in §155.227(d)(2) of the final rule that an authorized

representative must notify the Exchange and the applicant or enrollee on whose behalf he or she is acting when the authorized representative no longer has legal authority to act on behalf of the applicant or enrollee.

Comment: Several commenters asked HHS to clarify which legal documentation may serve in the place of an affirmative representation to designate an authorized representative. Other commenters recommended clarifying that a power of attorney may be used for such a purpose only if it authorizes the holder to act in the types of activities permitted under §155.227(c). One commenter recommended that legal documentation to act as an authorized representative be required, as opposed to optional, to protect vulnerable applicants or enrollees. Another commenter recommended adding language that authorizes the Exchange to dictate the form or manner of the authorization. A few commenters also expressed concerns about the proposed requirement that the designation of an authorized representative be in writing including a signature or other legally binding format.

Response: In paragraph (a)(2), we outline the form and manner of how an applicant or enrollee may designate another person as his or her authorized representative, specifying that this designation should be in a legally binding format. We also provide examples of legal documentation that could be used to designate an authorized representative in lieu of a signed document, including, but not limited to, a court order establishing legal guardianship or a power of attorney. While we do not require that legal documentation be provided before the Exchange may recognize an individual as an authorized representative, we anticipate that Exchanges will have procedures in place to ensure that applicants and enrollees have control over whom they designate as an authorized representative. For example, Exchanges have flexibility to require that the designation should occur through a signed agreement or legally binding document. In general, an Exchange could accept any document that is valid for designating an authorized

representative in the state, and that permits the holder to perform the activities specified in §155.227(c), in place of an affirmative representation to designate an authorized representative. We emphasize that to be used in this manner, documentation has to give the authority needed to be an authorized representative for the activities specified in §155.227(c).

Comment: A few commenters inquired about the relationship between an authorized representative designated through the Exchange and a QHP issuer, and recommended that an applicant or enrollee be required to complete a separate authorization form to designate a representative to act on his or her behalf in interactions with the QHP issuer. Commenters expressed an understanding that QHP issuers would be responsible for developing and executing the authorized representative forms that govern interactions between the enrollee and the issuer.

Response: Subject to applicable law, we believe that the authorized representative designated by an applicant or enrollee through the Exchange process should also be able to serve in the same capacity with the QHP issuer, and that streamlining this process is important to minimize the burden on applicants or enrollees who need authorized representation. Therefore, we would urge QHP issuers to allow an Exchange authorized representative to serve in the same capacity with the QHP issuer. We note that the companion guide² that will be used by all Exchanges for sending enrollment data to QHP issuers has fields that may accommodate this information.

Comment: Some commenters suggested that HHS develop some conflict of interest standards to ensure that consumers are protected when interacting with entities that may benefit from becoming an authorized representative. Other commenters suggested banning all organizations from becoming authorized representatives, because some entities may benefit from becoming an authorized representative.

Response: We appreciate the comments and plan to monitor organizations acting as authorized representatives over time to determine whether more specificity is needed. Additionally, §155.227(e) of the final rule clarifies that authorized representatives must comply with applicable state and federal laws regarding conflicts of interest.

Comment: Several commenters recommended that an applicant or enrollee should be able to authorize their representative to engage in fewer than all of the activities described in the proposed rule.

Response: In the final rule, we maintain language specifying that an Exchange must allow applicants and enrollees to authorize a representative to perform the full range of activities listed in the rule. We also add language to §155.227(c) clarifying that the Exchange may (but need not) permit consumers to authorize fewer than all of the listed activities, so long as the Exchange is able to track the specific permissions for each authorized representative. We note that for plan years beginning before January 1, 2015, the FFE will not have the operational capacity to support the authorization of representatives to perform less than the full range of activities listed in the rule.

Comment: Several commenters urged that the provision in proposed §155.227(d) that the applicant or enrollee notify both the Exchange and the representative that the representative is no longer authorized to act on his or her behalf be removed. Other commenters suggested that the applicant or enrollee should notify only the Exchange.

Response: In the final rule, we clarify that the responsibility for notifying a representative whose authorization has been discontinued by an applicant or enrollee falls only on the Exchange.

Comment: One commenter expressed support for a policy that would permit the

Exchange to terminate a designation after a given period of time to be determined by the Exchange. This commenter noted that this aligns with the 5-year limit on authorizations from enrollees to allow Exchanges to request tax information for conducting annual redeterminations in accordance with §155.335(k).

Response: In the final rule, we have added a provision specifying that authorized representatives will notify the Exchange if they are no longer authorized to act in that capacity. As long as a person has the authority to act as an authorized representative, there is no need to terminate or reauthorize that relationship after a set amount of time. An applicant or enrollee may also modify the authorization at any time.

Comment: A commenter suggested that compliance agreements for authorized representatives should be available directly from HHS, instead of Exchanges, for entities such as multi-employer plans that are subject to federal regulation under ERISA, the Code, and the Taft-Hartley Act, but not to state insurance regulation. The commenter noted that the relationships between plans and plan participants and beneficiaries established under the Taft-Hartley Act should continue to be recognized in regulations implementing the Affordable Care Act.

Response: We expect that authorized representatives will be used primarily by applicants and enrollees who are unable to represent themselves or who are seriously challenged in representing themselves in their relationship with the Exchange. Accordingly, authorized representatives' agreements are between an applicant or enrollee and his or her authorized representative regarding representation before the Exchange.

Comment: One commenter sought clarification on whether staff or volunteers of organizations must be trained and certified as Exchange certified application counselors under proposed §155.225(b) to serve as authorized representatives.

Response: The rule does not require authorized representatives to be trained and certified as certified application counselors. The role of an authorized representative is distinct from the role of a certified application counselor. Specifically, certified application counselors, for which standards will be finalized in a future regulation, provide guidance and assistance to applicants and enrollees who will interact with the Exchange on their own behalf, while authorized representatives are commonly used by applicants or enrollees who are unable to represent themselves, and have the legal authority to actually sign for an applicant or enrollee and make other decisions on his or her behalf.

Comment: Several commenters suggested that requiring organizations to enter into agreements and follow a set of standards as proposed in §155.227(e) will lead to disruptions in the availability of assistance and lead to real harm to persons who need assistance. Other commenters expressed concerns that every authorized representative would have to be certified.

Response: In light of the commenters' concerns, and the protections for consumers that already apply to all Exchange authorized representatives, we have not finalized the proposed requirement that organizations and staff and volunteers of organizations sign a separate agreement. We recognize that authorized representatives are given significant authority, and accordingly, we need to ensure that the privacy and security of applicants' and enrollees' personal data are protected. We note that all authorized representatives, not just organizations and those working for organizations, will be subject to the privacy and security standards established and implemented by the Exchange consistent with 45 CFR 155.260 through agreements, as is required by 45 CFR 155.260(b)(2). This will be further clarified in subregulatory guidance. Since all authorized representatives will be subject to privacy and security standards, in this final rule, we removed the requirement for organizations and staff and volunteers of organizations to sign a separate agreement

We have also not finalized the provision in the proposed rule that would have subjected authorized representatives who are staff and volunteers of organizations, and their organizations, to the proposed standards for Exchange certified application counselors. This proposal was motivated in large part by a concern that staff and volunteers of such organizations might be likely to have conflicts of interest. This concern, however, is addressed by §155.227(e), which clarifies that authorized representatives must comply with applicable state and federal laws regarding conflicts of interest.

Comment: One commenter suggested requiring legal documentation when an applicant or enrollee changes or withdraws his or her authorization.

Response: Applicants and enrollees will not always have legal documents to substantiate discontinuing an authorization. When an applicant or enrollee appoints a new authorized representative, including to replace an existing authorized representative, he or she should follow the same process as an applicant or enrollee who appoints an authorized representative for the first time.

Comment: Another commenter recommended that an enrollee should not be able to designate an authorized representative if he or she failed to do so during the application process.

Response: We see no need to limit an applicant or enrollee's ability to designate an authorized representative solely to the application process, particularly as some enrollees may develop a need for an authorized representative after submitting an application, choosing a plan, and maintaining coverage for many years.

Comment: Several commenters sought clarification about whether an applicant or enrollee who applies through the Exchange with the assistance of an authorized representative and is subsequently transferred to the state Medicaid agency would need to redesignate his or her authorized representative.

Response: If the application is transferred to the state Medicaid agency, the authorized representative designation would be transferred as well.

Comment: One commenter inquired about whether the Exchange will be deemed liable for any breaches of confidentiality that are beyond the control of the Exchange. A commenter also requested that HHS modify language to make it clear that it is the legal duty of the authorized representative to maintain confidentiality in daily practice.

Response: We appreciate this comment and recognize that this issue applies more broadly. There are potentially some instances in which a person that provides application assistance, including an authorized representative, could negligently disclose an applicant's or enrollee's information under circumstances that the Exchange could not have prevented. We note that authorized representatives will need to comply with the same privacy and security standards that the Exchange adopts consistent with § 155.260, or with more stringent standards, pursuant to § 155.260(b). Additionally, paragraph (e) of the final rule requires authorized representatives to comply with applicable state and federal laws concerning conflicts of interest and confidentiality of information.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.227 of the proposed rule, with a few modifications. For clarity and consistency with the terminology defined in §155.20, and to make it clear that we intend authorized representatives to provide assistance both in the SHOP Exchanges and in the individual market Exchanges, we replaced the terms “individual” and/or “employee” with the terms “applicant” and/or “enrollee” to describe the people helped by authorized representatives. To further indicate that we intend authorized representatives to provide assistance both in the SHOP and in the individual market Exchanges, we clarify in §155.227(a) that an applicant or enrollee can designate an authorized representative in the

individual or small group market Exchange and have added “subpart H” to the regulation text to account for the functions that an authorized representative may perform in a SHOP. To avoid confusion with the defined term “qualified individual,” we use the term “person” instead of “individual” in the final rule when describing individual persons acting as an authorized representative.

We added paragraph (a)(5) to specify that the Exchange must provide information about the powers and duties of an authorized representative both to the applicant or enrollee and to the authorized representative. We redesignated proposed paragraphs (c)(1) through (c)(4) as (c)(1)(i) through (c)(1)(iv), and added a new paragraph (c)(2), which allows an Exchange to permit an applicant or enrollee to authorize a representative to perform fewer than all of the activities described in paragraph (c)(1) of this section, provided that the Exchange tracks the specific permissions of each authorized representative. Additionally, we removed paragraph (d)(1), and redesignated proposed paragraphs (d)(2) and (d)(3) as paragraphs (d)(1) and (d)(2). We modified the language in redesignated paragraph (d)(1) to explain that the Exchange, not the applicant or enrollee, will notify the authorized representative when an applicant or enrollee notifies the Exchange that he or she is no longer represented by his or her previously authorized representative. We further modified redesignated paragraph (d)(2) to clarify that an authorized representative will notify the Exchange and the applicant or enrollee on whose behalf he or she is acting when the authorized representative no longer has legal authority to act on behalf of the applicant or enrollee. We also deleted paragraph (e) and redesignated paragraphs (f) and (g) as (e) and (f), respectively. We also made the following technical corrections. We made a technical correction in paragraph (a)(1) to specify that authorized representatives are permitted to assist individuals apply for eligibility determinations or redeterminations for exemptions from the shared responsibility payment under subpart G of this part. We made technical corrections in

paragraphs (a)(2) and (g) to clarify that the designation of an authorized representative must be in a written document signed by the applicant or enrollee instead of saying it must be in writing, including a signature. We also added the word “must” to paragraphs (a)(3), (a)(4), and (f) to clarify that the activities described in those paragraphs are required Exchange functions. We made a technical correction in paragraph (d) to move the words “the applicant or enrollee notifies” to the paragraph they modify. Finally, we made a technical correction in paragraph (f), to clarify what is meant by legally binding format by adding “as described in §155.227(a)(2).”

5. General standards for Exchange notices (§155.230)

In §155.230, we proposed to make a technical correction in paragraph (a) to clarify that the general standards for notices apply to all notices sent by the Exchange to individuals or employers.

We also proposed to revise paragraph (a) by redesignating paragraph (a)(1) as paragraph (a)(4) and redesignating paragraph (a)(2) as paragraph (a)(5). We proposed to revise redesignated (a)(2) to change “; and” to “.” We proposed to add new paragraph (a)(1) to indicate that any notice required to be sent by the Exchange to individuals or employers must be written and include an explanation of the action that is reflected in the notice, including the effective date of the action, and we proposed to add new paragraph (a)(2) to require the notice to include any factual findings relevant to the action. We proposed to revise paragraph (a)(3) to clarify that the notice must include the citation to, or identification of, the relevant regulations that support the action. We note that the contents of notices are subject to privacy and security provisions in §155.260, including the limitations on disclosure of information.

Furthermore, we proposed to add paragraph (d) to allow the Exchange to provide notices either through standard mail, or if an individual or employer elects, electronically, provided that standards for use of electronic notices are met as set forth in §435.918, which contains a parallel

provision. We did not propose that the standards specifically described under proposed paragraph (d) would apply to the SHOP, and sought comment regarding this issue. We received the following comments concerning the proposed provisions for standards for Exchange notices:

Comment: Several commenters supported our proposal to clarify that the general standards for notices under §155.230 apply to notices sent by the Exchange to both individuals and employers, and they supported the changes and additions proposed under paragraph (a). Many commenters indicated that the Exchange should be required to include contact information for both customer service and consumer assistance resources in notices, and commenters indicated that HHS should make copies of the applicable statute or regulation available upon request by consumers. One commenter stated the notice needs to include a clear explanation of any next steps and the timeframe by which action needs to be taken, while another commenter emphasized that notices should contain information about where individualized and unbiased counseling is available for the individual. Lastly, a few commenters suggested that we add “laws or regulations” to §155.230(a)(3).

Response: In response to comments received, we clarify that while the standards under §155.230 generally do apply to notices sent by the individual market Exchange to both individuals and employers, HHS does not expect that the Exchange will have the information necessary to provide an employer with a choice to receive the notice specified in §155.310(h) regarding eligibility for advance payments of the premium tax credit electronically, as we do not expect that individuals will provide e-mail information for employers on the application. Accordingly, we expect that notices sent from the Exchange to employers will likely be provided by standard mail, at least in the early years of program implementation. We will continue to work with employers regarding how best to implement notices from the Exchange to employers in an efficient manner.

We intend to consider the suggestions regarding notice content in the development of model notices, and encourage Exchanges to do the same in developing notices they will use. We expect that notices will include clear information about next steps and timeframe by which action needs to be taken. We acknowledge the value of including contact information for both customer service and consumer assistance resources in notices. We recognize that including a list of all available consumer assistance resources will make the notice longer, and so note that this is an area in which Exchanges have flexibility. We also note that applicable federal regulations are and will remain available through public websites.

Comment: Several commenters reinforced their support for the use of plain language to help notify enrollees of their rights and to properly explain health coverage options that may be available to consumers. One commenter recommended the notice include clear information about how to get help if the individual does not understand the notice, as well as clear information that an individual does not have to take the premium tax credit in advance.

Response: All notices specified under 45 CFR parts 155 and 156 are required to meet the accessibility standards described under §155.205(c), which specify that information must be provided in plain language and in a manner accessible to limited English proficient individuals. We expect Exchanges to make consumers aware of the reconciliation process applicable to advance payments of the premium tax credit as a part of the initial Exchange educational materials, as well as at the time that an individual selects a QHP. HHS is working with states to identify all key messages that should be communicated to individuals through notices and other Exchange processes, and will take these comments into consideration for implementation.

Comment: Commenters generally expressed support for the electronic notice standards proposed under §155.230(d), while some expressed concerns or suggestions related to the proposed standards. Commenters raised a variety of concerns about how consumers who elect to

receive electronic notices may not actually receive them, including as a result of not checking e-mail regularly. One commenter urged that Exchanges should be required to change the enrollee's delivery method for notices if the Exchange finds that electronic notices are not being opened. One commenter suggested that written notifications should cease only after clear and unambiguous expression from an enrollee that they no longer wish to receive paper notifications, and that the Exchange should be required to track whether electronic notices are delivered and opened by an enrollee. Another commenter recommended that individuals be allowed to decide which notices they receive electronically or by mail. One commenter suggested that electronic notices should be in addition to, rather than replace, mailed paper notices. Lastly, one commenter recommended modifying the notice provision so that if an individual elects to receive electronic notices, the Exchange also always would send a mailed notice in addition to the electronic notice when the Exchange is taking an adverse action or when the consumer is required to take an additional action to maintain his or her eligibility for enrollment in a QHP, advance payments of the premium tax credit, or cost-sharing reductions.

Response: We do not expect that the Exchange will track and monitor when an individual opens e-mails and electronic notices. As described in the electronic notice standards under §435.918, which are incorporated by reference under §155.230(d), applicants will receive paper notices by mail until they affirmatively elect to receive electronic notices. We expect Exchanges to remain consistent in their overall approach to distributing notices, as required under §155.230(d). Individuals will be able to control how they receive notices. Additionally, under §435.918(b)(6), an individual will be able to request any notice posted in the individual's electronic account to be sent through regular mail. Furthermore, nothing precludes the Exchange from providing an individual with the choice to receive some types of notices electronically and others through regular mail (for example, notices concerning adverse actions). Accordingly, we

are finalizing this provision as proposed, with one modification to allow the individual market Exchange to choose to delay the implementation of the process described in 42 CFR 435.918(b)(1) regarding sending a mailed confirmation of the choice to receive electronic notices, given the time available for implementation.

Comment: Some commenters supported the exclusion of the SHOP Exchange from the electronic notice standards under §155.230(d), while others expressed support for the SHOP being able to send all notices electronically. Many commenters urged that employers in the SHOP should have a choice regarding to how they receive notices, and some expressed concern about employers not having a choice. One commenter recommended that the SHOP be allowed to choose between offering both written and electronic notices, to allow qualified employers and employees to select which method they prefer; or to only offer paper notices. The commenter noted that allowing states to adopt an electronic-only approach for notice delivery might be problematic for some employers. Another commenter indicated that the proposed rule is not clear about what the default format would be for notices sent by the SHOP.

Response: Based on the comments received and because we believe it is important for employers to be able to choose how they receive notices, we are modifying the proposed rule to allow an employer or employee in any SHOP to elect to receive electronic notices, provided that the standards for electronic notices in §435.918(b)(2), (b)(3), (b)(4), and (b)(5) are met for the employer or employee. Accordingly, the SHOP must: (1) Permit the employer or employee to change such election, at any time, and inform the employer or employee of this right; (2) Post notices to the employer or employee's electronic account within one business day of notice generation; (3) Send an e-mail or other electronic communication alerting the employer or employee when a notice has been posted; and (4) If an electronic communication is

undeliverable, send the notice by regular mail within three business days of the date of the failed electronic communication.

Comment: Several commenters asked for clarification regarding how electronic notice standards apply to QHP issuers, and they suggested that QHP issuers also be allowed to offer enrollees the option of receiving electronic notices. Some commenters recommended that the Exchange adopt electronic notice standards for QHP issuers similar to those applicable to the individual market Exchange. One commenter recommended that the single, streamlined application include an option for applicants to elect to receive notices from the QHP issuer electronically, in addition to the election to receive notices from the Exchange electronically. One commenter requested that a provision be added permitting managed care organizations to provide electronic notices.

Response: The provisions related to electronic notice standards under part 155 of the proposed rule apply to the individual market and SHOP Exchange. We acknowledge the importance of QHP issuers being able to send, and enrollees being able to choose to receive, electronic notices, and we clarify that nothing in this regulation precludes QHP issuers from offering their enrollees the option to receive notices electronically. We understand that most QHP issuers already make electronic notices available as an option to their current enrollees, and we are supportive of QHP issuers continuing to make this option available to enrollees when they are participating in the Exchange.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.230 of the proposed rule with a few modifications. We renumber proposed paragraph (d) as paragraph (d)(1) and modify it to specify the electronic notice standards for an individual market Exchange, while also adding paragraph (d)(2) to establish the electronic notice standards for a SHOP. We also add language

to allow the individual market Exchange to choose to delay the implementation of the process described in 42 CFR 435.918(b)(1) regarding sending a mailed confirmation of the choice to receive electronic notices. We provide in paragraph (d)(2) that an employer or employee in any SHOP may elect to receive electronic notices, provided that the requirements for electronic notices in §435.918(b)(2), (b)(3), (b)(4), and (b)(5) are met for the employer or employee.

6. Definitions and general standards for eligibility determinations (§155.300)

In §155.300, we proposed technical corrections in paragraph (a) to the definitions of “minimum value,” “modified adjusted gross income,” and “qualifying coverage in an eligible employer-sponsored plan,” and also removed the definition of “adoption taxpayer identification number.” We are finalizing the technical corrections as proposed, with an additional technical correction to specify the appropriate definition of minimum value.

Comment: Several commenters recommended that HHS should not cross-reference in §155.300 to the affordability standard for eligible employer-sponsored coverage in the Department of the Treasury’s premium tax credit regulation, 26 CFR 1.36B-0 et seq., as the Department of the Treasury regulation is based on individual rather than family coverage.

Response: The Department of the Treasury maintains the legal authority to interpret and implement the eligibility standards for the premium tax credit, including those related to affordability and minimum value of coverage in an eligible employer-sponsored plan, because those are based on provisions of the Code. The proposed technical corrections do not revise the policy regarding the Exchange’s determination of the affordability of eligible employer-sponsored coverage, but simply update the cross-reference to align with the Department of the Treasury’s implementing regulation. As such, we are finalizing the technical corrections as proposed.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.300 of the proposed rule with a technical correction to specify the appropriate definition of minimum value.

7. Options for conducting eligibility determinations (§155.302(a) and (b), and (d))

In §155.302, we promulgated provisions as interim final with request for comments in the Exchange final rule (77 FR 18310, at 18451-52). We proposed to modify some of the provisions in §155.302 in the proposed rule (78 FR 4594, 4635).

In paragraph (a) of the interim final rule, we provided that the Exchange may fulfill its minimum functions under this subpart by either executing all eligibility functions, directly or through contracting arrangements described in §155.110(a), or through a combination of this approach and one or both of the approaches identified in paragraphs (b) and (c), which apply when other entities make eligibility determinations for insurance affordability programs. We proposed a revision to the interim final rule in paragraph (a)(1) to specify that Medicaid and CHIP eligibility determinations made by the Exchange may only be made by a government agency that maintains personnel standards on a merit basis.

In paragraph (b) of the interim final rule, we provided that the Exchange may conduct an assessment of eligibility for Medicaid and CHIP rather than an eligibility determination for Medicaid and CHIP, provided that the Exchange make such an assessment based on the applicable Medicaid and CHIP MAGI-based income standards and citizenship and immigration status, using verification rules and procedures consistent with Medicaid and CHIP regulations, without regard to how such standards are implemented by the state Medicaid and CHIP agencies.

In paragraph (b)(2) of the interim final rule, we provided that notices and other activities that must be conducted in connection with an eligibility determination for Medicaid or CHIP would be conducted by the Exchange consistent with the standards identified in this subpart or by the applicable state Medicaid or state CHIP agency consistent with applicable law.

In paragraph (b)(3) of the interim final rule, we provided that if the Exchange assesses an applicant potentially eligible for Medicaid or CHIP, the Exchange would transmit such the applicant's information to the State Medicaid or CHIP agency for a formal determination of eligibility for such insurance affordability program. We explained in the preamble to the interim final rule that the Exchange would consider the applicant ineligible for Medicaid or CHIP for purposes of eligibility for advance payments of the premium tax credit and cost-sharing reductions until the state Medicaid or CHIP agency notified the Exchange that the applicant was eligible for Medicaid or CHIP.

In paragraph (b)(4) of the interim final rule, we proposed that if the Exchange assesses an applicant not potentially eligible for Medicaid or CHIP based on the applicable Medicaid and CHIP MAGI-based income standards, the Exchange must consider such an applicant as ineligible for Medicaid or CHIP for purposes of determining eligibility for advance payments of the premium tax credit and cost-sharing reductions, and notify the applicant and provide him or her with the opportunity to withdraw his or her application for Medicaid and CHIP or request a full determination of eligibility for Medicaid and CHIP from the applicable state agencies. To the extent that an applicant withdraws his or her application for Medicaid and CHIP, the applicant would not receive a formal approval or denial for Medicaid and CHIP.

We proposed a revision to the interim final rule in paragraph (b)(4)(i)(A) to specify that, if an applicant who is not assessed as potentially eligible for Medicaid or CHIP by the Exchange withdraws his or her application for Medicaid or CHIP, and then appeals his or her eligibility determination for advance payments of the premium tax credit or cost-sharing reductions and is found potentially eligible for Medicaid or CHIP, the Medicaid or CHIP application is not considered withdrawn. The purpose of this revision is to reinstate the Medicaid and CHIP

application date, which is used in determining the effective date of coverage under Medicaid and CHIP.

We provided in paragraph (b)(4)(i)(B) that the Exchange must notify and provide an applicant who is assessed as not potentially eligible for Medicaid and CHIP with the opportunity to request a full determination of eligibility for Medicaid and CHIP by the applicable state Medicaid and CHIP agencies. For an applicant who requests a full Medicaid and CHIP determination, we provided that the Exchange must transmit all information provided as part of the application, update, or renewal that initiated the assessment, and any information obtained or verified by the Exchange to the state Medicaid and CHIP agency. We provided that the Exchange must consider such an applicant as ineligible for Medicaid or CHIP for purposes of determining eligibility for advance payments of the premium tax credit and cost-sharing reductions until the state Medicaid or CHIP agency notifies the Exchange that the applicant has been determined eligible for Medicaid or CHIP.

We provided in paragraph (b)(5) that, under an assessment model discussed above, the Exchange must adhere to the eligibility determination for Medicaid or CHIP made by the Medicaid or CHIP agency. We provided in paragraph (b)(6) that the Exchange and the applicable state Medicaid and CHIP agencies must enter into an agreement specifying their respective responsibilities in connection with eligibility determinations for Medicaid and CHIP, which requirement complements the standards in §435.1200(d). In accordance with these standards, when the Exchange performs an assessment and transmitted it to the state Medicaid or CHIP agency, and the Exchange is providing advance payments of premium tax credits pending an eligibility determination for Medicaid and CHIP, the Exchange will receive a notification of the final determination of eligibility for Medicaid and CHIP made by the receiving agency. This

approach helps avoid duplicative requests for information from applicants and verification of information.

We proposed a revision to the interim final rule in paragraph (b)(5) to specify that the Exchange also will adhere to the appeals decision for Medicaid or CHIP eligibility determinations made by the state Medicaid or CHIP agency or appeals entity for such agency.

In paragraph (d) of the interim final rule, we provided the standards to which the Exchange must adhere when assessments of eligibility for Medicaid and CHIP based on MAGI and eligibility determinations for advance payments of the premium tax credit and cost-sharing reductions are made in accordance with paragraphs (b) and (c); such standards include that all eligibility processes are streamlined and coordinated across applicable agencies, that such arrangement does not increase administrative costs and burden on applicants, enrollees, beneficiaries, or application filers, or increase delay, and that applicable requirements under part 155 and section 6103 of the Code are met.

Comment: Several commenters raised concerns regarding §155.302(a) as promulgated in the interim final rule, as they believed it could permit non-public agencies to conduct eligibility determinations for Medicaid and CHIP, which they worried would have a negative impact on consumer assistance, timeliness, accuracy, and the potential for conflicts of interest. Some commenters wanted to ensure that agreements between state Medicaid agencies and private entities related to the eligibility determination process would be relayed to HHS for appropriate review. Several commenters recommended clear language to specify that a private Exchange is not permitted to make final determinations regarding an applicant's eligibility for Medicaid and CHIP. One commenter wanted HHS to strengthen the conflict of interest language and specify that the Exchange may not contract out eligibility determinations for advance payments of the

premium tax credit and cost-sharing reductions due to such determinations being inherently governmental.

Response: We appreciate these comments regarding the interim final rule, as well as comments received regarding the proposed revisions to paragraph (a)(1) of the interim final rule that would specify that any contracting arrangement for eligibility determinations for Medicaid and CHIP is subject to the standards in 42 CFR 431.10(c)(2). In response to these comments, we are finalizing §155.302(a) with the proposed revision to paragraph (a)(1), with a minor clarification to specify that the reference to 42 CFR 431.10(c)(2) is specific to contracting arrangements for eligibility determinations for Medicaid and CHIP. Specifically, this means that an Exchange contractor may make eligibility determinations for Medicaid and CHIP if it is a government agency or public authority that maintains personnel standards on a merit basis. We note that 42 CFR 431.10(d) specifies that agreements regarding the delegation of eligibility determinations by state Medicaid agencies must be available to the Secretary, upon request. Exchanges are permitted to contract eligibility determinations for advance payments of the premium tax credit and cost-sharing reductions in accordance with §155.110(a).

Comment: Many commenters expressed concerns about the potential bifurcation of the eligibility process under §155.302(b) for Medicaid, CHIP, and advance payments of the premium tax credit and cost-sharing reductions in terms of its impact on various stakeholders. Commenters urged that HHS maintain the “no wrong door” approach envisioned by the Affordable Care Act to ensure that an individual is appropriately screened for all relevant insurance affordability programs. As such, some commenters requested that by 2016, HHS revisit the decision to allow states to implement eligibility systems in the manner as described in the interim final rule, while also evaluating whether more Exchanges move from making assessments to determinations during the intervening time period. Commenters recommended

that, if HHS retains this provision, HHS should specify that states must demonstrate they have the capacity to manage electronic accounts and applicant information in so as not to increase the burden on individuals and families by requesting duplicate information or increase the administrative costs for state Medicaid and CHIP agencies related to file transfers or unnecessarily duplicative verification processes. Some commenters wanted HHS to require the Exchange to notify the transferring program that it had received the electronic account and report its final eligibility determination, to protect applicants. Furthermore, commenters urged HHS to establish a process for monitoring and enforcing the standards, as well as educating the public, regarding the division of eligibility responsibilities between the Exchange and relevant Medicaid and CHIP agencies. Commenters stated that if such monitoring uncovers noncompliance with performance standards or other requirements, HHS should require the Exchanges and state Medicaid and CHIP agencies to submit corrective action plans.

Response: We appreciate the suggestions from commenters, and note that many of these recommendations are already included in the interim final rule. We intend to monitor the efficiency of how states implement assessment or determination models to determine whether to propose revisions in future years. We believe that the existing language in §155.302(b) is augmented by §155.345(g) and 42 CFR 435.1200, which specify that the Exchange and the state Medicaid and CHIP agencies must have the capacity to manage electronic accounts, and also that the Exchange will notify the transferring Medicaid or CHIP agency regarding the receipt of an electronic account as well as of its final eligibility determination. Accordingly, we do not modify this provision further to address these comments. Although we do not establish a formal process for monitoring and taking enforcement action for noncompliance with these standards in the regulation text, HHS will continue to evaluate the need for such processes during the implementation of these regulations.

Comment: Several commenters suggested that states should adopt procedures that would allow Exchanges to assess eligibility for Medicaid based on factors other than MAGI, and potentially also allowing the Exchange to assess eligibility for other programs, including the Supplemental Nutritional Assistance Program. Some commenters urged HHS to require Exchanges to develop appropriate screening standards to identify vulnerable populations that might be eligible for certain programs on a basis other than MAGI.

Response: This comment is outside the scope of §155.302(b) of the interim final rule, as this provision only concerns the use of MAGI determinations, while §155.345(b) concerns the duties of the Exchange for Medicaid eligibility based on factors other than MAGI. We note that Exchanges are not precluded from entering into agreements with Medicaid and CHIP agencies to make eligibility determinations for Medicaid based on factors other than MAGI.

Comment: Some commenters requested that HHS provide greater specificity throughout §155.302(b) to indicate that contracting agreements, verifications rules and standards, notices, and other activities discussed must adhere to the specific standards of §§155.302(d) and 155.345(g), and 42 CFR part 431, subpart E.

Response: As noted earlier, §155.302(b) only applies in place of the standards elsewhere in subpart D that specify that the Exchange will make eligibility determinations for Medicaid and CHIP based on MAGI, rather than assessments; it does not conflict with standards provided elsewhere in subpart D that address other components of the eligibility process that are unaffected by whether the Exchange is making assessments or determinations of eligibility for Medicaid and CHIP. As such, Exchanges are still guided by other provisions in subpart D, such as §155.345(g). Provisions in 42 CFR part 431 concern standards for Medicaid agencies, which continue to apply to Medicaid agencies in accordance with that part notwithstanding the role of the Exchange for Medicaid eligibility. Finally, §155.302(a)(2) already specifically states that

use of the option in §155.302(b) is subject to §155.302(d), so we do not believe that it is necessary to add further references to §155.302(d).

Comment: Some commenters supported the increased level of flexibility for the Exchange to make assessments of eligibility for Medicaid and CHIP based on MAGI, rather than determinations. However, these commenters expressed concerns about relying on applicants who are not assessed as potentially eligible for Medicaid or CHIP based on MAGI to self-identify as potentially eligible based on non-MAGI standards or proactively request a full determination from the state Medicaid and CHIP agencies, as opposed to placing greater burden on the Exchange to take additional steps to proactively identify applicants who might be Medicaid eligible based on non-MAGI standards. One commenter also asked HHS to clarify that in cases where an Exchange conducts an assessment of Medicaid eligibility; the assessment must include an assessment of Medicaid eligibility on bases other than MAGI. These commenters suggested that HHS encourage states to utilize a process whereby individuals who enroll in a QHP, but are subsequently determined eligible for Medicaid, are able to transition into the same carrier's Medicaid product if the QHP also operates a Medicaid health plan.

Response: We appreciate the concerns regarding how to create a streamlined process that is minimally burdensome on individuals and families, and results in accurate eligibility determinations. Under §155.345(b) and (c), the Exchange will evaluate applications for applicants who are not eligible for Medicaid based on MAGI for possible Medicaid eligibility based on factors other than MAGI, and must provide an opportunity for applicants and enrollees to request a full determination of Medicaid eligibility based on factors other than MAGI. If the Exchange evaluates an applicant as potentially eligible for Medicaid based on factors other than MAGI, or the applicant or enrollee requests a full determination of Medicaid eligibility, §155.345(d) specifies that the Exchange will transmit the applicant's information to the state

Medicaid agency for a full determination. The Exchange has the same responsibilities regarding eligibility for Medicaid based on factors other than MAGI under the assessment and the determination models, which we believe is appropriate because the single, streamlined application that will be used by the Exchange does not request all the information necessary to conduct a full determination of Medicaid eligibility based on factors other than MAGI. Rather, it includes an opportunity for an application filer to indicate that an applicant has limitations in daily activities or lives in a medical facility or nursing home, which are factors that are considered in determining eligibility for Medicaid based on factors other than MAGI. If answered affirmatively, the Exchange will trigger a referral to the applicable state Medicaid agency such that the state Medicaid agency can determine the applicant's eligibility for Medicaid, including based on factors other than MAGI. Further, we note that the assessment of eligibility for Medicaid based on MAGI is designed to be a robust evaluation, and we expect that the number of applicants who will receive an assessment that is inconsistent with the final determination will be limited. We note that while comments related to HHS encouraging a process to help individuals transition between QHPs and Medicaid products of the same carrier is outside the scope of this regulation, Exchanges maintain the flexibility to pursue such an option.

Comment: Some commenters noted the need for high levels of coordination between the Exchange and state Medicaid and CHIP agencies. A few commenters also wanted HHS to provide guidance with a view toward minimizing the situations in which an individual will enroll in a QHP through the Exchange pending the outcome of a Medicaid or CHIP eligibility determination and then be subsequently determined eligible for Medicaid or CHIP.

Response: We agree that a high degree of coordination is needed to manage an assessment model, and believe that the language in §155.302(b) and (d), as well as §155.345,

prescribes an appropriate set of standards. We recognize the challenges that may occur related to individuals who enroll in a QHP pending the outcome of a Medicaid or CHIP eligibility determination, but we believe that these are outweighed by the benefits associated with providing eligible individuals with health coverage pending the completion of an eligibility determination for Medicaid or CHIP, and we note that enrolling in a QHP through the Exchange during such a period is the individual's choice. With that, we expect that as states implement their Exchanges and as eligibility systems for the Exchange, Medicaid, and CHIP mature, the need for multiple entities to take part in processing an application will lessen, and the time needed to complete the entire eligibility process will also decrease, which will reduce the need for interim coverage.

Comment: One commenter worried that the remainder of subpart D concerning the eligibility process was not updated to reflect §155.302(b).

Response: We note that §155.302(b) provides that the Exchange may conduct an assessment of MAGI-based eligibility for Medicaid and CHIP, rather than a determination of eligibility for Medicaid and CHIP, in accordance with the specified standards, “[n]otwithstanding the requirements of this subpart[.]” In view of this language, we did not update other provisions in subpart D to reflect §155.302(b). We note that §155.302(b) does not supersede other provisions, such as those in §155.345, that set additional standards for Exchanges in coordinating with Medicaid and CHIP agencies.

Comment: Some commenters worried that the Exchange assessment provision would allow the Exchange to assess eligibility without applying Medicaid rules and procedures. Commenters recommended that, under an assessment model, the Exchange should provide presumptive eligibility for Medicaid, which they believed was particularly important for children and pregnant women, while the application is transferred to the Medicaid and CHIP agencies and

a determination is made. One commenter suggested HHS develop a universal model for tracking children as they move from one coverage type to another, which Exchanges should be required to implement.

Response: Section 155.302(b)(1) specifies that an assessment will be made based on, “the applicable Medicaid and CHIP MAGI-based income standards and citizenship and immigration status, using verification rules consistent with 42 CFR parts 435 and 457, without regard to how such standards are implemented by the State Medicaid and CHIP agencies.” We maintain this language in this final rule, which ensures that the Exchange will use standard Medicaid rules and procedures in making an eligibility assessment. We appreciate the commenter’s recommendations related to presumptive eligibility, but note that HHS’ approach in establishing an assessment model was premised on having the Medicaid or CHIP agency make all eligibility determinations that result in the provision of benefits under Medicaid or CHIP. Accordingly, we do not specify that the Exchange will make presumptive determinations under an assessment model. HHS will continue to work with Exchanges and Medicaid and CHIP agencies to ensure that vulnerable populations, such as children and pregnant women, receive the correct eligibility determinations for insurance affordability programs in a timely fashion.

Comment: Some commenters recommended that the interim final rule be amended to eliminate or strictly limit differences between the procedures used by Exchanges in assessing eligibility for Medicaid and CHIP, and those used by state Medicaid and CHIP agencies in determining eligibility, with HHS permitting Federally-facilitated Exchanges and State Partnership Exchanges to have slightly more flexibility for differences than State-based Exchanges.

Response: We agree that the differences between the procedures used by Exchanges and their partner Medicaid and CHIP agencies in conducting eligibility determinations should be

limited, and believe that §155.302(b)(1) already accomplishes this to a significant extent. We reiterate that an assessment under §155.302(b) will be robust and will involve the execution of detailed MAGI-based eligibility rules and verification procedures. Further, we believe that there is little reason for the use of an assessment model in a state that operates a state-based Exchange, given the availability of shared information technology services and the status of the state-based Exchange as a state, rather than a federal, entity. We intend to continue to work closely with states to ensure that systems and processes are appropriately integrated, with the goal of reducing administrative costs, burden on consumers, and the time needed to complete the eligibility process.

Comment: Several commenters recommended that HHS set a specific timeliness standard regarding the electronic transmission of the application along with all relevant information collected from either the application or available electronic data sources from the Exchange to the state Medicaid or CHIP agency to ensure that eligibility determinations are provided without undue delay. Some commenters requested that HHS specify that an Exchange must complete an eligibility determination in no more than 30 days (with up to 60 days for evaluations based on factors other than MAGI under §155.345(b)) and complete the transfer of an individual's electronic file, where required, within one business day; some commenters also urged greater alignment between Exchange and Medicaid timeliness and other performance standards.

Response: In §155.302(b)(3) and (b)(4)(ii)(A), we specify that information will be transferred promptly, and without undue delay. Further, in §155.310(e)(1), we specify that the Exchange will make an eligibility determination promptly, and without undue delay. We believe that this is an appropriate approach to initial timeliness standards, given the fact that this is an entirely new program, and we intend to work closely with states to monitor and improve the

timeliness of all aspects of the eligibility and enrollment process. Further, we note that we agree with the commenter's suggestion regarding the alignment of performance standards, and intend to issue future guidance on this topic.

Comment: Several commenters suggested that HHS modify §155.302(b)(6) related to the standards for agreements entered into between the Exchange and state Medicaid and CHIP agencies to provide greater specificity regarding eligibility determinations, transfer procedures, notice and appeals processes, and consumer assistance. Additionally, these commenters asked that the agreements be made readily available to the public in addition to HHS, while also providing a period for public review and comments on the agreements prior to their approval by HHS.

Response: We finalize §155.302(b)(6) from the interim final rule with a clarification that, like the agreements specified in §155.345(a), the agreement under §155.302(b)(6) will be made available to HHS upon request. To the extent that the Secretary requests and obtains a copy of an agreement under §155.302(b)(6), the public can request the agreement through the Freedom of Information Act, 5 U.S.C. 552. The public may also obtain copies of these agreements under applicable state freedom of information laws. We believe that there are ample opportunities for public input for Exchange operations, particularly given that the standards that will govern the content of these agreements are specified in this regulation. We also note again that §155.302(b) does not supersede other provisions, such as those in §155.345, that set additional standards for Exchanges in coordinating with Medicaid and CHIP agencies.

Comment: One commenter wanted to ensure that HHS would review and approve all state Medicaid verification plans.

Response: This comment is outside of the scope of this regulation. We note, however, that as described in 42 CFR 435.945(j), state Medicaid verification plans must be available to the

Secretary of HHS upon request, thereby enabling appropriate oversight of verification standards.

Comment: One commenter sought clarification as to whether an Exchange could choose to perform neither an assessment nor a determination for Medicaid and CHIP.

Response: We clarify that the Exchange must make either determinations or assessments for Medicaid and CHIP based on MAGI for applications that include a request for an eligibility determination for insurance affordability programs. However, we note that the Exchange is permitted to contract with an eligible contracting entity, including the state Medicaid agency, to conduct eligibility determinations for Medicaid and CHIP, consistent with §155.302(a).

Comment: Several commenters recommended that an applicant who appears to be eligible for Medicaid based on factors other than MAGI be flagged by the Exchange early in the process, and if the Exchange does not assess such an applicant as potentially eligible for Medicaid or CHIP based on MAGI, the applicant should not have to request a full eligibility determination from the state agency under §155.302(b)(4)(i)(B) to receive an eligibility determination for Medicaid based on factors other than MAGI.

Response: As noted above, §155.302(b) does not supersede §155.345(b), which specifies that the Exchange will assess information provided on an application by an applicant who is not eligible for Medicaid based on MAGI to determine whether he or she is potentially eligible for Medicaid based on factors other than MAGI. We clarify that this provision applies in an Exchange that is implementing the option under §155.302(b), such that if the Exchange does not assess an applicant as potentially eligible for Medicaid based on MAGI, it will then examine the application to determine whether to transfer the applicant to the state Medicaid agency for consideration of Medicaid eligibility based on other factors.

Comment: Commenters recommended that the provision at §155.302(b)(4)(i)(A), allowing an individual the opportunity to withdraw his or her Medicaid and CHIP application, be

eliminated or modified to allow only individuals above a certain income threshold to withdraw their Medicaid and CHIP applications. Others commenters were concerned that language notifying an individual of his or her opportunity to withdraw would be confusing and lead to individuals being dissuaded from pursuing a Medicaid or CHIP eligibility determination.

Response: When an applicant requests an eligibility determination for insurance affordability programs, the single, streamlined application is an application for Medicaid and CHIP (as well as for eligibility for enrollment in a QHP through the Exchange, and related insurance affordability programs), so it needs to end in either a final determination of eligibility for Medicaid or CHIP (approval or denial), or a withdrawal of the application as it relates to Medicaid and CHIP. When a state Medicaid or CHIP agency elects to have the Exchange make assessments of Medicaid or CHIP eligibility, rather than determinations, the Exchange is unable to provide a final determination of Medicaid or CHIP eligibility, including a denial of Medicaid or CHIP eligibility. Accordingly, withdrawal allows the assessment model to function such that an applicant does not require a formal, final denial of Medicaid and CHIP from the state Medicaid or CHIP agency to gain eligibility for advance payments of the premium tax credit and cost-sharing reductions, if otherwise eligible. This approach provides significant efficiencies for consumers by not requiring multiple eligibility determinations, as well as for Exchanges and Medicaid and CHIP agencies. Given that the proposed approach preserves the application date for purposes of Medicaid and CHIP in the event of an appeal, we note that the only implication of withdrawing an application in this context is that the applicant can no longer request a determination from the state Medicaid or CHIP agency based on the withdrawn application, and would instead need to submit another application to be considered for those programs (other than on appeal).

We acknowledge commenters' concerns regarding the potential for confusion when an applicant is given the opportunity to withdraw his or her Medicaid and CHIP application. To reduce the potential for consumer confusion and administrative burden on the consumer and the Exchange associated with this requirement, we offer the following option in implementing this provision. Upon notifying an applicant that the Exchange has assessed him or her as not potentially eligible for Medicaid or CHIP, the Exchange will provide an opportunity for the applicant to request a determination of Medicaid or CHIP eligibility from the state Medicaid or CHIP agency. Rather than expressly asking the applicant if he or she wants to withdraw the application for purposes of Medicaid or CHIP eligibility (instead of requesting a determination from the state agencies), the Exchange may consider the application withdrawn for purposes of Medicaid and CHIP eligibility if the applicant does not affirmatively request a determination from the state Medicaid or CHIP agency within a time period specified in the notice to the applicant, provided that the notice that communicates the opportunity to request a determination from the state Medicaid or CHIP agency and the time limit for doing so also specifies that the Exchange will take this approach to withdrawal. This will allow an appropriate disposition for each application, as it relates to Medicaid and CHIP, and will help alleviate any confusion associated with the opportunity to expressly withdraw an application, without creating any adverse impacts for consumers.

Comment: A few commenters requested language that explicitly preserves the date of application when an applicant withdraws his or her Medicaid or CHIP application.

Response: Provisions related to preserving the date of the Medicaid or CHIP application are contained in this final rule at 42 CFR 435.907(h).

Comment: Commenters supported the inclusion of language that requires the application to not be considered withdrawn if, upon appeal, the applicant is found potentially eligible for

Medicaid or CHIP. A few commenters requested that any subsequent review finding potential eligibility for Medicaid or CHIP be sufficient to nullify the withdrawal.

Response: We are finalizing proposed language requiring the application to not be considered withdrawn if, upon appeal, the applicant is found potentially eligible for Medicaid or CHIP. The additional suggestions to amend this provision would expand the scope of the provision beyond its intended scope. Further, it would be impossible to administer the commenters' suggestion to nullify a withdrawal when any future review finds potential eligibility for Medicaid or CHIP eligibility, beyond the parameters established in this rule, since subsequent eligibility determinations and redeterminations will not necessarily be connected to the withdrawn application.

Comment: Commenters supported the additional proposed language in §155.302(b)(5) requiring the Exchange to adhere to State Medicaid or CHIP agency appeals decisions.

Response: We are finalizing the proposed language with a modification such that the Exchange appeals entity, in addition to the Exchange, will adhere to the eligibility determination or appeals decision for Medicaid or CHIP made by the Medicaid or CHIP agency, or the appeals entity for such agency.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.302(a) with one clarification that any contracting arrangement for eligibility determinations for Medicaid and CHIP is subject to the standards in §431.10(c)(2). We are finalizing the provision proposed in §155.302(b)(5) with a slight technical modification to add "Exchange appeals entity." We are finalizing §155.302(b)(6) of the interim final rule issued at 77 FR 18310, 18451-52 with a modification to specify that the agreement under §155.302(b)(6) must be made available to HHS upon request. We are finalizing the provisions proposed in paragraph (d) of the proposed rule without

modification. We are otherwise finalizing the other provisions of the interim final rule with the exception of §155.302(c), which we are not finalizing at this time. We are leaving the text of §155.302(c) as an interim final rule as published at 77 FR 18310, 18451-52.

8. Eligibility standards (§155.305)

In §155.305, we proposed to add paragraph (a)(3)(v) regarding residency standards for eligibility for enrollment in a QHP when an individual attests to being temporarily absent from the service area of the Exchange but intends to return to the service area of the Exchange and otherwise meets the residency standards, unless another Exchange verifies that the individual meets the residency standard in that Exchange. We also proposed technical corrections within paragraph (f) to replace the references to section 36B of the Code to the application Treasury regulations.

We proposed to amend paragraph (f)(3) to clarify the availability of advance payments of the premium tax credit and cost-sharing reductions to applicants enrolled in a QHP, that is not a catastrophic plan, through the Exchange. We did not receive specific comments on this amendment, and we are thus finalizing the provision as proposed.

We also proposed to add paragraph (h) to codify the eligibility standards for enrollment through the Exchange in a QHP that is a catastrophic plan, which are based on age or having in effect a certificate of exemption from the shared responsibility payment under section 5000A of the Code in specific categories. We proposed that all Exchanges must conduct eligibility determinations for a QHP that is a catastrophic plan within the Exchange.

Comment: Commenters generally offered support for the provision at §155.305(a)(3)(v) specifying that the Exchange not deny or terminate an individual's eligibility for enrollment in a QHP through the Exchange if he or she meets the residency standards described in paragraph (a)(3) but for a temporary absence from the service area of the Exchange. A few

commenters recommended deleting the phrase that allowed the Exchange to deny or terminate eligibility if another Exchange verifies that the individual meets the residency standard of such Exchange; others suggested rephrasing the provision to allow an individual to maintain residency in the Exchange service area unless he or she is enrolled in another Exchange. Commenters recommending revisions disagreed with how this language would limit an applicant's ability to establish residency, under the rules described in §155.305(a)(3), in more than one Exchange.

Response: We are finalizing the provision without the proposed clause “unless another Exchange verifies that the individual meets the residency standard of such Exchange.” As commenters pointed out, under some circumstances, certain individuals may establish residency for purposes of Exchange enrollment in multiple Exchange service areas simultaneously (for example, under §155.305(a)(3)(iv)(B), if a parent expects to claim a child who lives in another state on the parent's tax return, the child may enroll in a QHP through the Exchange either in the child's state of residence, or the parent's state of residence). Accordingly, while generally, applicants will establish residency in the Exchange service area in which they intend to reside, since there are exceptions to this general principle, this clause limiting residency to one Exchange service area is unnecessary.

Comment: In response to the provision proposed at §155.305(a)(3)(v), some commenters expressed concern about operational challenges specific to providing and coordinating coverage while individuals are temporarily residing outside the Exchange service area. A few commenters asked that we further define the term “temporary” to ensure that the term is used consistently across Exchanges, and to help reduce consumer confusion and administrative inefficiencies.

Response: We acknowledge that coordinating care for applicants while they are temporarily absent from the service area of the Exchange through which they enroll in a QHP may present challenges for QHP issuers. However, we believe this challenge is outweighed by

the importance of maintaining continuity of coverage while an individual is temporarily absent from a particular Exchange service area. Additionally, in paragraph (a)(3)(v), we specify that “temporarily absent” means the applicant must intend to return to the Exchange service area when the purpose of the absence has been accomplished, so we do not believe that further definition is required in regulation. To ensure that applicants understand the implications of applying for coverage through a particular Exchange, we encourage Exchanges to notify applicants that they may want to apply for coverage through the Exchange where they meet the residency requirements and wish to most frequently access benefits.

Furthermore, this provision should not be construed to impose any additional requirements on QHP issuers related to maintaining networks outside the Exchange service area or coordinating care for applicants temporarily absent from the Exchange service area.

Comment: Commenters were divided regarding the Exchange’s role in determining eligibility for catastrophic plans inside and outside the Exchange, as some expressed support for what they interpreted as HHS limiting enrollment for catastrophic coverage to enrollment through the Exchange in QHPs that are catastrophic plans and urged flexibility for an Exchange to decide not to conduct eligibility determinations for catastrophic plans, while other commenters requested that the Exchange conduct eligibility determinations for QHPs that are catastrophic plans for enrollment both through and not through the Exchange. Commenters also urged HHS to clarify that an applicant still must be determined eligible for a QHP to enroll in a catastrophic plan through the Exchange. Commenters wanted to ensure that the Exchange would provide clear information to applicants considering purchasing different QHPs, including by describing the significance of enrolling in a catastrophic plan for applicants who are also determined eligible for advance payments of the premium tax credit.

Response: We note that paragraph (h) only concerns eligibility for enrollment through the Exchange in a QHP that is a catastrophic plan. The Exchange will not be conducting eligibility determinations for enrollment outside the Exchange, including in a catastrophic plan. In finalizing this provision, we are modifying the provision from its proposed form to clarify that an individual must be determined eligible for enrollment in a QHP through the Exchange in accordance with §155.305(a) in addition to meeting the specific eligibility standards for enrollment in a catastrophic QHP through the Exchange. We believe that maintaining the provision specifying that the Exchange will determine eligibility for a QHP that is a catastrophic plan through the Exchange preserves flexibility for young adults and people for whom coverage would otherwise be unaffordable to have access to health coverage, and thus confirm that Exchanges will conduct determinations of eligibility for enrollment in a QHP that is a catastrophic plan through the Exchange. We expect that Exchanges will fully inform qualified individuals regarding the implications of enrolling in a QHP that is a catastrophic plan through the Exchange as they consider various health coverage options, particularly as it affects their eligibility for insurance affordability programs.

Comment: Some commenters wanted us to clarify that Exchanges would grant certificates of exemption to all applicants eligible for enrollment in a catastrophic plan, which applicants could use to enroll in catastrophic plans outside the Exchange (at least temporarily), and suggested that issuers of catastrophic plans outside the Exchange should be permitted to rely solely on an attestation by the applicant that he or she is eligible to enroll in a catastrophic plan.

Response: This provision does not concern catastrophic plans offered outside of the Exchange. As discussed in the Market Reforms final rule at 78 FR 13423, the statutory provisions related to eligibility for catastrophic plans apply to such coverage offered both inside and outside an Exchange. We maintain that approach and clarify that nothing in this proposal

modifies the Market Reforms final rule related to the eligibility standards for a catastrophic plan. Similarly, the eligibility standards for catastrophic plans generally are specified at §156.155(a)(5), which provides that a catastrophic plan can only cover an individual who has either not attained the age of 30 prior to the first day of the plan or policy year, or has received a certificate of exemption in specified categories. While we specify that the Exchange will only conduct determinations of eligibility for enrollment through the Exchange in a QHP that is a catastrophic plan, in HHS' Exemptions and Miscellaneous Minimum Essential Coverage proposed rule, at 78 FR 7368, we propose that the Exchange will determine eligibility for exemptions from the shared responsibility payment, and will provide a notice and an exemption certificate number to any individual determined eligible for such an exemption. If that provision is finalized as proposed, an issuer of a catastrophic plan offered outside the Exchange could request a copy of this notice from an applicant to validate his or her eligibility for enrollment in the catastrophic plan.

Comment: Some commenters requested that the Exchange's eligibility standards for enrollment through the Exchange in a QHP that is a catastrophic plan align with preamble language in the Market Reforms proposed rule at 77 FR 70601 such that an enrollee who turns 30 in the middle of a coverage year would remain enrolled in the catastrophic plan for the duration of the plan year. One commenter also sought clarification that for coverage obtained through the Exchange, the first day of the plan year will always be the first of the year.

Response: The eligibility standards related to age described in this provision follow the approach discussed within the Market Reforms proposed rule at 77 FR 70601. As such, we clarify that an enrollee turning 30 in the middle of a coverage year could remain enrolled in a QHP that is a catastrophic plan through the Exchange for that particular coverage year as long as he or she was not 30 prior to beginning of the plan year. We note that §147.104(b)(1)(ii)

clarifies that in the individual market, the coverage effective dates must align with §155.410 regarding initial open enrollment, and as such, for coverage obtained in the individual market through the Exchange, the first day of the plan year will always be the first day of the calendar year.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.305 of the proposed rule with two slight modifications: to remove the clause “unless another Exchange verifies that the individual meets the residency standard of such Exchange” in paragraph (a)(3)(v), and to revise paragraph (h)(1) to clarify an applicant must be eligible for enrollment in a QHP through the Exchange to be determined eligible for enrollment through the Exchange in a QHP that is a catastrophic plan.

9. Eligibility process (§155.310)

In §155.310, we proposed to add paragraph (i) regarding a certification program under the Secretary’s program for determining eligibility for advance payments of the premium tax credit and cost-sharing reductions in accordance with section 1411(a) of the Affordable Care Act. We noted that this certification program would be distinct from the notice to employers required by section 1411(e)(4)(B)(iii) of the Affordable Care Act and paragraph (h) of §155.310. We proposed that the certification to the employer would consist of methods adopted by the Secretary of Treasury as part of the determination of potential employer liability under section 4980H of the Code. We clarified that the certification program would address not only individuals on whose behalf advance payments of the premium tax credit and cost-sharing reductions are provided, but also individuals claiming the premium tax credit only on their tax returns. We solicited comments on this proposal.

We proposed to amend previous language from paragraphs (i) and (i)(1), and combine those paragraphs in new paragraph (j), to align with proposed revisions in §155.335, which

specified that the Exchange will redetermine eligibility on an annual basis for all qualified individuals, not only enrollees. We proposed to remove the previous paragraph (i)(2), which addressed situations in which a qualified individual did not select a plan before the date on which his or her eligibility would have been redetermined as a part of the annual redetermination process. Due to the proposed change to §155.335(a), this paragraph would no longer be necessary. We received the following comments concerning the proposed provisions:

Comment: One commenter expressed support for the proposal to implement a certification process consisting of methods adopted by the Secretary of Treasury as part of the determination of potential employer liability under section 4980H of the Code, as described in proposed §155.310(i). In addition, several commenters expressed concern over the disclosure of applicant information to the employer for use in the certification process. Commenters were concerned that disclosing names in this context could have a chilling effect on employees who wish to seek Exchange coverage, making it less likely that individuals would enroll.

Response: For purposes of the certification program proposed and finalized in §155.310(i), we believe that only the minimum personally identifiable information necessary should be released to an employer. Additional information regarding the certification program is found in the regulations associated with §4980H of the Code.

Comment: Commenters recommended removing the provision specifying that the Exchange will have an applicant attest to the accuracy of the information on file for him or her when he or she was previously determined eligible for enrollment in a QHP through the Exchange, did not select a QHP during his or her enrollment period, or was ineligible for an enrollment period, and then seeks a new enrollment period prior to his or her annual redetermination. Commenters characterized this as an undue burden on qualified individuals,

since enrollees are not required to make the same attestation about their eligibility criteria remaining constant.

Response: This provision was largely carried over from the Exchange final rule, with modifications to address changes proposed in §155.335. It is important for the Exchanges to ensure all eligibility criteria are satisfied with accurate information, before determining eligibility for benefits, some of which the enrollee could be liable to repay if eligibility information is not accurate at the time of enrollment. Moreover, enrollees are required to report changes that may affect their eligibility based on the standards in §155.305 throughout the year, and thus no additional burden is being placed on qualified individuals. Lastly, one alternative to this proposal would be to require qualified individuals who do not enroll in coverage when initially determined eligible to file a new application, which would be more burdensome than the approach in §155.310(j). Accordingly, we are finalizing §155.310(j) as proposed, with a slight technical correction for clarity to note that this paragraph only refers to an applicant who is determined eligible for enrollment in a QHP through the Exchange.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.310 of the proposed rule with a technical correction to specify that paragraph (j) only refers to an applicant who is determined eligible for enrollment in a QHP through the Exchange .

10. Verification process related to eligibility for enrollment in a QHP through the Exchange (§155.315)

In §155.315, we proposed a technical correction in paragraph (b)(2) to clarify the procedures for an Exchange when the Social Security Administration indicates an individual is deceased.

We proposed to clarify the circumstances that trigger the inconsistency process described in paragraph (f)(1) and (2), such as when required electronic data is not contained within the electronic data source, and when sources of required data are not reasonably expected to be available within two days of the initial attempt to reach the data source. We also proposed to amend paragraph (f)(4) to clarify that during the clerical error resolution period provided in paragraph (f)(1), as well as during the period provided in paragraph (f)(2)(ii), the Exchange proceeds with the eligibility determination and provides eligibility for enrollment in a QHP and advance payments of the premium tax credit and cost-sharing reductions, as applicable, during such period, to the extent the applicant is otherwise qualified and meets the standards specified in paragraph (f)(4).

We proposed to add paragraph (j) concerning the verification process related to eligibility for enrollment through the Exchange in a QHP that is a catastrophic plan. We proposed that the Exchange may either accept the applicant's attestation of age without further verification or examine available electronic data sources that have been approved by HHS for this purpose. To verify an applicant's exemption from the shared responsibility payment, we proposed that this would be accomplished either through use of the Exchange's records, or through verification of paper documentation if the certificate was issued by a different Exchange. In terms of the inconsistency process described in paragraph (f) of this section, we noted that applicant would not be determined eligible for enrollment through the Exchange in a QHP that is a catastrophic plan until verification of necessary information can be completed. We received comments that addressed both the eligibility standards and verification process related to QHPs that are catastrophic plans offered through the Exchange, and have addressed those comments above the preamble to §155.305(h). As such, we are finalizing this paragraph as proposed.

Comment: Several commenters supported our proposed technical correction in paragraph (b)(2) regarding situations in which the Social Security Administration indicates that an individual is deceased. Others recommended allowing additional time, and many commenters suggested providing an additional 90 days when an applicant has demonstrated a good faith effort to resolve the issue. Some commenters sought clarification on the availability of appeal rights regarding inconsistencies with Social Security Administration data, specifically, whether individuals had the right to appeal during the 90-day period or whether they must wait until after a final determination has been made.

Response: As noted in §155.315(f)(3), the Exchange has the authority to extend the inconsistency period within §155.315(f)(2)(ii) based on a good faith effort on the part of the applicant. We note that an applicant will not be able to appeal an eligibility decision until he or she receives a notice containing an approval or denial of eligibility. Further details regarding appeals will be provided in subsequent rulemaking. We continue to work with the Social Security Administration and other federal agencies to determine the role of other federal agencies in the appeals process. Accordingly, we are finalizing the provision as proposed.

Comment: Some commenters disagreed with the proposal at §155.315(f) that specifies that the Exchange must trigger the inconsistency period when electronic data is required but it is not reasonably expected that data sources will be available within 2 days of the initial request to the data source. Commenters recommended that if verification cannot occur promptly, or in “real time,” the inconsistency period should be triggered immediately, along with the provision of eligibility based on an applicant’s attestation. Some commenters mentioned specifically that an inability to verify citizenship and immigration status through electronic data should lead to the immediate trigger of the inconsistency period, to align with Medicaid regulations.

Commenters supported timelines according to which the Exchange should be required to contact the application filer for documentation or additional information when data sources are unavailable. Some commenters supported the requirement of a 2-day period prior to requesting information from the application filer, and some recommended extending it to 5 days.

Commenters also recommended that the Exchange continue to attempt data matches after notifying the application filer so the entire burden is not immediately shifted to the application filer.

Response: Since the publication of the proposed rule, we have confirmed that data from IRS, SSA, and DHS should be available every day. Accordingly, we are modifying the proposed provision to finalize the rule to reduce the waiting period reduced from 2 days to 1 day. Further, we also add new paragraph (f)(6) to clarify the applicability of §155.315(f).

First, in paragraph (f)(6), we specify that that the Exchange will not apply such a waiting period when electronic data to support the verifications specified in §155.315(d) (residency), or §155.320(b) (minimum essential coverage, other than minimum essential coverage in an eligible employer-sponsored plan) is required but it is not reasonably expected that electronic data sources will be available within 1 day of the initial request to the data source; instead, the Exchange will accept the applicant's attestation regarding the factor of eligibility for which the unavailable data source is relevant. While the data matching described in this subpart for these factors of eligibility is important, we do not believe that it should hold up an eligibility determination or cause the eligibility process to default to paper documentation when electronic data sources are unavailable. We also note that the use of electronic data as a primary method of verification of residency is an option for Exchanges. In addition, we clarify that §155.320(d)(3)(iii) specifies that when the Exchange does not have information from data sources for the verifications related to enrollment in an eligible employer-sponsored plan and

eligibility for qualifying coverage in an eligible employer-sponsored plan, the Exchange will move forward with a sampling process.

Second, we clarify that §155.320(c)(3) (family size and income for purposes of eligibility for advance payments of the premium tax credit and cost-sharing reductions) already specifies procedures to address situations in which electronic data sources with information about current, MAGI-based income are unavailable. We believe that these procedures should continue to govern these situations.

We acknowledge commenters' concerns about providing eligibility determinations in a timely fashion when electronic data sources are delayed in responding or do not respond. The proposed language at §155.315(f) minimizes the administrative and consumer burden associated with requesting documentation and providing coverage for a short period of time (when electronic data sources may quickly become available and indicate eligibility for a different insurance affordability program), with the need to provide prompt eligibility determinations. Accordingly, when electronic data from IRS, SSA, or DHS is necessary but unavailable, and it is reasonably expected that the necessary electronic data source will be available within 1 day, the Exchange will wait 1 day before making an eligibility determination, so as to not generate an eligibility determination that may be shown to be invalid less than 24 hours later. This approach also avoids the need to request documentation when an electronic data match will make the documentation request unnecessary less than 24 hours later. If it is not reasonably expected that the necessary electronic data source will be available within 1 day, or it is reasonably expected that the necessary electronic data source will be available within 1 day, but this expectation proves incorrect, then the Exchange will determine the applicant's eligibility using his or her attestation regarding the factor of eligibility for which the electronic data source is unavailable, and will follow the remaining procedures in §155.315(f) to attempt to complete the verification.

We believe this approach is responsive to commenters' concerns and satisfies the need to reduce administrative burden and the burden on application filers while still ensuring accurate eligibility determinations. We also note that the Exchange has the flexibility to continue checking whether such data sources have become available leading up to the triggering of the inconsistency period and during such inconsistency period.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.315 of the proposed rule, with a few modifications. We are modifying paragraph (f) to provide that if key electronic data sources are unavailable and not reasonably expected to be available within 1 day, the Exchange will make an eligibility determination based on an applicant's attestation and trigger the inconsistency period in paragraph (f). The proposed language specified a 2-day period. We also added a new paragraph (f)(6) to clarify that the Exchange will accept an applicant's attestation regarding three specific factors of eligibility when electronic data is required but it is not reasonably expected that data sources will be available within 1 day of the initial request to the data source. We are also modifying paragraph(f)(5) of this section by deleting paragraph (f)(5)(ii) and combining paragraph (f)(5)(i) with paragraph (f)(5), because the language that previously appeared in paragraph (f)(5)(ii) regarding effective dates conflicted with the requirements under §155.330(f). Lastly, we modify the language in paragraph (j) related to the verification of eligibility for enrollment through the Exchange in a QHP that is a catastrophic plan for purposes of clarity.

11. Verifications related to eligibility for insurance affordability programs (§155.320)

In §155.320, we proposed to amend and make technical corrections in paragraph (c)(1), in accordance with the legislative change made by Pub. L. 112-56 concerning the treatment of Social Security benefits related to MAGI, to incorporate Social Security benefits when verifying projected annual household income. We also proposed to remove language concerning an

adoption taxpayer identification number, and to replace references to section 36B of the Code with the applicable Treasury regulation. We received comments supporting these revisions without further suggestions, and are thus finalizing the amendments and technical corrections as proposed.

We proposed to amend and make technical corrections in paragraph (c)(3) to specify that the Exchange verify that neither advance payments of the premium tax credit nor cost-sharing reductions are already provided on behalf of an individual, and align with the revised policy that the Exchange incorporate Social Security benefits when verifying projected annual household income. We did not receive specific comments regarding the proposed changes to paragraph (c)(3), and are thus finalizing the changes as proposed.

We proposed to clarify when additional verification is necessary as part of the process to verify an expected increase in projected annual household income when compared to annual income data. We proposed to add language regarding the circumstances under which annualized current income data will be sufficient to support an expected decrease in projected annual household income. We also proposed to replace references to section 36B of the Code with references to the applicable Treasury regulation.

We proposed to consolidate paragraphs (d) and (e), currently entitled “Verification related to enrollment in an eligible employer-sponsored plan” and “Verification related to eligibility for qualifying coverage in an eligible employer-sponsored plan,” respectively, into new paragraph (d). The standards proposed in paragraph (d) set forth the rules for verifying enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan. We proposed that the Exchange must verify whether an applicant reasonably expects to be enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which

coverage is requested. As a result of the proposed consolidation of paragraphs (d) and (e), we proposed to redesignate paragraph (f) as paragraph (e).

In paragraph (d)(2), we proposed the data sources the Exchange will use to verify access to employer-sponsored coverage, which include 1) data about enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan from any electronic data sources that are available to the Exchange and which have been approved by HHS for this purpose based on evidence showing that such data sources are sufficiently current, accurate, and minimize administrative burden; 2) data regarding enrollment in an eligible employer-sponsored plan or eligibility for qualifying coverage in an eligible employer-sponsored plan based on federal employment obtained by transmitting identifying information specified by HHS to HHS; 3) data from the SHOP that operates in the state in which the Exchange is operating; and 4) any available data regarding the employment of an applicant and the members of his or her household, as defined in 26 CFR 1.36B-1(d), from any electronic data sources that are available to the Exchange and have been approved by HHS for this purpose, based on evidence showing that such data sources are sufficiently current, accurate, and minimize administrative burden.

We proposed that data regarding employment would not be used to identify inconsistencies that need to be resolved to maintain eligibility, and would instead only be used to determine whether an individual should be part of the pool of individuals from which a sample is taken for review. We solicited comment on whether data regarding employment should only be used as a point of information for applicants to help prompt accurate attestations, and not as a point of comparison for the purposes of identifying inconsistencies as part of the verification described in this paragraph, since these data sources do not directly address enrollment in an eligible employer-sponsored plan or eligibility for qualifying coverage in an eligible employer-

sponsored plan. We also solicited comment on the feasibility of making the necessary systems connections by October 1, 2013, and whether alternative approaches should be considered for the first year of operations.

To verify enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan, we proposed that the Exchange follow the inconsistency process specified in §155.315(f) if an applicant's attestation is not reasonably compatible with information from a data source authorized by HHS, data regarding federal employment, data from SHOP, or other information provided by the application filer or in the records of the Exchange. Further, if the Exchange does not have any of the information from a data source authorized by HHS, from data regarding federal employment, or from data from the SHOP for an applicant, and either does not have any available electronic data regarding the employment of an applicant and the members of his or her household or an applicant's attestation is not reasonably compatible with any available data regarding the employment of an applicant and the members of his or her household, we proposed that the Exchange would place the applicant into a pool of applicants from which it would select a statistically-significant sample of applicants, from whose employers the Exchange would request information regarding enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan.

We solicited comments on whether handling inconsistencies with any available data regarding the employment of an applicant and the members of his or her household through the sampling process, rather than through the procedures specified in §155.315(f), is a suitable approach.

We requested comments on a methodology by which an Exchange could generate a statistically significant sample of applicants and whether there are ways to focus the sample on

individuals who are most likely to have access to affordable, minimum value coverage.

In clause (d)(3)(iii)(A), we proposed that the Exchange would provide notice to an applicant who is selected as part of the sample indicating that the Exchange would be contacting any employer identified on the application for the applicant and the members of his or her household, as defined in 26 CFR 1.36B-1(d), to verify whether the applicant is enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested. We sought comment on ways the Exchange may communicate this sampling process to consumers with the intention of minimizing confusion.

We proposed that the Exchange would proceed with all other elements of the eligibility determination using the applicant's attestation while the sample-based review is occurring, and provide eligibility for enrollment in a QHP through the Exchange to the extent that an applicant is otherwise qualified. Consistent with §155.315(f), we proposed that during the sample-based review, the Exchange would ensure that advance payments of the premium tax credit and cost-sharing reductions are provided on behalf of an applicant who is otherwise qualified for such payments and reductions, as described in under §155.305 of this subpart, if the tax filer attests to the Exchange that he or she understands that any advance payments of the premium tax credit paid on his or her behalf are subject to reconciliation.

When an applicant is selected for the sample-based review, we proposed in clause (d)(3)(iii)(D) that the Exchange make reasonable attempts to contact any employer identified on the application for the applicant and the members of his or her household, as defined in 26 CFR 1.36B-1(d), to verify whether the applicant is enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested.

We discussed one alternative approach, under which the Exchange would request documentation from consumers who were selected as part of the sample, instead of attempting to contact their employers. We chose not to propose this approach since the application will already solicit all necessary information from consumers, so it is unclear what would be gained through a second information request to consumers. We solicited comment on this alternative and other alternatives to implement this process while minimizing burden on consumers, employers, and Exchanges. We also sought comment on ways the Exchange can most efficiently interact with employers, including other entities that employers may rely upon to support this process, such as third-party administrators.

In clause (d)(3)(iii)(E), we proposed that if the Exchange receives any information from an employer relevant to the applicant's enrollment in an eligible employer-sponsored plan or eligibility for qualifying coverage in an eligible employer-sponsored plan as a result of the sample-based review, the Exchange would determine the applicant's eligibility based on such information and in accordance with the effective dates specified in §155.330(f) of this subpart and, if such information changes the applicant's eligibility determination, notify the applicant and his or her employer or employers of such determination in accordance with the notice requirements specified in §155.310(g) and (h) of this part.

We also proposed that if, after a period of 90 days from the date on which the notice specified in clause (d)(3)(iii)(A) is sent to the applicant, the Exchange is unable to obtain the necessary information from an employer, the Exchange will determine the applicant's eligibility based on his or her attestation regarding that employer. We solicited comment on this proposal to not provide an additional notice to the applicant and his or her employer when the applicant's eligibility does not change as a result of the sample-based review and whether it is preferable to include an additional notice to the applicant and employer at the end of the 90-day period.

In clause (d)(3)(iii)(G), we proposed that to carry out the sampling process described above, the Exchange must only disclose an individual's information to an employer to the extent necessary for the employer to identify the employee. We solicited comments on this proposed approach and whether there are ways these procedures can further minimize burden on the Exchange, employers, and consumers.

We also highlighted steps we are taking to help consumers with providing information related to access to employer-sponsored coverage on the application. We suggested the use of a voluntary pre-enrollment template to assist applicants in gathering the information about access to coverage through an eligible employer-sponsored plan as required by the Exchange to determine eligibility for advance payments of the premium tax credit and cost-sharing reductions. We sought comments on the use of this pre-enrollment template and ways it could be used to assist consumers with providing the necessary information to complete the verification described in paragraph (d) while minimizing burden on employers.

Lastly, in paragraph (d)(4), we also proposed that the Exchange may rely on HHS to conduct this verification. We proposed that under this option, the Exchange would send applicant information to HHS; HHS would take on all verification activities specified in regulation, including data matching with the Office of Personnel Management (OPM), SHOP, available employment data, and the sample-based review; and the Exchange would integrate the result into its eligibility process and send the individual and employer notices described in §155.310(g) and (h) of this part. Further, we proposed that under such an arrangement, the Exchange and HHS would enter into an agreement specifying their respective responsibilities in connection with the verifications described in paragraph (d); other activities required in connection with the verifications described are performed by the Exchange in accordance with the standards identified in this subpart or by HHS in accordance with the agreement; and the

Exchange provides all relevant application information to HHS through a secure, electronic interface, promptly and without undue delay. We solicited comments on this proposed option.

Comment: In reference to the proposed language at §155.320(c)(3)(vi)(C), which specifies that the Exchange will request additional information regarding projected annual household income when an application filer's attestation is in excess of annual income data, but below annualized current income data by a "significant amount," commenters recommended that the phrase "significant amount" be replaced with a percent threshold. Some commenters recommended a threshold of 20 percent, specifically.

Response: To preserve the Exchange's flexibility to determine what may constitute a significant amount, we are finalizing this provision as proposed.

Comment: Commenters recommended replacing the standard "not reasonably compatible" with the term "significantly and materially incompatible," defined further by commenters as "making an important change to the outcome." Such commenters suggested only using the process described in §155.315(f) if an attestation is significantly and materially incompatible with other information. Further, commenters suggested easing verification rules for individuals who comply with information requests, including attestations, and for whom required data is not available.

Response: In §155.300(d) of the Exchange final rule, we include in the definition of "reasonably compatible" that the "difference or discrepancy does not impact the eligibility of the applicant, including the amount of advance payments of the premium tax credits or category of cost-sharing." This definition allows for Exchange flexibility in verifying application information, and where appropriate, the final rule provides for a more prescriptive reasonable compatibility standard, in reference to specific verifications. We believe it is an ideal approach to provide flexibility in the case of many verifications, but for areas in which the outcome of the

eligibility determination is sensitive to small changes, provide a more specific approach.

Therefore, we finalize the reasonable compatibility standards used in §155.320(c), with some changes described herein, and without changing the overall definition of “reasonable compatibility,” defined in §155.300(d), which is used throughout Exchange and Medicaid regulations.

For income verification, for the first year of operations, we are providing Exchanges with temporarily expanded discretion to accept an attestation of projected annual household income without further verification, as described below. Under current regulations, when data described in paragraph (c)(1)(i) of this section is available for the tax household but the attested annual household income is more than 10 percent below the annual income computed in accordance with clause (c)(3)(ii)(A) of this section, the Exchange must use annualized data from the MAGI-based income sources, specified in paragraph (c)(1)(ii), to the extent it is available, to verify the attestation of annual household income. If such data is not available or does not support the attestation, clause (c)(3)(vi)(C) specifies that the Exchange must follow the procedures specified in §155.315(f)(1) through (4), which includes requesting documentation to verify the attestation of project annual household income. The attestation is not supported by the data when the attestation is more than 10 percent below the annual income as computed using data sources. For the first year of operations, we will exercise enforcement discretion under this provision such that each Exchange will have the option, only when the attestation under (c)(3)(ii)(B) is greater than ten percent below the annual household income computed in accordance with clause (c)(3)(ii)(A) and MAGI-based income data from the sources specified in paragraph (c)(1)(ii) is unavailable to request a reasonable explanation for the discrepancy from the applicant, and if such explanation is insufficient, follow the procedures specified in §155.315(f)(1) through (4) for a statistically significant sample of the population that would otherwise be subject to such

procedures under clause (c)(3)(vi)(D). For those individuals who are not part of this sample, the Exchange may accept the attestation of projected annual household income without further verification for purposes of the Exchange's eligibility determination. We expect that any Exchange that exercises this option will monitor the process closely and adjust the targeting and size of the sampled population as needed to ensure an effective verification process. We note that we believe this exercise of enforcement discretion concerning the Exchange's obligations to verify income information in these specific circumstances is made in the context of all information – including the actual household income amounts for 2014 – being available at the end of the year for the reconciliation performed under section 36B(f) of the Code.

Comment: We received comments that asked if, following the 90-day inconsistency period under §155.315(f), when invoked under clause (c)(3)(vi)(C) of this section, the applicant has not responded and data sources indicate that the applicant is eligible for Medicaid or CHIP, the Exchange should notify the applicant and offer to enroll him or her in Medicaid or CHIP, in states where the Exchange can make that determination, or transmit the file to the Medicaid or CHIP agency if the Exchange cannot make that determination.

Response: This recommendation is not specific to §155.320(c)(3). However, we note that, under §155.320(c)(3)(iii), an attestation that reflects an increase compared to the tax data would generally be accepted without further verification (for purposes of eligibility for advance payments of the premium tax credit and cost-sharing reductions); therefore, if an applicant attests to a projected annual household income that would qualify him or her for advance payments of the premium tax credit or cost-sharing reductions but MAGI-based income sources indicate that income is lower than the applicant's attestation, even if such data indicates Medicaid or CHIP eligibility, the attestation would be accepted without further verification. We note that this

scenario assumes that the applicant has not attested to projected annual household income that would be consistent with eligibility for Medicaid or CHIP under the applicable MAGI standard.

Comment: One commenter expressed support for continuing to examine ways in which employer reporting under the Affordable Care Act can be streamlined both in timeframe and in the number of elements to prevent inefficient or duplicative reporting.

Response: We agree with the commenter. As stated in the proposed rule, the Administration will continue to consider ways to streamline reporting under the Affordable Care Act.

Comment: One commenter recommended that applicants should first attest to whether or not they have any offer of coverage. The commenter suggested it is unnecessary to verify enrollment in or eligibility for qualifying coverage in an eligible employer-sponsored plan for everyone who applies for insurance affordability programs. Another commenter recommended that the Exchange only ask for general information about employee contributions to the employer-sponsored plan, eligibility for the plan, and whether the plan provides minimum value rather than specifically identifying to the employer the particular employee who has requested premium tax credits.

Response: We appreciate the commenter's suggestion regarding ways to expedite the application process, and are working to consider similar suggestions received based on the public comment period for the single, streamlined application. To this end, we have designed the employer-sponsored coverage section of the single, streamlined application to ask a threshold question of whether the individual has an offer of coverage through a job, including an offer through a spouse or parent's job and then if the answer is "no," allow the individual to skip the remaining employer-sponsored coverage questions on the application. We will also collect employer contact information as necessary to send the employer notice described in §155.310(h).

The paper application for enrollment in a QHP through the Exchange and insurance affordability programs can be found at:

http://www.cciio.cms.gov/resources/other/Files/AttachmentC_042913.pdf.

Comment: We received several comments regarding available data sources proposed in §155.320(d)(2). Some commenters suggested that HHS work on developing an employer-sponsored coverage data source that would be available to states at a significantly reduced cost.

One commenter specifically recommended that data sources that reflect information regarding employment be used as a point of information for applicants only, and not as a basis for identifying an inconsistency that must be resolved to maintain eligibility. The commenter suggested that relying on employment data to support the verification of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan may create a barrier to coverage and unduly delay enrollment of eligible applicants.

One commenter requested that data regarding federal employment as specified in §155.320(d)(2)(ii) be made available through the federal data services hub and requested that HHS release a technical description of the service as soon as possible.

Response: As one commenter noted, HHS conducted an extensive search of available data sources and found that no comprehensive data source will be available by October 1, 2013. Current legislative and operational barriers prohibit HHS from requiring employers to report information directly to Exchanges or requiring Exchanges to obtain employer data from the Internal Revenue Service. The proposed rule included an interim solution to support this verification until a more robust verification process can be developed. We remain committed to working with any interested parties on solutions that make employer reporting more efficient.

We agree with the comment above suggesting that employment data not be used as the basis for generating inconsistencies or identifying individuals for inclusion in the sample-based review, since it is not specific to employer-sponsored coverage. Accordingly, we do not believe that it is necessary to specify the use of employment data, and so are removing paragraph (d)(2)(iv) and modifying paragraph (d)(3)(iii) to remove the provision specifying that the Exchange will obtain employment data. We clarify that notwithstanding this deletion, Exchanges may use employment data as a tool to assist consumers in providing accurate attestations to the Exchange regarding employer-sponsored coverage.

Lastly, we are currently working with our federal partners at the Office of Personnel Management to develop a service through the hub to verify data regarding federal employment as is necessary to implement proposed 155.320(d)(2)(ii). We expect to release a detailed technical description of this service in the near future.

Comment: We received several comments on the pre-enrollment template developed to assist consumers with collecting information related to eligibility for qualifying coverage in an eligible employer-sponsored plan. Many commenters expressed support for the voluntary template and efforts to facilitate employers reporting such information to Exchanges. One commenter suggested that employers pre-populate the form and distribute it online to employees without being specifically requested to do so by individual employees. Another commenter expressed concern over asking employees to gather information from employers, suggesting that it could pose problems and force employees not to seek Exchange coverage.

A few commenters suggested ways to implement the template including providing the template on the date of hire or in conjunction with other information about employer-sponsored coverage provided by the employer to employees. One commenter suggested large employers have an incentive to report this information to employees to avoid having employees request

information from them on an individual basis. Another commenter suggested that the template would need to allow employers to report multiple premium contributions and/or plan actuarial values.

Response: We developed the pre-enrollment template, which is a tool to help an individual complete the questions related to employer-sponsored coverage on the single, streamlined application, based on extensive input from employers and other stakeholders. While the use of the template is voluntary, we believe it will facilitate the collection of related employer-sponsored coverage information from employers, and in doing so, streamline the application process, and increase the accuracy of eligibility determinations. To this end, we also note that employers have the option of combining the employer coverage tool with the notice specified under section 18B of the Fair Labor Standards Act, as added by section 1512 of the Affordable Care Act found at this link, <http://www.dol.gov/ebsa/pdf/FLSAwithplans.pdf>. As noted in the proposed rule, we also anticipate that employers will find additional ways to provide this information to their employees, including posting this pre-populated tool on a company website, or making this information available during benefit fairs, and we are supportive of additional efforts by employers to disseminate this information efficiently. The employer coverage tool can be found at:

http://cciio.cms.gov/resources/other/Files/AttachmentC_042913.pdf.

Comment: Several commenters generally supported the sampling approach proposed in §155.320(d)(3)(iii) and noted that contacting the employer directly is the most accurate and efficient way to verify information regarding access to qualifying employer-sponsored coverage. One commenter specifically supported the proposed approach to rely on the Exchange to reach out to employers for information about employer-sponsored coverage rather than relying on individuals to get the information from their employer.

Some commenters expressed concern over the sampling approach, suggesting the process was burdensome for employers and Exchanges. Commenters urged HHS to develop sampling procedures that are as unobtrusive as possible and do not create confusion for an individual or an individual's employer. One commenter urged the Administration to encourage States to use uniform processes in conjunction with HHS. One commenter recommended that final regulations specify timelines and specific information required for employer responses under §155.320(d)(3)(iii). Another commenter also recommended that final regulations permit employers to designate third-party administrators to respond and act on their behalf for the sample-based review.

Some noted that contacts to employers create risks for employees who may have a very weak position or status with employers. Some commenters suggested that employees should be able to opt out of having the Exchange contact their employer. One commenter suggested that any verification process adopted by HHS should not invite retaliation against employees in any way. Another commenter suggested that the notice to employers in §155.310(h) communicate that employers are explicitly prohibited from retaliating against employees and provide accessible information about how employees may pursue a complaint or seek redress, including the time limit for filing a complaint.

Response: We believe the sampling approach proposed in §155.320(d)(3)(iii) is the best interim approach for effectively completing this verification while minimizing burden on Exchanges and employers. As noted in the proposed rule, we believe that employers are in the best position to provide information regarding the employer-sponsored coverage that they offer to their employees. We maintain the approach of relying on Exchanges to reach out to a select number of employers to verify applicant information with some minor clarifications.

We also appreciate the concerns raised related to burden on Exchanges and employers. We intend for Exchanges to contact employers in a standardized manner and only ask for information that is necessary for verifying access to qualifying employer-sponsored coverage. We do not include a timing standard for employers to respond to Exchange inquiries; however we expect that employers will respond to Exchange inquiries in a timely manner. With that stated, as proposed and finalized in §155.320(d)(3)(iii)(F), after a period of 90 days, the Exchange will conclude the sample-based review.

Regarding the recommendation that final regulations permit employers to designate third-party administrators to respond and act on their behalf for this verification, we note that this rule finalizes standards related to Exchanges and therefore standards regarding activities of employers are outside the scope of this regulation. However, we believe that this would be a feasible approach, as long as it is consistent with any other authorities that may govern the delegation of employer responsibilities to other entities.

We also acknowledge the comment expressing the concern that contacting employers might create risks for employees who may have a very weak position or status with employers. Section 18C of the Fair Labor Standards Act, as added by section 1558 of the Affordable Care Act, provides protections for employees that prohibit discrimination because the employee has received advance payments of the premium tax credit or cost-sharing reductions, and for other specified reasons.

Allowing an individual to opt out of the sampling process under §155.320(d)(3)(iii) would prevent the Exchange from receiving accurate information for some individuals and increase the potential for a tax liability for the tax filer at tax filing. The opt-out process would also compromise the randomness, and potentially the statistical validity of the sample. Accordingly, we do not adopt this suggestion.

Comment: We received several comments strongly supporting the approach in §155.320(d)(3)(iii)(C), reflecting the statutory requirement in section 1411(e)(4) of the Affordable Care Act, allowing an individual to receive advance payments of the premium tax credits and cost-sharing reductions during the 90-day sampling period if the individual is otherwise qualified. One commenter supported the recognition that applicants should be made aware that any advance payments of the premium tax credit could be subject to reconciliation. We also received comments in support of the provision in §155.320(d)(3)(iii)(F) allowing the Exchange to use an applicant's attestation if no information is received from the employer. Another commenter noted that the burden of resolving inconsistencies should fall first on the Exchanges and only reach individuals when the Exchanges have exhausted all available means to resolve the inconsistency.

Response: We believe it is important for the eligibility determination process to be consistent in how and when the Exchange requests supporting documentation throughout the eligibility determination process and to avoid unnecessary delay in eligibility determinations. We agree with commenters regarding the importance of collecting an attestation from a tax filer regarding his or her understanding of reconciliation prior to making advance payments of the premium tax credit, and therefore maintain this in the final rule. Additionally, we are finalizing our proposal to rely on an applicant's attestation if the Exchange is unable to obtain the necessary information from an employer.

Comment: One commenter was concerned that the timeframe for employers to provide information (within 90 days of notice regarding the Exchange's intent to verify the applicant's enrollment in an eligible employer-sponsored plan or eligibility for qualifying coverage through an eligible employer-sponsored plan) is too long and recommended shortening this period to 30 days.

Response: In proposed section §155.320(d)(3)(iii), which we maintain in the final rule, we provide that an Exchange will proceed with an applicant's eligibility determination during the sampling process and ensure that advance payments of the premium tax credit and cost-sharing reductions are provided on behalf of an applicant who is otherwise qualified for such payments and reductions. This process is intended to ensure that eligibility determinations are not delayed due to the Exchange not being able to contact an employer. Under our authority under section 1411(a) and (d) of the Affordable Care Act and after consideration of a shorter timeframe, we came to the conclusion that 90 days is consistent with other similar processes, such as the inconsistency period specified in §155.315(f), and will also allow an appropriate opportunity for receiving a response from employers.

Comment: Commenters supported the option to allow an Exchange to fulfill the requirements of this verification by relying on HHS to perform it. One commenter noted that this option is particularly helpful as no acceptable data sources will be available in their state by October 1, 2013. One commenter was pleased with this provision, noting that it welcomed efforts to reduce administrative and cost burdens involved with Exchange eligibility determination processes. One commenter expressed the need for more information from HHS specifying the steps it will take to complete this verification, and detail on the particular information HHS anticipates it will need. One commenter suggested a provision be included in the agreement between HHS and the Exchange to hold applicants harmless if a glitch in communication occurs. The commenter also suggested that consumers should not be required to submit duplicative information. One commenter asked that HHS consider expanding its employer-sponsored plan enrollment and eligibility verification process to include the sending of notices to individuals and employers described in §155.310(g) and (h), which occurs after an eligibility determination is made.

Response: After reviewing and considering the appropriate public comments and completing a technical analysis, we have concluded that the service described in the proposed rule is not feasible for implementation for the first year of operations. This service would involve a large amount of systems development on both the state and federal side, which cannot occur in time for October 1, 2013. As such, in the final rule, we maintain the proposed language, with a clarification that the option to rely on HHS to perform this verification is effective for eligibility determinations that are effective on or after January 1, 2015—meaning that the Exchange will be able to rely on HHS to perform this function as part of the eligibility determination system under section 1411 of the Affordable Care Act beginning with open enrollment for the 2015 plan year.

To provide relief to state-based Exchanges that were planning to rely on this service, we note that we are also delaying the date by which an Exchange must implement the sample-based review. For eligibility determinations for insurance affordability programs that are effective before January 1, 2015, we added paragraph (d)(3)(iv) to specify that if the Exchange does not have any of the information specified in §155.320(d)(2)(i) through (d)(2)(iii) for an applicant, the Exchange may accept the applicant's attestation regarding enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested without further verification, instead of following the procedure in §155.320(d)(3)(iii).

While we believe it is important for Exchanges to implement the procedure in §155.320(d)(3)(iii) to support program integrity and minimize financial risks on behalf of the tax filer at reconciliation, we acknowledge that some Exchanges may not have the resources and operational capability to conduct the sampling process in the first year. We note that the FFE will implement the verification process as specified in §155.320(d).

For October 1, 2013, we expect that Exchanges will use OPM data provided by HHS and available through the hub and SHOP data available through the SHOP that corresponds to the individual market Exchange to identify inconsistencies with attested information, and follow the process established in §155.315(f) to resolve any such inconsistencies. We plan to continue working closely with Exchanges, and may propose regulatory amendments as necessary, to implement an increasingly effective verification process over time.

We also note that we considered whether the distribution of notices could be part of a future service performed by HHS. The eligibility notices cited by the commenter involve information beyond what is involved with this verification service, including individual eligibility results, and the commenter's proposal therefore would add significant complexity to an already-complex service. Accordingly, we are finalizing this provision as proposed.

Comment: We solicited comment regarding the feasibility of making the necessary systems connections to support the verification of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan by October 1, 2013, and whether alternative approaches should be considered for the first year of operations. Several commenters expressed general support of the approach to verifying access to qualifying employer-sponsored coverage. However, one commenter expressed concern over the complexity of the verification procedures and questioned whether Exchanges will be able to implement these processes consistently by October 1, 2013. A small number of commenters recommended that HHS consider limiting verification to those situations in which it is essential to comply with the Affordable Care Act. One commenter agreed with the recommendation that the proposed strategy for verification should be temporary and that it should be revisited in 2016 when more data become available.

Response: We appreciate feedback from commenters on the proposed approach. We acknowledge the timing concerns with implementing the policies in the proposed rule for October 1, 2013 and will continue to work with Exchanges to develop interim solutions within the general construct of these regulations and related guidance. We believe that the proposed approach is minimally burdensome, particularly based on the approval of use of a sample-based review provided in §155.320(d)(3)(iii) instead of an inconsistency process, and another approach would necessitate manual review for a larger number of individuals. Accordingly, in the final rule, we maintain the provisions proposed in §155.320(d) with continued anticipation that the strategy will evolve as additional data and data sources become available and as more information is gained when the sample-based review is implemented.

Comment: One commenter recommended that HHS allow Exchanges the flexibility to define the factors that would trigger the sample-based review and how to conduct the necessary investigations. Another commenter proposed that Exchanges should have flexibility to use whatever information they have at their disposal to identify individuals who are likely to have employer-sponsored coverage and to conduct a minimum number of follow up reviews.

Response: We recognize that some Exchanges may have access to additional data sources that could be useful for these purposes. We note that proposed §155.320(d)(2)(i), which we are finalizing as proposed, allows the use of electronic data sources that are approved by HHS, which could include state-based or state-developed data sources. We encourage states to work with HHS to incorporate these data sources and other existing processes into the Exchange verification process.

Comment: We received several comments on standards related to notices proposed throughout §155.320. Commenters suggested that any notices be clearly written in plain language at an appropriate reading level for employees with limited education and LEP

individuals. One commenter recommended that notice of applicants' appeal rights be provided to applicants if information from an employer results in a change to their eligibility status.

Specifically regarding the notice described in §155.320(d)(3)(iii), one commenter suggested the notice clearly specify that the employee was selected as part of a purely random sample, rather than due to any indication of misinformation or inappropriate action on the part of the employee. Additionally, one commenter supported HHS developing notices and otherwise educating employers to help employers understand their potential tax liabilities. Finally, one commenter urged Exchange personnel, Navigators, certified application counselors and all consumer assistance personnel to be trained on these verification procedures.

Response: All notices described in this part are subject to the general notices standards under §155.230, which include standards related content provided in the notice, including notice of appeal rights, and that the notices must conform to accessibility and readability standards. We agree that information regarding this verification will be important for Navigators and other entities helping consumers apply for coverage and intend to include information about this verification process related in training materials and other guidance documents produced by HHS.

Comment: One commenter raised concerns over the potential for confusion that could result from unnecessary notifications to employers by Exchanges, for example, when employers receive the notice specified in §155.310(h) regarding potential tax liability under §4980H of the Code even though the employer may not in fact have any tax liability.

Response: The proposed rule did not modify the requirements related to the employer notice as described in §155.310(h) and therefore the comment is outside of the scope of this rule.

Comment: One commenter recommended that the verification process and information supplied should be considered confidential, and recommended that the final rule include

language clarifying this and prohibiting the sharing of this information with anyone not directly required to verify the information. The commenter specified that the employer representative verifying the information at request of the Exchange should be prohibited from sharing the Exchange's request for the information with any person not directly responsible for providing the information.

Response: We agree with the suggestion that information supplied during the verification process described in §155.320(d)(3)(iii) should be protected and not disclosed to unauthorized parties. When an Exchange reaches out to an employer to confirm whether an applicant is enrolled in an eligible employer-sponsored plan or eligible for qualifying coverage in an eligible employer-sponsored plan, we do not intend for the Exchange staff to disclose the employee's household income or any other taxpayer information, except the employee's name or other identifying information. The employer would need to identify the employee to provide the Exchange with information about the plan options available to the employee. The Exchange would rely on information provided by the employee or employer when communicating with the employer, so that only the appropriate employer representatives are consulted during the sample-based review. We also note that like all information created, collected, used, or disclosed by the Exchange, information regarding employer-sponsored coverage is subject to the privacy and security protections established in §155.260.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.320(c) without modification. We are finalizing the provisions proposed in §155.320(d), with a few modifications. In paragraph (d)(2)(iii), we clarify that the Exchange must obtain any available data from the SHOP that corresponds to the state in which the Exchange is operating. In paragraph (d)(3)(iii), we modify language to specify that the Exchange must select a statistically significant random sample of

applicants for whom the Exchange does not have any of the information specified in paragraphs (d)(2)(i) through (d)(2)(iii). Based on comments suggesting that employment data only be used to prompt applicants to encourage accurate attestations, we removed paragraph (d)(2)(iv).

Additionally, we clarified paragraph (d)(4) to specify that the ability for the Exchange to satisfy the provisions of paragraph (d) by relying on HHS is effective for eligibility determinations for advance payments of the premium tax credit and cost-sharing reductions that are effective on or after January 1, 2015, and to clarify that the division of responsibilities under this option is subject to guidance issued by the Secretary. To accommodate this change, we added paragraph (d)(3)(iv) to clarify that for eligibility determinations for advance payments of the premium tax credit and cost-sharing reductions that are effective before January 1, 2015, if the Exchange does not have any of the information specified in paragraphs (d)(2)(i) through (d)(2)(iii) for an applicant, the Exchange may accept an applicant's attestation regarding enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested, without further verification under paragraph (d)(3)(iii) of this section. Additionally, we deleted paragraph (d)(4)(iv) to remove the agreement associated with having HHS conduct this verification. Finally, we removed paragraph (e) and redesignated paragraph (f) as paragraph (e). As a result of the consolidation of former paragraphs (d) and (e) in paragraph (d) of this final rule, we also make a technical correction to §155.615(f)(2)(i) to modify the cross-reference in that provision to reference §155.320(d).

12. Eligibility redetermination during a benefit year (§155.330)

In §155.330, we proposed to amend paragraph (d)(1) to clarify that the Exchange would only conduct periodic examination of data sources to identify eligibility determinations for Medicare, Medicaid, CHIP, or the BHP, for enrollees on whose behalf advance payments of the

premium tax credit or cost-sharing reductions are being provided. We also proposed revising paragraph (e) to specify how the Exchange would proceed when data matching indicates that an individual is deceased, such that the Exchange would modify eligibility status to account for the data after 30 days without a response to the notice sent. In situations where the Exchange identifies updated information regarding income, family size, or family composition, except information regarding death, we clarified that the enrollee-reported information would be subject to verification.

We also solicited comments about adding a provision to specify that Exchanges would include language in the eligibility determination notice after a redetermination resulting in a change in an enrollee's level of cost-sharing reductions to also describe the specific changes to an enrollee's deductible, co-pays, coinsurance, and other forms of cost-sharing reductions if they remained enrolled in the same QHP.

We proposed to amend paragraph (f) to incorporate changes as a result of eligibility appeals decisions, as well as changes that affect only enrollment or premiums, but do not affect eligibility. The proposed changes to paragraph (f) were designed to align eligibility effective dates and enrollment effective dates with one another, and to accommodate the limited situations in which retroactive eligibility may be necessary.

In paragraph (f)(1), we proposed that changes resulting from a redetermination, from an appeal decision, or affecting enrollment or premiums only, be implemented on the first day of the month following notice of the change. In paragraph (f)(2), we proposed that the Exchange may determine a reasonable point in a month, no earlier than the 15th, after which a change will not be effective until the first day of the month after the month specified in paragraph (f)(1).

In paragraph (f)(3), we proposed that the Exchange must implement changes resulting in a decreased amount of advance payments of the premium tax credit or cost-sharing reductions

that occur after the 15th of the month, on the first day of the month after the month specified in paragraph (f)(1). In paragraph (f)(4), we proposed that the Exchange must implement changes that result in an increased level of cost-sharing reductions that occur after the 15th of the month, on the first day of the month after the month specified in paragraph (f)(1). Changes that result in an increased amount of advance payments of the premium tax credit would be implemented under paragraphs (f)(1) and (f)(2).

In paragraph (f)(5), we proposed that the Exchange implement a change associated with birth, adoption, placement for adoption, marriage, or loss of minimum essential coverage, on the coverage effective dates described in §155.420(b)(2)(i) and (ii). In paragraph (f)(6), we proposed that the Exchange may implement a change associated with the events described in §155.420(d)(4), (d)(5), and (d)(9) on an effective date that is based on the specific circumstances of each situation. In redesignated paragraph (f)(7), we proposed to maintain the existing language of what was originally paragraph (f)(3).

Comment: Commenters expressed general support for HHS' proposal regarding when the Exchange determines through periodic data matching that an individual is deceased. One commenter sought clarification about whether the Exchange could terminate coverage retroactively to the date of death to align with non-group market standards.

Response: In response to comments, we clarify in finalizing §155.430(d) that the Exchange will terminate coverage retroactively to the date of death. This revision is discussed in more detail in the response to comments regarding that provision below.

Comment: Multiple commenters expressed strong support for including a provision in the final rule such that Exchange would include language regarding a change in an enrollee's level of cost-sharing reductions as a result of a redetermination in the eligibility determination notice sent to the enrollee. Several commenters requested that the notice also include

information about the enrollee's eligibility for a special enrollment period as well as the deadline to make a decision to select a new plan if they so desired. Commenters also recommended that the notice include the potentially negative financial impact of changing QHPs. One commenter requested additional guidance regarding the implementation of cost-sharing reductions generally, and another stated that it could not comply with such a proposed change in Exchange design at this stage.

Response: We clarify that §155.230(a)(1) specifies that the Exchange will provide language in the eligibility determination notice to the enrollee explaining the action reflected in the notice, which in this case includes the fact that an enrollee has been determined eligible for a new cost-sharing reduction level, his or her eligibility for a special enrollment period, the requisite deadlines, and the possible ramifications if an enrollee decides to change QHPs (for example, deductible resetting, whereby an individual who had accrued expenses towards the deductible cap for his or her previous QHP would have to start again from \$0 in making cost-sharing payments towards the deductible and out-of-pocket limit). Since regulations do not specify that the Exchange will provide detailed, plan-specific information on cost-sharing reductions after initial plan selection, we will not require that it be provided by the Exchange when a change occurs. Rather, we expect that QHPs will make this information available. We will also not specify that the Exchange will describe the specific changes that could occur in different plans, which could require as many variations as there are plans. Exchanges maintain the flexibility to provide more detail. HHS provided general guidance regarding the implementation of cost-sharing reductions in subpart E of the final Payment Notice at 78 FR 15410, 15474 et. seq.

Comment: Commenters generally supported the effective dates we proposed in §155.330(f). Several commenters urged HHS to prioritize continuity of coverage in defining

effective dates. Other commenters cautioned against requiring eligibility effective dates that would necessitate the return or repayment of claims, premiums, advance payments of the premium tax credit, or cost-sharing reduction payments.

Response: We appreciate the importance of continuity of coverage, as well as the importance of clarity for consumers. As such, we are finalizing the provisions proposed in §155.330(f), with two modifications for clarity. First, we consolidate the provisions formerly proposed in §155.330(f)(3) and §155.330(f)(4) into a single provision covering decreases in advance payments of the premium tax credit and changes in cost-sharing reductions. Second, we remove the requirement formerly proposed in §155.330(f)(7), because the termination of coverage requirement in §155.430(d)(3) renders §155.330(f)(7) duplicative.

Comment: Commenters requested that HHS require transparency and plain language in communicating effective dates to consumers, given the complexity of changing benefits, programs, and coverage.

Response: We agree that transparency and plain language are of the utmost importance, and urge states and QHP issuers to share successful communication strategies among one another. We note that §155.230(b) specifies that all notices will be in plain language. HHS will also share model notice language for Exchanges to adapt to their specific needs.

Comment: Some commenters questioned why advance payments of the premium tax credit and cost-sharing reductions could not always be implemented as of the first of the following month.

Response: The 15th-of-the-month cutoff specified in §155.330(f)(3) concerning changes that result in a decreased amount of advance payments of the premium tax credit and changes in levels of eligibility for cost-sharing reductions aims to prevent consumers from incurring financial liabilities that may result from such changes in eligibility, which could also be very

problematic for QHP issuers to implement. However, as noted above, Exchanges have flexibility to set a reasonable cut-off date for implementing changes that result in an increased level of advance payments of the premium tax credit, such that they could always be implemented on the first day of the following month. Accordingly, we are finalizing this provision as proposed.

Comment: Some commenters sought reassurance that Exchanges would remain the system of record - the final authority on applicants' and enrollees' eligibility for enrollment through the Exchange and receipt of advance payments of the premium tax credit and cost-sharing reductions - and that all changes would be communicated to QHP issuers. Some commenters also requested flexibility for issuers to communicate changes to enrollees, consistent with current practices.

Response: Exchanges are intended to be the final authority on applicants' and enrollees' eligibility for enrollment in a QHP through the Exchange, advance payments of the premium tax credit, and cost-sharing reductions (subject to applicable appeals). As specified in §155.310(g) and §155.400(b)(1), Exchanges will communicate information about all eligibility and enrollment changes to both enrollees and their health insurance issuers in a timely fashion. We also encourage QHP issuers to communicate transparently with enrollees regarding changes to their coverage, including how changes in an enrollee's eligibility for cost-sharing reductions may affect the enrollee's out-of-pocket costs related to coverage, provided that such communications are not confusing for consumers.

Comment: Commenters supported our proposal in paragraph (f)(4) of this section to align enrollment effective dates with eligibility effective dates, but sought clarification on eligibility effective dates for individuals who opt not to select a new plan upon experiencing one of the special enrollment period triggering events described in §155.420(b)(2).

Response: We clarify that the eligibility effective dates in §155.330(f)(4) apply only in situations in which an individual uses the special enrollment period to select a plan upon experiencing one of the triggering events described in §155.420(b)(2). Eligibility for individuals who experience a change related to marriage, birth, adoption, placement in foster care, or loss of minimum essential coverage, and who opt to maintain their existing QHP, follows the effective dates otherwise specified within §155.330(f).

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.330, with some modifications. First, we clarified that the effective dates in paragraph (f)(1)(ii) are based on the date specified in the appeal decision, and removed cross-references to appeals provisions in paragraph (f)(1)(ii), as we are not finalizing provisions related to eligibility appeals at this time. However, we maintain the substance of the provision, and intend to replace the cross-references when we finalize subpart F. Second, we consolidated the provisions formerly proposed in §155.330(f)(3) and §155.330(f)(4) into a single requirement in paragraph (f)(3) for decreases in advance payments of the premium tax credit and changes in cost-sharing reductions. Third, we modified newly designated (f)(4) to clarify that the Exchange will implement a change associated with the events described in §155.420(b)(2)(i) and (ii) of this part on the effective dates described in §155.420(b)(2)(i) and (ii) of this part respectively, instead of on the first day of the following month. Fourth, we removed the requirement formerly proposed in §155.330(f)(7), because the termination of coverage requirement in §155.430(d)(3) renders §155.330(f)(7) duplicative.

13. Annual eligibility redetermination (§155.335)

In §155.335, we proposed to amend paragraphs (a), (b), (c), (e), (f), (g), (h), (k), and (l) of this section to specify that subject to the limitations specified in paragraph (l) and new paragraph (m), the Exchange will conduct an annual eligibility redetermination for all qualified

individuals, not only those who are enrolled in a QHP. Our proposal was to replace the word “enrollee” with the term “qualified individual” in these paragraphs.

We proposed to amend paragraph (b) to include data regarding Social Security benefits as defined under 26 CFR 1.36B–1(e)(2)(ii). This reflects the revision we proposed to make in §155.320(c)(1)(i)(A).

We proposed to make technical corrections to paragraph (l) to specify that, if the Exchange does not have authorization to use a qualified individual's tax information, the Exchange will redetermine the qualified individual's eligibility only for enrollment in a QHP through the Exchange.

We proposed to add new paragraph (m), which would provide that, if a qualified individual does not select a QHP before the redetermination described in this section, and is not enrolled in a QHP through the Exchange at any time during the benefit year for which such redetermination is made, the Exchange must not automatically conduct a subsequent redetermination of his or her eligibility for a future benefit year.

Comment: Commenters supported HHS’ proposal to allow all qualified individuals to be redetermined for eligibility for enrollment in a QHP through the Exchange, regardless of whether they have enrolled in a QHP through the Exchange during the coverage year. Several commenters recommended omitting §155.335(m), the special rule, to allow states to continue redeterminations for non-enrolled qualified individuals, for at least 3 more years.

Response: We continue to believe that one redetermination for a qualified individual who does not select a QHP represents an appropriate balance between providing consumers with a streamlined ability to obtain coverage and the burden on the Exchange associated with redeterminations and on consumers who are not interested in enrolling. We intend to monitor take-up rates within the FFE and encourage state-based Exchanges to do the same, as this data

will inform whether changes to this policy might be appropriate in the future. Accordingly, we are finalizing this provision as proposed.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.335 of the proposed rule without modification, except we reserve paragraphs (c)(1) and (c)(2) as we continue to evaluate the appropriate information that will be included in the annual redetermination notice, and modify paragraph (c)(3) such that the previous reference to paragraph (c)(1), which is now reserved, instead refers to paragraph (b), which accurately refers to the updated information being retrieved by the Exchange.

14. Administration of advance payments of the premium tax credit and cost-sharing reductions (§155.340)

In §155.340, we proposed technical corrections in paragraphs (b) and (c) to replace the reference to section 36B of the Code to the applicable Treasury regulation. We did not receive specific comments on this section, and are thus finalizing the provision as proposed.

Summary of Regulatory Changes

We are finalizing the technical corrections proposed in §155.340 of the proposed rule to specify the appropriate definition of minimum value.

15. Coordination with Medicaid, CHIP, the Basic Health Program, and the Pre-existing Condition Insurance Plan (§155.345)

In §155.345, we proposed to make a technical correction to paragraph (a) to clarify that the agreements that the Exchange enters into with the agencies administering Medicaid, CHIP, and the BHP, if applicable, must include a clear delineation of the responsibilities of each “agency” as opposed to each “program.” We proposed to amend paragraph (a)(2) to specify that the agreement the Exchange enters into with other agencies administering insurance affordability

programs addresses the responsibilities of each agency to ensure prompt determinations of eligibility and enrollment in the appropriate program without undue delay, based on the date the application is submitted to, or redetermination is initiated by, the Exchange or another agency administering an insurance affordability program. We proposed to change the ordering of agencies listed for purposes of clarity. We also proposed to redesignate paragraph (a)(3) as paragraph (a)(4), and add a new paragraph (a)(3) to ensure that, as of January 1, 2015, the agreement delineates responsibilities for the provision of a combined eligibility notice, as defined in §435.4, to individuals and members of the same household, to the extent feasible, for enrollment in a QHP through the Exchange and for all insurance affordability programs. Section 155.345(a)(3)(i) proposed that prior to January 1, 2015, the notice include coordinated content, as defined in §435.4, while §155.345(a)(3)(ii) and (g)(7) addressed the implementation of a combined eligibility notice requirement as of January 1, 2015.

We proposed a phased-in approach for the provision of a combined eligibility notice in cases where the Exchange is performing assessments of eligibility for Medicaid and CHIP based on MAGI.

We noted that, based on the operational readiness of the Exchange and other agencies administering insurance affordability programs, combined eligibility notices may be implemented earlier than January 1, 2015, but that in states where the FFE is conducting assessments rather than final determinations of eligibility, the FFE will only be able to provide an eligibility notice that includes coordinated content prior to January 1, 2015 (and not combined eligibility notices) for eligibility determinations made by the FFE.

We proposed to make a technical correction in paragraph (f) to cite to the applicable Treasury regulation instead of Section 36B of the Code.

We proposed a series of technical corrections throughout paragraphs (f) and (g) to clarify various provisions and to redesignate paragraphs as necessary to accommodate the changes described in the proposed rule. We proposed to add paragraph (g)(7) to require combined eligibility notices effective January 1, 2015.

Comment: We received comments recommending that notices be consolidated and coordinated for all family members applying together even when individuals are eligible for different programs, at the very least for the initial eligibility determination notice. Commenters suggested that all notices need to clearly state by name all individuals to whom the notice applies, especially when notices are regarding termination. Some commenters indicated that the notice with coordinated content should clearly inform an individual what he or she is or may be eligible for, and should never begin with the ineligibility information. Commenters suggested that all agreements between the Exchange and the agencies administering Medicaid and CHIP be approved by HHS and be made publicly available, including on a public website. Some commenters stated that the public should be given an opportunity to provide input on the agreements and any changes that are made to the agreements.

Response: We are finalizing this section as proposed, with minor modifications to reserve two provisions for finalization at a future date. We anticipate that initial eligibility determination notices will be consolidated for family members who apply together. Additionally, we expect that information about the program for which an individual is eligible, if any, will be displayed in notices before information about programs for which the individual is not eligible. We are reserving paragraphs (a)(3) and (g)(7), regarding coordinated content and combined notices, respectively, which we intend to finalize at a later date with the parallel Medicaid provisions. The Federally-facilitated Exchange will provide coordinated content in notices for October 1, 2013. We will take these recommendations into consideration as we

develop model eligibility determination notices. We are not specifying that agreements between Medicaid and CHIP agencies and Exchanges be approved by HHS, as we think that the standards included in regulation represent an appropriate level of federal oversight at this time. However, we will work with Exchanges to monitor operations over time, and reevaluate this decision as needed.

Comment: Many commenters expressed support for combined eligibility notices. Some commenters expressed general support of the phased in approach for combined eligibility notices, but strongly recommended minimizing the delay in the implementation of combined notices so that it only affects the initial annual open enrollment period. Commenters suggested that the requirement for a combined eligibility notice should be effective for redetermination notices and eligibility notices for the open enrollment period beginning on October 15, 2014. Some commenters were supportive of the January 1, 2015 implementation date of combined eligibility notices, while others recommended a January 1, 2016 implementation date. One commenter recommended that the effective date be set as January 1, 2014, and that HHS allow those states that cannot update their technology in time for January 2014 to seek approval from HHS for delaying implementation, rather than a nationwide delay in implementation. Many commenters asked HHS to reiterate that the phased-in approach does not diminish the principles of the Affordable Care Act to promote coordination between the Exchange, Medicaid, and CHIP, beginning in October 2013.

Response: We appreciate commenters' suggestions. We intend to finalize this provision at a future date with the parallel Medicaid provision, and so have reserved paragraph (g)(7) for the purposes of this rule. The Federally-facilitated Exchange will provide coordinated content in notices for October 1, 2013.

Comment: Several commenters noted that state flexibility is important in determining when to issue combined or separate, coordinated eligibility notices. One commenter opposed the requirement for agencies administering insurance affordability programs to provide coordinated content in notices before January 1, 2014, and specifically recommended that at initial annual open enrollment each agency should be responsible for issuing its own eligibility determination notice based on the eligibility determination completed for the program or programs that agency administers, without regard for the other insurance affordability programs. Many other commenters, however, expressed support for a coordinated eligibility notice prior to the implementation of a combined eligibility notice. Another commenter believed that the state is best suited to determine which agency should provide the notice of eligibility determination, and opposed to the requirement under §155.345(a)(3)(ii) that the combined eligibility notice be provided by the agency that makes the last determination of eligibility. One commenter noted that HHS should consider additional situations where a combined eligibility notice is feasible, but not beneficial to the applicant(s). Another commenter suggested that HHS consider additional flexibility for notices to be sent immediately for consumers who receive a final eligibility determination, and include an explanation in the notice about the status of any other determinations that are in progress for other applicants in the household.

Many commenters stated that HHS should ensure that the combined eligibility notice includes complete information about Medicaid appeal rights. Other commenters stated that the combined eligibility notice should include a statement that the individual might be eligible for additional benefits and more affordable coverage through Medicaid, and specify how the individual can be screened for Medicaid eligibility.

Response: In the proposed rule, HHS noted two situations in which the combined eligibility notice would not be advantageous for consumers, and HHS sought comment on

additional situations in which the combined eligibility notice would not be advantageous. As one commenter suggested, HHS explained one situation in which a combined eligibility notice is not appropriate is where multiple family members apply together, and some members receive a final eligibility determination while other members need to be transferred to a different agency for a final determination to be made for other insurance affordability programs. We will work closely with states to determine when the issuance of a combined eligibility notice is not appropriate, including situations in which it is not advantageous for the last agency that makes a determination of eligibility based on MAGI to issue a combined eligibility notice. Furthermore, we clarify that while the Exchange will make determinations or assessments of MAGI-based eligibility for Medicaid and CHIP in accordance with §155.305(c) and (d), and §155.302(b), the Exchange is not required to complete the Medicaid and CHIP enrollment process for eligible individuals.

We expect that combined eligibility notices will include a description of appeal rights in accordance with §155.230(a)(5), including Medicaid appeal rights, as well as information about how an individual can request a full eligibility determination from the state Medicaid or CHIP agency. And, as noted above, we intend to finalize paragraphs (a)(3) and (g)(7) at a future date alongside parallel Medicaid provisions, and we are reserving these paragraphs for the purposes of this final rule.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.345 of the proposed rule with a few minor modifications. We reserve §§155.345(a)(3) and (g)(7) for finalization at a later date. Pursuant to the discussion in the preamble associated with 42 CFR 431.10(c) and (d), we add new paragraph (h) to clarify that the Exchange and the Exchange appeals entity must adhere to the eligibility determination or appeals decision for Medicaid or CHIP made by the State

Medicaid or CHIP agency, or the appeals entity for such agency, which is consistent regardless of whether the Exchange is making eligibility determinations or assessments for Medicaid and CHIP. Accordingly, we redesignate previous paragraphs (h) and (i) as paragraphs (i) and (j).

16. Special eligibility standards and process for Indians (§155.350)

In §155.350, we proposed to make a technical correction in paragraph (a)(1) to replace the reference to section 36B of the Code with a reference to the applicable Treasury regulation. We did not receive specific comments on this section, and are thus finalizing the provision as proposed.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.350 of the proposed rule without modification.

17. Enrollment of qualified individuals into QHP's (§155.400)

In §155.400, we proposed to add paragraph (b)(3) to clarify the requirement that the Exchange send updated eligibility and enrollment information for all enrollment-related transactions to HHS promptly and without undue delay. This added further specificity to the existing requirement that the Exchange send eligibility and enrollment information to HHS under paragraph (b)(1) of this section. After considering several comments in response to this proposal, we are finalizing the provision as proposed.

Comment: Commenters were supportive of the proposal that the Exchange would send updated information for all enrollment-related transactions to HHS promptly and without undue delay. One commenter sought clarification about cancellations, and wanted to ensure that QHP issuers did not violate the Affordable Care Act's ban on discrimination in coverage of benefits related to preexisting conditions. Another commenter inquired about whether the specific issuer

reporting requirements associated with this provision may vary according to the different Exchange models.

Response: We note that the cancellations by QHP issuers referred to in the preamble to this provision in the proposed rule could occur for various reasons, such as when an individual voluntarily cancels his or her health insurance selection before the coverage effective date. In terms of issuer reporting requirements, each Exchange maintains flexibility to determine its own issuer reporting requirements relative to enrollment transactions, consistent with the law and applicable regulations. This provision specifically addresses only the requirement that the Exchanges report updated eligibility and enrollment information to HHS.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.400 of the proposed rule without modification.

18. Special enrollment periods (§155.420)

In §155.420, we proposed to clarify the scope of the special enrollment periods throughout this section and add paragraph (a)(2) clarifying that our usage of “dependent” refers to any individual who is or who may become eligible for coverage under the terms of a QHP because of a relationship to a qualified individual enrollee.

We proposed to amend paragraph (b) to specify that the effective dates described therein apply both to qualified individuals first enrolling in a QHP through the Exchange through a special enrollment period, as well as to current enrollees. As the effective dates regarding advance payments of the premium tax credit and cost-sharing reductions are now addressed in §155.330(f), we proposed removing such language in paragraph (b)(2)(i). We also solicited comments as to whether we should expand the special effective dates in paragraph (b)(2)(i) concerning birth, adoption, or placement of adoption to cover children placed in foster care as

well, which would also necessitate a corresponding change to the triggering events described within paragraph (d)(2) that specifically address that special enrollment period.

We proposed to add paragraph (b)(2)(iii) regarding the effective dates for a special enrollment period under paragraphs (d)(4), (d)(5), and (d)(9) to align with a similar provision proposed in §155.330(f). This would ensure that the Exchange could tailor an effective date based on the circumstances surrounding an error by the Exchange, a contract violation by the QHP issuer, or other “exceptional circumstances”.

To align the effective dates under this section with the effective dates for eligibility as proposed in §155.330(f), we proposed to add paragraph (b)(4) to ensure that the Exchange adhere the modified effective dates related to advance payments of the premium tax credit and cost-sharing reductions proposed in §155.330(f). As such, we proposed to remove language in paragraphs (b)(2) and (b)(3) that previously addressed this issue.

We also proposed to amend paragraph (d) to specify which triggering events will allow a qualified individual or enrollee, or his or her dependent to qualify for a special enrollment period. This was designed to permit all members of a household, in certain situations, to enroll in or change QHP’s together in response to an event experienced by one member of the household, and we proposed technical corrections throughout paragraph (d) to ensure that the revised language allows for the dependent to qualify for a special enrollment period as well, subject to whether the QHP covers the dependent. While we did not modify the scope of each triggering event described within paragraph (d), we solicited comments regarding whether we should permit such movement of related individuals for other special enrollment periods.

We proposed to add language specifying that the triggering event in the case of a QHP decertification is the date of the notice of decertification, whereas the triggering event in all other

cases associated with a qualified individual or his or her dependent losing minimum essential coverage is the date the individual or dependent loses eligibility for minimum essential coverage.

We also proposed to amend paragraphs (d)(6)(i) and (ii) to specify that the Exchange will provide a special enrollment period for an enrollee or his or her dependent enrolled in the same QHP who is determined newly eligible or newly ineligible for advance payments of the premium tax credit or who experiences a change in eligibility for cost-sharing reductions. We also modified the language within paragraph (d)(6)(iii) to allow a qualified individual or his or her dependent who is enrolled in qualifying coverage in an eligible employer-sponsored plan and who are determined newly eligible for advance payments of the premium tax credit to qualify for this special enrollment period prior to when he or she will cease to be eligible for qualifying coverage in an eligible employer-sponsored plan, provided that eligibility for advance payments of the premium tax credit and cost-sharing reductions are not available for an individual who is enrolled in an eligible employer-sponsored plan. Allowing these qualified individuals or dependents to be determined eligible for this special enrollment period up to 60 days prior to the end of his or her employer-sponsored coverage protects them from potential gaps in coverage.

Finally, we proposed to add a new paragraph (d)(10) to provide a special enrollment period for a qualified individual or his or her dependent that is enrolled in an eligible employer-sponsored plan that does not provide qualifying coverage, and is allowed to terminate his or her existing coverage. The Exchange would allow such an individual to access this special enrollment period up to 60 days prior to the end of his or her coverage in an eligible employer-sponsored plan, to protect them from potential gaps in coverage.

Comment: Several commenters supported our clarification in paragraph (a) aligning the definition of “dependent” to refer to those family members that would be eligible to enroll in coverage under a QHP, and commended HHS for allowing dependents to change QHPs or enroll

in a new QHP together with their family members for certain special enrollment periods when eligible. Some commenters wanted to ensure that family members would be adequately informed about the benefits of enrolling in plans together as well as the potential drawbacks of failing to do so. However, several comments also raised concerns that this proposed definition was too plan-specific and would ultimately lead to greater confusion among families in terms of eligibility for special enrollment periods. Other commenters sought flexibility for the definition of “dependent” to correspond with state law, as opposed to a potentially narrower definition set by a QHP issuer.

Response: We believe that clarifying that the meaning of “dependent” aligns with 26 CFR 54.9801–2, the regulation implementing section 9801(f) of the Code, throughout this section, including for the special enrollment periods not specified in section 9801(f) of the Code, helps to promote efficient operations and uniform standards to guide QHP issuers and Exchanges. Furthermore, this will ensure that state laws regarding the definition of “dependent” will be maintained within the Exchange, as this does not contradict state laws, but rather corresponds with state laws that already require issuers cover certain dependents. We intend to provide the appropriate information through the eligibility determination notice to an individual and their family members to adequately inform them of all of their options when determined eligible for a special enrollment period.

Comment: Some commenters supported our proposal to expand certain special enrollment periods to dependents to allow family members to enroll in a new QHP together in response to an event experience by one member of the tax household, while others sought clarification or an expansion of this approach to other triggering events. Commenters requested clarification as to whether the proposed rules sought to limit the applicability of special enrollment periods to dependents enrolled in the same QHP with an enrollee, or to members of

the tax household who may be receiving a portion of the advance payments of the premium tax credit, as well as if paragraph (d)(2) limited the special enrollment period to only the qualified individual and the “new” dependent. Other commenters recommended that the special enrollment period in paragraph (d)(3) related to citizenship or immigration status should apply both to the individual who is newly qualified along with eligible dependents.

Response: As noted above regarding the definition of “dependent”, family members eligible to enroll in a QHP are determined eligible for a special enrollment period when specified in paragraph (d) of this section. This is not limited to only those members of a tax household on whose behalf advance payments of the premium tax credit are provided or who are enrolled in the same QHP. When a family member who experiences any of the triggering events in paragraph (d) of this section, that includes dependents in addition to qualified individuals or enrollees, selects a QHP as part of a special enrollment period, the Exchange will permit all members of the tax household to enroll together assuming they are all eligible to enroll in the particular QHP. If a specific family member experiences a triggering event, but fails to select a QHP within the relevant special enrollment period, his or her dependent does not have the ability to choose a different QHP during this period separately. Furthermore, in response to comments, we clarify that the special enrollment period in paragraph (d)(3) of this section, related to citizenship or immigration status, will apply to both the individual who is newly qualified as well as his or her dependents, if eligible for coverage under a QHP. We note that the special enrollment period described in paragraph (d)(3) only applies to an individual who was not previously a citizen, national, or lawfully present, as opposed to an individual switching between one of these statuses.

Comment: In response to HHS’ solicitation for comments regarding modifying the special effective dates in paragraph (b)(2), which correspond directly to the triggering events

described within paragraph (d)(2), many commenters urged HHS to include the placement of a foster child as a triggering event within the special enrollment period. Several commenters also raised concerns about our proposed modifications to the triggering event for the special enrollment period described in paragraph (d)(6), related to being newly eligible or ineligible for advance payments of the premium tax credit, or a change in eligibility for cost-sharing reductions. Some commenters opposed our proposal that only enrollees would be eligible for this special enrollment period if newly eligible or ineligible for advance payments of the premium tax credit instead of qualified individuals at any point during the coverage year, and recommended that we not finalize this proposal in favor of retaining the language adopted in the Exchange final rule.

Response: We appreciate the comments regarding placement in foster care as it related to special effective dates, and will add language in paragraph (b)(2) to include the placement of a foster child as one of the triggering events listed therein, as well as make the corresponding change regarding the special enrollment period in paragraph (d)(2). We note, however, that due to the availability of Medicaid to foster children, it is unclear how frequently this special enrollment period will be used. Due to ongoing considerations regarding the risk pool, we are finalizing our proposed modifications to paragraph (d)(6) to specify that this special enrollment period only applies to those individuals who are already enrolled in a QHP through the Exchange.

Comment: Multiple commenters expressed general support for the modifications we proposed to special enrollment periods throughout paragraph (d), including our proposal to allow a prospective special enrollment period for qualified individuals enrolled in eligible employer-sponsored coverage to prevent gaps in coverage. In regards to the proposed revision to paragraph (d)(6)(iii) related to employer-sponsored coverage, some commenters suggested that

the triggering event should not be limited to when an individual is enrolled in employer-sponsored coverage, but should also cover non-enrolled individuals whose offer of employer-sponsored coverage does not meet the affordability or minimum value standards. Other commenters wanted HHS to allow a qualified individual to be determined eligible for advance payments of the premium tax credit within the window of their special enrollment period, but prior to when their employer-sponsored coverage ended.

Response: We believe that individuals with an affordable offer of employer-sponsored coverage that meets minimum value should be encouraged to enroll in a plan with their employer. If after enrolling, their lowest-cost self-only plan option changes during the coverage year such that it no longer meets the affordability and minimum value standards, and an individual reports this to the Exchange, the Exchange will accordingly determine them eligible for a special enrollment period under paragraph (d)(6). As such, this provision creates incentives for individuals to enroll in affordable employer-sponsored coverage, while also minimizing potential gaps in coverage if a change in coverage occurs during the year such that an applicant would be newly eligible for advance payments of the premium tax credit if their employer terminates coverage or changes their plan options. In addition, we are consolidating proposed paragraph (d)(10), which provided a special enrollment period to an individual who was enrolled in non-qualifying coverage in an eligible employer-sponsored plan, into paragraph (d)(6) and modifying it to clarify that consistent with the eligibility standards for advance payments of the premium tax credit, the special enrollment period is available for an individual who is enrolled in any eligible employer-sponsored plan, and is not eligible for qualifying coverage in an eligible employer-sponsored plan. For example, this modification ensures that an individual who is enrolled in family coverage but for whom the lowest-cost self-only plan is unaffordable in accordance with the Code can access this special enrollment period, as intended in the proposed

regulation. We will maintain the prospective ability for an enrollee to select a QHP up to 60 days before their eligible employer-sponsored coverage ends or their employer allows him or her to drop coverage if the lowest-cost self-only plan offer is non-qualifying. We note that the Exchange cannot provide an individual with advance payments of the premium tax credit while he or she is enrolled in eligible employer-sponsored coverage, as specified in 26 CFR 1.36B-2(a)(2).

Comment: A few commenters raised concerns regarding the notice that individuals would receive if determined eligible for a special enrollment period, and wanted to ensure that the notice would prevent confusion by providing clear guidance to individuals by helping them understand the premiums they would be responsible for, and to help them enroll in a QHP in a timely fashion.

Response: The Exchange will not have information regarding actual premiums at the time of an initial eligibility determination notice, since an individual will not have selected a plan at that point. HHS also developed model notices, released alongside this final rule, that reflect how an Exchange should clearly communicate an individual's eligibility for an SEP and the instructions for how he or she can enroll in a QHP.

Comment: Several commenters also urged HHS to specify additional triggering events for special enrollment periods. Some commenters recommended additional triggering events described in Medicare Part D, unaffordable rate increases, and misinformation provided to an individual regarding minimum essential coverage or advance payments of the premium tax credit or cost-sharing reductions. One commenter wanted HHS to include any change in family size as a triggering event, raising particular concerns about pregnancy to allow a woman enrolled in a catastrophic plan to change QHPs prior to the birth of a newborn. Several commenters requested that HHS clarify that certain triggering events would qualify as a special enrollment period under

“exceptional circumstances” described in paragraph (d)(9) of this section, such as provider religious objections to covering certain health services to women.

Response: We believe that the current special enrollment periods previously proposed appropriately account for changes in circumstances that necessitate when individuals would need to select a new or different QHP and balance these needs with considerations regarding the risk pool. In addition, we note that §147.104(b)(2) specifies that in 2014, an Exchange must provide a special enrollment period for individuals enrolled in non-calendar year individual health insurance policies beginning on the date that is 30 days prior to the date the policy year ends in 2014.

Furthermore, a state may establish additional special enrollment periods to supplement those described in this section as long as they are more consumer protective than those contained in this section and otherwise comply with applicable laws and regulations.

HHS intends to issue further guidance related to how Exchanges will determine the triggering events that constitute “exceptional circumstances” under paragraph (d)(9) of this section. For the issue raised regarding provider religious objections, we believe that there are other remedies available to consumers who encounter such situations.

Comment: One commenter sought clarification that the special enrollment periods only apply to the individual market as opposed to the small group market.

Response: We confirm that the language in §155.420 regarding special enrollment periods only applies in its entirety to the individual market. Separate provisions pertain to the small group market as discussed at §155.725(a)(3), which excludes §155.420(d)(3) and (d)(6).

Comment: Some commenters raised concerns regarding our proposals within this section that pertain to effective dates. Commenters requested clarification on whether the effective dates related to errors by the Exchange or contract violations by QHP issuers would involve setting

retroactive enrollment dates. Some commenters suggested that the Exchange provide flexibility to individuals related to retroactivity for errors as some individuals may not want the Exchange to implement an earlier effective date. If allowing for retroactivity, commenters urged that the Exchange's flexibility related to errors or contract violations should only be provided to correct the unfair outcome. Commenters asked that the effective date be set for the individual on what it would have been without the error, and requested that the Exchange only set the effective date according to paragraph (b)(1) of this section if the date on which the determination would have been effective without the error cannot be ascertained. Several commenters also raised concerns about HHS' proposal to remove the language about effective dates for advance payments of the premium tax credit and cost-sharing reductions within this section. Some commenters worried about an Exchange instituting earlier effective dates under paragraph (b)(3) of this section, particularly the FFE in 2014.

Response: Outside of a technical correction within paragraph (b)(3) of this section, we did not propose any changes to the provision related to the Exchange instituting earlier effective dates if all participating QHP issuers agree to effectuate coverage in a shorter timeframe. We believe that there are sufficient regulatory safeguards for QHP issuers in 2014 if they inform the Exchange that they are not prepared to institute earlier effective dates. In terms of the Exchange's flexibility related to retroactive eligibility and enrollment in cases of errors or contract violations, we note that the outcome is still contingent on an individual selecting a QHP when determined eligible for a special enrollment period. This preserves the ability for an individual to choose to enroll on a particular date, or to choose not to enroll.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.420 of the proposed rule with the following modifications. First, in paragraphs (b)(2)(i) and (d)(2), we expand the special

enrollment period and special effective dates for birth, adoption, and placement for adoption to also include placement in foster care. Second, in paragraph (d)(3), we clarify that the special enrollment period for an individual who was not a citizen, national, or lawfully present non-citizen and gains such status also applies to his or her dependents, if eligible under the Exchange eligibility rules. Third, we modify paragraph (d)(6) to incorporate the special enrollment period proposed in paragraph (d)(10), with modifications to reflect that it accommodates individuals who are enrolled in an eligible employer-sponsored plan, but are not eligible for qualifying coverage in an eligible employer-sponsored plan. Accordingly, we delete paragraph (d)(10).

19. Termination of coverage (§155.430)

In §155.430, we proposed to amend paragraph (b)(1) to clarify that it specifically refers to enrollee-initiated terminations. We proposed to add paragraph (b)(1)(i) to account for circumstances in which, through periodic data matching, an Exchange finds an enrollee eligible for other minimum essential coverage, thus resulting in the enrollee's ineligibility for advance payments of the premium tax credit. We also proposed in paragraph (b)(1)(ii), that at the time of plan selection, the Exchange would provide a qualified individual with the opportunity to choose to remain enrolled in a QHP if the Exchange identifies that he or she has become eligible for other minimum essential coverage, and the enrollee does not request a termination in accordance with paragraph (b)(1)(i).

We proposed to amend paragraph (d)(1) to specify that changes in advance payments of the premium tax credit and cost-sharing reductions, including terminations, adhere to the effective dates specified in §155.330(f).

Comment: Several commenters cautioned against requiring retroactive termination effective dates that would necessitate the return or repayment of claims, premiums, advance payments of the premium tax credit, or cost-sharing reduction payments. However, other

commenters urged HHS to modify termination effective dates in §155.430(d) such that for qualified individuals who gained, or were going to gain other coverage, the termination effective dates would be the day before the other coverage begins, regardless of when the enrollee notifies the Exchange of his or her other coverage.

Response: We appreciate the comments concerning this provision, and have modified the termination effective date at §155.430(d)(2)(iii) for enrollee-requested terminations such that QHP issuers and Exchanges may only terminate coverage effective on or after the date on which the enrollee requests termination, and not retroactively. We have also clarified in §155.430(d)(2)(iv) that the last day of coverage in a QHP for an enrollee who is determined eligible for Medicaid, CHIP or the BHP is the day before the individual is determined eligible for such coverage, rather than retroactive to the Medicaid or CHIP eligibility effective date.

Comment: One commenter recommended amending §155.430(d) to specify that changes in eligibility, including terminations, must adhere to the effective dates specified in §155.330(f), to ensure alignment of processes.

Response: We agree with the commenter, and have modified the termination effective dates in §155.430(d)(3) to cross-reference §155.330(f).

Comment: Commenters sought clarification of why an enrollee who is eligible for other minimum essential coverage would elect to remain enrolled in a QHP without advance payments of the premium tax credit.

Response: While 26 CFR 1.36B-2 specifies that premium tax credits are not available to support enrollment in a QHP through the Exchange for an individual who is eligible for other minimum essential coverage, such an individual is free to remain enrolled in a QHP through the Exchange, without advance payments of the premium tax credit and cost-sharing reductions, if he or she remains eligible for enrollment in a QHP through the Exchange. It is possible that an

individual would want to maintain enrollment without advance payments of the premium tax credit and cost-sharing reductions for continuity of coverage reasons. As we proposed in 155.430(b)(2)(ii), the Exchange must provide an opportunity at the time of QHP selection for an individual to choose to remain enrolled in a QHP if he or she has become eligible for other minimum essential coverage. If the individual does not choose to remain enrolled in a QHP upon such a change, the Exchange would initiate termination upon completion of the redetermination process specified in §155.330.

Comment: Commenters recommended that in addition to the opportunity at plan selection, enrollees should be given a second opportunity to elect to remain enrolled in a QHP without advance payments of the premium tax credit and cost-sharing reductions when the Exchange finds the enrollee is eligible for other minimum essential coverage through a periodic data match.

Response: Exchanges are free to provide additional opportunities for individuals to request termination, or to request to remain enrolled in a QHP without advance payments of the premium tax credit or cost-sharing reductions, upon losing eligibility for such benefits. In paragraph (b)(1)(ii), we have clarified that the opportunity provided at the time of plan selection is effective both in cases of periodic data matching as well as when an enrollee reports gaining eligibility for other minimum essential coverage that would make him or her ineligible for advance payments of the premium tax credit and cost-sharing reductions.

Comment: A commenter raised a concern that the proposed revision to the termination provision in §155.430(b)(2) broadly permits an individual whose coverage was already effectuated during the initial open enrollment period to notify the Exchange or QHP issuer of his or her termination of coverage, and switch QHPs.

Response: Individuals are free to terminate enrollment in a QHP through the Exchange at any time. Individuals who wish to begin other coverage in a QHP through the Exchange must be within an open or special enrollment period to do so. Each Exchange has the flexibility to decide whether to allow enrollees for whom coverage has been effectuated to change QHPs during any remaining time in an open or special enrollment period. For October 1, 2013, the FFE will not permit an enrollee to change QHPs in such a situation. As noted above, such an individual may qualify for a new special enrollment period as specified in 45 CFR 155.420.

Comment: One commenter noticed that the proposed provisions did not clarify whether the Exchange would be permitted to terminate coverage retroactively to the date of death. The commenter recommended that the Exchanges have the flexibility to align with non-group market standards, and allow for retroactive terminations when the Exchange obtains updated information regarding a death.

Response: We agree with the commenter, and have added paragraph §155.430(d)(7) to clarify that in the case of termination due to death, the last day of coverage is the date of death, which means that coverage could be terminated retroactively.

Comment: A commenter noticed that there were conflicting provisions regarding terminations at §155.430 and §156.270(b). Section 156.270(b) specifies that QHP issuers must notify both the Exchange and enrollees of the effective date and reason for termination at least 30 days prior to the last day of coverage, and §155.430(d) specifies that in some cases, QHP issuers may effectuate termination in fewer than 30 days.

Response: We have modified §156.270(b) in this final rule to align the coverage termination standards for Exchanges and QHP issuers. We have also clarified that QHP issuers will promptly notify both enrollees and the Exchange of the termination reason and termination effective date when the QHP initiates a termination.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.430 of the proposed rule, with the following modifications: We modified paragraph (b)(1)(ii) to specify that the opportunity provided by the Exchange at the time of plan selection for an individual to choose to remain enrolled in a QHP if he or she becomes eligible for other minimum essential coverage applies both to situations in which eligibility for other minimum essential coverage is identified via a periodic data match, as well as situations in which the individual reports the change to the Exchange. We modified the termination effective date provision at paragraph (d)(2)(iii), for enrollee-requested terminations, such that QHP issuers and Exchanges may only terminate prospectively, not retroactively. We modified paragraph (d)(2)(iv), which concerns terminations for enrollees who are determined eligible for Medicaid, CHIP or the BHP, such that the last day of coverage is the day before the individual is determined eligible for such coverage, rather than retroactive to the Medicaid or CHIP eligibility effective date. We also modified the termination effective dates in paragraph (d)(3) to cross-reference §155.330(f). We added paragraph (d)(7) to clarify that in the case of termination due to death, the last day of coverage is the date of death. In addition, we are finalizing an amendment to §156.270(b) to align the coverage termination requirements for Exchanges and QHP issuers.

D. Medicaid Premiums and Cost Sharing

1. Responses to General comments (§447.51 through §447.57)

Comment: Many commenters supported the streamlined and consolidated approach to the revised cost sharing rules. One commenter believed that removing the distinction between the requirements of sections 1916 and 1916A of the Act was confusing and lost some of the differences in the statutory provisions. The commenter was also concerned that under the revised rules, states will no longer have to explicitly invoke the use of alternative (section 1916A

of the Act) cost sharing through the state plan amendment process. One commenter stated that CMS should not provide more specific requirements in the regulations to give states more flexibility.

Response: We maintain the streamlined and consolidated structure in the final regulation, which we believe is consistent with the flexibilities and limitations provided in both sections 1916 and 1916A of the Act. We believe that consolidation will simplify the rules for beneficiaries, providers, and states, and will also simplify the state plan amendment (SPA) process. States will continue to be required to submit a SPA to impose new or revised cost sharing or premiums, and CMS will review such SPAs to ensure compliance with the regulations and statute.

Comment: Two commenters recommended that rather than remove current §447.58 and reserve it, this provision should be used to implement the long-standing statutory provision that the cost sharing provisions of sections 1916 and 1916A of the Act cannot be waived unless a state meets the criteria required under section 1916(f) of the Act.

Response: The terms of section 1916(f) of the Act, relating to the requirements states must meet for the Secretary to approve a waiver of the cost sharing provisions of sections 1916 and 1916A of the Act are clear. We do not believe it is necessary at this time to issue regulations setting forth the Secretary's substantive authority under section 1115 of the Act, and such an action would be outside of the scope of this rulemaking. We note that we issued procedural regulations at 77 FR 11678(Feb. 27, 2012) governing demonstration applications in accordance with section 1115(d) of the Act (as added by section 10201(i) of the Affordable Care Act).

Comment: One commenter stated that given the statutory constraints implemented in the regulations, states should be given additional flexibility through the use of a standard waiver template applicable to newly eligible adults. One commenter stated that for MAGI-based

eligibility groups, states should be able to impose premiums and cost sharing on individuals with income over 100 percent of the FPL that is equivalent to what those individuals would be subject to if they were enrolled in the Exchange.

Response: Section 1916A of the Act and these regulations provide considerable flexibility for states to impose cost sharing on individuals with income over 100 percent of the FPL, including the ability to target cost sharing, charge higher amounts, and make the cost sharing enforceable. But the statute provides for cost sharing protections for the Medicaid population that are not the same as the protections for individuals enrolled in coverage through the Exchange. To waive the Medicaid cost sharing requirements and go beyond the flexibilities provided in section 1916A of the Act for individuals covered under the state plan, the Secretary must find that the requirements of section 1916(f) of the Act have been met. We do not believe that a template for waiving the cost sharing requirements in accordance with section 1916(f) of the Act is needed at this time. Except for certain specified eligibility groups, sections 1916 and 1916A of the Act limit premiums imposed under the state plan on those with income over 150 percent of the FPL.

Comment: One commenter noted that it appears we left in place §§447.66 through 447.82 of the current regulations and suggested that CMS remove these sections.

Response: This was a drafting error and we have removed those sections in the final rule. Those sections reflected alternative premiums and cost sharing requirements under section 1916A of the Act that have been integrated into new streamlined cost sharing regulations that reflect both sections 1916 and 1916A of the Act.

2. Definitions (§447.51)

We proposed to add a definition for premiums, which includes enrollment fees and other similar charges. We also proposed to add a definition for cost sharing to encompass deductibles,

copayments, coinsurance, and other similar charges. Because each of these charges would be included within cost sharing, we proposed to remove separate requirements related to deductibles, copayments, and coinsurance; instead all cost sharing would be subject to a single set of rules. We also proposed new definitions for purposes of the premium and cost sharing regulations for preferred drugs, emergency and non-emergency services, and alternative non-emergency service providers, since the cost sharing rules vary for these items and services. We received the following comments concerning the proposed definitions:

Comment: Several commenters recommended that we revise the definition of alternative non-emergency service provider at §447.54 to mean “a Medicaid-participating provider, such as a physician’s office, health care clinic, community health center, hospital outpatient department, or similar provider that is actually available and accessible and can provide clinically appropriate services for the diagnosis or treatment of a non-emergency condition in a timely manner.”

Response: We are finalizing the definition as proposed in §447.51. The revisions suggested by the commenters regarding the alternative non-emergency provider being available and accessible and being able to provide for the diagnosis or treatment of a non-emergency condition are implicit in the requirements that must be met at §447.54(d) before the imposition of cost sharing for non-emergency use of the ED. However, we have revised the definition of non-emergency services for clarity; this revision is not a substantive change.

Comment: Several commenters recommended that we remove the term “coinsurance” from the definition of cost sharing at §447.51, since few states charge coinsurance and the statute does not use the term. They discussed that eliminating the term “coinsurance” would further the goal of simplification.

Response: We agree that very few states elect the option to charge coinsurance, but it is still an option available to states under the statute, which allows for other “similar charges.”

Therefore we are maintaining the term “coinsurance” in the definition of cost sharing in the final rule. With the streamlining of the regulations in this final rule, states that do elect to charge coinsurance must ensure it does not exceed the limits defined in §447.52-54.

Comment: We solicited comments on whether we should add definitions of “inpatient stay” and “outpatient services” to take into account situations in which an individual is discharged and soon thereafter returns to an inpatient facility for continued treatment of the same condition. One commenter supported the inclusion of a definition of “inpatient stay” and recommended that we adopt the approach taken in Medicare to define a “benefit period” and prohibit a second copay for any inpatient stay within the same benefit period. Some commenters also supported the addition of a definition of “outpatient services” giving states broad flexibility to determine which services may be subject to cost sharing. No commenters opposed adding definitions of these terms.

Response: We are adding a definition of “inpatient stay” in the final rule at §447.51 to mean the services received during a continuous period of inpatient days in either a single medical institution or multiple medical institutions, and also to include a return to an inpatient institution after a brief period when the return is for treatment of a condition that was present in the initial period. We also add that the definition of “inpatient” has the same meaning as in §440.2. We believe this is in the best interest of beneficiaries with chronic conditions who may have frequent visits to the hospital or other institution for treatment of the same condition, and is consistent with the limitations on cost sharing established in the statute. We also add a definition of “outpatient services” for purposes of cost sharing to mean any service or supply not meeting the definition of an inpatient stay. This definition will include cost sharing for any services outside an institutional setting, not otherwise exempt by statute or regulations, excluding drugs and non-emergency use of the hospital emergency department which are defined separately. We

note that these definitions are applicable only to cost sharing and do not constitute any change in definition specific to the provision of benefits or services.

Comment: One commenter requested CMS provide additional information to states regarding how the proposed definition of cost sharing will affect the offset to expenses that states can report for Medicaid FFP (§447.51).

Response: Nothing in the definition of “cost sharing” at §447.51 changes the rule related to FFP. Per §447.56(e), which is unchanged from current rules, no FFP is available for any premiums or cost sharing that should have been paid by the beneficiary, except for amounts that the agency pays as bad debts of providers who are paid in accordance with Medicare reasonable cost principles.

Comment: One commenter recommended revising the definition of a premium at §447.51 to exclude enrollment fees because premiums are generally applied on an annual or periodic basis whereas enrollment fees are generally a onetime payment. The commenter recommends that states should have the flexibility to require an enrollment fee in addition to premiums.

Response: The statute defines a premium to include any enrollment fee or similar charge, and therefore the limitations on total premium charges include both premiums and enrollment fees. As the Secretary does not have the authority to change this requirement, we are finalizing the definition of premiums as proposed. States do have the flexibility to impose both a monthly premium and an initial enrollment fee within the limitations for premiums described in this rule.

3. Update to Maximum Nominal Cost Sharing (§447.52)

We proposed to implement sections 1916(a)(3) and (b)(3) of the Act relating to nominal cost sharing, and to revise the maximum amount of nominal cost sharing for outpatient services. For beneficiaries with incomes at or below 100 percent of the FPL, cost sharing for outpatient

services may not exceed nominal. For those with income above 100 percent of the FPL, cost sharing can either be limited to nominal or may extend up to 10 or 20 percent of the cost of the service, depending on the income of the beneficiary. Currently, maximum allowable nominal cost sharing is tied to what the agency pays for the service, not to exceed \$3.90 for services for which the state pays more than \$50. Because this can be confusing and burdensome for states, providers, and beneficiaries, we proposed to allow instead a flat \$4 maximum allowable charge for outpatient services. This is a modest \$0.10 increase from the current maximum, and as we noted as a basis for the proposed rule, the majority of state services are reimbursed at more than \$50. The proposed changes are discussed in more detail in the January 22, 2013 Medicaid Eligibility Expansion proposed rule (78 FR 4658 and 4659). We received the following comments concerning the proposed update to the maximum nominal cost sharing provisions:

Comment: Many commenters wanted CMS to eliminate cost sharing for Medicaid beneficiaries altogether because of the extensive research showing that cost sharing on low-income populations creates barriers to accessing needed care, with particular consequence for those with special health care needs. One commenter recommended that CMS revise the cost sharing regulations to align with the lowest eligibility threshold for Medicaid based on modified adjusted gross income created by the Affordable Care Act (for example, 133 percent of the FPL) and create two tiers of cost sharing – one for those with income at or below 133 percent of the FPL and one for those with income above 133 percent of the FPL. One other commenter recommended that individuals with income below 133 percent of the FPL should be exempt from cost sharing.

Response: We recognize the studies indicating that cost sharing may impact beneficiaries' access to needed and prescribed services, given the low incomes of most of those who are enrolled in Medicaid. However, the statute authorizes states to impose cost sharing,

subject to certain limitations. Additionally, the Affordable Care Act did not modify the cost sharing provisions of sections 1916 and 1916A of the Act. Section 1916A of the Act distinguishes between individuals with income at or below 100 percent of the FPL, those with income above 100 and at or below 150 percent of the FPL, and those with income above 150 percent of the FPL. We do not have the authority to revise the income thresholds set out in statute or to preclude states from imposing cost sharing on individuals with income under 133 percent of the FPL consistent with the limitations in sections 1916 and 1916A of the Act, as implemented in these regulations. States do not, of course, have to implement cost sharing to the extent authorized by the statute, and most do not do so. We note that in §447.51 of the final rule we add a definition of Federal poverty level (FPL) to use the acronym throughout the regulation. No substantive change is intended.

Comment: Several commenters stated that cost sharing is unnecessary in the context of managed care because the point of managed care is to manage utilization and ensure care is provided in the most appropriate settings. The commenters argue that managed care already achieves the goals that states are attempting to achieve through cost sharing and that cost sharing interferes with the medical management effectuated through managed care programs. Another commenter believed the rules did not provide enough flexibility in the managed care context. One commenter requested that CMS clarify that Medicaid agencies can permit managed care organizations to not impose cost sharing on enrollees.

Response: While managed care can play a role in ensuring more appropriate utilization of health care services, the statute does not limit the imposition of cost sharing to fee-for-service delivery systems. In general, states may not establish different cost sharing requirements for beneficiaries served by a fee-for-service versus a managed care delivery system unless all beneficiaries have the same opportunity to participate in fee-for-service versus

managed care and to enjoy the benefits of lower cost sharing imposed under one service delivery mechanism versus the other. Section 4708(b) of the Balanced Budget Act of 1997 specifically removed the statutory cost sharing exemption for enrollees in managed care organizations. Managed care organizations may choose not to impose state plan cost sharing on their members, but the state must still consider the amount of cost sharing under the state plan in determining the actuarial soundness of the capitated payment to the managed care organization. Section 1916A of the Act allows states to target cost sharing to specified eligibility groups, as described at §447.52(d) of this final rule, and states may target cost sharing specifically to those eligibility groups who may be enrolled in managed care, but the targeting must be based on the eligibility group and not solely on the basis of enrollment in managed care. However, states may charge different co-pays to incentivize the use of certain care models—for example lower co-pays to encourage use of primary care medical homes or other patient-centered coordinated care models—to the extent that those models provide a different service from those offered at a more traditional medical provider, and the particular model of care is broadly available to beneficiaries. This is permissible because the state is differentiating co-payments based on the service provided, and because all individuals have the choice to receive such services, comparability is met.

Comment: Some commenters recommended that CMS should restore the use of the term “nominal,” as that term is used in the existing regulations. They argue that the Act specifically limits cost sharing to “nominal” amounts and directs the Secretary to determine what constitutes a “nominal” amount each year to ensure that cost sharing amounts are not onerous for beneficiaries.

Response: The streamlining proposed does not negate the requirements at section 1916 of the Act that cost sharing for certain populations be nominal in amount. Section 1916 of the

Act gives the Secretary authority to define nominal cost sharing, which we do at proposed §§447.52, 447.53 and 447.54. The amounts described in these sections are the maximum that can be imposed on individuals with income at or below 100 percent of the FPL, since these individuals may not be subject to the higher cost sharing allowable under section 1916A of the Act. The proposed amounts will be updated annually based on the CPI-U, starting October 1, 2015. As mentioned, in streamlining the regulations implementing sections 1916 and 1916A of the Act, we did not use the term “nominal” in the regulatory text, but the amounts permitted were set based on the determination that they were nominal amounts.

Comment: Many commenters agreed with severing the tie between maximum cost sharing amounts and what the agency pays for the service but believed that a flat \$4 maximum amount proposed at §447.52 was too burdensome for Medicaid beneficiaries with income at or below 100 percent of the FPL. Many commenters recommended that CMS should set maximum cost sharing amounts based on the income and health status of the beneficiaries and recommended using Medicare as a model, which establishes two tiers for Part D copayments for individuals with income at or below 100 percent of the FPL and individuals with incomes over 100 percent of the FPL, and recommend the Medicaid cost sharing maximum should be limited to \$2.10 for those at or below 100 percent of the FPL which is the approximate average of the FY 2013 maximum copayment amounts.

Response: Sections 1916 and 1916A of the Act allow for different levels of cost sharing for individuals with income at or below 100 percent of the FPL versus those with income over 100 percent of the FPL, similar to the two-tiered structure established for Medicare Part D which the commenters recommend. Section 1916A of the Act further differentiates maximum cost sharing levels for those with income above 100 or at or below 150 percent of the FPL and those with income over 150 percent of the FPL. Current regulations already allow states to charge all

non-exempt beneficiaries up to \$3.90 for many services, and as described previously, we believe the \$4 maximum charge is comparable, particularly given that the next update to this nominal amount has been postponed under this rule until October 1, 2015. We also note that while this is the maximum level at which states may set their cost sharing obligations, they may establish lower levels of cost sharing.

We note that under current regulations at §447.56, states have the option to establish different cost sharing charges for individuals at different income levels. We inadvertently omitted this section from the proposed rule and are restoring this option in the final rule at §447.52(g). We specify in the final rule that if the state imposes cost sharing charges that vary by income, it must ensure that lower income individuals have lesser cost sharing than higher income individuals.

Comment: One commenter expressed concern that the simplified \$4 maximum for individuals with income at or below 100 percent of the FPL would create a disparity with the percentage-based maximum cost sharing for individuals with income above 100 percent of the FPL.

Response: It was not our intent to establish a cost sharing system under which lower income beneficiaries could be subjected to higher cost sharing than their higher income counterparts. Our intent was to define maximum nominal cost sharing, as described under sections 1916(a)(3) and (b)(3) of the Act, as \$4 for outpatient services. If a state seeks to use the authority provided under section 1916 of the Act to impose nominal cost sharing on individuals with income at or below 100 percent of the FPL, such cost sharing must also be applied to individuals with income above 100 percent of the FPL. Section 1916 of the Act does not allow for targeted cost sharing on different groups of individuals, so any cost sharing established under this authority is applicable to all non-exempt individuals. The 10 and 20 percent maximums

established for individuals with income over 100 percent of the FPL are specific to cost sharing established under the authority of section 1916A of the Act. This authority specifically allows for cost sharing of up to 10 percent of the cost of the service for individuals above 100 and at or below 150 percent of the FPL and 20 percent for individuals with income above 150 percent of the FPL, with slightly different maximums for drugs and non-emergency use of the emergency department. For a specific outpatient service, a state may establish nominal cost sharing under the authority of section 1916 of the Act for all non-exempt individuals covered under the state plan in an amount not to exceed \$4 (as adjusted for inflation), and the state may also establish targeted cost sharing for specified individuals under section 1916A of the Act for that same outpatient service, in an amount not to exceed 10 percent of the cost of the service. In such a case, the cost sharing imposed under the section 1916 authority may not exceed 10 percent of the cost of the service if that amount is less than the maximum nominal amount allowed for individuals with income under 100 percent of the FPL, because the state must ensure that lower income individuals are charged less than individuals with higher income, as described at §447.52(g).

Comment: We solicited comments on the best approach to cost sharing for an inpatient stay for individuals with income at or below 100 percent of the FPL. We indicated we were considering a maximum cost sharing amount less than what is allowed in current regulation. Most commenters believed that the current regulations allowing cost sharing of up to 50 percent of what the agency pays for the first day of inpatient care was too great a burden for individuals at this income level. A few commenters recommended a maximum copayment of \$10, one commenter recommended \$100, and many recommended that the cost sharing for inpatient care should be the same as for outpatient services and be limited to \$4.

Response: We are revising the regulations to limit maximum cost sharing charges for an

inpatient stay, for individuals with income at or below 100 percent the FPL, to \$75. This \$75 limit will encompass most hospital cost sharing established by state Medicaid programs today and will align with the ratio of cost sharing for inpatient versus outpatient services with similar charges provided under private insurance plans. To provide a transition period for the small number of states with existing inpatient cost sharing exceeding \$75, we are adding a new paragraph at §447.52(b)(2). Under paragraph (b)(2), states with inpatient cost sharing that exceeds \$75, as of **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, must submit a plan to CMS that provides for reducing inpatient cost sharing to \$75 by July 1, 2017. We redesignate the succeeding paragraphs, accordingly.

Comment: We solicited comments on whether we should define nominal cost sharing differently for community-based long term services and supports (LTSS) due to the frequency with which these services are provided and utilized by beneficiaries. Many commenters supported a separate approach to LTSS because they are concerned about the financial burden that an individual needing these services could face if a state were allowed to charge up to \$4 for each service and most recommended that such services be exempted from cost sharing. Commenters were also concerned that allowing cost sharing for LTSS would discourage individuals from utilizing LTSS and leave many to opt for institutional care, which is more costly for states in the long run. Some commenters recommended that consideration be given to limiting the number of copayments permitted per week, month, or other specified timeframe for those with significant service needs, including adults with serious mental illness. One commenter opposed establishing different limits for community-based long term services and supports as it would be administratively burdensome for states. This commenter also pointed out that no specific mention is made in the regulations to long-term care community-based services

provided under sections 1915(c), 1915(d), 1915(i), or 1915(k) of the Act. The commenter suggested that perhaps these defined packages are the more appropriate starting place if separate cost-sharing rules for these services are considered, but we need to take into account the fact that some individuals already contribute to the cost of these services in accordance with the post-eligibility treatment of income rules under part 435 subpart H.

Response: We agree with commenters that additional protections for non-exempt individuals receiving community-based LTSS are appropriate to ensure that receiving care in the community, rather than in an institution, remains a financially viable option for such individuals, but the statute does not authorize the Secretary to require an exemption. We note that few states now impose cost sharing on LTSS. We encourage all states to consider the significant consequences of imposing cost sharing on such services, and remind states that they are required to comply with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act as interpreted in the Olmstead v. L.C. and E.W. (“Olmstead”) to ensure they are not placing individuals at risk of institutionalization. While we are not directing an exemption for LTSS, we agree with commenters that additional protections are necessary for individuals with high service needs, and we are revising the proposed aggregate limit for premiums and cost sharing to protect all beneficiaries with high medical needs. As discussed further under §447.56, the 5 percent aggregate limit applies to all individuals regardless of income. In addition, if premiums and cost sharing could exceed 5 percent of family income, states are required to have a mechanism to track such premiums and cost sharing in a manner that does not rely on beneficiaries. To provide protections to individuals with high service needs and ensure their cost sharing does not exceed the aggregate limit, we encourage states to consider prospectively ending a beneficiary’s cost sharing obligation at a specified time of the applicable month or quarter given the frequency of utilization and the predictability of services provided under an approved plan of care, for

example. We note that such an approach must take into account the cost sharing for items or services that may be received outside the plan of care, such as drugs for example, which would also contribute to the 5 percent aggregate limit.

We considered different options for a separate definition of nominal cost sharing specific to LTSS but have determined the most effective way to ensure ongoing affordability of care for beneficiaries who are frequent and regular consumers of care, including but not limited to those who need LTSS, is to ensure that there is an effective aggregate cap on cost sharing. Aggregate out of pocket limits are a common practice in the commercial market and we believe the extension of the aggregate limit is consistent with industry practice and will provide the greatest protections for beneficiaries, consistent with statutory provisions, while still maintaining states' flexibility to establish appropriate cost sharing mechanisms for their programs.

Comment: One commenter believed that proposed §447.52(b)(2), which relates to maximum allowable cost sharing when the state does not have fee-for-service payment rates, is confusing and could be read to only apply to those with income at or below 100 percent of the FPL.

Response: We agree and have revised the paragraph, redesignated in this final rule as §447.52(b)(3), to be clear that, “in states that do not have fee-for-service payment rates, any cost sharing imposed on individuals at any income level may not exceed the maximum amount established for individuals with income at or below 100 percent of the FPL.” The same clarification to the regulation text is made at §447.53(c).

Comment: Some commenters recommended that the Secretary provide states the flexibility to determine the cost sharing methodology that best aligns with their delivery system and provider categories, for example allowing flat co-payments and premiums, co-payments based on a percentage of what the agency pays for the service, or premiums calculated as a

percentage of family income.

Response: The regulations at proposed §§447.52, 447.53 and 447.54 establish maximum limits on the cost sharing that states can impose. While we are no longer requiring that the maximum cost sharing amounts be based on what the agency pays for the service, nothing in the regulations preclude states from setting their cost sharing amounts on such basis provided that the amounts charged do not exceed maximum permissible levels. Similarly, provided that the specific limits set out in the statute and codified in the regulations – including the aggregate limit not to exceed 5 percent of family income – are respected, states have the flexibility under §447.55 to structure premiums in the manner suggested, although, as noted, statutory authority to impose premiums is limited.

Comment: We received several comments suggesting we clarify that states can apply different levels of cost sharing for their current Medicaid populations as compared to adults who will become eligible under the adult group.

Response: In general, any cost sharing established under the state plan must apply to all beneficiaries who are not specifically exempted per the requirements at §447.56(a) to ensure comparability. There are two exceptions to this requirement, as follows. First, states may vary the cost sharing obligation by income level, reflected at §447.52(g) of the final rule, such that individuals with family income below a certain threshold could be subject to lower cost sharing than those at higher income levels. A state could, for example, decide not to impose cost sharing on individuals with incomes below 50 percent of the FPL, and to impose a \$1 copayment on individuals with income above 50 percent of the FPL. We note that states should have adequate processes in place to ensure providers and beneficiaries are aware of who can be charged what cost sharing so it is appropriately applied. Second, reflected at §447.52(d), as redesignated in the final rule, states may establish different levels of cost sharing for targeted groups of individuals

with income above 100 percent of the FPL. In this final rule, we clarify that for cost sharing imposed for non-preferred drugs and non-emergency services furnished in an ED, states may target to specified individuals with income below 100 percent of the FPL as well as those above, as discussed below. Thus, states could impose different cost sharing on individuals eligible in the new Adult group, or any other eligibility group, with income greater than 100 percent of the FPL than that imposed on other beneficiaries.

Comment: One commenter stated that proposed §447.52(f), which lists the information that must be included in the state plan for each cost sharing charge imposed, is revised from the current regulations at §447.53(d) but that we did not provide a rationale for the revisions.

Response: We consolidated the state plan requirements currently contained in §§447.53(d) and 447.68 into one new section, redesignated as §447.52(i) in the final regulation. The state plan requirements for tracking beneficiary cost sharing related to the aggregate limit are contained in §447.56(f)(2) of this final rule. In consolidating the state plan requirements for cost sharing under the authority of both sections 1916 and 1916A of the Act, we sought generally to maintain the current requirements, while removing any unnecessary regulatory provisions. For example, we removed the requirement that states describe the basis for determining the charge, because these regulations no longer require states to base their cost sharing charges on what the agency pays for the service and this provision was no longer necessary. We note that we are making minor technical changes to paragraph §447.52(i)(4) to improve the structure of the paragraph and delete extraneous language. No substantive changes are intended.

Comment: One commenter recommended that CMS require that state plans identify whether a cost sharing charge is being imposed under the authority of section 1916 or section 1916A of the Act.

Response: With the streamlining of the regulations we do not believe it is necessary for states to specify what authority they are relying on to impose cost sharing. In their state plan, the states seeking to impose or continue cost sharing will need to detail who will be subject to cost sharing, for what service, how much, and whether providers may deny services for lack of payment. We will review state plan amendments to ensure compliance with sections 1916 and 1916A of the Act and these regulations.

Comment: One commenter requested that we clarify that the regulation authorizes states to allow providers to deny services for nonpayment of cost sharing, but does not confer authority on states to require providers to do so. One commenter recommended that we include a provision that providers are not prevented from reducing or waiving the application of a cost sharing requirement on a case-by-case basis.

Response: The requirements at §§447.52(e)(1) and (e)(2), as redesignated in this final rule, are clear that, while states may allow providers to deny services to individuals with income above 100 percent of the FPL who have failed to pay cost sharing charges, states are not required to permit providers to do so (and providers may only deny services if the state opts to permit them to do so). Further, §447.52(e)(3) is clear that even if the state exercises this option, providers are not prohibited from nonetheless electing to provide the service to individuals who do not pay their cost sharing obligations. This is not at state option – it is a provider option– and we do not believe it is necessary to be included in the state plan.

Comment: A few commenters suggested that the regulations authorize states to allow providers to deny services for non-payment of cost sharing charges in more situations, including for those with income at or below 100 percent of the FPL. The commenters believe that such provider enforcement, particularly in the context of nonemergency use of the emergency room, would be appropriate.

Response: We are unable to extend the scope of the regulations beyond the statutory authority provided in sections 1916 and 1916A of the Act, both of which only allow states to impose provider-enforceable cost sharing to non-exempt individuals with income over 100 percent of the FPL and thereby assure the provision of services to lower income individuals who may not be able to afford the charge. These provisions of sections 1916 and 1916A of the Act cannot be waived unless the state meets the requirements of section 1916(f) of the Act.

Comment: One commenter recommended that the table at §447.52(b) be clarified to clearly specify that the amounts are maximum amounts to correspond with the language in §447.52(b).

Response: We agree with the commenter and have made the revision to §§447.52(b), 447.53(b) and 447.54(b).

Comment: One commenter asked if cost sharing must be imposed or if it is an allowable activity.

Response: States are not required to impose cost sharing, it is an option. Some states do not impose cost sharing. Furthermore, if a state does impose cost sharing, it has the option to charge less than the maximum amounts. Many states do so today.

Comment: One commenter requested clarification as to whether §447.52(e) (relating to the prohibition against multiple charges) includes premiums.

Response: §447.52(e) has been redesignated as §447.52(f) in this final rule and pertains to cost sharing only, which is defined in §447.51 to include any copayment, coinsurance, deductible or similar charge. Premiums are not encompassed in this definition, and states may impose both a premium and cost sharing on a given individual subject to the applicable conditions on such charges.

Comment: One commenter recommended revising the rule to allow states to waive or

reduce cost-sharing for outpatient services delivered by designated high-value providers or in high-value care settings, even if those services may otherwise be subject to cost-sharing. One commenter requested clarification that the cost sharing rules may not be applied to different types of practitioners based on their licensure and that cost sharing within a category of services is not used to discriminate against health care practitioners acting within their state-defined licensure.

Response: Nothing in the regulations prevents a state from determining which services are subject to cost sharing and the amount charged, or by what type of provider the service is delivered. As suggested by the commenter, states could differentiate cost sharing for services provided by a designated high value provider as long as the state ensures that all beneficiaries have access to such providers.

Comment: One commenter recommended that we include in the final rule, language currently at §447.60 that was omitted from the proposed rule, which requires that any cost sharing charges imposed by managed care organization on Medicaid enrollees be in accordance with the requirements set forth in the regulations.

Response: We agree with the commenter. The omission of this provision was not intentional and we have included this requirement in the final rule at §447.52(h).

Comment: One commenter believed that if deductibles are an option for a state, they should be administered at an individual level on an annual basis because the commenter believes monthly and/or family-level deductibles are complex, confusing, and not the standard generally used by health plans especially when combined with other cost sharing.

Response: Deductibles are permitted at an individual level under the statute and these regulations. Any deductible imposed by a state must be within the maximum amounts established in §§447.52-54, and subject to the aggregate limit described in §447.56(f) of this

final rule.

4. Higher Cost Sharing Permitted for Individuals with Incomes above 100 percent of the FPL (§447.52)

We proposed to consolidate the current multiple cost sharing rules implementing sections 1916 and 1916A of the Act, respectively, into one set of streamlined cost sharing regulations for both statutory authorities at proposed §447.52. Under section 1916 of the Act, states may impose nominal cost sharing on individuals not exempted by the statute. Under section 1916A of the Act, statute states may impose cost sharing at higher than nominal levels for nonexempt individuals with incomes above 100 percent of the FPL. For individuals with income above 100 and at or below 150 percent of the FPL, section 1916A of the Act permits cost sharing for nonexempt services up to 10 percent of the cost paid by the state for such services. (Different rules, discussed below, pertain to cost sharing for drugs and emergency department services). For individuals with income above 150 percent of the FPL, such cost sharing may not exceed 20 percent of the cost paid by the state. We received the following comments concerning the proposed provision for higher cost sharing permitted for individuals with incomes above 100 percent of the FPL:

Comment: A few commenters were concerned that we proposed to permit cost sharing for children.

Response: We did not propose new policy in the proposed rule related to cost sharing for children. Section 1916A of the Act permits states to impose cost sharing on certain children by exempting children covered under mandatory eligibility categories. This statutory option, implemented at §447.70 of the current regulations, is retained in this rulemaking at §447.56(a)(1)(i) through (VI). We revised the description of children who are exempt from premiums and cost sharing at §447.56(a)(1)(i)(iii) to reflect the consolidation of different

statutory eligibility groups for children under a single regulatory section at §435.118 of the March 2012 final rule. We also made a technical change to the description of children exempt from premiums and cost sharing under §447.56(a)(1)(i)(iv) to reflect the changes in the types of assistance available under Title IV-E of the Act. These are not substantive changes and are intended solely to assist states in appropriately identifying those children who may be charged premiums and cost sharing and exempting those who may not, as described in the statute.

Comment: One commenter recommended that CMS specify health centers' statutory responsibility related to the grants provided under section 330 of the Public Health Services Act (PHSA) to provide services regardless of ability to pay and clarify that states may not impose on health centers any obligations that conflict with these requirements. The same commenter also recommended that CMS add an exception at §447.56(c)(3), entitling FQHCs to full Medicaid payment in situations in which they are required to collect cost sharing that would directly conflict with the section 330 requirements to waive a portion of the Medicaid cost sharing, and at §447.56(e)(1) to authorize FFP for cost sharing amounts waived by an FQHC. At a minimum, the commenter recommends that CMS and HRSA issue joint guidance to minimize the tension between the Medicaid and section 330 of the PHSA regulations concerning patient payment obligations for services provided by FQHCs.

Response: The obligations of FQHCs related to their section 330 grants, as well as reimbursement to FQHCs, are beyond the scope of this regulation. This regulation does not require that FQHCs bill patients for cost sharing, but it does require that the payment to the provider take into account the cost sharing obligation. This requirement that states deduct a beneficiary's cost sharing obligation from the payment to providers is not new policy. It is contained in current regulations at §§447.57 and 447.82, redesignated at §447.56(c) in this final rule. FQHC services are not specified as exempt from cost sharing under sections 1916 or

1916A of the Act and we do not believe that the Secretary has authority to mandate that states nonetheless exempt such services from cost sharing based on FQHCs' section 330 obligations. States, however, do have the flexibility to exempt particular services (including FQHC services) from cost sharing and/or to adjust the amount of cost sharing imposed, consistent with the regulations.

Comment: Some commenters recommended permitting flat-dollar copayments for all income groups, which they think would be easiest for enrollees and providers to understand and for Medicaid plans to administer. One commenter requested that we clarify how a limit based on 10 percent of the cost the agency pays for the service for individuals with family income above 100 percent but at or below 150 percent of the FPL and 20 percent of the cost the agency pays for the service for individuals with income over 150 percent of the FPL, would apply to FQHC services reimbursed under the prospective payment system (PPS). The commenter is concerned that because the amount of reimbursement under the PPS varies by health center, the maximum allowable cost sharing obligation for a particular service or visit would differ from health center to health center, and that this would be administratively burdensome for states, managed care plans, and providers; inequitable for beneficiaries; and could impede access to FQHC services. The commenter recommends that we revise the rule to provide that the maximum cost sharing for all individuals for FQHC services reimbursed under the PPS rate be the same as the maximum rate for individuals with income at or below 100 percent of the FPL.

Response: Section 1916A of the Act sets the maximum allowable cost sharing for individuals with income over 100 percent and at or below 150 percent of the FPL at 10 percent of what the agency pays for the service and for individuals with income over 150 percent of the FPL, at 20 percent of what the agency pays. We do not have the authority to change the maximum amount to a flat fee. We note that these percentages represent the maximum

allowable charges. States have the flexibility to establish lesser cost sharing amounts for any service, and they may use a flat fee as long as it does not exceed the maximum level permitted. In determining the cost sharing for a particular service, states also can use the average payment made for the service across providers or units of the service to develop a consistent cost sharing amount within the maximum amount allowed by statute and regulation.

Comment: One commenter asked for clarification regarding the definitions of income that states should use in setting cost sharing charges, other than to say that the definitions of household income in §435.603 should be used in determining the aggregate limit on cost-sharing. The commenter sought further clarification on the meaning of “family income” and suggested that states be required to describe their methodology in their state plan for approval by the Secretary as reasonable.

Response: In the interest of streamlining the requirements and reducing administrative burden, we are not requiring states to include, in their state plans, the methodology for determining income specific to premiums and cost sharing. For individuals whose financial eligibility is determined based on modified adjusted gross income (MAGI), “family income” for the purposes of imposing premiums or cost sharing or for defining the aggregate limit means “household income” using MAGI-based methods, as set forth in §435.603. For individuals who are exempt from MAGI under section 1902(e)(14)(D) of the Act, implemented at §435.603(j) of the regulations, we are still examining options related to income determinations.

Comment: One commenter stated that we do not have the authority to allow targeted cost sharing because it would violate comparability and recommended that we delete proposed §447.52(c), relating to “targeted cost sharing.” Another commenter stated that additional targeting and variation of cost sharing within groups would add unnecessary complexity and should not be used.

Response: We are retaining the option for states to target cost sharing to specified groups of individuals. Comparability is required for cost sharing imposed under section 1916 of the Act. However, section 1916A(a)(1) of the Act provides that, “a State, at its option and through a state plan amendment, may impose premiums and cost sharing for any group of individuals (as specified by the State) and for any type of services ... and may vary such premiums and cost sharing among such groups or types, consistent with the limitations established under this section.” This provision is codified in current regulations at §447.62(a). Therefore, at redesignated §447.52(d) of the final rule states may apply targeted cost sharing on specified groups of individuals; such cost sharing is limited to individuals with income over 100 percent of the FPL, per the requirements of section 1916A of the Act. We have revised §447.52(d), adding paragraphs (1) and (2) to clarify that for cost sharing imposed for non-preferred drugs and non-emergency services furnished in an ED, the state may target to individuals below 100 percent of the FPL as well as those above, as allowed by section 1916A of the Act.

Comment: We solicited comments on whether the regulations should specify ways in which states may target different defined groups of individuals (with income over 100 percent of the FPL) for differential cost sharing under proposed §447.52(c). One commenter suggested that the regulation should make it clear that targeting must be reasonable, that individuals with lower incomes may not be charged more than those with higher incomes, and that targeting may not discriminate based on gender, physical or mental disability, age, race, ethnicity, or any other protected classification. Another commenter requested that the Secretary include criteria that must be considered by states in targeting cost sharing to particular types of beneficiaries.

Response: Section 1916A of the Act gives states authority to target premiums and cost sharing to any group of individuals with income above 100 percent of the FPL (for cost sharing

imposed for non-preferred drugs or non-emergency use of the emergency department, states can target to individuals at all income levels as discussed above), and to vary such premiums and cost sharing among the groups. In examining all the possible ways in which targeting could be applied, we believe targeting based on eligibility group or income level are the only targeting methods consistent with section 1916A of the Act, which will not lead to discriminatory practices. Thus, states can choose to impose premiums or cost sharing on individuals with income above 100 percent of the FPL in particular eligibility groups and to vary them by income level within the group. States may not target solely on the basis of delivery system – managed care, fee-for-service, and primary care case management – but may target eligibility groups covered through a specific service delivery system like managed care. States may not target based on disease-type or chronic condition. We note that states can impose cost sharing on whichever non-exempt service they choose for individuals at any income level subject to limitations in the regulations, and are not required to impose cost sharing on all non-exempt services in the state plan. For the recommendation regarding lower income versus higher income individuals, as noted above, we added §447.52(g) to specify that if a state imposes income-related charges, it may not impose a higher charge for lower-income individuals than is charged for higher-income individuals.

5. Cost sharing for drugs (§447.53)

We proposed to establish a single provision governing cost sharing for drugs which would apply to nonexempt individuals at all income levels. To provide additional flexibility to states, and to further encourage the use of preferred drugs, we proposed to define “nominal cost sharing” as no more than \$8 for non-preferred drugs and \$4 for preferred drugs for individuals with income at or below 150 percent of the FPL. For individuals with family income above 150 percent of the FPL, per section 1916A(c) of the Act, a higher cost sharing charge may be

established for non-preferred drugs, not to exceed 20 percent of the cost the agency pays for the drug. While states may not impose cost sharing on exempt individuals for preferred drugs, states may elect to impose cost sharing for non-preferred drugs on individuals who are otherwise exempt up to the nominal cost sharing amount. Cost sharing for a non-preferred drug must be limited to the amount imposed for a preferred drug if the individual's prescribing provider determines that the preferred drug for treatment of the same condition either will be less effective for the individual or will have adverse effects for the individual or both. Under the proposed rule, states would have the flexibility to apply differential cost sharing for preferred versus non-preferred drugs. For example, a state may charge \$1 for preferred and \$5 for non-preferred drugs or \$0 for preferred and \$8 for non-preferred drugs. We received the following comments concerning the proposed cost sharing for drugs provisions:

Comment: A few commenters suggested we take an approach that distinguishes between formulary generic and formulary brand drugs (instead of preferred and non-preferred). One commenter noted that this approach may be more helpful in the managed care context. One commenter requested clarification as to whether the requirement that all drugs be considered preferred for cost sharing purposes if the agency does not differentiate between preferred and non-preferred, is a de facto preferred status. The commenter was concerned that this could result in lower cost sharing for more expensive brand name drugs that are not identified by the state as non-preferred. One commenter was opposed to the definition of preferred drugs at proposed §447.51 to include all drugs if the agency does not differentiate between preferred and non-preferred drugs.

Response: Section 1916A of the Act allows states to have different cost sharing levels for preferred and non-preferred drugs, but does not speak to generic versus brand name drugs. States may use a variety of methods to determine preferred and non-preferred drugs including

whether the drug is a brand or generic. States also maintain other cost control measures, such as mandatory generic substitution policies. The definition of preferred drugs, which includes all drugs if the agency does not differentiate between preferred and non-preferred drugs, is consistent with section 1916A(c) of the Act and current regulations at §447.70(a).

Comment: Several commenters disagreed with the proposed policy to allow cost sharing for up to \$4 for preferred drugs and \$8 for non-preferred drugs. They described research showing that even low prescription drug copayments may cause very low income people to defer filling prescriptions. The commenters argue that Medicaid beneficiaries cannot be incentivized to select a preferred drug, as is accomplished with some success among middle class consumers; instead, with such high cost sharing differentials, Medicaid enrollees will go without the “non-preferred” drug even if it is medically necessary and would work far more effectively than a preferred drug. These commenters recommend that CMS define nominal drug cost sharing in relation to the income and health status of the Medicaid population and amend the table at §447.53(b) to establish maximum cost sharing as follows: individuals with family income at or below 150 percent of the FPL – Preferred drugs: \$1.10, Non-preferred drugs: \$3.30; individuals with family income exceeding 150 percent of the FPL – Preferred drugs: \$1.10; Non-preferred drugs: \$4.20. Two other commenters expressed concern with the \$8 copay for non-preferred drugs if states have latitude to classify most or all of the brand-name drugs in a therapeutic class as non-preferred. One commenter stated the proposed increase in cost sharing is unnecessary because states already have many tools to control prescription drug costs and have high utilization of generic drugs. Other commenters appreciated the flexibility proposed for cost sharing. One commenter welcomed the increased maximum cost sharing, and one commenter stated that allowing states to charge higher cost sharing for non-preferred drugs, when effective, lower-cost alternatives are available, is a reasonable policy.

Response: We agree that cost sharing is just one of many tools that states may use to manage drug utilization, and states may determine that higher cost sharing does not enhance their efforts to promote the use of preferred drugs. However, we also agree that it is a tool permitted under the statute. In the final rule we are maintaining the option for states to impose cost sharing of up to \$4 for preferred drugs and \$8 for non-preferred drugs for all individuals, including those with income at or below 150 percent of the FPL, and for those with income above 150 percent of the FPL, to continue to establish higher non-preferred drug cost sharing of up to 20 percent of the cost of the drug. As described at §447.53(e), as revised in the final rule, if a prescriber finds that the non-preferred drug is medically necessary, the state must have a process in place to limit cost sharing for that drug to the amount for preferred drugs.

Comment: One commenter suggested that the final rule require a cap on cost sharing for non-preferred drugs as a necessary protection for this vulnerable population.

Response: The 5 percent aggregate limit on cost sharing in the current regulation and included in this final regulation at §447.56(f) applies to all cost sharing, including that for non-preferred drugs. States have the option to establish additional cost sharing limits for particular services, such as drugs at §447.56(f)(5) of the final rule, but we do not have the authority to mandate a cost sharing cap specific to non-preferred drugs.

Comment: A few commenters stated that CMS was circumventing the statutory requirements of section 1916A of the Act by setting two different maximum “nominal” amounts for preferred and non-preferred drugs because the Act requires that cost sharing for all drugs imposed on individuals with income under 150 percent of the FPL must not exceed the “nominal” cost sharing as otherwise determined under section 1916 of the Act. Additionally, the commenter notes that section 1916A of the Act explicitly allows states to charge up to twice the nominal amount for non-emergency care furnished in an emergency department, so if Congress

intended to allow the same for non-preferred drugs, Congress would have provided such an option in the statute.

Response: Section 1916 of the Act gives the Secretary the authority to define nominal cost sharing. There is nothing in the statute which requires a single definition of what is considered to be nominal. Moreover, the general cost differential between preferred and non-preferred drugs merits a different nominal maximum for each type, therefore we believe it is appropriate to establish a \$4 nominal maximum for preferred drugs and an \$8 nominal maximum for non-preferred drugs.

Comment: One commenter expressed concern for vulnerable populations that require certain classes of drugs, such as HIV antiretroviral drugs, and recommended they be available at the “preferred” drug cost-sharing level.

Response: States have the discretion to designate which covered drugs within each class of drugs will be considered preferred or non-preferred. Beneficiaries must always have access to necessary drugs at the preferred drug rate because a given drug cannot be considered non-preferred unless the state has an equivalent drug available at the preferred rate. In addition, §447.53(e), as revised in this final rule, requires states to provide a non-preferred drug at the preferred drug cost sharing level, if the prescribing provider determines that the preferred drug would be less effective or have adverse effects on the individual.

Comment: A few commenters recommended that we convert the non-preferred prescription drug copayment to a flat dollar amount for individuals with incomes over 150 percent of the FPL instead of basing cost sharing on what the agency pays for the drug.

Response: As discussed above, section 1916A of the Act sets the maximum allowable non-preferred drug cost sharing level for individuals with income over 150 percent of the FPL at 20 percent of what the agency pays for the drug. CMS does not have the authority to change the

maximum amount allowed to a flat fee, but states may construct their charges as flat fees as long as such fees are within the maximums established by law.

Comment: One commenter supported the proposed increase of allowable cost sharing for non-preferred drugs when Medicaid recipients and not Medicaid pharmacy providers bear responsibility for the higher cost sharing. The commenter requested that, when enhanced cost sharing for prescription drugs is implemented, we mandate states to condition services on the payment of such cost sharing. Alternatively, the commenter requested that CMS mandate states to develop a mechanism whereby participating pharmacies can submit unpaid cost sharing amount to the state for payment. One commenter recommended that HHS require states to implement cost sharing provisions for prescription drugs and to permit providers to withhold medication (whether preferred or non-preferred) from beneficiaries for failure to pay cost sharing.

Response: The imposition of premiums or cost sharing is an option permitted states under sections 1916 and 1919A of the Act and cannot be mandated by the Secretary. The statute stipulates that providers, including pharmacies, may not deny services to individuals with income at or below 100 percent of the FPL due to inability to pay their cost sharing obligation. States have the option to allow providers to deny services to individuals with income over 100 percent of the FPL if they do not pay required cost sharing. If a state opts to allow providers to deny services if the individual does not pay the cost sharing, this must be indicated in their state plan. Regardless of whether an individual pays the cost sharing, states must deduct the payment made to the provider by the amount of the individual's cost sharing obligation in accordance with §447.56(c) of this final rule. We do not have the statutory authority to alter these requirements in the manner being suggested by the commenters.

Comment: One commenter requested clarification as to whether states have the option to

impose cost sharing for non-preferred drugs on individuals otherwise exempt from cost sharing. One commenter recommended that states should have the option to impose cost sharing on exempt individuals for certain classes of prescription drugs that the state identifies as elective or controversial, such as narcotics.

Response: Section 1916A of the Act allows states to impose cost sharing for non-preferred drugs on otherwise exempt individuals, provided that such cost sharing does not exceed a nominal amount. At §447.53(b) of the final rule, we have defined nominal cost sharing for preferred drugs as no more than \$4 and for non-preferred drugs at no more than \$8. We are revising §447.53(d) in the final rule to clarify that cost sharing for non-preferred drugs imposed on otherwise exempt populations cannot exceed the nominal amount defined in §447.53(b) in accordance with section 1916A(c) of the Act. While states may impose cost sharing on some drugs and not other drugs, all cost sharing must be consistent with the requirements of §447.53(b) and, if there are no drugs identified as non-preferred drugs in a class, cost sharing for drugs in that class cannot exceed the nominal amounts for preferred drugs. Identification of “elective” or “controversial” drugs is beyond the scope of this regulation.

Comment: A few commenters stated that the proposed cost-effectiveness standard for determining which drugs are non-preferred is inappropriate and does not include the anti-discrimination protections contained in the Affordable Care Act. The commenter believed that this standard would threaten access to needed treatment and would result in broad, one-size-fits-all policies that do not reflect important differences in individual beneficiary needs and circumstances. One commenter recommended that the definition of preferred drugs not be restricted to low-cost or exclusively generic agents, and should encourage the inclusion of high-value brand agents, especially when a generic equivalent is not available. The commenter believed that preferred and non-preferred drugs should be chosen based on clinical value, not

solely on the basis of acquisition price. One commenter recommended that the definition of preferred and non-preferred drugs be determined based on clinical assessment of the individual. One commenter recommended that the definition of preferred drugs be expanded to include the generic equivalent of brand named drugs.

Response: The definition of preferred drugs for cost sharing purposes at §447.51 does not prescribe the type of drugs that the state designates as preferred or non-preferred, and requiring the inclusion of certain drugs on a state's preferred drug list is beyond the scope of this regulation. However we do not believe that preferred drug programs limit individuals' access to necessary drugs. These regulations require that states establish a process through which a beneficiary can access a non-preferred drug, which his or her provider has determined to be medically necessary for the beneficiary, with cost sharing limited to the amount applicable to preferred drugs. We believe that this policy would not violate any non-discrimination standards since all beneficiaries are subject to the Medicaid requirements of the preferred drug list, which direct that it be developed in a manner that does not discriminate against any particular class of individual, or type of disability or disease. In addition, as previously noted in guidance (SMDL #04-006, September 9, 2004), states need to assure that patients continue to have access to needed medications so in addition to cost considerations, a preferred drug list should be based on clinical criteria that considers the efficacy of the drug to others in that class.

Comment: Several commenters were concerned that allowing states to impose cost sharing of up to 20 percent of what the agency pays for a non-preferred drug, for individuals with income over 150 percent of the FPL, would be overly burdensome for individuals with chronic conditions.

Response: Section 1916A(2)(B) of the Act provides for the flexibility to impose cost sharing at these levels for individuals with incomes above 150 percent of the FPL. We did not

propose to change this flexibility, which is codified at §447.74 of the current regulations, and is moved to §447.53 in this final rule. The Secretary does not have the authority to change or reduce the percentage of the cost of the item or service that is the maximum allowable cost sharing because the statute is clear. We note that such cost sharing is subject to the aggregate limit codified at §447.56(f) of this final rule.

Comment: Several commenters suggested that we revise §447.53(e) to provide more detailed requirements for the process states must have in place to allow for cost sharing at the preferred drug level, in the case of a non-preferred drug that the prescribing provider has determined would be less effective or may adversely affect the individual. The commenters stated that any process should take into account the electronic claims processing used by pharmacies and pharmacists and should be easy for the prescriber to invoke. Several commenters also recommended that states be required to describe their process in the state plan and provider manuals. One commenter believed that this requirement undermined the intent of the regulations to encourage the use of less expensive preferred drugs because for a state to actually cover a non-preferred drug, the prescriber already has to receive prior-authorization, meaning most, if not all non-preferred drugs would have to be provided at the lower cost sharing amount.

Response: States must have a process in place for providing prior authorization of medically necessary drugs that meets the existing requirements at section 1927(d)(5) of the Act, therefore we are not prescribing additional requirements in this regulation or requiring states to describe the process in their state plan. However, we are revising the final rule to add the word “timely” to the process states must use to allow for cost sharing at the preferred drug level in accordance with the section 1927 of the Act. We will monitor state implementation and determine whether additional guidance is necessary.

6. Cost sharing for emergency department (ED) services (§447.54)

Sections 1916(a)(3) and 1916(b)(3) of the Act, allow states to obtain a waiver to impose cost sharing for non-emergency use of the ED that does not exceed twice the nominal amount for other outpatient services. Section 1916A(e)(2)(A) of the Act also allows cost sharing for individuals with income above 100 percent of the FPL and at or below 150 percent the FPL in an amount not to exceed twice the nominal amount as determined by the Secretary. We proposed to consolidate current regulations at §447.54(b) and §447.72 related to non-emergency use of the ED into proposed §447.54. To facilitate states' ability to utilize flexibility provided in existing regulations, for all individuals with income at or below 150 percent of the FPL, we proposed to allow cost sharing of no more than \$8, which represents twice nominal, for non-emergency use of the ED without requiring a waiver. The proposed changes are discussed in more detail in the January 22, 2013 Medicaid Eligibility Expansion proposed rule (78 FR 4659 and 4660). We received the following comments concerning the proposed provision for cost sharing specific to non-emergency use of the ED:

Comment: Many commenters opposed the policy to allow up to \$8 for non-emergency use of the ED because it might cause individuals with incomes at or below 150 percent of the FPL to forego necessary services, including potentially lifesaving services, and because many Medicaid beneficiaries go to the ED because they lack access to regular sources of primary care. Foregoing necessary services may result in adverse health outcomes requiring more expensive care later. Many commenters recommended that the maximum allowable cost sharing should be set at \$3.30 for individuals with family income at or below 100 percent of the FPL, \$6.30 for individuals with family income from 101-150 percent of the FPL and \$12.00 for individuals with family income above 150 percent of the FPL. Several other commenters recommended that the maximum allowable cost sharing amount for non-emergency use of the ED be limited to \$4 to align with the what is proposed for other services. Several commenters recommended that CMS

allow states the flexibility to impose cost sharing for non-emergency use of the ED that exceeds \$8, to decrease inappropriate use of the ED. One commenter recommended that up to three times the outpatient services copayment (rather than two) should be allowed in states that are working to expand access to alternative options for care. Many commenters recommended that for individuals with family income at or below 100 percent of the FPL, we revise the regulations to allow cost sharing for non-emergency use of the ED, only when no cost sharing (rather than lesser cost sharing) is imposed to receive such care through an outpatient department or other alternative health care provider in the geographic area of the hospital ED involved.

Response: We believe it is important for states to have options to incentivize care in the most appropriate settings and to encourage individuals to develop a regular source of care, to the extent that beneficiaries are assured timely access to needed care. One option to achieve this is through cost sharing initiatives, therefore, we are finalizing §447.54(b) as proposed, however we note that we have made some minor technical changes in the final rule to spell out the term emergency department instead of using the acronym ED and to refer to non-emergency services instead of treatment. The technical changes are for clarification only and are not intended to be substantive. The \$8 maximum for non-emergency use of the ED is twice the nominal amount for outpatient services, which is the maximum allowable cost sharing permitted under sections 1916 and 1916A of the Act for individuals with income at or below 150 percent of the FPL. The statute does not limit the amount states can impose for non-emergency use of the ED on individuals with income over 150 percent of the FPL (other than through the aggregate cap of 5 percent of family income), and we do not have the authority to limit such cost sharing through regulation. Section 1916 of the Act requires that there be an accessible alternative provider to provide the services, but does not require that there be no cost sharing for such services and section 1916A of the Act requires there be lesser cost sharing for services provided by the

alternative provider, or no cost sharing if the cost sharing is being applied to an otherwise exempt individual. To streamline the requirements to make it administratively feasible for states to meet this requirement, we are maintaining the proposed policy in the final rule that services provided by an alternative provider must be available with lesser cost sharing or no cost sharing only if the individual is otherwise exempt from cost sharing. We note that for individuals with income at or below 100 percent of the FPL the state may not allow a provider – including a hospital ED – to deny services in the event that an individual is unable to pay the cost sharing.

We note that in the final rule we are deleting §431.57 of this subchapter relating to the waiver of cost sharing requirements for states to impose cost sharing for non-emergency services furnished in an ED. This language is redundant with §447.54(b) of the final rule, which allows states may impose cost sharing up to twice the nominal amount for such services through the state plan. In addition to this technical change, we updated the citations to the cost sharing regulations at §§435.121, 435.831, 436.831, 438.108, 440.250, 447.15, 447.20, and 457.540.

Comment: One commenter recommended that CMS make public the amount of documented Medicaid savings in states that have imposed cost sharing for non-emergency use of the ED.

Response: We are not revising the rule to require states to document savings. However, we will examine available options for sharing best practices and other data available from states with successful ED diversion programs.

Comment: Several commenters noted a drafting error at §447.54(c), which they believe should be revised to read: “... not to exceed the maximum amount established in paragraph (b) of this section...” The commenters also believed we made an error in §447.54(d), which they think should read “... to impose cost sharing under paragraph (a), (b) or (c) of this section of non-emergency....”

Response: We agree that there was a drafting error in paragraph (c) and have corrected the provision in this final rule. However, paragraph (d) was written as intended, and is finalized as proposed. Paragraphs (a) and (c) provide the authority to impose cost sharing, while paragraph (b) describes the maximum allowable amounts.

Comment: One commenter recommended that cost sharing for non-emergency use of the ED should be permitted for any visit to the ED that does not result in an inpatient stay.

Response: Sections 1916 and 1916A of the Act prohibit cost sharing for emergency services. As there are many emergency conditions and services that do not result in an inpatient stay, the commenters' suggested policy would violate the statute.

Comment: Many commenters recommended that states that impose cost sharing for non-emergency services provided in an ED be required to permit newly-enrolled individuals to make at least one non-emergency ED visit before requiring them to pay this cost-sharing obligation.

Response: States have the option to establish such a policy under current regulations and the new rule as finalized, but we do not think it appropriate to require it.

Comment: Some commenters suggested that we designate underserved areas and/or certain periods of time in which insufficient access warrants exemption from cost sharing for non-emergency use of the ED.

Response: Per §447.54(d), before imposing cost sharing for non-emergency use of the ED, the hospital must provide the individual with a name of and location of an available and accessible provider and provide a referral to coordinate scheduling. If geographical or other circumstances prevent the hospital from meeting this requirement, the cost sharing may not be imposed.

Comment: Several commenters asked that we refrain from adding more specificity or requirements in the regulation itself, for example imposing further requirements or pre-

conditions on a state's authority to impose cost sharing for non-emergency services provided in an ED, which they believed would limit the ability of states to account for variation across states. A few commenters were concerned that we had added a new requirement in stipulating that hospitals ensure that an alternative provider is available to provide needed services with lesser or no cost sharing. They were concerned the use of the term "ensure" in proposed §447.54(d)(2)(ii) would require hospitals to "ensure" something beyond their control, presenting unnecessary administrative burden for state administrators and hospitals. Many commenters stated that CMS should remove the requirements at proposed §447.54(d)(2)(iii) that ED staff provide a referral and coordinate scheduling with an available and accessible alternative non-emergency services provider, because it is administratively burdensome and takes time and resources away from patient care. In addition, they argue that compliance is infeasible given hospitals' limited access to current, accurate information on the availability of appointments with other providers. The commenters believed that these requirements will make it difficult for states to take up the option afforded under the statute and that it would be less costly for an ED to provide treatment for the non-emergency conditions than to coordinate a referral. One commenter stated that the requirement to provide a referral is unnecessary because in many state managed care programs, every enrollee has a primary care provider and 24-hour call-in lines are available, enabling hospitals providing the care to contact either the enrollee's primary care provider or the 24-hour call-in line as an alternative to following the steps listed in §447.54(d). Another commenter stated that the language in proposed §447.54(d)(2)(iii) differs from the requirement at current §447.80(b)(2)(iii), and that the revised language would impose additional burdens on states' ability to effectively implement cost sharing. The commenter noted that current §447.80(b)(2)(iii) requires hospitals to provide "a referral to coordinate scheduling of treatment by an available and accessible alternative non-emergency services provider," while proposed

§447.54(d)(2)(iii) requires hospitals to “coordinate scheduling and provide a referral for treatment by this provider.”

Response: We did not intend to add additional requirements for hospitals related to cost sharing for non-emergency use of the ED. Rather, our intent was to clarify the existing language. To eliminate any confusion, we are replacing the word “ensure” with “determine” in §447.54(d)(2)(iii), as redesignated in the final regulation. This is consistent with the statutory requirement that before collecting cost sharing for non-emergency use of the ED, hospitals must provide individuals with the name and location of an available and accessible provider that can provide the service with lesser or no cost sharing. States share in this responsibility, of course, and will need to work with hospitals to ensure that hospitals are able to determine whether such care is available and accessible. The goal underlying the policy is to ensure that the right care is provided at the right time in an appropriate setting.

The language in proposed §447.54(d)(2)(iii), redesignated at §447.54(d)(2)(iv) of this final rule, was intended to clarify the referral requirement, which is in current regulation at §447.80(b)(2), and which reflects statutory language. We did not intend to change the substance of the rule. However, to avoid any confusion we are revising §447.54(d)(2)(iv) to reinstate the language from the current rule that hospitals must provide a referral to coordinate scheduling for treatment by an alternative provider. To confirm that the alternative non-emergency services provider is “actually available and accessible” as required by statute, it is important that scheduling be done onsite, with the beneficiary present, to the maximum extent possible. We recognize that this may not be possible during certain hours of the night, in which case follow-up scheduling may be necessary. Hospitals can and should take advantage of the existence of a call line and assigned primary care providers in satisfying the coordination requirements in the statute and regulations, and states should assure, before imposing such cost sharing, that

procedures are in place that can facilitate hospitals' ability to carry out these responsibilities, including outside of regular business hours.

Comment: One commenter requested clarification of the referral requirement, including whether a patient should have a scheduled appointment, or just the information necessary to make an appointment, with an alternative provider when he or she leaves the hospital; whether community clinics or FQHCs may serve as alternative, non-emergency providers for referral from the ED; and the appropriate process for completing a referral when physician offices are closed. One commenter requested that we define "timely manner" in proposed §447.54(d)(2)(ii).

Response: The regulations are not prescriptive on the exact process to be used by hospitals. States have flexibility to establish processes to meet the coordination goals in the statute and regulations in a manner that best accommodates their systems and provider networks. The extent to which a state relies on managed care or establishes patient centered medical homes, for example, may impact how a state would meet the requirements in the regulation. As noted above, whenever possible, hospitals should attempt to schedule the appointment while the patient is present, but if that is not feasible, the hospital would need to follow up to ensure that an alternative provider is "actually available and accessible" in a timely manner, as required by statute.

Section 1916A (e)(4)(B) of the Act describes an alternative non-emergency services provider as one "that can provide clinically appropriate services for the diagnosis or treatment of a condition contemporaneously with the provision of the non-emergency services that would be provided in an emergency department." Any Medicaid participating providers, including clinics that can do so, are acceptable. Because we do not think that there is a uniform definition of timeliness that is appropriate for all situations, we are not defining "timely manner" in the regulation. In meeting a general timeliness standard, however, states should direct hospitals to

consider the medical needs of the individual to assess (1) whether care is needed right away or if a short delay in treatment would be sufficient, and (2) any particular challenges the person may face in accessing follow-up care, such as leave from employment, child care, or ability to receive language assistance services or accessible care for people with disabilities. States will need to work with the hospitals, non-emergency providers, and managed care organizations participating in their Medicaid programs to design a referral network and system that fulfills the statutory requirements prior to imposing cost sharing amounts for non-emergency services provided by a hospital ED. The intent of this provision is to provide an additional tool to ensure that care is provided in a timely and appropriate manner to drive better quality at lower costs. It is not to be implemented in a way that results in people not getting the care they need.

Comment: One commenter believed that we omitted from proposed §447.54(d) some of the statutory requirements that hospitals must meet before collecting cost sharing for non-emergency use of the ED, including the obligation to inform the recipient that he or she does not have an emergency medical condition and the requirement to notify the recipient of the applicable cost sharing for treatment of a non-emergency condition in the ED.

Response: We did not omit any of the statutory requirements in the proposed rule. The requirement that the hospital inform individuals whether or not they need emergency services, and of the cost sharing obligation to receive services in the ED is implicit in the requirements that the assessment be performed and that the hospital provide the individual with the name and location of an available and accessible alternative provider that can provide services with lesser or no cost sharing. We do not see a need to state as much explicitly in the text of the regulation. However, for clarity, we have added a new paragraph (i) at §447.54(d)(2) requiring hospitals to “inform the individual of the amount of his or her cost sharing obligation for non-emergency services provided in the emergency department.” Proposed §§447.54(d)(2)(i) through (iii) are

redesignated in this final rule as §§447.54(d)(2)(ii) through (iv), respectively.

Comment: A few commenters recommended that the Secretary ensure that the safeguards at §447.54(d) are observed by states that impose cost sharing for non-emergency use of the ED.

Response: We will ensure through the state plan amendment process that the requirements of §447.54(d) are met, and expect to oversee implementation to the extent feasible.

Comment: One commenter recommended that the final rule include requirements for oversight and reporting to ensure that higher cost-sharing is not imposed without verification of the availability of alternative providers able to furnish non-emergency care. In addition, the commenter recommended enhanced requirements for verification in rural and other areas with a shortage of primary care physicians and specialists that will see Medicaid patients that there is available and accessible care by an alternative provider. A few commenters recommended that, at a minimum, the ED should be required to specify what the particular patient's cost-sharing obligation will be, including in the case of a patient with income above 150 percent of the FPL, that the patient may be responsible for 100 percent of the charges. The commenter also believed that, prior to an emergency room providing non-emergency care to a Medicaid beneficiary the hospital should be required to obtain written consent from the individual to receive the non-emergency care in the ED and to take responsibility for any cost-sharing obligation for such care.

Response: The statute, codified at §447.54(d) in this rulemaking, sets forth clear requirements that states must effectuate to establish cost sharing for non-emergency use of the ED, including a requirement that hospitals provide information on available and accessible providers who can provide the needed non-emergency services with lesser or no cost sharing. States must ensure that hospitals are able to meet these requirements, whether in a rural, suburban, or urban setting. We ensure that states are in compliance with the statute and regulations through the state plan amendment process and will consider whether further

reporting is necessary for oversight purposes. For cost sharing for individuals with income above 150 percent of the FPL, we note that the statute does not require states to make such patients responsible for 100 percent of the charges for non-emergency use of the ED, but also does not limit the cost sharing that states can impose on individuals in this income bracket for non-emergency use of the ED. At proposed §447.52(b)(3), finalized in this rulemaking at §447.52(c), any cost sharing imposed for any service may not equal or exceed the amount the agency pays for the service; such cost sharing is also limited by the 5 percent aggregate limit described at §447.56(f).

Comment: Several commenters stated that the rule does not provide a clear methodology for determining "non-emergency" status. One commenter highlighted the preamble discussion in the proposed regulation about the difficulty in determining whether a service is needed to address an emergency situation based on Current Procedural Terminology (CPT) codes alone, and the lack of guidance on other standards that could be used, and requested that CMS more clearly define "non-emergency" or provide states latitude to define as needed. Another commenter shared our concerns about CPT codes and noted that, while the imposition of non-emergency ED cost sharing is not administratively feasible without some type list, any protocols must also avoid violation of the emergency screening requirements under the Emergency Medical Treatment and Active Labor Act (EMTALA). One commenter stated that the EMTALA requirements are sufficient to determine which individuals should be subject to cost sharing for non-emergency use of the ED, and that states should not have to describe the processes in the state plan. Another commenter expressed concern about beneficiaries' general ability to distinguish between "emergency" and "non-emergency" symptoms. The commenter was concerned that adequate protections be in place to ensure that beneficiaries are not punished for seeking emergency care when doing so is appropriate under a prudent layperson standard.

Another commenter agreed that in distinguishing between “emergency” and “non-emergency” conditions, hospitals must use the prudent layperson definition, not a discharge diagnosis. One commenter stated clinical reviews of ER claims to look at presenting conditions such as chest pain seem would be administratively burdensome, and could delay treatment, referral, or payment to providers. Other commenters requested that we either clearly define “non-emergency” services or provide states with the latitude to define them as needed, and several commenters asked us to maintain the maximum level of flexibility in the rule to facilitate appropriate and feasible implementation of non-emergency ED cost sharing.

Response: “Non-emergency” services are defined at §447.51, which cross references to the current definition of emergency services at §438.114. This definition relies on a prudent layperson standard, in that a medical condition manifests itself by acute symptoms of sufficient severity that a prudent layperson that possesses an average knowledge of health and medicine could deduce that they need emergency medical attention. We agree that it is difficult to implement a system to differentiate non-emergency from emergency services for cost sharing purposes in a way that ensures beneficiary protections consistent with the prudent layperson standard. We continue to believe that the use of diagnosis and procedure codes alone is not an appropriate process for determining non-emergency services, as doing so would not adequately protect beneficiaries legitimately seeking ED services based on the prudent layperson standard, for whom a CPT code assigned after care is provided may indicate a non-emergency condition. We sought comments on feasible methodologies for states and hospitals to use to make this distinction, but did not receive any recommendations. Therefore, we are not making any revisions in the final rule to prescribe how states can and should distinguish between “emergency” and “non-emergency” conditions for cost sharing purposes. We remain open to states’ proposals for distinguishing between “emergency” and “non-emergency” conditions and

will review such proposals through the state plan amendment process. As successful models emerge we will develop further guidance.

Comment: One commenter asked if would be reasonable to have the Medicaid agency reimburse hospitals for the medical screening that they must conduct. Another commenter asked if a hospital could be reimbursed for providing a referral and giving advice on other appropriate providers.

Response: To the extent the provider properly bills the Medicaid agency for an assessment or evaluation conducted on a Medicaid beneficiary, the provider would be entitled to payment for the service as provided for in the state's Medicaid State plan. States may also establish payment specifically for the medical screening exam required by EMTALA and/or for coordination of referrals to alternative non-emergency services providers.

Comment: One commenter suggested that CMS allow hospitals to charge the maximum allowable cost-sharing amount for non-emergent care, and then refund the beneficiary if needed. The commenter expressed concern that hospitals will not be able to impose cost sharing on beneficiaries after they have left the ED.

Response: The statute requires that before providing and imposing cost sharing for non-emergency services in an ED, the hospital must inform the beneficiary of the cost sharing obligation tied to those services and provide the name and location of an available, accessible, alternative provider that can provide the services with no or lesser cost sharing. This allows the beneficiary to forgo treatment in the ED if they do not have the ability to pay the cost sharing. If the individual decides to stay and receive the services at the ED, the hospital can impose the cost sharing while the person is still present.

Comment: One commenter stated that for hospitals, the collection of Medicaid cost-sharing amounts for non-emergency care in ED settings can prove difficult, leading to lack of

payment and increases in bad debt.

Response: The statute allows states to impose cost sharing for non-emergency care in an ED and sets out the requirements that hospitals must meet to collect such cost sharing. We do not have the authority to take away this option or ignore the statutory requirements and will work with states and the hospital community to share best practices and potentially issue further guidance.

Comment: One commenter requested clarification as to whether urgent care centers are subject to the guidelines for cost sharing for non-emergency use of the ED.

Response: No, this rule only pertains to non-emergency services furnished in an ED.

Comment: A few commenters supported what they believed was a new option regarding cost sharing for non-emergency services provided in the ED to beneficiaries who are otherwise exempt from cost sharing.

Response: This is not a new option. This is a statutory option described at section 1916A(e)(2)(B) of the Act and codified in current regulations at §447.70(b).

Comment: One commenter stated that instead of focusing on cost sharing, which could result in harm to patients, we should focus on best practices for medically sound ways of reducing unnecessary emergency department visits, such as electronic exchange of patient information, care coordination, patient education on appropriate use of the ED, and guidelines for prescribing narcotics. One commenter was concerned that focusing on cost sharing does not address why patients seek care in an ED, and that hospitals trying to decrease non-emergency ED use will inadvertently run afoul of either EMTALA or their state's emergency access rules. The commenter recommended that some form of safe harbor be established for hospitals trying, in good faith, to encourage the most appropriate use of resources for non-emergency care.

Response: We agree that there are many strategies which states can and have

implemented to address the problem of non-emergency use of hospital EDs. However, whether or not cost sharing is the most effective way to address non-emergency use of the ED, it is an option provided to states in the statute. We are available to work with all states in exploring the full range of options to reduce non-emergency use of the ED, and to share best practices which emerge.

7. Premiums (§447.55)

We proposed one simplified, consolidated section of the regulations to implement the options authorized under sections 1916 and 1916A of the Act relating to the imposition of premiums on individuals with family income above 150 percent of the FPL, and describe the options to impose premiums for specific populations. The proposed changes are discussed in more detail in the January 22, 2013 Medicaid Eligibility Expansion proposed rule (78 FR 4660). We received the following comments concerning the proposed premiums provisions:

Comment: Several commenters recommended that we revise proposed §447.55(a)(2) to clarify that states are allowed to impose premiums on qualified disabled and working individuals if the individual's income exceeds 150 percent of FPL. The commenters also noted that proposed §447.55(c) does not reflect statutory requirements in section 1916 of the Act that limit aggregate premium expenses for individuals provided medical assistance under section 1902(a)(10)(A)(ii)(XV) or 1902(a)(10)(A)(ii)(XVI) of the Act and the Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA), to no more than 7.5 percent of the individual's family income for those whose annual income does not exceed 450 percent of the FPL.

Response: We agree with the commenters. Due to a drafting error, the allowable premiums and limitations described at proposed §447.55 were not clear. We have revised paragraph (a) and paragraph (c) (redesignated as paragraph (b) for clarity), of §447.55 to address this error. Paragraph (b)(1) describes the limitations on prepayment; paragraph (b)(2) describes

the options for terminating an individual for failure to pay, paragraph (b)(3) describes the statutory requirements noted by the commenter for individuals receiving medical assistance under TWWIA, and paragraph (b)(4) describes the state's option to waive premiums for any individual or family. In addition to these clarifications, we revised the description of pregnant women who may be charged premiums at §447.55(a)(1) to reflect the consolidation of different statutory eligibility groups for pregnant women under a single regulatory section at §435.116 of the March 2012 final rule. This is not a substantive change and is intended solely to assist states in appropriately identifying those beneficiaries who may be charged premiums, as described in the statute. As noted above, we made a similar revision to the description of children who are exempt from premiums and cost sharing at §447.56(a)(1)(i) through (iii) of this final rule.

Comment: Several commenters recommended that §447.55 be revised to clarify that premiums can only be imposed on medically needy individuals after their spend-down amount is met and they are receiving Medicaid; they cannot be included as part of the spend down.

Response: An individual cannot be subject to a premium unless he or she is eligible for Medicaid. States may not impose a premium until the month in which the individual has met his or her spend-down and becomes eligible.

Comment: Several commenters recommended that the regulations require a process for waiving premiums in cases of undue hardship; and that the process adopted by a state should be set forth in the state plan and reflected in state law and other public documents. One commenter asked for CMS to provide examples of "hardship."

Response: The decision to waive premiums due to hardship is a matter of state policy. Such policies do not require prior authorization from the Secretary. Therefore we are not revising the regulations as suggested.

Comment: One commenter stated that "sliding scale" premiums imposed on the

medically needy under §457.55 must actually "slide" so that there is a lowest-income group of individuals for whom there is no premium and that premiums for higher income individuals increase linearly or quasi-linearly up to \$20 for those at or near 150 percent of the FPL. One commenter stated the \$20 allowable premium should be removed from the regulation.

Response: Section 1916 of the Act expressly permits states to impose premiums on medically needy individuals on a sliding scale, but does not require that the lowest income medically needy individuals are charged \$0 premiums. Current regulations at §447.52 allow for premiums on a sliding-scale basis up to \$19, and we are finalizing the proposal to increase that amount to \$20. We have revised the regulations at §447.55(a)(5) to clarify that, if premiums are imposed on medically needy individuals on a sliding scale, the agency must impose an appropriately higher premium for individuals at higher levels of income, with \$20 being the maximum allowable premium at the highest income level. States may choose to set their highest premium at a level below \$20.

Comment: One commenter asked for clarification of the consequences for "non-payment" that are described at proposed §447.55(c)(1)(ii) and (2)(ii). The commenter recommends that termination be allowed for failure to make full payment, and that partial payment is not adequate to prevent termination from the program.

Response: As noted previously, due to a drafting error, we have revised §447.55(c) (redesignated as paragraph (b) of the final rule) to clarify the consequences for non-payment for all individuals subject to premiums. As described in paragraph (2), except for medically needy individuals, states have the option to terminate any individual who has failed to pay all or part of his or her premium obligation. The state may not terminate an individual prior to 60 days after the failure to pay the premium. The state may not terminate an individual who, during that time period, has paid the premium due in full. To reiterate current policy, we also added a new

paragraph (5) to §447.56(b) to indicate that no further consequences can be applied for non-payment of Medicaid premiums, including “lock-out” periods. We note that we redesignated paragraph (c) as paragraph (b) in the final rule to move the state plan requirements after the section related to consequences for non-payment. This change is to improve the flow of the regulation and is not intended to be substantive.

Comment: One commenter was concerned that proposed §447.55(c) would permit states to terminate Medicaid coverage for failure to pay premiums for as little as 60 days. While the commenter calls this an improvement over the current regulation, which they believe does not establish any minimum grace period, the commenter believed that states should be encouraged to work with beneficiaries on a payment schedule to avoid a termination.

Response: Proposed §447.55(c), redesignated as §447.55(b) in the final rule, does not represent new policy. This option, established under both sections 1916 and 1916A of the Act, is currently codified at §447.80 for individuals with income over 150 percent of the FPL who are subject to premiums under section 1916A of the Act. In this final rule, we are simply codifying the requirements as they relate to premiums imposed under the authority of section 1916(c) of the Act.

8. Limitations on Premiums and Cost sharing (§447.56)

We proposed a single streamlined approach to implement the limitations on premium and cost sharing established under sections 1916 and 1916A of the Act wherever the policies align. Sections 1916(a), (b), and (j), and 1916A(b)(3) of the Act specify certain groups of individuals as exempt from premiums and/or cost sharing, including certain children, pregnant women, certain American Indians and Alaska Natives (AI/ANs), certain individuals residing in an institution, individuals receiving hospice care and individuals eligible under the optional eligibility group for individuals with breast and cervical cancer under §435.213 of this part. The

proposed changes are discussed in more detail in the January 22, 2013 Medicaid Eligibility Expansion proposed rule (78 FR 4660 and 4661). We received the following comments concerning the proposed limitations on premiums and cost sharing provisions:

Comment: Two commenters recommended that proposed §447.54(c), which permits states to impose cost sharing for non-emergency use of the ED on individuals otherwise exempt from cost sharing, should not apply to AI/AN beneficiaries who are exempt from cost sharing.

Response: We are finalizing the regulation as proposed. Sections 1916A(c)(2)(B) and 1916A(e)(2)(B) of the Act permit states to charge nominal cost sharing to individuals otherwise exempt from cost sharing under section 1916A(b)(3)(B) of the Act for non-preferred drugs and non-emergency use of an ED. There is no differential treatment under the statute for AI/ANs as compared to other individuals who are otherwise exempt from cost sharing. However, such cost sharing must be limited to the nominal and neither a pharmacy nor a hospital ED may deny services if the individual does not pay the cost sharing.

Comment: We solicited comments about requiring states to periodically renew an AI/AN's cost sharing exemption based on current or previous use of a service from an Indian health care provider or through referral under contract health services. A number of commenters supported proposed §447.56(a)(1)(vii) to exempt AI/ANs who are currently receiving, or have ever received a service from an Indian health care provider or through referral under contract health services from any cost sharing. Several commenters were concerned that requiring renewal of status for the exemption would be administratively burdensome for both AI/AN individuals and state Medicaid agencies and could lead to exempt individuals being subject to impermissible cost sharing. A few commenters recommended that if renewal of the AI/AN exemption status is required, that such renewal be limited to no more than once every three years, which is the period of time used by IHS for determining "active users" in an IHS or tribal

service unit. No commenters supported a renewal policy for AI/AN exemption.

Response: We are adopting the AI/AN exemption as proposed because we do not see any particular utility in requiring renewal of status, since the underlying eligibility for IHS or tribal health services is unlikely to change, and we agree that renewal of status can be burdensome for both the beneficiary and the provider. Once the exemption for an individual at §447.56(a)(1)(x), as redesignated in this final rule, is established, a renewal of such exemption will not be necessary. We note that we added a definition of contract health service at §447.51 for clarity and made a technical correction under the definition of Indian to reflect revised citations to 25 U.S.C due to changes made by the Affordable Care Act. We do not intend these to be substantive changes to the regulations.

Comment: One commenter recommended we permit states to implement specific processes to track separate cost sharing for AI/ANs related to the 5 percent aggregate limit as permitted by current regulation.

Response: We do not see a need for states to separately track cost sharing for AI/AN beneficiaries, the majority of whom are exempt from cost sharing under the regulations. For any individuals permissibly subject to cost sharing, the same 5 percent aggregate limit applied to other beneficiaries, and the same requirement to track cost sharing charges, would apply.

Comment: A few commenters suggested states should have broad latitude in applying verification procedures to exempt AI/ANs who are eligible for or currently or have ever received a service from an Indian provider or through referral under contract health services (CHS) from premiums and cost sharing respectively, and that procedures that create the least burden on individuals, including electronic processes, be employed by states. They recommended that self-attestation of status for the AI/AN cost sharing exemption be permitted, that if verification is required that electronic data matching should be used to the maximum extent possible, and that

we provide a list of possible documents which states could use when electronic verification is not available.

Response: There are no specific federal requirements regarding the process for verifying premiums and cost sharing exemptions for AI/ANs. States have flexibility to establish their own processes for verifying who is eligible to receive or has ever received a service from an Indian provider or through referral under CHS, including the use of self-attestation, electronic data matches or reasonable paper documentation, as long as the process is not unduly burdensome on AI/ANs.

Comment: One commenter requested that CMS clarify that family planning supplies are exempt from differential cost-sharing for non-preferred drugs. Another commenter recommended that CMS clarify that the limitations on premiums and cost sharing also apply to family planning-related services, including office visits. Commenters believed that this clarification is particularly important for coverage of family planning under the state plan, permitted under section 1902(a)(10)(A)(ii)(XXI) of the Act, as added by section 2303 of the Affordable Care Act, which defines “medical assistance” covered under this option to include both family planning and family planning-related services.

Response: Under sections 1916 and 1916A of the Act and §447.53 and §447.70 of the current regulation, family planning services and supplies, including contraceptives and pharmaceuticals for which the state properly claims or could claim at an enhanced federal match, are exempt from cost sharing. We did not propose any changes to this exemption, which is codified at §447.56(a)(2)(ii) of this final rule. We do not have the statutory authority to require states to exempt “family planning-related services,” which are a separate category of services, but states have the option to do so.

Comment: One commenter requested that we clarify that pregnant women receiving

services during a period of presumptive eligibility are also exempt from premiums and cost sharing.

Response: Individuals who are receiving benefits during a presumptive eligibility period, but who have not yet been determined Medicaid eligible by the agency, based on a regular application, including pregnant women, may not be subjected to the premiums. In addition, all pregnancy-related services are exempt from cost sharing, including during a period of presumptive eligibility. As described in the March 2012 final eligibility rule, “Pregnancy related services” is presumed to include all services otherwise covered under the state plan unless the state has justified classification of a service as not pregnancy-related in its state plan.

Comment: Many commenters supported the provision in proposed §447.56(a)(1)(v) to give states the option to exempt individuals from cost sharing if they are receiving long term services and supports in a home or community-based setting and are required to contribute to the cost of care in a manner similar to the post-eligibility treatment of income for institutionalized individuals under part 435 subpart H of the regulations. Many commenters recommended that we require states to exempt such individuals because imposing cost sharing could push individuals into more restrictive settings in violation of the requirements of the Americans with Disabilities Act (ADA), as applied by the Supreme Court in the Olmstead decision. A few commenters recommended that we require states to exempt all individuals receiving services in a home and community-based setting regardless of whether they are required to contribute to the cost of their care. Finally, one commenter asked that we clarify that we are not proposing to extend the same post-eligibility treatment of income rules used for institutional services to individuals receiving services in a home and community based setting who, in addition to any contribution for the cost of their care, also generally have to cover other basic living expenses, such as for housing and food, and would not be able to cover such expenses if they were required

to contribute all but a nominal amount of their income to cover the cost of the services received, as is the case for institutionalized individuals.

Response: As noted above, we do not see a statutory basis to require this exemption, therefore in the final rule, at §447.56(a)(1)(viii), as redesignated, we maintain the option for states to exempt individuals receiving services in a home and community-based setting, whose medical assistance is reduced by amounts reflecting available income other than required for personal needs. This option is consistent with state authority under section 1916A of the Act to target cost sharing to specified groups. In addition, states may target cost sharing at particular types of services, and could determine not to impose cost sharing on home and community-based services. We also note that if an individual has his or her medical assistance reduced to account for available income, the individual would be able to deduct any premiums or cost sharing from the calculation of available income used to determine the level of medical assistance provided. There would be no modification of current regulations relating to post-eligibility treatment of income or share-of-cost. Again, we remind states of their obligations under Olmstead.

Comment: One commenter recommended that former foster care children covered under §435.150 should be exempt from premiums and cost sharing. Several commenters recommended that states be given the express option to exclude medically frail individuals from cost sharing.

Response: While we understand that these are populations upon which states may not wish to impose cost sharing, we do not see a clear basis to support a federally-mandated exemption. States are free to use targeted cost sharing, in accordance with §447.52(d), to limit the impact of cost sharing as needed to address issues of non-exempt populations that the state determines are particularly vulnerable.

Comment: One commenter requested clarification on the provision at §447.56(c)(3),

which is specific to providers that the agency reimburses under Medicare reasonable cost reimbursement principles. The commenter asked whether the policy that an agency may increase its payment to offset uncollected deductible, coinsurance, copayment, or similar charges that are bad debts of such providers was a change or consistent with current law.

Response: This policy is contained in the current regulations at §447.57(b). However, consistent with the new definition of cost sharing included at §447.51 of this final rule, we are replacing the reference to “deductible, coinsurance, copayment, or similar” with “cost sharing” in the final rule.

Comment: Many commenters recommended that we amend sections 1916 and 1916A of the Act to clarify that the preventive services included in the EHBs are exempt from cost sharing, because low income individuals enrolled in Medicaid ABPs may be responsible for cost sharing for some of the preventive services that are available to higher income individuals in the private market with no cost sharing.

Response: Section 1916A of the Act and the final rule at §447.56(a)(2)(iii) do require exemption of preventive services for children under age 18. At a minimum such services must include those specified at §457.520, which reflect the well-baby and well child care and immunizations in the Bright Futures guidelines issued by the American Academy of Pediatrics. We do not see a basis to broaden this statutory exemption under the Medicaid program to extend to preventive services for older individuals. States have the flexibility to exempt additional services from cost sharing and could determine to exempt preventive services for all beneficiaries.

Comment: Many commenters recommended that we exempt services associated with “never events” from cost sharing.

Response: We agree with commenters that services associated with “never events”

should not be subject to cost sharing. In accordance with §447.26(c)(1), “no medical assistance will be paid for “provider preventable conditions” as defined in this section. We interpret medical assistance in this context to include any state plan imposed cost sharing, and providers, who are not permitted to claim reimbursement from the agency for these services, also are not entitled to charge the beneficiary any cost sharing amount. To clarify this requirement, we have included provider-preventable services, also known as “never events,” among the list of exempted services at §447.56(a)(2)(v).

Comment: One commenter recommended that we revise §447.56(a)(2)(iv) to require that all services provided to pregnant women be considered as pregnancy-related, except those services specifically identified in the state plan as not being related to the pregnancy, only if the state is able to justify and the Secretary concurs, that the service is not pregnancy-related.

Response: States have the discretion to determine pregnancy-related services within the parameters of §440.210(a)(2). We are seeking to align the standard related to cost sharing with what is required for the provision of pregnancy-related services, and maintain in the final rule that all services provided to pregnant women will be considered pregnancy related unless the state has justified classification of a service as not pregnancy-related in its state plan.

Comment: One commenter asked that we clarify what is meant by "nonexempt" and "otherwise exempt populations," per the reference to allowing states to impose cost-sharing at higher than nominal levels for nonexempt individuals and applying cost sharing to otherwise exempt populations at §447.56.

Response: Exempt populations are defined at sections 1916(a), (b) and (j) and 1916A(b) of the Act and at §447.53 and §447.70 of the current regulations. These populations are exempt from cost sharing under section 1916 and 1916A(a) of the Act, respectively, but are not exempt from cost sharing under section 1916A(c) or (e) of the Act, which pertain to alternative cost

sharing for non-preferred drugs and non-emergency use of the ED. These exemptions were consolidated at §447.56(a) of the proposed rule and maintained in the final rule. When using the term “nonexempt” we are referring to beneficiaries who do not fall into one of the groups exempted under §447.56(a) of the final rule and therefore may be subject to cost sharing. “Otherwise exempt populations” refers to those populations that are generally required to be exempted from cost sharing but are not exempt from cost sharing under section 1916A(c) or (e) of the Act. Section 1916A of the Act allows states to impose cost sharing for drugs and non-emergency use of the ED on “otherwise exempt populations,” meaning that such cost sharing may be imposed on beneficiaries who are exempted from all other cost sharing per §447.56(a).

Comment: Many commenters were concerned that the aggregate limit described in proposed §447.56(f) does not apply to individuals with income at or below 100 percent of the FPL. Another commenter was concerned that these rules created a new requirement for states to apply the aggregate limit to cost sharing imposed under section 1916 of the Act. A few commenters urged the Secretary to lower the aggregate limit to something less than 5 percent.

Response: Under sections 1916 and 1916A of the Act, aggregate premiums and cost sharing imposed may not exceed 5 percent of an individual’s income. This is a statutory limit and we do not have the authority to require states to apply a lower cap. However, we are revising the final regulation at §447.56(f)(1), and redesignating the succeeding paragraphs accordingly, to provide that the aggregate limit applies to all premiums and cost sharing incurred by all individuals in the Medicaid household, at all income levels. At §447.56(f)(2) of the final rule, we maintain the requirement in current regulation that states must track all incurred Medicaid premiums and cost sharing for all members of the Medicaid household, if such premiums and cost sharing could place any family member at risk of reaching the aggregate limit.

Comment: Many commenters recommended we revise proposed §447.56(f)(3) to require states to inform beneficiaries, at risk of reaching the aggregate limit, of the automated process used to track premiums and cost sharing, and how they can obtain ongoing information about how far they are from reaching the limit.

Response: Section 447.56(f)(2), as redesignated in this final rule, requires that if a state imposes cost sharing that could result in individuals reaching the aggregate limit, the state must describe their process for tracking the premiums and cost sharing in their state plan. Current regulations at §447.64(d)(2), redesignated at §447.56(f)(3) in this final rule, do require the state to notify beneficiaries and providers when the beneficiary reaches the cap. We are revising this paragraph to restore language currently in §447.68(d) that was inadvertently removed in the proposed rule indicating that the state must inform beneficiaries and providers of the beneficiaries' aggregate limit. States must also have a process in place for beneficiaries to request a reassessment of their aggregate limit. We believe these rules provide the best balance between minimizing administrative burden on states and modernizing the Medicaid program to ensure beneficiaries are not charged amounts in excess of the aggregate. We do not believe these rules prevent states from establishing processes by which beneficiaries can regularly check their status regarding the aggregate limit. To allow states flexibility, we are not specifying the mechanisms by which such notifications must occur.

Comment: One commenter recommended that the regulation should use a single, annual (not monthly) cost sharing maximum, such as that used for the Part D low-income subsidy, since renewals are completed on an annual basis, and therefore cost-sharing maximums are most effectively implemented on a well-established calendar-year basis.

Response: Section 1916A of the Act requires that the aggregate limit be applied on a monthly or quarterly basis as determined by the state; an annual limit is not permitted under the

statute.

Comment: Once commenter requested that we clarify what is meant by “premiums or cost sharing rules that could place beneficiaries at risk of reaching the aggregate family limit” in proposed §447.56(f)(3).

Response: If a state imposes premiums and/or cost sharing at a level that could result in cumulative premiums and cost sharing exceeding 5 percent of a beneficiary’s family income (for all family members on Medicaid, over the course of a month or quarter as determined by the state), the state must implement an effective tracking mechanism to ensure the cap is not exceeded. For example, a state may establish a prescription drug copayment targeted to individuals with family income above 150 percent of the FPL, and set the copay at \$1 for preferred drugs and \$2 for non-preferred drugs. If this is the only cost sharing to which these individuals are subject, and they do not pay a premium, then it is unlikely that any beneficiary would accumulate cost sharing charges in excess of 5 percent of his or her family income, and the state would not have to establish a tracking mechanism. However, if these same beneficiaries were also assessed a premium of 4 percent of family income, beneficiaries may be at risk of reaching the aggregate limit and the state would need to establish a tracking mechanism. Anyone with income under 100 percent of the FPL, who is subject to any cost sharing would likely be at risk of reaching the aggregate limit and a tracking mechanism would likely be required. We will work with states to determine their need for a tracking mechanism through the state plan amendment process.

We note that if more than one Medicaid beneficiary resides in a household, then the premiums or copayments of each beneficiary in the household would count toward the aggregate limit. We do not specifically define when cost sharing may place beneficiaries at risk of reaching the aggregate limit, because of the many different combinations of cost sharing and

premium charges which it would be possible for states to impose. We will monitor state compliance through the state plan amendment process.

Comment: One commenter requested further guidance on ways to track cost sharing for beneficiaries who change plans during the year.

Response: For individuals who change plan mid-year, the state must establish a mechanism to continue tracking through the transition to ensure that they do not exceed the cap. Alternatively, a state could suspend any additional cost sharing until the next monthly or quarterly period begins. We have in the past encouraged, and continue to encourage, states to track cost sharing through their Medicaid Management Information System (MMIS). As we review state plan amendments and conduct audits, we will share best practices that emerge among states to promote effective and efficient tracking systems.

Comment: Many commenters recommended that we remove the requirement at proposed §447.56(f)(3) that states have an automated mechanism for tracking each family's incurred premiums and cost sharing because it is costly and presents a substantial administrative and operational burden on state Medicaid agencies, their contractors, and providers. Instead, the commenters recommended that the state should have an opportunity to develop its own mechanism for tracking a Medicaid enrollee's premium and cost sharing spending. A few commenters also recommended that states should have the option of having the enrollees track their own information. One commenter asked that we clarify that a state that delegates responsibility for the administration of cost sharing to managed care organizations must ensure the availability of complete and timely information necessary for performing this role.

Response: We have revised §447.56(f)(2) in this final rule to remove the word "automated" and replace it with "effective." CMS will review state proposals through the state plan amendment process to ensure that tracking mechanisms employed by states are effective in

ensuring that incurred premiums and cost sharing do not exceed the aggregate limit and that the tracking mechanism does not rely on beneficiaries. We note that under current regulations states must account for cost sharing amounts in their MMIS to ensure appropriate provider payment and must calculate each family's aggregate limit--from data in the state's eligibility system--and provide that information to the beneficiary. States may claim federal matching funds to update their MMIS and eligibility systems as necessary to implement a tracking system that uses the data already available in their systems to implement the aggregate limit. States have the flexibility to develop any effective process that does not rely on beneficiaries, and contains timely and accurate information so that beneficiaries do not exceed their aggregate limits. In addition, a state may delegate this responsibility, as appropriate, to their managed care organizations although we are not requiring that they do so. Tracking of premiums and cost sharing is standard industry practice among health plans, including those that participate in the Medicaid program, and is consistent with implementing the requirements of the Affordable Care Act out-of-pocket limits for all Americans, which will require tracking by all private health insurance plans.

Comment: One commenter stated that the flexibilities provided in the proposed rule, including the higher cost sharing limits, are negated by the continued application of the aggregate limit. The commenter argues that the high cost sharing limits effectively will serve as a provider rate cut, which will trigger further decrease in access to health care for Medicaid beneficiaries. The commenter recommends that we allow exceptions to the 5 percent aggregate limit and the automated tracking requirements, allowing states to propose in their state plan reasonable assumptions and methodologies to limit maximum out-of-pocket costs at an individual or family level. The commenter believed such an approach, coupled with provisions for exceptions and an appeals process involving clear timelines to preserve access to care, would

be consistent with the spirit of the statute.

Response: We do not understand the connection that the commenter is making between the aggregate limit and effective provider reimbursement rates. Once the limit is reached, the beneficiary may not be charged any cost sharing amounts, and providers will be paid the full reimbursement rate by the state. Regardless, the application of an aggregate limit, which is common practice in commercial insurance as well, is required by section 1916A of the Act, as added by the Deficit Reduction Act of 2005; we do not have authority to eliminate this requirement through regulation.

9. Beneficiary and Public Notice Requirements (§447.57)

We proposed to codify existing policy to ensure that beneficiaries, providers, and the general public all have access to effective notice of Medicaid premium and cost sharing charges. Appropriate vehicles for providing notice might include the agency website, newspapers with wide circulation, web, and print media reaching racial, ethnic, and linguistic minorities, stakeholder meetings, and formal notice and comment in accordance with the state's administrative procedures. We received the following comments concerning the proposed provisions for beneficiary and public notice requirements:

Comment: One commenter asked for clarification on what constitutes a method to which applicants, beneficiaries, and providers are “likely to have access,” and whether publication on a state website would be an acceptable method. One commenter strongly disagreed that state legislative hearings do not provide sufficient public, beneficiary and provider notice and recommended that such hearings be included as one of the options for providing sufficient notice.

Response: To allow flexibility for different state processes while ensuring provision of meaningful notice, we are not prescribing the particular method or format that states must use to

provide the required notice, but instead proposed parameters at §447.57, finalized with one revision (discussed below) in this rulemaking, regarding what constitutes sufficient notice. We provided examples of acceptable methods in the preamble to the proposed rule, including notice on the state agency's website. As stated in the preamble to the proposed rule, we do not believe that legislation discussed at a hearing or posted on a website is adequate, since state legislation and legislative hearings often are not accessible or understandable to many beneficiaries, providers or other interested members of the public.

Comment: Many commenters supported the proposal to require that states provide additional public notice if proposed cost sharing is substantially modified during the state plan amendment (SPA) approval process. Many of these same commenters also recommended that we require states to provide at least a 30-day comment period on any revisions to a SPA involving premiums or cost sharing charges. A few commenters were concerned that the proposed rule would be too burdensome on states and recommended that no additional public notice requirements be imposed on states.

Response: We have revised the regulations at §447.57(c) to require states to provide additional public notice if proposed cost sharing is substantially modified during the SPA approval process. We are also applying this rule to premiums that are substantially modified during the SPA process. We are not, however, accepting the recommendation that states should have to provide a second 30 day comment period for any revisions made to the state's cost sharing policy during the SPA approval process, as we believe this would be overly burdensome on states and significantly delay the SPA process.

III. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule. We received many comments about the complexity of the proposed rules and the significance of the

changes that need to be made to fully implement the provisions of the Affordable Care Act. Many commenters were concerned about the short timeframes for implementation and about states' ability to make needed changes to policy, operations, and information technology systems. We recognize that the timing of this rule may result in implementation challenges, especially from a systems perspective. Therefore, we have evaluated the provisions of the January proposed rule that are necessary to meet the deadlines and are finalizing in this rule only those provisions that we believe states will be reasonably able to (or have already been planning to) implement by January 1, 2014. Remaining provisions will be finalized in future rulemaking. Those provisions, included in this final rule, that differ from the proposed rule are as follows:

Change to §431.10

- Clarified responsibilities of single state agency related to delegation of fair hearings.

Change to §431.201

- Added the definition of “send.”

Change to §431.205

- Clarified language in §431.205(b).

Change to §431.206

- Clarified in §431.206(d) that an individual has a right to a hearing before the Medicaid agency instead of the Exchange or Exchange appeals entity.

Change to §435.603

- Specified in §435.603(d)(4) that the 5 percent disregard should be applied to the highest income standard in the applicable Title of the Act under which the individual may be determined eligible using MAGI-based methodologies.

Change to §435.908

- Deleted paragraph §435.908(c)(3)(i).

Change to §435.918

- Allowed for delayed implementation of electronic notices and required that the Agency ensure that an individual's election to receive notices electronically is confirmed by regular mail and that the individual is informed of his or her right to change such election.

Change to §435.923

- Clarified in §435.923(a) that any authorization granted under operation of state law may serve in place of written authorization by the applicant or beneficiary.

Change to §435.1015

- Clarified that states are required to consider the cost sharing requirements of the private health plan when determining whether premium assistance is a cost-effective option.

Changes to §435.1110

- Revised §435.1110(c)(1) to make clear that states electing to limit the presumptive eligibility determinations which hospitals can make must permit the hospitals to make presumptive eligibility determinations based on income for all of the populations included in §435.1102 and §435.1103
- Adding paragraph (d)(3) to provide that the agency may disqualify a hospital as a qualified hospital only after it has first provided the hospital with additional training or taken other reasonable corrective action measures.

Change to §435.1200

- Codified §435.1200 (d) (5) of proposed rule at §435.1200 (d)(6).

Changes to §447.51

- Added definition of “inpatient stay” and “outpatient services.”
- Added definition of Federal poverty level (FPL) to use the acronym throughout the regulation. No substantive change is intended.
- Added a definition of contract health service, for clarity (not a substantive change to the regulations).

Changes to §447.52

- Revised the maximum cost sharing allowed for an inpatient stay to \$75 and added a new paragraph at (b)(2), to require states with inpatient cost sharing that exceeds the amount in the final rule, as of **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, to submit a plan to CMS that provides for reducing inpatient cost sharing to \$75 on or before July 1, 2017.
- Revised paragraph (b)(3) to be clear that, “in states that do not have fee-for-service payment rates, any cost sharing imposed on individuals at any income level may not exceed the maximum amount established for individuals with income at or below 100 percent of the FPL
- Revised §447.52(d), adding paragraphs (1) and (2) to clarify that for cost sharing imposed for non-preferred drugs and for non-emergency services provided in a hospital emergency department under, the agency may target to a specified group of individuals regardless of income.
- Added and amended paragraph (g) to restore the option to establish different cost sharing charges for individuals at different income levels.
- Added paragraph (h) to restore requirement that any cost sharing charges imposed by managed care organization on Medicaid enrollees be in accordance with the requirements set forth in the regulations.

- Added paragraph (i) to consolidate the state plan requirements currently contained in §447.53(d) and §447.68.

Changes to §447.53

- Revised paragraph (d) to clarify that cost sharing for non-preferred drugs imposed on otherwise exempt populations cannot exceed the nominal amount defined in §447.53(b) in accordance with section 1916A(c) of the Act.
- Revised paragraph (e) to require that states must have a timely process to allow for cost sharing at the preferred drug level if the prescribing provider determines that the preferred drug would be less effective or have adverse effects on the individual to ensure that access to necessary drugs is not delayed.

Changes to §447.54

- Amended paragraph (d)(2)(iii) to replace the word “ensure” with “determine.”
- Added new paragraph (i) at §447.54(d)(2) requiring hospitals to inform the individual of the amount of his or her cost sharing obligation for non-emergency services provided in the ED

Changes to §447.55

- Due to a drafting error we revised this section to accurately reflect who can be charged premiums and what consequences for non-payment exist for specified groups
- Revised at paragraph (a)(1) the description of pregnant women who can be charged premiums to reflect the consolidation of different statutory eligibility groups for pregnant women under a single regulatory section at §435.116 of the March 2012 final rule. This is not a substantive change and is intended solely to assist states in appropriately identifying those pregnant women who may be charged as described in the statute.

- Revised paragraph (a)(5) to clarify that, if premiums are imposed on a sliding scale, the agency must impose an appropriately higher premium for individuals at higher levels of income, with \$20 being the maximum allowable premium at the highest income level.
- Added a new paragraph (5) to §447.55(b) to indicate that no further consequences can be applied for non-payment of Medicaid premiums, including “lock-out” periods.

Changes to §447.56

- Revised at paragraph (a)(1)(i) the description of children who are exempt from premiums and cost sharing at §447.56(a)(1)(i) through (iii) and (iv) to reflect the consolidation of different statutory eligibility groups for children under a single regulatory section at §435.118 of the March 2012 final rule, and to reflect the changes in the types of assistance available under Title IV-E of the Act. These are not substantive changes and are intended solely to assist states in appropriately identifying those children who may be charged premiums and cost sharing and exempting those who may not, as described in the statute.
- Amended paragraph (a)(2)(v) to include provider-preventable services, also known as “never events,” among the list of exempted services .
- Revised paragraph (f)(2) to restore language currently in §447.68(d) that was inadvertently removed in the proposed rule indicating that the state must inform beneficiaries and providers of the beneficiaries’ aggregate limit.

Changes to §447.57

- Revised language at paragraph (c) to require states to provide additional public notice if proposed cost sharing is substantially modified during the SPA approval process.

Change to §457.110

- Required that states provide individuals with a choice to receive notices and

information required under this subpart and subpart K of this part, in electronic format or by regular mail.

Change to §457.570

- Adding paragraph (c)(2)

Change to §457.810

- Added language requiring protections against substitution of coverage in states that operate premium assistance programs.

Changes to §155.20

- Clarifies the definition of advance payments of the premium tax credit.

Changes to §155.200

- Removes the reference to subpart F, as it will be finalized in a future rule.

Changes to §155.227

- Clarifies that for the purpose of §155.227, the terms “applicant” and “enrollee” describe people on whose behalf authorized representatives are acting, and that the term “person” describes an individual acting as an authorized representative.
- Clarifies that authorized representatives are permitted to provide assistance in the individual and SHOP Exchanges, as well as for individuals seeking an exemption from the shared responsibility payment.
- Adds language ensuring that the Exchange provides information to both the applicant or enrollee and the authorized representative regarding the powers and duties of an authorized representative.
- Adds language allowing an Exchange to permit an applicant or enrollee to authorize their representative to perform fewer than all of the activities described in this section, provided that the Exchange tracks the specific permissions of each authorized representative.

- Clarifies that an authorized representative will notify the Exchange and the applicant or enrollee on whose behalf he or she is acting when the authorized representative no longer has legal authority to act on behalf of the applicant or enrollee.
- Clarifies that the Exchange, not the applicant or enrollee, will notify the authorized representative when an applicant or enrollee notifies the Exchange that an authorized representative is no longer acting on his or her behalf.
- Removes the provision that organizations as well as staff and volunteers of organizations must enter an agreement with the Exchange.

Changes to §155.230

- Clarifies electronic notice standards for an individual market Exchange, and specifies that the individual market Exchange may choose to delay the implementation of the process described in §435.918(b)(1) regarding sending a mailed confirmation of the choice to receive electronic notices.
- Adds standards to distinguish notice standards for a SHOP and adds language to allow an employer or employee in any SHOP to elect to receive electronic notices.

Changes to §155.300

- Clarifies the appropriate cross-reference for the definition of minimum value.

Changes to §155.302

- Clarifies that any contracting arrangement for eligibility determinations for Medicaid and CHIP is subject to the standards in §431.10(c)(2).
- Clarifies that the Exchange appeals entity, in addition to the Exchange, must adhere to the eligibility determination or appeals decision for Medicaid or CHIP made by the Medicaid or CHIP agency, or the appeals entity for such agency.

- Specifies that the agreement under §155.302(b)(6) will be made available to HHS upon request.

Changes to §155.305

- Removes the clause “unless another Exchange verifies that the individual meets the residency standard of such Exchange” related to temporary residence.
- Clarifies that an applicant must be eligible for enrollment in a QHP through the Exchange to be determined eligible for enrollment through the Exchange in a QHP that is a catastrophic plan.

Changes to §155.310

- Clarifies that the provision regarding duration of eligibility determinations without enrollment only refers to an applicant who is determined eligible for enrollment in a QHP through the Exchange.

Changes to §155.315

- Modifies procedures for situations in which key data sources are unavailable and not reasonably expected to be available within 1 day, such that the Exchange will make an eligibility determination based on an applicant’s attestation and trigger the inconsistency period in paragraph (f).
- Clarifies that the Exchange will accept an applicant’s attestation regarding three specific factors of eligibility when electronic data is required but it is not reasonably expected that data sources will be available within 1 day of the initial request to the data source, and that for purposes of eligibility for advance payments of the premium tax credit and cost-sharing reductions, other sections in this subpart already address situations in which data regarding MAGI-based income is unavailable.

- Clarifies that paragraph (f)(5)(i) of this section will follow the effective dates specified in §155.330(f)
- Modifies the language concerning the verification related to eligibility for enrollment through the Exchange in a QHP that is a catastrophic plan for the purpose of clarity.

Changes to §155.320

- Clarifies that the Exchange must obtain any available data from the SHOP that corresponds to the State in which the Exchange is operating.
- Modifies language to specify that the Exchange must select a statistically significant random sample of applicants for whom the Exchange does not have any of the information specified in paragraphs (d)(2)(i) through (d)(2)(iii).
- Removes language specifying that the Exchange must use any available data regarding employment of an applicant and members of his or her household.
- Specifies that for eligibility for enrollment in a QHP through the Exchange that is effective before January 1, 2015, if the Exchange does not have any of the information specified in paragraphs (d)(2)(i) through (d)(2)(iii) for an applicant, the Exchange may accept an applicant's attestation regarding enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested without further verification, instead of following sampling procedures.
- Clarifies that the ability for the Exchange to satisfy the provisions of paragraph (d) of this section by relying on HHS is effective for eligibility for enrollment in a QHP through the Exchange that is effective on or after January 1, 2015, and clarifies that the division of responsibilities under this option is subject to guidance issued by the Secretary.

- Removes language concerning the agreement associated with having HHS conduct this verification.

Changes to §155.330

- Removes cross-references to appeals provisions, and clarifies that an Exchange must implement changes resulting from an appeal decision on the date specified in the appeal decision.
- Consolidates standards for decreases in advance payments of the premium tax credit and changes in cost-sharing reductions.
- Specifies that a change associated with birth, adoption, placement for adoption and placement in foster care must be implemented on the coverage effective date described in §155.420(b)(2)(i) and (ii).
- Removes duplicative cross-references regarding termination of coverage.

Changes to §155.340

- Clarifies the appropriate cross-reference for the minimum value standard

Changes to §155.345

- Reserves paragraphs (a)(3) and (g)(7) for future finalization.
- Clarifies that the Exchange and Exchange appeals entity will adhere to the eligibility determination or appeals decision relating to an individual's eligibility for Medicaid or CHIP made by the state's Medicaid or CHIP agency or the appeals entity for such agency.

Changes to §155.420

- Clarifies that the special effective dates for birth, adoption, and placement for adoption also apply to placement in foster care.
- Expands special enrollment period for birth, adoption, and placement for adoption to also include placement in foster care.

- Clarifies that the special enrollment period for an individual who was not a citizen, national, or lawfully present non-citizen and gains such status also applies to his or her dependents, if eligible for coverage through the Exchange.
- Modifies the special enrollment period for enrollees newly eligible or ineligible for advance payments of the premium tax credit or who experience a change in eligibility for cost-sharing reductions to reflect that the special enrollment period accommodates individuals enrolled in an eligible employer-sponsored plan, but not eligible for qualifying coverage in an eligible employer-sponsored plan.

Changes to §155.430

- Modifies language to allow applicants and enrollees to request termination from their QHP, in the event they report access to other minimum essential coverage and become ineligible for advance payments of the premium tax credit and cost-sharing reductions.
- Modifies standards for enrollee-requested termination effective dates, such that QHP issuers and Exchanges may only terminate prospectively, and not retroactively.
- Clarifies that terminations for enrollees who are determined eligible for Medicaid, CHIP or the BHP, such that the last day of coverage is the day before the individual is determined eligible for such coverage, rather than retroactive to the Medicaid or CHIP eligibility effective date.
- Aligns termination effective dates to appropriately cross-reference with eligibility effective dates.
- Adds language to clarify that in the case of termination due to death, the last day of coverage is the date of death.

Changes to §156.270

- Modifies coverage termination requirements such that standards for QHP issuers align with those for Exchanges.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the January 22, 2013 (78 FR 4593) proposed rule, we requested public comment on each of the rule's information collection requirements (ICRs). The comments and our response are discussed below.

Background

This final rule continues to implement key provisions of the Affordable Care Act including the completion of the streamlining of eligibility for children, pregnant women, and adults that were initiated in the Medicaid eligibility final rule published on March 23, 2012 (77 FR 17144). This rule also modifies CHIP rules relating to substitution of coverage and premium lock-out periods, which are important to a coordinated system of coverage across programs.

Finally, this rule includes provisions related to authorized representatives, the procedures for verifying access to qualifying employer-sponsored coverage, catastrophic coverage and other provisions related to eligibility and enrollment.

The policies in this rule will result in a reduction in burden for individuals applying for and renewing coverage, as well as for states. The Medicaid program and CHIP will be made easier for states to administer and for individuals to navigate by streamlining Medicaid eligibility and simplifying Medicaid and CHIP eligibility rules for most individuals. Even though there are short-term burdens associated with the implementation of the final rule, the Medicaid program and CHIP will be easier for states to administer over time due to the streamlined eligibility and coordinated efforts for Medicaid, CHIP, and the new affordable insurance exchanges.

The final rule also continues to implement provisions related to the establishment of Exchanges. This final rule: (1) specifies standards related to authorized representatives, (2) outlines criteria related to the verification of enrollment in and eligibility for minimum essential coverage through an eligible employer-sponsored plan, and (3) further specifies or amend standards related to other eligibility and enrollment provisions. The description of the burden estimates associated with these provisions is included in the information collection requirements outlined in section D.

Section A outlines the information collection requirements that involve Medicaid and CHIP eligibility and enrollment. Section B outlines the information collection requirements that involve Exchange eligibility and enrollment.

We used data from the Bureau of Labor Statistics to derive average costs for all estimates of salary in establishing the information collection requirements. Salary estimates include the cost of fringe benefits, calculated at 35 percent of salary, which is based on the June 2012 Employer Costs for Employee Compensation report by the U.S. Bureau of Labor Statistics.

A. Medicaid and CHIP Information Collection Requirements (ICRs) to be Addressed through Separate Notices and Comment Process Under the Paperwork Reduction Act

1. ICRs Regarding State Plan Amendments

1a. Sections 431.10, 431.11, 431.206, 431.211, 431.213, 431.230, 431.231, 431.240, 435.110, 435.116, 435.603, 435.907, 435.908, 435.918, 435.1101, 435.1102, 435.1103, 435.1110, 435.1200, 435.1205, 440.130, 440.210, 440.220, 440.305, 440.315, 440.330, 440.335, 440.345, 447.52-54, 457.110, 457.340, 457.350, 457.351, 457.355, 457.570, and 457.805

These amendments to the Medicaid and CHIP state plans are necessary to reflect changes in statute and federal policy. While we are aware of the need to estimate the PRA burden associated with the submission of state plan amendments related to the provisions identified above, those amendments will be addressed as part of the electronic state plan filing process being developed by CMS (the MACPro system) and submitted to OMB for approval under OCN 0938-1188 (CMS-10434).

1b. Sections 435.113, 435.114, 435.223, and 435.510

Since we are eliminating the provisions in §§435.113, 435.114, 435.223, and 435.510, states will no longer be required to submit state plan amendments related to those provisions. The provisions have been approved by OMB under OCN 0938-1147).

B. Medicaid Eligibility and Enrollment

1. ICRs Regarding Delegation of Eligibility Determinations and Appeals (§§431.10(c), 431.11, and 457.1120)

In §431.10(c), a state may delegate authority to make eligibility determinations and to conduct fair hearings. States generally have written agreements with various entities for similar purposes. Under this final rule, agreements may need to be modified or new agreements established. However, states that use the same agency to administer more than one program (for

example, Medicaid and the Exchange) will not need an agreement for the determination of eligibility by that agency.

Delegation of eligibility determinations was approved under OMB control number 0938-1147. This rule sets out changes in the existing requirement related to the type of agencies that can make Medicaid and CHIP eligibility determinations. These amendments do not change the burden associated with the requirement. Medicaid and CHIP agencies will need to establish new agreements to delegate authority to conduct eligibility appeals. The burden associated with the delegation of appeals is the time and effort necessary for the Medicaid and CHIP agencies to create and execute the agreements with the organization to which they are delegating authority.

There are 53 Medicaid agencies (the 50 states, the District of Columbia, Northern Mariana Islands, and American Samoa) and 43 CHIP agencies, for a total of 96 agencies. For the purpose of developing the cost, we estimate that half of these agencies will establish an agreement with an organization to conduct fair hearings. We estimate a one-time burden of 50 hours to develop an agreement that can be used with the organization. It will take an additional 10 hours for Medicaid and 10 hours for a separate CHIP agency to negotiate and execute the agreement with the organization for a total time burden of 2,880 hours $[(53 + 43)/2 \times (50 + 10)]$ across all agreements. For the purpose of the cost, we estimate it will take a health policy analyst 40 hours at \$49.35 an hour and a senior manager 10 hours at \$79.08 an hour to complete the model agreement (for a total of \$2,764.80) plus 10 additional hours (\$49.35) for a health policy analyst to execute a completed agreement with each organization. The estimated cost for each agreement is \$3,258.30 for a total cost of \$156,398.40.

2. ICRs Regarding Fair Hearing Processes (§§431.205(e), and 431.206(d) and (e))

In §§431.205(e) and 431.206(e), the hearing system and information must be accessible to persons who are limited English proficient and to persons with disabilities. While states are

required to make the hearing system accessible, we believe the associated burden is exempt from the PRA (see 5 CFR 1320.3(b)(2)) since we believe that the time, effort, and financial resources necessary to comply with this requirement will be incurred by persons during the normal course of their activities and should, therefore, be considered as a usual and customary business practice.

In §431.206(d), states are required to inform individuals that they may have their hearing before the agency (instead of the Exchange or the Exchange appeals entity) and the method by which the individual may make such election. There are 53 Medicaid agencies (the 50 states, the District of Columbia, Northern Mariana Islands, and American Samoa) and 43 CHIP agencies for a total of 96 agencies that will be subject to this requirement. The burden associated with providing this choice is developing the process and workflow to enable the choice and sending the request for the fair hearing to the appropriate agency. We estimate it will take each agency an average of 70 hours to create the process and workflow required in providing the choice. For the purpose of the cost, we estimate it will take a health policy analyst 40 hours at \$49.35 an hour, a senior manager 10 hours at \$79.08 an hour, and a computer programmer 20 hours at \$52.50 to complete the process and workflow. The estimated cost for each agency is \$3814.80. The total estimated cost is \$366,220.80.

3. ICRs Regarding Application Counselors (§435.908(c))

In §435.908(c), states have the option to authorize certain staff and volunteers of organizations to act as certified application counselors. The burden associated with the requirements to assist individuals with the application process is the time and effort necessary for the state to create agreements with these organizations, to create a registration process for assistors, and to train staff on the eligibility and confidentiality rules and requirements and how to assist applicants with the completing the application.

We estimate the 50 states, the District of Columbia, Northern Mariana Islands, and American Samoa will establish agreements with on average 20 organizations in their state or territory for a total of 1,060 agreements related to application assistance. As part of this estimate, we assumed that state Medicaid and CHIP agencies will be party to the same agreements and, therefore, will not establish separate agreements.

The first burden associated with this provision is the time and effort necessary for the state Medicaid and CHIP agencies to establish an agreement. To develop an agreement, we estimate that it will take each of the 53 states and territories 50 hours to develop a model agreement. For the purpose of the cost, we estimate it will take a health policy analyst 40 hours at \$49.35 an hour and a senior manager 10 hours at \$79.08 to develop an agreement. The estimated cost is \$2,764.80 (per state) or \$146,534.40 (total) while the total annual hour burden is 2,650 hours.

To negotiate and complete the agreement, we estimate that each of the 53 states/territories will execute 20 agreements. For the purpose of the cost, we estimate it will take a health policy analyst 10 hours at \$49.35 an hour to execute each agreement. The estimated cost is \$9,870 (per state) or \$523,110 (total) while the total annual hour burden is 10,600 hours.

To develop and execute the model agreements, the total cost is \$669,644.40 for 13,250 hours of labor.

The next burden associated with this provision is the time and effort necessary for the 53 states and territories to establish the registration process and workflow for the application counselors. We estimate it will take each state or territory an average of 70 hours (3,710 total hours) to create the registration process and workflow for the application counselors. For the purpose of the cost, we estimate it will take a health policy analyst 40 hours, at \$49.35 an hour, a senior manager 10 hours, at \$79.08 an hour, and a computer programmer 20 hours at \$52.50 to

complete the registration process and workflow. The estimated cost for each state or territory is \$3,814.80. The total estimated cost is \$202,184.40.

The next burden associated with this provision is the time and effort necessary for the 53 state Medicaid and CHIP agencies to provide training to the application counselors. For the purpose of the cost, we estimate it will take a training specialist 40 hours at \$26.64 an hour and a training and development manager 10 hours at \$64.43 an hour to develop training materials for the application counselors, for a total time burden of 2,650 hours. The estimated cost for each state or territory is \$1,709.90. The total estimated cost is \$90,624.70.

Lastly, we estimate that each state or territory will offer 50 hours of training sessions to train individuals to assist applicants with Medicaid and CHIP applications for a total time burden of 2650 hours. For the purpose of the cost, we estimate it will take a training specialist 50 hours at \$26.64 an hour to train the application counselors. The estimated cost for each agency is \$1,332. The total estimated cost is \$70,596.

4. ICRs Regarding Eligibility Determination Notices (§435.918, §457.110,)

In §435.918 and §457.110, states must electronically provide notices to individuals when elected.

The burden associated with the requirements to deliver notices is the time necessary for the state staff to: familiarize themselves with the requirements related to notices; (2) develop the language for approval, denial, termination, suspension, and change of benefits notices; and (3) program the language in the Medicaid and CHIP notice systems so that the notice can be populated and generated based on the outcome of the eligibility determination and be delivered in an electronic format.

We estimate 53 state Medicaid agencies (the 50 states, the District of Columbia, Northern Mariana Islands, and American Samoa) and 43 CHIP agencies (in states that have a separate or

combination CHIP), totaling 96 agencies, will be subject to this requirement. We estimate that it will take each Medicaid and CHIP agency 194 hours annually to develop, automate, and distribute the notice of eligibility determination. For the purpose of the cost burden, we estimate it will take a health policy analyst 138 hours at \$49.35 an hour, a senior manager 4 hours at \$79.08, an attorney 20 hours at \$90.14, and a computer programmer 32 hours at \$52.50 to complete the notices. The estimated cost burden for each agency is \$10,609.42. The total estimated cost burden is \$1,018,504.30, and the total annual hour burden is 18,624 hours.

5. ICRs Regarding Authorized Representatives (§435.923(a))

Section 435.923(a) sets out minimum requirements for the designation of authorized representatives. We are also applying these provisions to state CHIP agencies through the addition of a cross reference in §457.340.

We are aware of the need to estimate the PRA burden associated with the collection of information related to authorizing an individual to act as a representative of an applicant, to permit self-attestation for individuals who do not have access to documentation, and the citizenship and immigration verification requirements. These requirements were addressed as part of the single, streamlined application under OCN 0938-1191 (CMS-10440).

6. ICRs Regarding Presumptive Eligibility Determined by Hospitals (§435.1110)

Under §435.1110(d)(1), states may establish state-specific standards for qualified hospitals that conduct presumptive eligibility determinations related to the success of assisting individuals determined presumptively eligible who submit a regular application and/or are approved for eligibility by the agency. States also have a great deal of flexibility in determining and implementing the standards appropriate for their programs as well as appropriate corrective action measures for hospitals which do not meet the state standards.

This change is necessary to reflect changes in federal policy. A state's election of state-specific standards will affect their Medicaid state plan. While we are aware of the need to estimate the burden associated with the submission of the state plan amendment, that amendment will be addressed under the electronic state plan filing process being developed by CMS (the MACPro system) and submitted to OMB for approval under OCN 0938-1188 (CMS-10434). The amendment and its estimated burden will also be made available for public comment through the PRA process.

In §§435.1101(b) and 457.355 (by reference to §435.1101), states are required to provide qualified entities with training in all applicable policies and procedures related to presumptive eligibility. The burden associated with this provision is the time and effort necessary for the states and territories to provide training to the hospitals. We estimate 50 states, the District of Columbia, Northern Mariana Islands, and American Samoa will be subject to this requirement. As part of this estimate, we assumed that state Medicaid agencies and CHIP agencies, where there are separate agencies, will develop and use the same training.

For the purpose of the cost, we estimate it will take a training specialist 40 hours at \$26.64 an hour and a training and development manager 10 hours at \$64.43 an hour to develop training materials for the qualified entities, for a total time burden of 2,650 hours. The estimated cost for each state or territory is \$1,709.90. The total estimated cost is \$90,624.70.

We also estimate that each state or territory will offer 50 hours of training sessions to qualified entities, for a total time burden of 2,650 hours. For the purpose of the cost, we estimate it will take a training specialist 50 hours at \$26.64 an hour to train the qualified entities. The estimated cost for each agency is \$1,332. The total estimated cost is \$70,596.

7. ICRs Regarding ABP SPA-related Requirements (§§440.305, 440.315, 440.330, 440.335, 440.345, 440.347, 440.360, and 440.386)

In the proposed rule, CMS requested comment on habilitative services (§440.347(d)) and on the “medically frail” definition (§440.315(f)). Comments and CMS’ response can be found in section B.3.a of this preamble. We also requested comment on essential health benefits (rehabilitative and habilitative services and devices) (§440.347). See section II.B. of this preamble for the comments and our response. Additional comments were solicited for exempt individuals (modifying definition of “medically frail”) (§440.315). Comments and CMS’ response can be found in the ABP portion of this preamble.

CMS also received many comments on the proposed changes to: (1) the public notice requirement in §440.386 (see section II.B.7.b. of this preamble for the comment and our response); (2) public notice in §440.386 and prescription drug coverage in §440.345(f) (see section II.B.3.i. of this preamble for the comment and our response); (3) essential health benefits (non-discrimination policy) under §440.347 (see section II.B.2.d of this preamble); and (4) EPSDT and other required benefits (family planning services and supplies) under §440.345 (see the comments and responses section of the ABP portion of this preamble). As a result of comments received, CMS is finalizing the public notice requirements in this final rule without change.

We also received a number of comments requesting clarification to our statement in the preamble that the section 1927 requirements apply to the ABP prescription drug benefit.

Specifically, commenters requested clarification, as part of this final rule, as to how section 1927 of the Act applies to prescription drug coverage under the ABP since ABP requirements for prescription drug coverage must meet the minimum EHB prescription drug requirements at section 1937 of the Act. Based upon those comments, we have clarified in the regulation that when states pay for covered outpatient drugs under a state’s ABP, the section 1927 requirements apply. There is no additional information collection burden associated with this clarification.

While this rule has finalized policy related to these provisions, these policies do not result in any additional information collection requirements. Rather, the policy clarifications are interpretations of information that is already being collected.

The information collection requirements and burden estimates associated with §§440.305, 440.315, 440.330, 440.335, 440.345, 440.347, 440.360, and 440.386 have been approved by OMB through March 31, 2016, under OCN 0938-1188 (CMS-10434). This rule will not impose any new or revised SPA-related reporting, recordkeeping, or third party disclosure requirements and, therefore, does not require additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

8. ICRs Regarding Cost Sharing and Premiums (§§447.52, 447.53, 447.54, 447.55 and 447.56)

The Deficit Reduction Act of 2005 (DRA) established a new section 1916A of the Act, which gives states additional flexibility, allowing for alternative premiums and cost sharing, beyond what is allowed under section 1916 of the Act, for somewhat higher income beneficiaries. Such alternative cost sharing may be targeted to specific groups of beneficiaries and payment may be required as a condition of providing services. Thus, in accordance with the DRA we reviewed and made changes to the current cost sharing and premiums regulations under §§447.52 through 447.56.

In a review of these sections we found that 45 states including the District of Columbia impose cost-sharing and 40 states impose premiums on beneficiaries. While these provisions are subject to the PRA, we believe that any changes a state makes to its current state plan under any of these sections is a usual and customary practice under 5 CFR 1320.3(b)(2) and, as such, the burden associated with it is exempt from the PRA.

For those states electing to impose cost-sharing or premiums for the first time will only need to submit a state plan amendment one time for review. We estimate it will take each

agency in this circumstance an average of 2 hours to fill out the state plan pre-print for either cost-sharing or premiums and submit it for approval. Thus we anticipate six states may impose cost-sharing and 11 states and the District of Columbia may impose premiums on beneficiaries. For the purpose of the cost burden, we estimate it will take a health policy analyst 1 hour at \$49.35 an hour and a senior manager 1 hour at \$79.08 an hour to complete the process and submission of each new state plan amendment. The estimated cost burden for each agency is \$128.43. The total estimated cost burden is \$2,183.31.

9. ICRs Regarding Beneficiary and Public Notice Requirements (§447.57)

In §447.57(a), 53 Medicaid agencies will be required to make available a public schedule describing current premiums and cost sharing requirements containing the information in paragraphs (a)(1) through (6). In §447.57(b), agencies are required to make the public schedule available to those identified in paragraphs (b)(1) through (4).

Prior to submitting a SPA for Secretary approval to establish or modify existing premiums or cost sharing or change the consequences for non-payment, §447.57(c) requires that the state: (1) provide the public with advance notice of the SPA (specifying the amount of premiums or cost sharing and who is subject to the charges); (2) provide a reasonable opportunity to comment on SPAs that propose to substantially modify premiums and cost sharing; (3) submit documentation to demonstrate that these requirements were met; and (4) provide additional public notice if cost sharing is modified during the SPA approval process.

In §447.57(d), the information must be provided in a manner that ensures that affected beneficiaries and providers are likely to have access to the notice and are able to provide comments on proposed state plan amendments.

We estimate it will take each Medicaid agency an average of 6 hours to create the process and workflow required in providing the schedule and notice. For the purpose of the cost burden,

we estimate it will take a health policy analyst 4 hours at \$49.35 an hour and a senior manager 2 hours at \$79.08 an hour to complete the process and workflow. The estimated cost burden for each agency is \$355.56. The total estimated cost burden is \$18,844.68.

C. Part 155 --Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

For purposes of presenting an estimate of paperwork burden, we reflect the participation of 18 State-Based Exchanges. It is important to note that the Exchange provisions found in part 155, subparts D and E discussed below involve several information collections that will occur through the single, streamlined application for enrollment in a QHP and for insurance affordability programs described in §155.405. We have accounted for the burden associated with these collections in the Supporting Statement for Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Health Benefits Exchanges, Medicaid, and Children's Health Insurance Program Agencies (CMS-10440; OCN 0938-1191).

We also highlight that the Supporting Statement includes several information collections from regulatory provisions finalized in the Exchange final rule (77 FR 18310). We have included these information collections in this PRA package to address PRA requirements related to those provisions as they were not included in the information collection section of the Exchange final rule.

Lastly, we have not included information regarding information collections associated with certified application counselors, eligibility appeals, and SHOP coordination with individual market Exchanges, which we will finalize at a future date with the corresponding regulatory provisions.

1. ICRs Regarding Authorized Representatives (§155.227)

Section 155.227(a) provides that an applicant or enrollee, subject to applicable privacy and security requirements, may designate an individual person or organization as his or her authorized representative. One method for designating an authorized representative is by submitting legal documentation of the representative's authority. Exchanges have the option to make available an "Appointment of Authorized Representative Form" at the time of application or anytime thereafter for an individual to designate an authorized representative. Such a form would collect identifying and contact information about the applicant, enrollee, and requested authorized representative. Requested data elements would include the following for both the applicant or enrollee and the requested representative: name, address, phone number, email address, date of birth, and relationship. The applicant, enrollee, or authorized representative could obtain the form from the Exchange website or from an assister (such as a Navigator, non-Navigator in-person assister, etc.), and could submit it to the Exchange by mail or online at any time. We expect that the Exchange would use this information to authorize the authorized representative to act on behalf of the applicant or enrollee. An authorized representative could also submit this form if the applicant or enrollee is unable to do so.

HHS is currently developing a model Appointment of Authorized Representative Form to be used by the Federally-facilitated Exchanges and will make that form available to State-based Exchanges, which would also decrease the burden on State-based Exchanges to develop such a form. If a state opts not to use the form provided by HHS, we estimate the burden associated for the time and effort necessary for a State-based Exchange to develop the Appointment of Authorized Representative Form to be 30 hours. This includes a 10 hours from a mid-level health policy analyst at an hourly cost of \$49.35 and 10 hours from an operations analyst at an hourly cost of \$54.45 for drafting the form with 4 hours of managerial oversight at an hourly cost

of \$79.08 and 6 hours of legal review at an hourly cost of \$90.14. The estimated cost per State-based Exchange is \$1,895, for a total cost of \$34, 113 for 18 State-based Exchanges.

For an applicant, enrollee, or prospective authorized representative, we estimate that it will take up to 5 minutes to review instructions and complete an Appointment of Authorized Representative Form. While we expect most applicants, enrollees, or prospective authorized representatives to complete the Authorized Representative Form, an applicant, enrollee, or prospective authorized representative may also comply with this provision by providing the necessary information online, by phone, by mail, or in-person. We expect a similar burden on the applicant, enrollee, or authorized representative to comply with this provision through such means. If the applicant, enrollee, or authorized representative chooses to submit an “Appointment of Authorized Representative Form,” the burden for a State-based Exchange to process the submitted information will be approximately 10 minutes at a cost of \$3.39 per submission. We anticipate that an eligibility support staff person will scan, digitize, and link the form to an applicant’s or enrollee’s account, review the submitted information, and update the authorized representative’s and applicant’s or enrollee’s account, if applicable.

2. ICRs Regarding Notices (§§155.302, 155.310, 155.315, 155.320, 155.330, 155.335, 155.345, 155.355, 155.410, 155.715, 155.720, 155.725, and 155.1080)

Several provisions in subparts D and E outline specific scenarios in which the Exchange will send a notice to individuals and employers throughout the eligibility and enrollment process. HHS is currently developing model eligibility determination notices and several other models for notices described in 45 CFR parts 155, 156, and 157 which will decrease the burden on Exchanges to establish such notices. For some notices, the Exchange will include specific notice text in another notice, such as the eligibility determination notice, rather than send an entirely separate notice (effectively, two notices are combined into one). The purpose of these notices is

to alert the individuals and employers who receive the notice of actions taken by the Exchange. When possible, we anticipate that the Exchange will consolidate notices when multiple members of a household are applying together and receive an eligibility determination at the same time. The notice may be in paper or electronic format but must be in writing and sent after an eligibility determination has been made by the Exchange. We anticipate that a large volume of enrollees will request electronic notification while others will opt to receive the notice by mail. As a result of certain enrollees opting to receiving the notice by mail in some instances, we estimated the associated mailing costs for the time and effort needed to mail notices in bulk to enrollees as appropriate.

We expect that the electronic eligibility determination notice will be dynamic and include information tailored to all possible outcomes of an application throughout the eligibility determination process. To develop the paper and electronic notices, Exchange staff will need to learn eligibility rules and draft notice text for various decision points, follow up, referrals, and appeals procedures. A health policy analyst, senior manager, and legal counsel will review the notice. The Exchange will then engage in review and editing to incorporate changes from the consultation and user testing including review to ensure compliance with plain writing, translation, and readability standards. We intend that Exchanges will work closely with the state Medicaid or CHIP agency to develop coordinated notices. Finally, a developer will program the template notice into the eligibility system so that the notice may be populated and generated in the correct format according to an individual's preference to receive notices, via paper or electronically, as the applicant moves through the eligibility process.

If a state opts not to use the model notices provided by HHS, we estimate that the Exchange effort related to the development and implementation of the eligibility notice will necessitate 44 hours from a health policy analyst at an hourly cost of \$49.35 to learn eligibility

rules and draft notice text; 20 hours from an attorney at an hourly cost of \$90.14 and 4 hours from a senior manager at an hourly cost of \$79.08 to review the notice; and 32 hours from a computer programmer at an hourly cost of \$52.50 to conduct the necessary development. In total, we estimate that this will take a total of 100 hours for each Exchange, at a cost of approximately \$5,971 per Exchange and a total cost of \$107,478 for 18 State-Based Exchanges. We expect that the burden on the Exchange to maintain this notice will be significantly lower than to develop it.

Section 155.310(h) specifies that the Exchange will notify an employer that an individual in an employee's tax household has been determined eligible for advance payments of the premium tax credit and/or cost-sharing reductions based in part on the employer not offering minimum essential coverage or not offering qualifying coverage in an eligible employer-sponsored plan. Upon making such an eligibility determination, the Exchange will send a notice to the employer with information identifying the employee, along with a notification that the employer may be liable for the payment under section 4980H of the Code, and that the employer has a right to appeal this determination. Because this notice will be sent to an employer at the address as provided by an application filer on the application, we anticipate all of these notices will be sent by mail. As a result, we estimated the associated mailing costs for the time and effort needed to mail notices in bulk to employers. Like the eligibility notice, the employer notice above will be developed and programmed into the eligibility system. However, unlike the eligibility notice, we expect the information on the employer notice to be minimal in comparison to the eligibility notice and therefore the burden on the Exchange to develop the notice to be substantially less. Further, as with the individual eligibility notice, HHS will provide model notice text for Exchanges to use in developing this notice.

3. ICRs Regarding Verification of Enrollment in an Eligible Employer-Sponsored Plan and

Eligibility for Qualifying Coverage in an Eligible Employer-Sponsored Plan (§155.320)

Section 155.320(d) proposes the process for the verification of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan. Paragraph (d)(2) specifies that the Exchange will obtain relevant data from any electronic data source available to the Exchange which has been approved by HHS, as well as data from certain specified electronic data sources. This will involve the development and execution of data sharing agreements; however, this burden is already captured in the data sharing agreements described in §155.315. As these verification activities will all be electronic, we do not expect for there to be any additional burden than that which is required to design the overall eligibility and enrollment system.

Paragraph (d)(3)(iii)(A) proposes that the Exchange provide notice to certain applicants indicating that the Exchange will be contacting any employer identified on the application to verify whether the applicant is enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested. The burden associated with this notice to certain applicants is addressed in 155.310(g) as this will not be a separate notice, but incorporated into the eligibility determination notice described in the above paragraph.

In paragraph (d)(3)(iii)(D), we propose that the Exchange make reasonable attempts to contact any employer to which the applicant attested employment to verify whether the applicant is enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested. We note that the flexibility we provide to State-Based Exchanges for the first year of operations will significantly reduce the burden of this information collection in the first year.

It is difficult to estimate the burden associated with this information collection as the

calculation involves identifying the number of individuals for whom employer-sponsored coverage information will be unavailable. As such, below, we estimate the time and cost associated with the Exchange making a reasonable attempt to contact one employer. We estimate the time associated with this information collection to be a total of 2.2 hours per employer at a total cost of \$34.

4. ICRs Regarding Electronic Transmissions (§§155.310, 155.315, 155.320, and 155.340)

Sections 155.310, 155.315, 155.320, 155.330, and 155.340 involve the electronic transmission of data to determine eligibility for enrollment in a QHP and for insurance affordability programs. Section 155.310(d)(3) specifies that the Exchange must notify the state Medicaid or CHIP agency and transmit all information from the records of the Exchange for an applicant determined eligible for Medicaid or CHIP to the Medicaid or CHIP agency to ensure that the Medicaid or CHIP agency can provide the applicant with coverage promptly and without undue delay. This applicant information will be transmitted electronically from the Exchange to the agency administering Medicaid or CHIP once a determination has been made that the applicant is eligible for such program. The purpose of this data transmission is to notify the agency administering Medicaid or CHIP that an individual is newly eligible and thus the agency should facilitate enrollment in a plan or delivery system. Data will be transmitted through a secure electronic interface.

Sections 155.315 and 155.320 include transactions necessary to verify applicant information. We expect there to be no transactional burden associated with the electronic transactions needed to implement §§155.315 and 155.320. As these transmission functions will all be electronic, we do not expect for there to be any additional burden than that which is required to design the overall eligibility and enrollment system.

In §155.340, the Exchange must provide the relevant information, such as the dollar amount of the advance payment and the cost-sharing reductions eligibility category, to enable advance payments of the premium tax credit and cost-sharing reductions, reconciliation of the advance payments of the premium tax credit, and administration of the employer responsibility requirements. As we anticipate that these transmissions of information will all be electronic, we do not expect for there to be any additional burden than that which is required to design the overall eligibility and enrollment system.

5. ICRs Regarding Reporting Changes (§§155.315, 155.330, and 155.335)

Section 155.315(f) outlines the process for resolving inconsistencies identified through the verification process. In §155.330(c)(1), we state that the Exchange will verify any information reported by an enrollee in accordance with the processes specified in §§155.315 and 155.320 prior to using such information in an eligibility redetermination. Section 155.335(e) provides that the Exchange will require a qualified individual to report any changes for the information listed in the notice described in §155.335(c) of this section within 30 days from the date of the notice. It is not possible at this time to provide estimates for the number of applicants for whom a reported change will necessitate the adjudication of documentation, but we anticipate that this number will decrease as applicants become more familiar with the eligibility process and as more data become available. As such, for now, we note that the burden associated with this provision is one hour for an individual to collect and submit documentation, and 12 minutes (or 0.2 hours) for eligibility support staff at an hourly cost of \$28.66 to review the documentation.

6. ICRs Regarding Enrollment and Termination (§§155.400, 155.405, and 155.430)

In part 155, subpart E, we describe the requirements for Exchanges in connection with enrollment and disenrollment of qualified individuals through the Exchange. These information

collections are associated with sending eligibility and enrollment information to QHP issuers and to HHS, maintaining records of all enrollments in QHPs through the Exchange, reconciling enrollment information with QHP issuers and HHS, and retaining and tracking coverage termination information. The burden estimates associated with these provisions include the time and cost to meet these record requirements. We estimate that it will take 142 hours annually for an Exchange to meet these recordkeeping requirements for a total of 2,556 hours for 18 State-Based Exchanges.

In the case of the requirement related to termination standards, the burden includes estimates related to the maintenance and transmission of coverage termination information, as well as the time and effort needed to develop the system to collect and store the information. We estimate that it will take 30 hours of a health policy analyst at an hourly rate of \$58.05, 20 hours for a computer programmer at an hourly rate of \$52.50, and 20 hours for an operations analyst at an hourly rate of \$54.45 for a total of 70 hours annually per Exchange and a total of 1,260 hours for 18 Exchanges, for the time and effort to meet this standard. We estimate a cost of \$3,881 for one Exchange and a total cost of 69,858 for 18 State-Based Exchanges.

7. ICRs Regarding Agreements (§§155.302 and 155.345)

Section 155.345(a) specifies that an Exchange and the corresponding state Medicaid and CHIP agencies will enter in to an agreement regarding the coordination of eligibility determinations, and §155.302(b)(6) specifies that to the extent that an Exchange is making assessments of eligibility for Medicaid and CHIP, rather than determinations, the Exchange will enter into an agreement with the state Medicaid and CHIP agencies regarding this arrangement. These agreements are necessary to minimize burden on individuals, ensure prompt determinations of eligibility and enrollment in the appropriate program without undue delay and to provide standards for transferring an application between the Exchange and other entities

administering insurance affordability programs. The specific number of agreements needed may vary depending on how states choose to divide responsibilities regarding eligibility determinations; where the Exchange is making assessments, we expect that the agreement described in §155.302(b)(6) will be combined with the agreement in §155.345(a).

The burden associated with this provision is the time and effort necessary for the Exchange to establish or modify an agreement for eligibility determinations and coordination of eligibility and enrollment functions. If an Exchange chooses to draft separate agreements for each insurance affordability program, then the estimate will likely increase.

In either case, we estimate it will take each Exchange an average of 105 hours to create a new agreement, although we assume that such agreements will be largely standardized across states, and that HHS will provide model agreements for state Medicaid and CHIP agencies and the Exchange to use. This includes a mid-level health policy analyst and an operations analyst reviewing the agreement with managerial oversight and comprehensive review of the agreement by operations analyst. We estimate a cost of \$6,733 per Exchange.

8. ICRs Regarding Notices from QHP Issuers (§§156.260, 156.265, 156.270, and 156.290).

First, §156.260(b) provides that QHP issuers will notify a qualified individual of his or her effective date of coverage, in accordance with the effective dates of coverage established by the Exchange in accordance with §155.410(c) and (f). Second, under §156.270(b), QHP issuers will send a notice of termination of coverage to an enrollee if the enrollee's coverage in the QHP is being terminated in accordance with §155.430(b)(1)(i), (b)(2)(ii) or (b)(2)(iii). Third, §156.270(f) provides that QHP issuers will provide enrollees with a notice about the grace period for non-payment of premiums. QHP issuers will send this notice to enrollees who are delinquent on premium payments. Fourth, §156.265(e) provides that QHP issuers will provide new enrollees with an enrollment information package, which we anticipate that issuers may

combine with the notification of coverage effective date described in §156.260(b). Lastly, under §156.290(b), QHP issuers will provide a notice to enrollees if the issuer elects not to seek recertification of a QHP.

We anticipate that some of the above QHP issuer required notices are similar in nature to the notices that issuers currently send to enrollees. For example, it is standard practice for issuers to provide new enrollees with information about their enrollment in a plan, their effective date of coverage, and if and when their coverage is terminating. Accordingly, we anticipate that QHP issuers will review, update, and revise notice templates that they utilize currently as they work to address the notice requirements described below and to ensure that the notices include the appropriate information. Similar to notices that will be issued by the Exchange, we expect that for QHP-issued notices, an analyst will develop text, and a peer analyst, manager, and legal counsel for the issuer will review the notices, including a review to ensure compliance with plain writing, language access, and readability standards as required under §156.250(c). Finally, a developer will need to incorporate programming changes into the issuer's noticing system to account for the changes and updates that will be necessary to ensure that the QHP issuer is in compliance with the notice standards set forth in this rule and to ensure the notice can be populated and generated according to an individual's preference to receive notices. We estimate that the burden related to the development and implementation of this notice will necessitate 44 hours from a health policy analyst at an hourly cost of \$49.35 to learn appeals rules and draft notice text; 20 hours from an attorney at an hourly cost of \$90.14 and four hours from a senior manager at an hourly cost of \$79.08 to review the notice; and 32 hours from a computer programmer at an hourly cost of \$52.50 to conduct the necessary development. In total, we estimate that this will take a total of 100 hours for each QHP issuer, at a cost of approximately

\$5,971 per issuer. We expect that the burden on QHP issuers to maintain this notice will be significantly lower than to develop it.

However, we believe that the burden estimate described under §155.310(g) likely represents an upper bound estimate of the burden on issuers to develop each of these notices as in some cases the notice described under §155.310(g) will be somewhat more dynamic to address the additional information we expect to be included in that notice.

Since the above estimate applies to one notice, and we described 5 notices under part 156, the total burden estimate is \$40,710. Due to uncertainty regarding the number of individuals who will choose to receive paper notices, as well as some uncertainty regarding the frequency of circumstances that will trigger notices in accordance with this part, we have only included an estimate of the printing and mailing costs for a QHP issuer to send one notice to a qualified individual or enrollee.

9. ICRs Regarding Notices and Third-Party Disclosures in the SHOP (§§157.205(e) and (f))

45 CFR part 157 includes several instances in which qualified employers participating in the SHOP Exchange will need to provide information to employees or to the SHOP Exchange. We include the data elements for these notifications in appendix A of this PRA package. For the individual market Exchange, we anticipate that a large share of enrollees will elect to receive electronic notices while the rest will receive notices by mail. We do not make this assumption for notices described here as we expect that qualified employers would provide notices to employees in whatever format the qualified employer usually provides notices to employees; in paper, electronically, or in a combination of both formats. We estimate that the associated printing costs for paper notices will be approximately \$0.10 per notice. We do not take mailing costs into consideration for notices provided by qualified employers, as we expect that if qualified employers provide notices in paper format, the employer may provide the employee

with the notice in person, instead of mailing the notice. We do not have a reasonable way to estimate total printing costs for notices provided by qualified employers in the SHOP Exchange due to uncertainty regarding the number of employees who will choose to receive paper notices, as well as some uncertainty regarding the frequency of circumstances that will trigger notices in accordance with this part.

First, §157.205(e) specifies that a qualified employer provide an employee with information about the enrollment process. A qualified employer will inform each employee that he or she has an offer of coverage through the SHOP Exchange, and instructions for how the employee can apply for and enroll in coverage. We anticipate that the qualified employer will also provide information about the acceptable formats in which an employee may submit an application; online, on paper, or by phone, as described under §157.205(c). If the employee being offered coverage was hired outside an initial or annual enrollment period, the notice will also inform the employee if he or she is qualified for a special enrollment period. Second, in §157.205(f) we provide that a qualified employer will notify the SHOP Exchange regarding an employee's change in eligibility for enrollment in a QHP through the SHOP Exchange, including when a dependent or employee is newly eligible, or is no longer eligible.

We expect that the information that qualified employers will provide to employees and the SHOP Exchange, as described above, will be somewhat standardized. Additionally, we anticipate that qualified employers will generate notices using a manual process. We expect that for a qualified employer to establish a notice, the qualified employer will need 20 hours from a human resources specialist at an hourly cost of \$40.68 to develop the text; and four hours from a human resources manager at an hourly cost of \$75.01 and ten hours from an attorney at an hourly cost of \$90.14 to review the notices. We do not anticipate that a developer will be needed to develop the notices described in this part since we expect that in most cases, these notices will

be manually generated on demand. Accordingly, we expect that the burden hours for developing each of the notices will be approximately 34 hours, for a total of 68 hours per qualified employer, at a total cost of \$4,030. We expect that the burden on the qualified employer to maintain the notices will be significantly lower than to develop the notices.

D. Summary of Annual Burden Estimates

TABLE 1: Proposed Annual Recordkeeping and Reporting Requirements

Regulation Section(s)	OMB & CMS ID #s	Respondents	Responses (total)	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting (\$)	Total Cost (\$)
42 CFR 431.10, 431.11, and 457.1120	OCN 0938-New; CMS-10456	48	48	60	2,880	3,258 (per respondent)	156,398
§§435.917, 435.918, 457.110, and 457.340	OCN 0938-New; CMS-10456	96	96	194	18,624	10,609 (per respondent)	1,018,504
§§435.923 and 457.340 (develop and execute agreements)	OCN 0938-New; CMS-10456	53	1060	12.5	13,250	12,635 (per respondent)	669,644
§§435.923 and 457.340 (create registration process and work flow)	OCN 0938-New; CMS-10456	53	53	70	3,710	3,815 (per respondent)	202,184
§§435.923 and 457.340 (develop training materials)	OCN 0938-New; CMS-10456	53	53	50	2,650	1,710 (per respondent)	90,625
§§435.923 and 457.340 (train application assistors)	OCN 0938-New; CMS-10456	53	53	50	2,650	1,332 (per respondent)	70,596
§§435.1101(b) and 457.355	OCN 0938-New; CMS-10456	53	53	50	2,650	1,710 (per respondent)	90,625
§447.57	0938-New; CMS-10456	53	53	6	318	210 (per respondent)	11,130
§155.227 (ICRs Regarding Authorized Representatives)	OCN 0938-New; CMS-	18	18	30	540	1,895 (per respondent)	34,113

Regulation Section(s)	OMB & CMS ID #s	Respondents	Responses (total)	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting (\$)	Total Cost (\$)
	10400						
§§155.302, 155.310, 155.315, 155.320, 155.330, 155.335, 155.345, 155.410, 155.715, 155.720, 155.725, and 155.1080 (ICRs Regarding Notices)	OCN 0938-New; CMS-10400	18	18	100	1,800	5,971 (per respondent)	107,478
§155.320 (ICRs Regarding Verification of Enrollment in an Eligible Employer-Sponsored Plan and Eligibility for Qualifying Coverage in an Eligible Employer-Sponsored Plan)	OCN 0938-New; CMS-10400	1	--	2.2	--	34 (for one respondent)	--
§§155.315, 155.330, 155.335 (ICRs Regarding Reporting Changes)	OCN 0938-New; CMS-10400	18	18	.2	--	29 (for one respondent)	5.73
§§155.400 and 405 (ICRs Regarding Enrollment)	OCN 0938-New; CMS-10400	18	18	142	2,556	7,254 (per respondent)	136,314
§155.430 (ICRs Regarding Termination)	OCN 0938-New; CMS-10400	18	18	70	1,260	3,881 (per respondent)	69,858
§§ 155.302, 155.345 (ICRs Regarding Agreements)	OCN 0938-New; CMS-10400	18	18	105	1,890	6,733 (per respondent)	121,194
§§156.260, 156.265, 156.270, and 156.290 (ICRs Regarding Notices from QHP Issuers)	OCN 0938-New; CMS-10400	18	18	100	1,800	5,971 (per respondent)	107,478
§157.205(e) and (f) (ICRs Regarding Notices and Third Party Disclosures in the SHOP)	OCN 0938-New; CMS-10400	--	--	68	--	4,030 (per respondent)	--
TOTAL					55,578		2,886,146.73

E. Submission of PRA-Related Comments

We have submitted a copy of this final rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access the CMS website at <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>, or call the Reports Clearance Office at 410-786-1326.

We invite public comments on these potential information collection requirements. If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this final rule; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, (CMS-2334-P) Fax: (202) 395-6974; or E-mail: OIRA_submission@omb.eop.gov. PRA-specific comments must be received by **[INSERT DATE 30 DAYS AFTER THE DATE OF PUBLIC INSPECTION AT THE OFFICE OF THE FEDERAL REGISTER]**.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993) and Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if

regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any 1 year). The Office of Management and Budget has determined that this rulemaking is “economically significant” within the meaning of section 3(f)(1) of Executive Order 12866, because it is likely to have an annual effect of \$100 million in any one year. Accordingly, we have prepared a Regulatory Impact Analysis that presents the costs and benefits of this rulemaking. The RIA published with the March 2012 Medicaid eligibility final rule detailed the impact of the Medicaid eligibility changes related to implementation of the Affordable Care Act. The majority of Medicaid eligibility provisions included in this final rule were described in that detailed RIA and do not need to be repeated here. In the April 30, 2010 final rule on State Flexibility for Medicaid Benefit Packages, the assumptions utilized in modeling the estimated economic impact of the associated provisions took into perspective the costs of the benefit package for the new adult group. Coverage of these benefits was already accounted for in the April 30, 2010 final rule, and therefore, does not need to be repeated here.

For coverage beginning on or after January 1, 2014, individuals and small businesses will be able to purchase private health insurance –known as qualified health plans-- through competitive marketplaces called Affordable Insurance Exchanges, or “Exchanges.” This final rule: (1) outlines criteria related to the verification of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan in connection with advance payments of the premium tax credit and cost-sharing reductions; and (2) further specifies or amends other eligibility and enrollment provisions to provide detail necessary for state implementation. This rule continues to afford states substantial discretion in

the design and operation of the Exchange established by a state, with greater standardization provided where directed by the statute or where there are compelling practical, efficiency or consumer protection reasons.

B. Estimated Impact of the Medicaid Premium and Cost Sharing Provisions

The provisions in this final rule related to Medicaid premiums and cost sharing clarify and update existing flexibilities and provide new flexibility for states for cost sharing for outpatient services, drugs, and non-emergency use of the emergency department. As states contemplate the changes required under the Affordable Care Act, more states may consider utilizing these flexibilities to either establish or expand cost sharing. We believe these proposed policies will encourage less costly care and decreased use of unnecessary services, which will reduce state and federal costs for the specified services. The following chart summarizes our estimate of the anticipated effects of this final rule.

TABLE 2: Estimated Total Impact of Changes in Maximum Medicaid Cost Sharing, FY 2014-2018, in millions of dollars

Year	2014	2015	2016	2017	2018	2014-2018
Federal	-25	-45	-70	-70	-70	-280
State	-15	-30	-45	-45	-50	-185
Total	-40	-75	-115	-115	-120	-465

Source: CMS' Office of the Actuary

We estimate that this final rule will result in total savings of \$465 million over 5 years, including \$280 million in cost savings to the federal government and \$185 million in savings to states. These savings may be attributed primarily to the increased maximum allowable cost sharing for outpatient services, drugs, and non-emergency use of the emergency department. Such savings are offset only nominally by the decreased maximum allowable cost sharing for an inpatient stay. In addition to direct savings from increased cost sharing, we assume some declines in utilization as enrollees subject to new cost sharing requirements choose to decrease their use of services.

C. Estimated Impact of Exchange Provisions

The provisions in this final rule amend select provisions of the Exchange Establishment final rule (77 FR 18319, March 27, 2012). Our approach in this regulatory impact analysis was to build off of the analysis presented in the Exchange Establishment final rule, available at <http://cciio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf>. We do not believe the provisions in this final rule significantly alter our prior estimates of the impact of Exchanges on the budget or on enrollment in health insurance, and therefore, this final rule does not significantly alter the regulatory impact analysis drafted as part of such rulemaking. This section summarizes benefits and costs of the Exchange provisions presented in this final rule.

1. Methods of Analysis

The estimates in this analysis reflect estimates from the FY 2014 President's Budget for State Planning and Establishment Grants, which incorporate the costs associated with state implementation of the provisions proposed in this rule.

2. Benefits of the Proposed Regulation

The provisions included in this final rule amend provisions of the Exchange Establishment final rule. We do not believe the modifications made significantly alter the benefits associated with these provisions. Therefore, we refer to the benefits discussion included in the regulatory impact analysis associated with the Exchange Establishment final rule for a full analysis. The Exchange Establishment final rule regulatory impact analysis can be found at <http://cciio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf>.

3. Costs of the Proposed Regulation

The Affordable Care Act and the implementing regulations found in subpart D of this final rule and the Exchange Establishment final rule provide for a streamlined system based on simplified eligibility rules, and an expedited process that will facilitate enrollment of eligible

individuals and minimize costs to states, Exchanges and to the federal government. To support this new eligibility structure, states seeking to operate Exchanges are expected to build new or modify existing information technology (IT) systems. We believe that how each state builds and assembles the components necessary to support its Exchange and Medicaid infrastructure will vary and depend on the level of maturity of current systems, current governance and business models, size, and other factors. It is important to note that, although states have the option to establish and operate an Exchange, there is no federal requirement that each state establish an Exchange. We believe the proposed provisions provide options and flexibility to states that minimize costs and burden on Exchanges, consumers, employers and other entities. We also believe that overall administrative costs may increase in the short term as states build IT systems; however, in the long term, states may see savings through the use of more efficient systems.

Any administrative costs incurred in the development of IT infrastructure to support the Exchange may be funded through Exchange Planning and Establishment Grants to states. The federal government expects that these grants will fund the development of IT systems that can be used by many states who either develop their own Exchanges or who partner with the federal government to provide a subset of Exchange services.³ Costs for IT infrastructure that will also support Medicaid must be allocated to Medicaid, but are eligible for a 90 percent federal matching rate to assist in development.⁴

In general, as noted in our discussion of benefits, we anticipate that the final rule will increase take-up of health insurance; therefore, one type of rule-induced cost will be associated

³ For example, CMS has awarded a number of Early Innovator grants to develop efficient and replicable IT systems that can provide the foundation for other states' work in this area. These amounts vary from \$6 million to \$48 million per state.

⁴ Medicaid Program; Federal Funding for Medicaid Eligibility Determination and Enrollment Activities, Final rule, 75 Fed. Reg. 21950 (April 19, 2011)

with providing additional medical services to newly-enrolled individuals. A recent study found that insured individuals received more hospital care and more outpatient care than their uninsured counterparts.⁵

Below we include estimated federal government payments related to grants for Exchange startup. States’ initial costs due to the creation of Exchanges will be funded by these grants. Performing eligibility determinations is a minimum function of the Exchange; therefore the Exchange costs to develop the infrastructure for the provisions included in this final rule are covered by these grant outlays.

TABLE 3: Estimated Federal Government Outlays for the Affordable Insurance Exchanges FY 2013 - FY2017, in billions of dollars

Year	2013	2014	2015	2016	2017	2013-2017
Grant Authority for Exchange Start up ^a	1.5	2.1	1.7	0.8	0.2	6.2

^a FY 2014 President’s Budget

D. Alternatives Considered

We considered two alternatives to the Exchange provisions.

- Alternative #1: Require paper documentation to verify access to employer-sponsored coverage.

Section 155.320(d) of the final rule provides a process for verification related to enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan. The proposed process relies on available electronic data sources, with the use of paper documentation in situations in which information submitted by an applicant is not reasonably compatible with information in electronic data sources, along with a sample-based review for situations in which no data is available.

⁵ Finkelstein, A. et al., (2011). The Oregon Health Insurance Experiment: Evidence from the First Year," *National*

The alternative model we considered would require the Exchange to require individuals to submit paper documentation to verify this information in all circumstances. This may increase the burden on individuals to submit this documentation to the Exchange, which may not be readily available to the applicant, but on employers, who will have to produce this information at the request of applicants, and will also require additional time and resources for Exchanges to accept and process the paper documentation needed for an eligibility determination. In addition, it could ultimately increase the amount of time it will take for an individual to receive health coverage through the Exchange or an insurance affordability program, could reduce the number of states likely to operate an Exchange due to increased administrative costs, and could dissuade individuals from seeking coverage through the Exchange.

- Alternative #2: Require Paper Notices from the Exchange

In §155.230(d), we provide that the Exchange will provide the option to an individual or employer to receive notices electronically. We anticipate that this will be accommodated by the Exchange generating electronic notices, storing them on a secure website, and notifying individuals and employers through a generic e-mail or text message communication that a notice is available for review.

The alternative model would require the Exchange to send all notices in paper form via US mail. This would significantly increase administrative costs for printing and mailing, and also generate significant volumes of undeliverable mail which would be returned to the Exchange.

Summary of Costs for Each Alternative

The paper-driven process outlined under alternatives 1 and 2 would ultimately increase the amount of time it would take for an individual to receive health coverage through the

Exchange or an insurance affordability program, would increase administrative costs, and would dissuade individuals from seeking coverage through the Exchange.

E. Limitations of the Analysis

A number of challenges face estimators in projecting the Exchange, Medicaid, and CHIP benefits and costs under the Affordable Care Act and its implementing regulations, including this final rule. Health care cost growth is difficult to project, especially for people who are currently not in the health care system – the population targeted for the Medicaid eligibility changes and new insurance affordability programs. Such individuals could have pent-up demand and thus have costs that may be initially higher than other enrollees in health coverage, while they might also have better health status than those who have found a way (for example, “spent down”) to enroll in Medicaid.

For the Exchange provisions, we use the President’s Fiscal Year 2014 Budget as an estimate of the costs associated with the Exchange provisions. It is difficult to isolate the effects associated with these particular provisions of the Affordable Care Act, and therefore, in this analysis, we discuss the evidence relating to the provisions of this final rule in combination with related provisions of the Affordable Care Act . Further, with limited previous data and experiences, there is even greater uncertainty than in estimating the implications of modifying a previously existing program. Accordingly, we supplement the regulatory impact analysis with a qualitative discussion on the specific provisions of this rule.

F. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4/), in Table X we have prepared an accounting statement table showing the classification of the impacts associated with implementation of this final rule.

TABLE 4: Accounting Statement: Classification of Estimated Net Costs and Transfers, (in millions)

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Benefits				
Annualized Monetized (\$million/year)	Not Estimated	2012	7%	2013 - 2017
	Not Estimated	2012	3%	2013 - 2017
Qualitative	The Exchanges, combined with other actions being taken to implement the Affordable Care Act, will improve access to health insurance, with numerous positive effects, including reduced morbidity and fewer medical bankruptcies. The Exchange will also serve as a distribution channel for insurance reducing administrative costs as a part of premiums and providing comparable information on health plans to allow for a more efficient shopping experience.			
Costs*				
Annualized Monetized (\$million/year)	1,311	2012	7%	2013 - 2017
	1,283	2012	3%	2013 - 2017
Qualitative	Unquantified costs include State implementation costs above the amount covered by Federal grants; and increased medical costs associated with more widespread enrollment in health insurance.			
Transfers				
Annualized Monetized (\$million/year)	54.4	2013	7%	2014 - 2018
	55.3	2013	3%	2014 - 2018
From Whom to Whom	Beneficiaries to Federal Government			
Annualized Monetized (\$million/year)	35.8	2013	7%	2014 - 2018
	36.5	2013	3%	2014 - 2018
From Whom to Whom	Beneficiaries to State Governments			

*These costs include grant outlays to States to establish Exchanges; most of these Exchange-establishment costs been included in the accounting statement for the Exchange final rule.

G. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) (RFA) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the final rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The Act generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a not-for-profit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

As discussed above, this final rule is necessary to implement certain standards related to the establishment and operation of Exchanges as authorized by the Affordable Care Act. Specifically, this final rule: (1) provides criteria related to the verification of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan; and (2) further specifies or amends standards related to other eligibility and enrollment provisions to provide detail necessary for state implementation.

The intent of this rule is to continue to afford states substantial discretion in the design and operation of an Exchange, with greater standardization provided where directed by the statute or where there are compelling practical, efficiency or consumer protection reasons.

For the purposes of the regulatory flexibility analysis, we expect the following types of entities to be affected by this final rule--(1) QHP issuers; and (2) employers. We believe that health insurers will be classified under the North American Industry Classification System (NAICS) Code 524114 (Direct Health and CMS-9989-P 166 Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$7 million or less will be considered small entities this NAICS code. Health issuers could also possibly be classified in

621491 (HMO Medical Centers) and, if this is the case, the SBA size standard will be \$30 million or less.

1. QHP Issuers

This rule proposes standards for Exchanges that affect eligibility determinations for enrollment in a QHP through the Exchange, advance payments of the premium tax credit, cost-sharing reductions, Medicaid, and CHIP. Although these standards are for Exchanges, they also affect health plan issuers that choose to participate in an Exchange. QHP issuers receive information from an Exchange about an enrollee to enable the QHP issuer to process the correct level of advance payments of the premium tax credit and cost-sharing reductions. The issuer of the QHP will adjust an enrollee's net premium to reflect the advance payments of the premium tax credit, as well as make any changes required to ensure that cost-sharing reflects the appropriate level of reductions. QHP issuers benefit significantly from advance payments of the premium tax credit and cost-sharing reductions, but may face some administrative costs relating to receiving enrollee information from an Exchange.

As discussed in the Web Portal interim final rule (75 FR 24470, 24481 (May 5, 2010)), HHS examined the health insurance industry in depth in the Regulatory Impact Analysis we prepared for the final rule on establishment of the Medicare Advantage program published on August 3, 2004 (69 FR 46866). In that analysis we determined that there were few, if any, insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for "small" business established by the SBA (currently \$7 million in annual receipts for health insurers, based on North American Industry Classification System Code 524114).⁶

Additionally, as discussed in the Medical Loss Ratio interim final rule (75 FR 74918), the

Department used a data set created from 2009 National Association of Insurance Commissioners (NAIC) Health and Life Blank annual financial statement data to develop an updated estimate of the number of small entities that offer comprehensive major medical coverage in the individual and group markets. For purposes of that analysis, the Department used total Accident and Health (A&H) earned premiums as a proxy for annual receipts. The Department estimated that there were 28 small entities with less than \$7 million in accident and health earned premiums offering individual or group comprehensive major medical coverage; however, this estimate may overstate the actual number of small health insurance issuers offering such coverage, because it does not include receipts from these companies' other lines of business.

2. Employers

The establishment of SHOP in conjunction with tax incentives for eligible employers will provide new opportunities for employers to offer affordable health insurance to their employees. A detailed discussion of the impact on employers related to the establishment of the SHOP is found in the RIA for the Exchange final rule, 77 FR 18010 (March 23, 2012) and available at <http://cciio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf>

Except in the Exchange provisions, few of the entities that meet the definition of a small entity as that term is used in the RFA (for example, small businesses, nonprofit organization, and small governmental jurisdictions with a population of less than 50,000) will be impacted directly by this final rule. Individuals and states are not included in the definition of a small entity. In addition, the impact of the majority of this rule was addressed in the RIA accompanying the March 2012 Medicaid eligibility rule (77 FR 17144, March 23, 2012). Therefore, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities, and we have not prepared a regulatory flexibility analysis.

‘Table of Size Standards Matched To North American Industry Classification System Codes,’ effective November

Additionally, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a final rule may have a significant economic impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this final rule will not have a direct economic impact on the operations of a substantial number of small rural hospitals.

H. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation, by state, local, or tribal governments, in the aggregate, or by the private sector. In 2013, that threshold is approximately \$141 million. This final rule does not mandate expenditures by state governments, local governments, tribal governments, in the aggregate, or the private sector, of \$140 million. The majority of state, local, and private sector costs related to implementation of the Affordable Care Act were described in the RIA accompanying the March 2012 Medicaid eligibility rule (77 FR 17144, March 23, 2012). Furthermore, the final rule does not set any mandate on states to set up an Exchange.

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct effects on states, preempts state law, or otherwise has federalism implications. We wish to note again that the impact of changes related

to implementation of the Affordable Care Act were described in the RIA of the March 2012 Medicaid eligibility rule (77 FR 17144, March 23, 2012). As discussed in the March 2012 RIA, we have consulted with states to receive input on how the various Affordable Care Act provisions codified in this final rule will affect states. We continue to engage in ongoing consultations with Medicaid and CHIP Technical Advisory Groups (TAGs), which have been in place for many years and serve as a staff level policy and technical exchange of information between CMS and the states. Through consultations with these TAGs, we have been able to get input from states specific to issues surrounding the changes in eligibility groups and rules that will become effective in 2014.

Because states have flexibility in deciding whether to implement an Exchange and, if a State opts to, in the design of its Exchange, state decisions will ultimately influence both administrative expenses and overall premiums. However, because states are not required to create an Exchange, these costs are not mandatory. For states electing to create an Exchange, the initial costs of the creation of the Exchange will be funded by Exchange Planning and Establishment Grants. After this time, Exchanges will be financially self-sustaining with revenue sources left to the discretion of the state. In the Department's view, while this final rule does not impose substantial direct effects on state and local governments, it has federalism implications due to direct effects on the distribution of power and responsibilities among the state and federal governments relating to determining standards relating to health insurance coverage (that is, for QHPs) that is offered in the individual and small group markets. Each state electing to establish a State-Based Exchange must adopt federal standards contained in the Affordable Care Act and in this final rule, or have in effect a state law or regulation that implements these federal standards. However, the Department anticipates that the federalism implications (if any) are substantially mitigated because states have choices regarding the

structure and governance of their Exchanges. Additionally, the Affordable Care Act does not require states to establish an Exchange; but if a state elects not to establish an Exchange or the state's Exchange is not approved, HHS will establish and operate an Exchange in that state. Additionally, states will have the opportunity to participate in state Partnership Exchanges that will allow states to leverage work done by other states and the federal government.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the states, the Department has engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners and consulting with state officials on an individual basis.

In accordance to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this regulation, the Department certifies that CMS has complied with the requirements of Executive Order 13132 for the attached proposed regulation in a meaningful and timely manner.

J. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), which specifies that before a rule can take effect, the federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, this final rule, and has been transmitted to Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects42 CFR Part 431

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs-health, Medicaid, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), Wages.

42 CFR Part 436

Aid to Families with Dependent Children, Grant programs-health, Guam, Medicaid, Puerto Rico, Supplemental Security Income (SSI), and Virgin Islands.

42 CFR Part 438

Grant programs-health, Medicaid, and Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs-health, Medicaid.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs-health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interest, Consumer protection, Grant programs-health, Grants administration, Health care, Health

insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, Safety, state and local governments, Technical assistance, Women, and Youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interest, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, Safety, State and local governments, Sunshine Act, Technical Assistance, Women, and Youth.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 431--STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

2. Section 431.10 is amended by revising paragraph (a), adding paragraph (b)(3), and revising paragraphs (c), (d), and (e) to read as follows:

§ 431.10 Single State agency.

(a) Basis, purpose, and definitions. (1) This section implements section 1902(a)(4) and (5) of the Act.

(2) For purposes of this part –

Appeals decision means a decision made by a hearing officer adjudicating a fair hearing under subpart E of this part.

Exchange has the meaning given to the term in 45 CFR 155.20.

Exchange appeals entity has the meaning given to the term “appeals entity,” as defined in 45 CFR 155.500.

Medicaid agency is the single State agency for the Medicaid program.

(b) * * *

(3) The single State agency is responsible for determining eligibility for all individuals applying for or receiving benefits in accordance with regulations in part 435 of this chapter and for fair hearings filed in accordance with subpart E of this part.

(c) Delegations. (1) Subject to the requirement in paragraph (c)(2) of this section, the Medicaid agency --

(i)(A) May, in the approved state plan, delegate authority to determine eligibility for all or a defined subset of individuals to—

(1) The single State agency for the financial assistance program under title IV-A (in the 50 States or the District of Columbia), or under title I or XVI (AABD), in Guam, Puerto Rico, or the Virgin Islands;

(2) The Federal agency administering the supplemental security income program under title XVI of the Act; or

(3) The Exchange.

(B) Must in the approved state plan specify to which agency, and the individuals for which, authority to determine eligibility is delegated.

(ii) Delegate authority to conduct fair hearings under subpart E of this part for denials of eligibility for individuals whose income eligibility is determined based on the applicable modified adjusted gross income standard described in § 435.911(c) of this chapter, to an Exchange or Exchange appeals entity, provided that individuals who have requested a fair hearing of such a denial are given a choice to have their fair hearing instead conducted by the Medicaid agency.

(2) The Medicaid agency may delegate authority to make eligibility determinations or to conduct fair hearings under this section only to a government agency which maintains personnel standards on a merit basis.

(3) The Medicaid agency –

(i) Must ensure that any agency to which eligibility determinations or appeals decisions are delegated –

(A) Complies with all relevant Federal and State law, regulations and policies, including, but not limited to, those related to the eligibility criteria applied by the agency under part 435 of

this chapter; prohibitions against conflicts of interest and improper incentives; and safeguarding confidentiality, including regulations set forth at subpart F of this part.

(B) Informs applicants and beneficiaries how they can directly contact and obtain information from the agency; and

(ii) Must exercise appropriate oversight over the eligibility determinations and appeals decisions made by such agencies to ensure compliance with paragraphs (c)(2) and (c)(3)(i) of this section and institute corrective action as needed, including, but not limited to, rescission of the authority delegated under this section.

(iii) If authority to conduct fair hearings is delegated to the Exchange or Exchange appeals entity under paragraph (c)(1)(ii) of this section, the agency may establish a review process whereby the agency may review fair hearing decisions made under that delegation, but that review will be limited to the proper application of federal and state Medicaid law and regulations, including sub-regulatory guidance and written interpretive policies, and must be conducted by an impartial official not directly involved in the initial determination.

(d) Agreement with Federal, State or local entities making eligibility determinations or appeals decisions. The plan must provide for written agreements between the Medicaid agency and the Exchange or any other State or local agency that has been delegated authority under paragraph (c)(1)(i) of this section to determine Medicaid eligibility and for written agreements between the agency and the Exchange or Exchange appeals entity that has been delegated authority to conduct Medicaid fair hearings under paragraph (c)(1)(ii) of this section. Such agreements must be available to the Secretary upon request and must include provisions for:

(1) The relationships and respective responsibilities of the parties, including but not limited to the respective responsibilities to effectuate the fair hearing rules in subpart E of this part;

(2) Quality control and oversight by the Medicaid agency, including any reporting requirements needed to facilitate such control and oversight;

(3) Assurances that the entity to which authority to determine eligibility or conduct fair hearings will comply with the provisions set forth in paragraph (c)(3) of this section.

(4) For appeals, procedures to ensure that individuals have notice and a full opportunity to have their fair hearing conducted by either the Exchange or Exchange appeals entity or the Medicaid agency.

(e) Authority of the single State agency. The Medicaid agency may not delegate, to other than its own officials, the authority to supervise the plan or to develop or issue policies, rules, and regulations on program matters.

3. Section 431.11 is amended by --

A. Removing paragraph (b).

B. Redesignating paragraphs (c) and (d), as paragraphs (b) and (c), respectively.

C. Revising newly redesignated paragraphs (b) and (c).

The revisions read as follows:

§431.11 Organization for administration.

* * * * *

(b) Description of organization. (1) The plan must include a description of the organization and functions of the Medicaid agency.

(2) When submitting a state plan amendment related to the designation, authority, organization or functions of the Medicaid agency, the Medicaid agency must provide an organizational chart reflecting the key components of the Medicaid agency and the functions each performs.

(c) Eligibility determined or fair hearings decided by other entities. If eligibility is

determined or fair hearings decided by Federal or State entities other than the Medicaid agency or by local agencies under the supervision of other State agencies, the plan must include a description of the staff designated by those other entities and the functions they perform in carrying out their responsibilities.

§ 431.57 [Removed]

4. Section 431.57 is removed.

5. Section 431.201 is amended by adding the definition of “send” in alphabetical order to read as follows:

§431.201 Definitions.

* * * * *

Send means deliver by mail or in electronic format consistent with §435.918 of this chapter.

* * * * *

6. Section 431.205 is amended by revising paragraphs (b)(1) and (2) to read as follows:

§ 431.205 Provision of hearing system.

* * * * *

(b) * * *

(1) A hearing before –

(i) The Medicaid agency; or

(ii) For the denial of eligibility for individuals whose income eligibility is determined based on the applicable modified adjusted gross income standard described in §435.911(c) of this chapter, the Exchange or Exchange appeals entity to which authority to conduct fair hearings has been delegated under § 431.10(c)(1)(ii), provided that individuals who have requested a fair hearing are given the choice to have their fair hearing conducted instead by the Medicaid

agency; at state option the Exchange or Exchange appeals entity decision may be subject to review by the Medicaid agency in accordance with § 431.10(c)(3)(iii); or

(2) An evidentiary hearing at the local level, with a right of appeal to the Medicaid agency.

* * * * *

7. Section 431.206 is amended by adding paragraphs (d) and (e) to read as follows:

§ 431.206 Informing applicants and beneficiaries.

* * * * *

(d) If, in accordance with § 431.10(c)(1)(ii), the agency has delegated authority to the Exchange or Exchange appeals entity to conduct the fair hearing, the agency must inform the individual in writing that –

(1) He or she has the right to have his or her hearing before the agency, instead of the Exchange or the Exchange appeals entity; and

(2) The method by which the individual may make such election;

(e) The information required under this section may be provided in electronic format in accordance with § 435.918 of this chapter.

8. Section 431.211 is revised to read as follows:

§431.211 Advance notice.

The State or local agency must send a notice at least 10 days before the date of action, except as permitted under §§ 431.213 and 431.214.

9. Section 431.213 is amended by revising the introductory text to read as follows:

§ 431.213 Exceptions from advance notice.

The agency may send a notice not later than the date of action if --

* * * * *

§ 431.230 [Amended]

10. In § 431.230, amend paragraph (a) introductory text by removing the term “mails” and adding in its place the term “sends”.

11. Section 431.231 is amended by revising the section heading and paragraph (c)(2) to read as follows:

§431.231 Reinstating services.

* * * * *

(c) * * *

(2) The beneficiary requests a hearing within 10 days from the date that the individual receives the notice of action. The date on which the notice is received is considered to be 5 days after the date on the notice, unless the beneficiary shows that he or she did not receive the notice within the 5-day period; and

* * * * *

12. Section 431.240 is amended by adding paragraph (c) to read as follows.

§431.240 Conducting the hearing.

* * * * *

(c) A hearing officer must have access to agency information necessary to issue a proper hearing decision, including information concerning State policies and regulations.

PART 435--ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

13. The authority citation for part 435 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

14. Section 435.110 is amended by republishing paragraph (c) introductory text and revising paragraph (c)(1) to read as follows:

§435.110 Parents and other caretaker relatives.

* * * * *

(c) Income standard. The agency must establish in its State plan the income standard as follows:

(1) The minimum income standard is a State's AFDC income standard in effect as of May 1, 1988 for the applicable family size converted to a MAGI-equivalent standard in accordance with guidance issued by the Secretary under section 1902(e)(14)(A) and (E) of the Act.

* * * * *

15. Section 435.116 is amended by republishing paragraph (d)(4) introductory text and revising paragraph (d)(4)(i) to read as follows:

§435.116 Pregnant women.

* * * * *

(d) * * *

(4) Applicable income limit for full Medicaid coverage of pregnant women. For purposes of paragraph (d)(1) of this section--

(i) The minimum applicable income limit is the State's AFDC income standard in effect as of May 1, 1988 for the applicable family size converted to a MAGI-equivalent standard in accordance with guidance issued by the Secretary under section 1902(e)(14)(A) and (E) of the Act.

* * * * *

16. Section 435.119 is amended by revising the introductory text in paragraph (b) to read as follows:

§435.119 Coverage for individuals age 19 or older and under age 65 at or below 133 percent FPL

* * * * *

(b) Eligibility. Effective January 1, 2014, the agency must provide Medicaid to individuals who:

* * * * *

§ 435.121 [Amended]

17. In §435.121 , amend paragraph (f)(1)(iii) by removing the reference “§ 447.52 or § 447.53” and by adding in its place the reference “§ 447.52, ,§ 447.53, or § 447.54”.

18. Section 435.603 is amended by—

A. In paragraph (b), adding the definitions of “Child,” “Parent,” and “Sibling” in alphabetical order.

B. Revising paragraphs (c) and (d)(1).

C. Adding paragraph (d)(4).

The revisions and additions read as follows:

§435.603 Application of modified adjusted gross income (MAGI).

* * * * *

(b) * * *

Child means a natural or biological, adopted or step child.

* * * * *

Parent means a natural or biological, adopted or step parent.

Sibling means natural or biological, adopted, half or step sibling.

* * * * *

(c) Basic rule. Except as specified in paragraph (i), (j) and (k) of this section, the agency must determine financial eligibility for Medicaid based on “household income” as defined in paragraph (d) of this section.

(d) * * *

(1) General rule. Except as provided in paragraphs (d)(2) through (d)(4) of this section, household income is the sum of the MAGI-based income, as defined in paragraph (e) of this section, of every individual included in the individual's household.

* * * * *

(4) Effective January 1, 2014, in determining the eligibility of an individual using MAGI-based income, a state must subtract an amount equivalent to 5 percentage points of the Federal poverty level for the applicable family size only to determine the eligibility of an individual for medical assistance under the eligibility group with the highest income standard using MAGI-based methodologies in the applicable Title of the Act, but not to determine eligibility for a particular eligibility group.

* * * * *

19. Section 435.907 is amended by adding paragraph (h) to read as follows.

§435.907 Application

* * * * *

(h) Reinstatement of withdrawn applications. (1) In the case of individuals described in paragraph (h)(2) of this section, the agency must reinstate the application submitted by the individual, effective as of the date the application was first received by the Exchange.

(2) Individuals described in this paragraph are individuals who –

(i) Submitted an application described in paragraph (b) of this section to the Exchange;

(ii) Withdrew their application for Medicaid in accordance with 45 CFR

155.302(b)(4)(A);

(iii) Are assessed as potentially eligible for Medicaid by the Exchange appeals entity.

20. Section 435.908 is amended by adding paragraph (c) to read as follows:

§435.908 Assistance with application and renewal.

* * * * *

(c) Certified Application Counselors. (1) At State option, the agency may certify staff and volunteers of State-designated organizations to act as application assisters, authorized to provide assistance to applicants and beneficiaries with the application process and during renewal of eligibility. To be certified, application assisters must be –

(i) Authorized and registered by the agency to provide assistance at application and renewal;

(ii) Effectively trained in the eligibility and benefits rules and regulations governing enrollment in a QHP through the Exchange and all insurance affordability programs operated in the State, as implemented in the State; and

(iii) Trained in and adhere to all rules regulations relating to the safeguarding and confidentiality of information and prohibiting conflict of interest, including regulations set forth at part 431, subpart F of this chapter, and at 45 CFR 155.260(f), regulations relating to the prohibition against reassignment of provider claims specified in §447.10 of this chapter, and all other State and Federal laws concerning conflicts of interest and confidentiality of information.

(2) For purposes of this section, assistance includes providing information on insurance affordability programs and coverage options, helping individuals complete an application or renewal, working with the individual to provide required documentation , submitting applications and renewals to the agency, interacting with the agency on the status of such

applications and renewals, assisting individuals with responding to any requests from the agency, and managing their case between the eligibility determination and regularly scheduled renewals.

Application assisters may be certified by the agency to act on behalf of applicants and beneficiaries for one, some or all of the permitted assistance activities.

(3) If the agency elects to certify application assisters, it must establish procedures to ensure that –

(i) Applicants and beneficiaries are informed of the functions and responsibilities of certified application assisters;

(ii) Individuals are able to authorize application assisters to receive confidential information about the individual related to the individual's application for or renewal of Medicaid; and

(iii) The agency does not disclose confidential applicant or beneficiary information to an application assister unless the applicant or beneficiary has authorized the application assister to receive such information.

(4) Application assisters may not impose, accept or receive payment or compensation in any form from applicants or beneficiaries for application assistance.

21. Section 435.918 is added to read as follows:

§435.918 Use of electronic notices.

(a) Effective no earlier than October 1, 2013 and no later than January 1, 2015, the agency must provide individuals with a choice to receive notices and information required under this part or subpart E of part 431 of this chapter in electronic format or by regular mail and must be permitted to change such election.

(b) If the individual elects to receive communications from the agency electronically, the agency must –

(1) Ensure that the individual's election to receive notices electronically is confirmed by regular mail.

(2) Ensure that the individual is informed of his or her right to change such election to receive notices through regular mail.

(3) Post notices to the individual's electronic account within 1 business day of notice generation.

(4) Send an email or other electronic communication alerting the individual that a notice has been posted to his or her account. The agency may not include confidential information in the email or electronic alert.

(5) Send a notice by regular mail within three business days of the date of a failed electronic communication if an electronic communication is undeliverable.

(6) At the individual's request, provide through regular mail any notice posted to the individual's electronic account.

22. Section 435.923 is added to read as follows:

§435.923 Authorized Representatives.

(a)(1) The agency must permit applicants and beneficiaries to designate an individual or organization to act responsibly on their behalf in assisting with the individual's application and renewal of eligibility and other ongoing communications with the agency. Such a designation must be in accordance with paragraph (f) of this section, including the applicant's signature, and must be permitted at the time of application and at other times.

(2) Authority for an individual or entity to act on behalf of an applicant or beneficiary accorded under state law, including but not limited to, a court order establishing legal guardianship or a power of attorney, must be treated as a written designation by the applicant or beneficiary of authorized representation.

(b) Applicants and beneficiaries may authorize their representatives to—

(1) Sign an application on the applicant's behalf;

(2) Complete and submit a renewal form;

(3) Receive copies of the applicant or beneficiary's notices and other communications from the agency;

(4) Act on behalf of the applicant or beneficiary in all other matters with the agency.

(c) The power to act as an authorized representative is valid until the applicant or beneficiary modifies the authorization or notifies the agency that the representative is no longer authorized to act on his or her behalf, or the authorized representative informs the agency that he or she no longer is acting in such capacity, or there is a change in the legal authority upon which the individual or organization's authority was based. Such notice must be in accordance with paragraph (f) of this section and should include the applicant or authorized representative's signature as appropriate.

(d) The authorized representative—

(1) Is responsible for fulfilling all responsibilities encompassed within the scope of the authorized representation, as described in paragraph (b)(2) of this section, to the same extent as the individual he or she represents;

(2) Must agree to maintain, or be legally bound to maintain, the confidentiality of any information regarding the applicant or beneficiary provided by the agency.

(e) The agency must require that, as a condition of serving as an authorized representative, a provider or staff member or volunteer of an organization must affirm that he or she will adhere to the regulations in part 431, subpart F of this chapter and at 45 CFR 155.260(f) (relating to confidentiality of information), § 447.10 of this chapter (relating to the prohibition against reassignment of provider claims as appropriate for a facility or an organization acting on

the facility's behalf), as well as other relevant State and Federal laws concerning conflicts of interest and confidentiality of information.

(f) For purposes of this section, the agency must accept electronic, including telephonically recorded, signatures and handwritten signatures transmitted by facsimile or other electronic transmission. Designations of authorized representatives must be accepted through all of the modalities described in § 435.907(a).

23. Add an undesignated center heading and 435.1015 to read as follows:

FFP for Premium Assistance

§435.1015 FFP for premium assistance for plans in the individual market.

(a) FFP is available for payment of the costs of insurance premiums on behalf of an eligible individual for a health plan offered in the individual market that provides the individual with benefits for which the individual is covered under the State plan, subject to the following conditions:

(1) The insurer is obligated to pay primary to Medicaid for all health care items and services for which the insurer is legally and contractually responsible under the individual health plan, as required under part 433 subpart D of this chapter;

(2) The agency furnishes all benefits for which the individual is covered under the State plan that are not available through the individual health plan;

(3) The individual does not incur any cost sharing charges in excess of any amounts imposed by the agency under subpart A of part 447; and

(4) The total cost of purchasing such coverage, including administrative expenditures, the costs of paying all cost sharing charges in excess of the amounts imposed by the agency under subpart A of part 447, and the costs of providing benefits as required by (a)(2) of this section, must be comparable to the cost of providing direct coverage under the State plan.

(b) A State may not require an individual to receive benefits through premium assistance under this section, and a State must inform an individual that it is the individual's choice to receive either direct coverage under the Medicaid State plan or coverage through premium assistance for an individual health plan. A State must require that an individual who elects premium assistance obtain through the insurance coverage all benefits for which the insurer is responsible and must provide the individual with information on how to access any additional benefits and cost sharing assistance not provided by the insurer.

Subpart L—Options for Coverage of Special Groups under Presumptive Eligibility

24. The heading for subpart L is revised as set forth above.

25. Section 435.1102 is amended by—

A. Revising the section heading.

B. Revising paragraph (a).

C. Removing “and” at the end of paragraph (b)(2)(iv)(B) and adding “and” at the end of paragraph (b)(2)(v)(B);

D. Adding paragraph (b)(2)(vi).

E. Revising paragraph (b)(3).

F. Removing paragraph (b)(4).

G. Adding paragraphs (d) and (e).

The revisions and additions read as follows:

§435.1102 Children covered under presumptive eligibility.

(a) The agency may elect to provide Medicaid services for children under age 19 or a younger age specified by the State during a presumptive eligibility period following a determination by a qualified entity, on the basis of preliminary information, that the individual has gross income (or, at state option, a reasonable estimate of household income, as defined in

§435.603 of this part, determined using simplified methods prescribed by the agency) at or below the income standard established by the State for the age of the child under §435.118(c) or under §435.229 if applicable and higher.

(b) * * *

(2) * * *

(vi) Do not delegate the authority to determine presumptive eligibility to another entity.

(3) Establish oversight mechanisms to ensure that presumptive eligibility determinations are being made consistent with the statute and regulations.

* * * * *

(d) The agency –

(1) May require, for purposes of making a presumptive eligibility determination under this section, that the individual has attested to being, or another person who attests to having reasonable knowledge of the individual’s status has attested to the individual being, a –

(i) Citizen or national of the United States or in satisfactory immigration status; or

(ii) Resident of the State; and

(2) May not –

(i) Impose other conditions for presumptive eligibility not specified in this section; or

(ii) Require verification of the conditions for presumptive eligibility.

(e) Notice and fair hearing regulations in subpart E of part 431 of this chapter do not apply to determinations of presumptive eligibility under this section.

26 Section 435.1103 is added to Subpart L read as follows:

§435.1103 Presumptive eligibility for other individuals.

(a) The terms of §435.1101 and §435.1102 apply to pregnant women such that the agency may provide Medicaid to pregnant women during a presumptive eligibility period

following a determination by a qualified entity that the pregnant woman has income at or below the income standard established by the State under §435.116(c), except that coverage of services provided to such women is limited to ambulatory prenatal care and the number of presumptive eligibility periods that may be authorized for pregnant women is one per pregnancy.

(b) If the agency provides Medicaid during a presumptive eligibility period to children under §435.1102 or to pregnant women under paragraph (a) of this section, the agency may also apply the terms of §§ 435.1101 and 435.1102 to the individuals described in one or more of the following sections of this part, based on the income standard established by the state for such individuals and providing the benefits covered under that section: §§ 435.110 (parents and caretaker relatives), 435.119 (individuals aged 19 or older and under age 65), 435.150 (former foster care children), and 435.218 (individuals under age 65 with income above 133 percent FPL).

(c)(1) The terms of §§ 435.1101 and 435.1102 apply to individuals who may be eligible under § 435.213 of this part (relating to individuals with breast or cervical cancer) or § 435.214 of this part (relating to eligibility for limited family planning benefits) such that the agency may provide Medicaid during a presumptive eligibility period following a determination by a qualified entity described in paragraph (c)(2) of this section that—

(i) The individual meets the eligibility requirements of §435.213; or

(ii) The individual meets the eligibility requirements of §435.214, except that coverage provided during a presumptive eligibility period to such individuals is limited to the services described in §435.214(d).

(2) Qualified entities described in this paragraph include qualified entities which participate as providers under the State plan and which the agency determines are capable of making presumptive eligibility determinations.

27. Section 435.1110 is added to Subpart L to read as follows:

§435.1110 Presumptive eligibility determined by hospitals.

(a) Basic rule. The agency must provide Medicaid during a presumptive eligibility period to individuals who are determined by a qualified hospital, on the basis of preliminary information, to be presumptively eligible subject to the same requirements as apply to the State options under §§ 435.1102 and 435.1103, but regardless of whether the agency provides Medicaid during a presumptive eligibility period under such sections.

(b) Qualified hospitals. A qualified hospital is a hospital that –

(1) Participates as a provider under the State plan or a demonstration under section 1115 of the Act, notifies the agency of its election to make presumptive eligibility determinations under this section, and agrees to make presumptive eligibility determinations consistent with State policies and procedures;

(2) At State option, assists individuals in completing and submitting the full application and understanding any documentation requirements; and

(3) Has not been disqualified by the agency in accordance with paragraph (d) of this section.

(c) State options for bases of presumptive eligibility. The agency may –

(1) Limit the determinations of presumptive eligibility which hospitals may elect to make under this section to determinations based on income for all of the populations described in §435.1102 and §435.1103; or

(2) Permit hospitals to elect to make presumptive eligibility determinations on additional bases approved under the State plan or an 1115 demonstration.

(d) Disqualification of hospitals. (1) The agency may establish standards for qualified hospitals related to the proportion of individuals determined presumptively eligible for Medicaid

by the hospital who:

(i) Submit a regular application, as described in §435.907, before the end of the presumptive eligibility period; or

(ii) Are determined eligible for Medicaid by the agency based on such application.

(2) The agency must take action, including, but not limited to, disqualification of a hospital as a qualified hospital under this section, if the agency determines that the hospital is not—

(i) Making, or is not capable of making, presumptive eligibility determinations in accordance with applicable state policies and procedures; or

(ii) Meeting the standard or standards established by the agency under paragraph (d)(1) of this section.

(3) The agency may disqualify a hospital as a qualified hospital under this paragraph only after it has provided the hospital with additional training or taken other reasonable corrective action measures to address the issue.

28. Section 435.1200 is amended by revising paragraph (d)(6) to read as follows:

§435.1200 Medicaid Agency responsibilities for a coordinated eligibility and enrollment process with other insurance affordability programs

* * * * *

(d) * * *

(6) Notify such program of the final determination of the individual’s eligibility or ineligibility for Medicaid.

* * * * *

29. Section 435.1205 is added to read as follows:

§435.1205 Alignment with exchange initial open enrollment period.

(a) Definitions. For purposes of this section –

Eligibility based on MAGI means Medicaid eligibility based on the eligibility requirements which will be effective under the State plan, or waiver of such plan, as of January 1, 2014, consistent with §§ 435.110 through 435.119, 435.218 and 435.603.

(b) Medicaid agency responsibilities to achieve coordinated open enrollment. For the period beginning October 1, 2013 through December 31, 2013, the agency must

(1) Accept all of the following:

(i) The single streamlined application described in §435.907.

(ii) Via secure electronic interface, an electronic account transferred from another insurance affordability program.

(2) For eligibility based on MAGI, comply with the terms of §435.1200 of this part, such that --

(i) For each electronic account transferred to the agency under paragraph (c)(1)(ii) of this section, the agency consistent with either of the following:

(A) Section 435.1200(c), accepts a determination of Medicaid eligibility based on MAGI, made by another insurance affordability program.

(B) Section 435.1200(d), determines eligibility for Medicaid based on MAGI.

(ii) Consistent with §435.1200(e), for each single streamlined application submitted directly to the agency under paragraph (b)(1)(i) of this section –

(A) Determine eligibility based on MAGI; and

(B) For each individual determined not Medicaid eligible based on MAGI, determine potential eligibility for other insurance affordability programs, based on the requirements which will be effective for each program, and transfer the individual's electronic account to such program via secure electronic interface.

(iii) Provide notice and fair hearing rights, in accordance with §435.917 of this part, part 431 subpart E of this chapter, and §435.1200 for those determined ineligible for Medicaid.

(3) For each individual determined eligible based on MAGI in accordance with paragraph (c)(2) of this section –

(i) Provide notice, including the effective date of eligibility, to such individual, consistent with §435.917 of this part, and furnish Medicaid.

(ii) Apply the terms of §435.916 (relating to beneficiary responsibility to inform the agency of any changes in circumstances that may affect eligibility) and §435.952 (regarding use of information received by the agency). The first renewal under §435.916 of this part may, at State option, be scheduled to occur anytime between 12 months from the date of application and 12 months from January 1, 2014.

(4) For eligibility effective in 2013, for all applicants –

(i) Consistent with the requirements of subpart J of this part, and applying the eligibility requirements in effect under the State plan, or waiver of such plan, as of the date the individual submits an application to any insurance affordability program –

(A) Determine the individual's eligibility based on the information provided on the application or in the electronic account; or

(B) Request additional information from the individual needed by the agency to determine eligibility based on the eligibility requirements in effect on such date, including on a basis excepted from application of MAGI-based methods, as described in §435.603, and determine such eligibility if such information is provided; and

(C) Furnish Medicaid to individuals determined eligible under this clause or provide notice and fair hearing rights in accordance with part 431 subpart E of this part if eligibility effective in 2013 is denied; or

(ii) Notify the individual of the opportunity to submit a separate application for coverage effective in 2013 and information on how to obtain and submit such application.

PART 436--ELIGIBILITY IN GUAM, PUERTO RICO, AND THE VIRGIN ISLANDS

30. The authority citation for part 436 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§436.831 [Amended]

31. In §436.831, amend paragraph (e)(1) by removing the reference “§447.51 or §447.53” and by adding in its place the reference “§447.52, §447.53, or §447.54”.

PART 438--MANAGED CARE

32. The authority citation for part 483 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§438.108 [Amended]

33. Section 438.108 is amended by removing the reference “§§447.50 through 447.60” and by adding in its place the reference “§§447.50 through 447.57”.

PART 440-SERVICES: GENERAL PROVISIONS

34. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

35. Section 440.130 is amended by revising paragraph (c) to read as follows:

§440.130 Diagnostic, screening, preventive, and rehabilitative services.

* * * * *

(c) Preventive services means services recommended by a physician or other licensed practitioner of the healing arts acting within the scope of authorized practice under State law to -

-

(1) Prevent disease, disability, and other health conditions or their progression;

- (2) Prolong life; and
- (3) Promote physical and mental health and efficiency.

* * * * *

36. Section 440.305 is amended by revising paragraphs (a) and (b) and removing paragraph (d).

The revisions read as follows:

§440.305 Scope.

(a) General. This subpart sets out requirements for States that elect to provide medical assistance to certain Medicaid eligible individuals within one or more groups of individuals specified by the State, through enrollment of the individuals in coverage, identified as “benchmark” or “benchmark-equivalent.” Groups must be identified by characteristics of individuals rather than the amount or level of FMAP.

(b) Limitations. A State may only apply the option in paragraph (a) of this section for an individual whose eligibility is based on an eligibility category under section 1905(a) of the Act that could have been covered under the State’s plan on or before February 8, 2006, except that individuals who are eligible under section 1902(a)(10)(A)(i)(VIII) of the Act must enroll in an Alternative Benefit Plan to receive medical assistance.

* * * * *

37. Section 440.315 is amended by revising the introductory text and paragraphs (f) and (h) to read as follows:

§440.315 Exempt individuals.

Individuals within one (or more) of the following categories are exempt from mandatory enrollment in an Alternative Benefit Plan, unless the individuals are eligible under section 1902(a)(10)(A)(i)(VIII) of the Act. Individuals in that eligibility group who meet the conditions

for exemption must be given the option of an Alternative Benefit Plan that includes all benefits available under the approved State plan.

* * * * *

(f) The individual is medically frail or otherwise an individual with special medical needs. For these purposes, the State’s definition of individuals who are medically frail or otherwise have special medical needs must at least include those individuals described in §438.50(d)(3) of this chapter, individuals with disabling mental disorders (including children with serious emotional disturbances and adults with serious mental illness), individuals with chronic substance use disorders, individuals with serious and complex medical conditions, individuals with a physical, intellectual or developmental disability that significantly impairs their ability to perform 1 or more activities of daily living, or individuals with a disability determination based on Social Security criteria or in States that apply more restrictive criteria than the Supplemental Security Income program, the State plan criteria.

* * * * *

(h) The individual is eligible and enrolled for Medicaid under §435.145 of this chapter based on current eligibility for assistance under title IV-E of the Act or under §435.150 of this chapter based on current status as a former foster care child.

* * * * *

38. Section 440.330 is amended by revising paragraph (d) to read as follows:

§440.330 Benchmark health benefits coverage.

* * * * *

(d) Secretary-approved coverage. Any other health benefits coverage that the Secretary determines, upon application by a State, provides appropriate coverage to meet the needs of the population provided that coverage. Secretarial coverage may include benefits of the type that are

available under 1 or more of the standard benchmark coverage packages defined in paragraphs (a) through (c) of this section, State plan benefits described in section 1905(a), 1915(i), 1915(j), 1915(k) or section 1945 of the Act, any other Medicaid State plan benefits enacted under title XIX, or benefits available under base benchmark plans described in 45 CFR 156.100.

(1) States wishing to elect Secretary-approved coverage should submit a full description of the proposed coverage (including a benefit-by-benefit comparison of the proposed plan to one or more of the three other benchmark plans specified above or to the State’s standard full Medicaid coverage package), and of the population to which coverage will be offered. In addition, the State should submit any other information that will be relevant to a determination that the proposed health benefits coverage will be appropriate for the proposed population.

(2) [Reserved]

39. Section 440.335 is amended by—

- A. Adding paragraphs (b)(7)and (8).
- B. Revising paragraph (c)(1).
- C. Removing paragraph (c)(3).

The revisions and additions read as follows:

§440.335 Benchmark-equivalent health benefits coverage.

* * * * *

(b) * * *

(7) Prescription drugs.

(8) Mental health benefits.

(c) * * *

(1) In addition to the types of benefits of this section, benchmark-equivalent coverage may include coverage for any additional benefits of the type which are covered in 1 or more of

the standard benchmark coverage packages described in §440.330(a) through (c) or State plan benefits, described in section 1905(a), 1915(i), 1915(j), 1915(k) and 1945 of the Act, any other Medicaid State plan benefits enacted under title XIX, or benefits available under base-benchmark plans described in 45 CFR 156.100.

* * * * *

40. Section 440.345 is amended by revising the section heading and adding paragraphs (b) through (f) to read as follows:

§440.345 EPSDT and other required benefits.

* * * * *

(b) Family planning. Alternative Benefit Plans must include coverage for family planning services and supplies.

(c) Mental health parity. Alternative Benefit Plans that provide both medical and surgical benefits, and mental health or substance use disorder benefits, must comply with the Mental Health Parity and Addiction Equity Act.

(d) Essential health benefits. Alternative Benefit Plans must include at least the essential health benefits described in §440.347, and include all updates or modifications made thereafter by the Secretary to the definition of essential health benefits.

(e) Updating of benefits. States are not required to update Alternative Benefit Plans that have been determined to include essential health benefits as of January 1, 2014, until December 31, 2015. States will adhere to future guidance for updating benefits beyond that date, as described by the Secretary.

(f) Covered outpatient drugs. To the extent states pay for covered outpatient drugs under their Alternative Benefit Plan's prescription drug coverage, states must comply with the requirements under section 1927 of the Act.

41. Section 440.347 is added to read as follows:

§440.347 Essential health benefits.

(a) Alternative Benefit Plans must contain essential health benefits coverage, including benefits in each of the following ten categories, consistent with the applicable requirements set forth in 45 CFR part 156:

- (1) Ambulatory patient services;
- (2) Emergency services;
- (3) Hospitalization;
- (4) Maternity and newborn care;
- (5) Mental health and substance use disorders, including behavioral health treatment;
- (6) Prescription drugs;
- (7) Rehabilitative and habilitative services and devices, except that such coverage shall be in accordance with §440.347(d);
- (8) Laboratory services;
- (9) Preventive and wellness services and chronic disease management; and
- (10) Pediatric services, including oral and vision care, in accordance with section 1905(r) of the Act.

(b) Alternative Benefit Plans must include essential health benefits in one of the state options for establishing essential health benefits described in 45 CFR 156.100, subject to supplementation under 45 CFR 156.110(b) and substitution as permitted under 45 CFR 156.115(b).

(c) States may select more than one base benchmark option for establishing essential health benefits in keeping with the flexibility for States to implement more than one Alternative Benefit Plan for targeted populations.

(d) To comply with paragraph (a) of this section, Alternative Benefit Plan coverage of habilitative services and devices will be based on the habilitative services and devices that are in the applicable base benchmark plan. If habilitative services and devices are not in the applicable base benchmark plan, the state will define habilitative services and devices required as essential health benefits using the methodology set forth in 45 CFR 156.115(a)(5).

(e) Essential health benefits cannot be based on a benefit design or implementation of a benefit design that discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life or other health conditions.

42. Section 440.360 is revised to read as follows:

§440.360 State plan requirements for providing additional services.

In addition to the requirements of §440.345, the State may elect to provide additional coverage to individuals enrolled in Alternative Benefit Plans, except that the coverage for individuals eligible only through section 1902(a)(10)(A)(i)(VIII) of the Act is limited to benchmark or benchmark-equivalent coverage. The State must describe the populations covered and the payment methodology for these benefits. Additional benefits must be benefits of the type, which are covered in 1 or more of the standard benchmark coverage packages described in §440.330(a) through (c) or State plan benefits including those described in sections 1905(a), 1915(i), 1915(j), 1915(k) and 1945 of the Act and any other Medicaid State plan benefits enacted under title XIX, or benefits available under base benchmark plans described in 45 CFR 156.100.

43. Section 440.386 is added to read as follows:

§440.386 Public notice.

Prior to submitting to the Centers for Medicare and Medicaid Services for approval of a State plan amendment to establish an Alternative Benefit Plan or an amendment to substantially modify an existing Alternative Benefit Plan, a state must have provided the public with advance

notice of the amendment and reasonable opportunity to comment for such amendment, and have included in the notice a description of the method for assuring compliance with §440.345 related to full access to EPSDT services, and the method for complying with the provisions of section 5006(e) of the American Recovery and Reinvestment Act of 2009.

PART 447--PAYMENTS FOR SERVICES

44. The authority citation for part 447 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

45. Section 447.15 is revised to read as follows:

§447.15 Acceptance of State payment as payment in full.

A State plan must provide that the Medicaid agency must limit participation in the Medicaid program to providers who accept, as payment in full, the amounts paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual. The provider may only deny services to any eligible individual on account of the individual's inability to pay the cost sharing amount imposed by the plan in accordance with §447.52(e). The previous sentence does not apply to an individual who is able to pay. An individual's inability to pay does not eliminate his or her liability for the cost sharing charge.

§447.20 [Amended]

46. In §447.20, amend paragraphs (a)(1) and (2) by removing the reference “§§447.53 through 447.56” wherever it occurs and adding in its place the reference “§§447.52 through 447.54”.

47a. Remove the undesignated center headings which appear above §§ 447.50, 447.51, 447.53, 447.59, and 447.62.

47b. Add a new undesignated center above revised §§ 447.50 through 447.57 to read as follows:

Medicaid Premiums and Cost Sharing

Sec.

447.50 Premiums and cost sharing: Basis and purpose.

447.51 Definitions.

447.52 Cost sharing.

447.53 Cost sharing for drugs.

447.54 Cost sharing for services furnished in a hospital emergency department.

447.55 Premiums.

447.56 Limitations on premiums and cost sharing.

447.57 Beneficiary and public notice requirements.

Medicaid Premiums and Cost Sharing

§447.50 Premiums and cost sharing: Basis and purpose.

Sections 1902(a)(14), 1916 and 1916A of the Act permit states to require certain beneficiaries to share in the costs of providing medical assistance through premiums and cost sharing. Sections 447.52 through 447.56 specify the standards and conditions under which states may impose such premiums and or cost sharing.

§447.51 Definitions

As used in this part –

Alternative non-emergency services provider means a Medicaid provider, such as a physician's office, health care clinic, community health center, hospital outpatient department, or similar provider that can provide clinically appropriate services in a timely manner.

Contract health service means any health service that is:

(1) Delivered based on a referral by, or at the expense of, an Indian health program; and

(2) Provided by a public or private medical provider or hospital that is not a provider or hospital of the IHS or any other Indian health program

Cost sharing means any copayment, coinsurance, deductible, or other similar charge.

Emergency services has the same meaning as in §438.114 of this chapter.

Federal poverty level (FPL) means the Federal poverty level updated periodically in the **Federal Register** by the Secretary of Health and Human Services under the authority of 42 U.S.C. 9902(2).

Indian means any individual defined at 25 U.S.C. 1603(13), 1603(28), or 1679(a), or who has been determined eligible as an Indian, under 42 CFR 136.12. This means the individual:

- (1) Is a member of a Federally-recognized Indian tribe;
- (2) Resides in an urban center and meets one or more of the following four criteria:
 - (i) Is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;
 - (ii) Is an Eskimo or Aleut or other Alaska Native;
 - (iii) Is considered by the Secretary of the Interior to be an Indian for any purpose; or
 - (iv) Is determined to be an Indian under regulations promulgated by the Secretary;
- (3) Is considered by the Secretary of the Interior to be an Indian for any purpose; or
- (4) Is considered by the Secretary of Health and Human Services to be an Indian for purposes of eligibility for Indian health care services, including as a California Indian, Eskimo, Aleut, or other Alaska Native.

Indian health care provider means a health care program operated by the Indian Health Service (IHS) or by an Indian Tribe, Tribal Organization, or Urban Indian Organization

(otherwise known as an I/T/U) as those terms are defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

Inpatient stay means the services received during a continuous period of inpatient days in either a single medical institution or multiple medical institutions, and also includes a return to an inpatient medical institution after a brief period when the return is for treatment of a condition that was present in the initial period. Inpatient has the same meaning as in §440.2 of this chapter.

Non-emergency services means any care or services that are not considered emergency services as defined in this section. This does not include any services furnished in a hospital emergency department that are required to be provided as an appropriate medical screening examination or stabilizing examination and treatment under section 1867 of the Act.

Outpatient services for purposes of imposing cost sharing means any service or supply not meeting the definition of an inpatient stay.

Preferred drugs means drugs that the state has identified on a publicly available schedule as being determined by a pharmacy and therapeutics committee for clinical efficacy as the most cost effective drugs within each therapeutically equivalent or therapeutically similar class of drugs, or all drugs within such a class if the agency does not differentiate between preferred and non-preferred drugs.

Premium means any enrollment fee, premium, or other similar charge.

§447.52 Cost sharing.

(a) Applicability. Except as provided in §447.56(a) (exemptions), the agency may impose cost sharing for any service under the state plan.

(b) Maximum Allowable Cost Sharing. (1) At State option, cost sharing imposed for any service (other than for drugs and non-emergency services furnished in an emergency department, as described in §§447.53 and 447.54 respectively) may be established at or below the amounts

shown in the following table (except that the maximum allowable cost sharing for individuals with family income at or below 100 percent of the FPL shall be increased each year, beginning October 1, 2015, by the percentage increase in the medical care component of the CPI-U for the period of September to September of the preceding calendar year, rounded to the next higher 5-cent increment):

Services	Maximum Allowable Cost Sharing		
	Individuals with Family Income ≤100% of the FPL	Individuals with Family Income 101-150% of the FPL	Individuals with Family Income >150% of the FPL
Outpatient Services (<i>physician visit, physical therapy, etc.</i>)	\$4	10 % of cost the agency pays	20% of cost the agency pays
Inpatient Stay	\$75	10 % of total cost the agency pays for the entire stay	20% of total cost the agency pays for the entire stay

(2) States with cost sharing for an inpatient stay that exceeds \$75, as of [OFR—Insert date of publication], must submit a plan to CMS that provides for reducing inpatient cost sharing to \$75 on or before July 1, 2017..

(3) In states that do not have fee-for-service payment rates, any cost sharing imposed on individuals at any income level may not exceed the maximum amount established , for individuals with income at or below 100 percent of the FPL described in paragraph (b)(1) of this section.

(c) Maximum cost sharing. In no case shall the maximum cost sharing established by the agency be equal to or exceed the amount the agency pays for the service.

(d) Targeted cost sharing. (1) Except as provided in paragraph (d)(2) of this section, the agency may target cost sharing to specified groups of individuals with family income above 100 percent of the FPL.

(2) For cost sharing imposed for non-preferred drugs under §447.53 and for non-emergency services provided in a hospital emergency department under §447.54, the agency may target cost sharing to specified groups of individuals regardless of income.

(e) Denial of service for nonpayment. (1) The agency may permit a provider, including a pharmacy or hospital, to require an individual to pay cost sharing as a condition for receiving the item or service if—

- (i) The individual has family income above 100 percent of the FPL,
- (ii) The individual is not part of an exempted group under §447.56(a), and
- (iii) For cost sharing imposed for non-emergency services furnished in an emergency department, the conditions under §447.54(d) of this part have been satisfied.

(2) Except as provided under paragraph (e)(1) of this section, the state plan must specify that no provider may deny services to an eligible individual on account of the individual's inability to pay the cost sharing.

(3) Nothing in this section shall be construed as prohibiting a provider from choosing to reduce or waive such cost sharing on a case-by-case basis.

(f) Prohibition against multiple charges. For any service, the agency may not impose more than one type of cost sharing.

(g) Income-related charges. Subject to the maximum allowable charges specified in §§ 447.52(b), 447.53(b) and 447.54(b), the plan may establish different cost sharing charges for individuals at different income levels. If the agency imposes such income-related charges, it must ensure that lower income individuals are charged less than individuals with higher income.

(h) Services furnished by a managed care organization (MCO). Contracts with MCOs must provide that any cost-sharing charges the MCO imposes on Medicaid enrollees are in

accordance with the cost sharing specified in the state plan and the requirements set forth in §§447.50 through 447.57.

(i) State Plan Specifications. For each cost sharing charge imposed under this part, the state plan must specify—

- (1) The service for which the charge is made;
- (2) The group or groups of individuals that may be subject to the charge;
- (3) The amount of the charge;
- (4) The process used by the state to—

(i) Ensure individuals exempt from cost sharing are not charged,

(ii) Identify for providers whether cost sharing for a specific item or service may be imposed on an individual and whether the provider may require the individual, as a condition for receiving the item or service, to pay the cost sharing charge; and

(5) If the agency imposes cost sharing under §447.54, the process by which hospital emergency room services are identified as non-emergency service.

§447.53 Cost sharing for drugs.

(a) The agency may establish differential cost sharing for preferred and non-preferred drugs. The provisions in §447.56(a) shall apply except as the agency exercises the option under paragraph (d) of this section. All drugs will be considered preferred drugs if so identified or if the agency does not differentiate between preferred and non-preferred drugs.

(b) At state option, cost sharing for drugs may be established at or below the amounts shown in the following table (except that the maximum allowable cost sharing shall be increased each year, beginning October 1, 2015, by the percentage increase in the medical care component of the CPI-U for the period of September to September of the preceding calendar year, rounded

to the next higher 5-cent increment. Such increase shall not be applied to any cost sharing that is based on the amount the agency pays for the service):

Services	Maximum Allowable Cost Sharing	
	Individuals with Family Income \leq 150% of the FPL	Individuals with Family Income $>$ 150% of the FPL
Preferred Drugs	\$4	\$4
Non-Preferred Drugs	\$8	20% of the cost the agency pays

(c) In states that do not have fee-for-service payment rates, cost sharing for prescription drugs imposed on individuals at any income level may not exceed the maximum amount established for individuals with income at or below 150 percent of the FPL in paragraph (b) of this section.

(d) For individuals otherwise exempt from cost sharing under §447.56(a), the agency may impose cost sharing for non-preferred drugs, not to exceed the maximum amount established in paragraph (b) of this section.

(e) In the case of a drug that is identified by the agency as a non-preferred drug within a therapeutically equivalent or therapeutically similar class of drugs, the agency must have a timely process in place so that cost sharing is limited to the amount imposed for a preferred drug if the individual's prescribing provider determines that a preferred drug for treatment of the same condition either will be less effective for the individual, will have adverse effects for the individual, or both. In such cases the agency must ensure that reimbursement to the pharmacy is based on the appropriate cost sharing amount.

§447.54 Cost sharing for services furnished in a hospital emergency department.

(a) The agency may impose cost sharing for non-emergency services provided in a hospital emergency department. The provisions in §447.56(a) shall apply except as the agency exercises the option under paragraph (c) of this section.

(b) At state option, cost sharing for non-emergency services provided in an emergency department may be established at or below the amounts shown in the following table (except that the maximum allowable cost sharing identified for individuals with family income at or below 150 percent of the FPL shall be increased each year, beginning October 1, 2015, by the percentage increase in the medical care component of the CPI-U for the period of September to September of the preceding calendar year, rounded to the next higher 5-cent increment):

Services	Maximum Allowable Cost Sharing	
	Individuals with Family Income ≤ 150% of the FPL	Individuals with Family Income >150% of the FPL
Non-emergency Use of the Emergency Department	\$8	No Limit

(c) For individuals otherwise exempt from cost sharing under §447.56(a), the agency may impose cost sharing for non-emergency use of the emergency department, not to exceed the maximum amount established in paragraph (b) of this section for individuals with income at or below 150 percent of the FPL.

(d) For the agency to impose cost sharing under paragraph (a) or (c) of this section for non-emergency use of the emergency department, the hospital providing the care must—

(1) Conduct an appropriate medical screening under §489.24 subpart G to determine that the individual does not need emergency services.

(2) Before providing non-emergency services and imposing cost sharing for such services:

(i) Inform the individual of the amount of his or her cost sharing obligation for non-emergency services provided in the emergency department;

(ii) Provide the individual with the name and location of an available and accessible alternative non-emergency services provider;

(iii) Determine that the alternative provider can provide services to the individual in a timely manner with the imposition of a lesser cost sharing amount or no cost sharing if the individual is otherwise exempt from cost sharing; and

(iv) Provide a referral to coordinate scheduling for treatment by the alternative provider.

(e) Nothing in this section shall be construed to:

(1) Limit a hospital's obligations for screening and stabilizing treatment of an emergency medical condition under section 1867 of the Act; or

(2) Modify any obligations under either state or federal standards relating to the application of a prudent-layperson standard for payment or coverage of emergency medical services by any managed care organization.

§447.55 Premiums.

(a) The agency may impose premiums upon individuals whose income exceeds 150 percent of the FPL, subject to the exemptions set forth in §447.56(a) and the aggregate limitations set forth in §447.56(f) of this part, except that:

(1) Pregnant women described in described in paragraph (a)(1)(ii) of this section may be charged premiums that do not exceed 10 percent of the amount by which their family income exceeds 150 percent of the FPL after deducting expenses for care of a dependent child.

(i) The agency may use state or local funds available under other programs for payment of a premium for such pregnant women. Such funds shall not be counted as income to the individual for whom such payment is made.

(ii) Pregnant women described in this clause include pregnant women eligible for Medicaid under §435.116 of this chapter whose income exceeds the higher of –

(A) 150 percent FPL; and

(B) If applicable, the percent FPL described in section 1902(l)(2)(A)(iv) of the Act up to 185 percent FPL.

(2) Individuals provided medical assistance only under sections 1902(a)(10)(A)(ii)(XV) or 1902(a)(10)(A)(ii)(XVI) of the Act and the Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA), may be charged premiums on a sliding scale based on income.

(3) Disabled children provided medical assistance under section 1902(a)(10)(A)(ii)(XIX) of the Act in accordance with the Family Opportunity Act, may be charged premiums on a sliding scale based on income. The aggregate amount of the child's premium imposed under this paragraph and any premium that the parent is required to pay for family coverage under section 1902(cc)(2)(A)(i) of the Act, and other cost sharing charges may not exceed:

(i) 5 percent of the family's income if the family's income is no more than 200 percent of the FPL.

(ii) 7.5 percent of the family's income if the family's income exceeds 200 percent of the FPL but does not exceed 300 percent of the FPL.

(4) Qualified disabled and working individuals described in section 1905(s) of the Act, whose income exceeds 150 percent of the FPL, may be charged premiums on a sliding scale based on income, expressed as a percentage of Medicare cost sharing described at section 1905(p)(3)(A)(i) of the Act.

(5) Medically needy individuals, as defined in §§435.4 and 436.3 of this chapter, may be charged on a sliding scale. The agency must impose an appropriately higher charge for each

higher level of family income, not to exceed \$20 per month for the highest level of family income.

(b) Consequences for non-payment. (1) For premiums imposed under paragraphs (a) (1), (a)(2), (a)(3) and (a)(4) of this section, the agency may not require a group or groups of individuals to prepay.

(2) Except for premiums imposed under paragraph (a)(5) of this section, the agency may terminate an individual from medical assistance on the basis of failure to pay for 60 days or more.

(3) For premiums imposed under paragraph (a)(2) of this section—

(i) For individuals with annual income exceeding 250 percent of the FPL, the agency may require payment of 100 percent of the premiums imposed under this paragraph for a year, such that payment is only required up to 7.5 percent of annual income for individuals whose annual income does not exceed 450 percent of the FPL.

(ii) For individuals whose annual adjusted gross income (as defined in section 62 of the Internal Revenue Code of 1986) exceeds \$75,000, increased by inflation each calendar year after 2000, the agency must require payment of 100 percent of the premiums for a year, except that the agency may choose to subsidize the premiums using state funds which may not be federally matched by Medicaid.

(4) For any premiums imposed under this section, the agency may waive payment of a premium in any case where the agency determines that requiring the payment will create an undue hardship for the individual or family.

(5) The agency may not apply further consequences or penalties for non-payment other than those listed in this section.

(c) State plan specifications. For each premium, enrollment fee, or similar charge imposed under paragraph (a) of this section, subject to the requirements of paragraph (b) of this section, the plan must specify—

- (1) The group or groups of individuals that may be subject to the charge;
- (2) The amount and frequency of the charge;
- (3) The process used by the state to identify which beneficiaries are subject to premiums and to ensure individuals exempt from premiums are not charged; and
- (4) The consequences for an individual or family who does not pay.

§447.56 Limitations on premiums and cost sharing.

(a) Exemptions. (1) The agency may not impose premiums or cost sharing upon the following groups of individuals:

- (i) Individuals ages 1 and older and under age 18 eligible under §435.118 of this chapter.
- (ii) Infants under age 1 eligible under §435.118 of this chapter whose income does not exceed the higher of –
 - (A) 150 percent FPL (for premiums) or 133 percent FPL (for cost sharing); and
 - (B) If applicable, the percent FPL described in section 1902(1)(2)(A)(iv) of the Act up to 185 percent FPL.
- (iii) Individuals under age 18 eligible under §435.120-§435.122 or §435.130 of this chapter.
- (iv) Children for whom child welfare services are made available under Part B of title IV of the Act on the basis of being a child in foster care and individuals receiving benefits under Part E of that title, without regard to age.
- (v) At state option, individuals under age 19, 20 or age 21, eligible under §435.222 of this chapter.

(vi) Disabled children, except as provided at §447.55(a)(4) (premiums), who are receiving medical assistance by virtue of the application of the Family Opportunity Act in accordance with sections 1902(a)(10)(A)(ii)(XIX) and 1902(cc) of the Act.

(vii) Pregnant women, except for premiums allowed under §447.55(a)(1) and cost sharing for services specified in the state plan as not pregnancy-related, during the pregnancy and through the postpartum period which begins on the last day of pregnancy and extends through the end of the month in which the 60-day period following termination of pregnancy ends.

(viii) Any individual whose medical assistance for services furnished in an institution, or at state option in a home and community-based setting, is reduced by amounts reflecting available income other than required for personal needs.

(ix) An individual receiving hospice care, as defined in section 1905(o) of the Act.

(x) An Indian who is eligible to receive or has received an item or service furnished by an Indian health care provider or through referral under contract health services is exempt from premiums. Indians who are currently receiving or have ever received an item or service furnished by an Indian health care provider or through referral under contract health services are exempt from all cost sharing.

(xi) Individuals who are receiving Medicaid because of the state's election to extend coverage as authorized by §435.213 of this chapter (Breast and Cervical Cancer).

(2) The agency may not impose cost sharing for the following services:

(i) Emergency services as defined at section 1932(b)(2) of the Act and §438.114(a) of this chapter;

(ii) Family planning services and supplies described in section 1905(a)(4)(C) of the Act, including contraceptives and pharmaceuticals for which the State claims or could claim Federal

match at the enhanced rate under section 1903(a)(5) of the Act for family planning services and supplies;

(iii) Preventive services, at a minimum the services specified at §457.520 of chapter D, provided to children under 18 years of age regardless of family income, which reflect the well-baby and well child care and immunizations in the Bright Futures guidelines issued by the American Academy of Pediatrics; and

(iv) Pregnancy-related services, including those defined at §§440.210(a)(2) and 440.250(p) of this chapter, and counseling and drugs for cessation of tobacco use. All services provided to pregnant women will be considered as pregnancy-related, except those services specifically identified in the state plan as not being related to the pregnancy.

(v) Provider-preventable services as defined in §447.26(b).

(b) Applicability. Except as permitted under §447.52(d) (targeted cost sharing), the agency may not exempt additional individuals from cost sharing obligations that apply generally to the population at issue.

(c) Payments to providers. (1) Except as provided under paragraphs (c)(2) and (c)(3) of this section, the agency must reduce the payment it makes to a provider by the amount of a beneficiary's cost sharing obligation, regardless of whether the provider has collected the payment or waived the cost sharing.

(2) For items and services provided to Indians who are exempt from cost sharing under paragraph (a)(1)(x) of this section, the agency may not reduce the payment it makes to a provider, including an Indian health care provider, by the amount of cost sharing that will otherwise be due from the Indian.

(3) For those providers that the agency reimburses under Medicare reasonable cost reimbursement principles, in accordance with subpart B of this part, an agency may increase its payment to offset uncollected cost sharing charges that are bad debts of providers.

(d) Payments to managed care organizations. If the agency contracts with a managed care organization, the agency must calculate its payments to the organization to include cost sharing established under the state plan, for beneficiaries not exempt from cost sharing under paragraph (a) of this section, regardless of whether the organization imposes the cost sharing on its recipient members or the cost sharing is collected.

(e) Payments to states. No FFP in the state's expenditures for services is available for—

(1) Any premiums or cost sharing amounts that recipients should have paid under §§447.52 through 447.55 (except for amounts that the agency pays as bad debts of providers under paragraph (c)(3) of this section; and

(2) Any amounts paid by the agency on behalf of ineligible individuals, whether or not the individual had paid any required premium, except for amounts for premium assistance to obtain coverage for eligible individuals through family coverage that may include ineligible individuals when authorized in the approved state plan.

(f) Aggregate limits. (1) Medicaid premiums and cost sharing incurred by all individuals in the Medicaid household may not exceed an aggregate limit of 5 percent of the family's income applied on either a quarterly or monthly basis, as specified by the agency.

(2) If the state adopts premiums or cost sharing rules that could place beneficiaries at risk of reaching the aggregate family limit, the state plan must indicate a process to track each family's incurred premiums and cost sharing through an effective mechanism that does not rely on beneficiary documentation.

(3) The agency must inform beneficiaries and providers of the beneficiaries aggregate limit and notify beneficiaries and providers when a beneficiary has incurred out-of-pocket expenses up to the aggregate family limit and individual family members are no longer subject to cost sharing for the remainder of the family's current monthly or quarterly cap period.

(4) The agency must have a process in place for beneficiaries to request a reassessment of their family aggregate limit if they have a change in circumstances or if they are being terminated for failure to pay a premium.

(5) Nothing in paragraph (f) shall preclude the agency from establishing additional aggregate limits, including but not limited to a monthly limit on cost sharing charges for a particular service.

§447.57 Beneficiary and public notice requirements.

(a) The agency must make available a public schedule describing current premiums and cost sharing requirements containing the following information:

(1) The group or groups of individuals who are subject to premiums and/or cost sharing and the current amounts;

(2) Mechanisms for making payments for required premiums and cost sharing charges;

(3) The consequences for an applicant or recipient who does not pay a premium or cost sharing charge;

(4) A list of hospitals charging cost sharing for non-emergency use of the emergency department; and

(5) A list of preferred drugs or a mechanism to access such a list, including the agency website.

(b) The agency must make the public schedule available to the following in a manner that ensures that affected applicants, beneficiaries, and providers are likely to have access to the notice:

(1) Beneficiaries, at the time of their enrollment and reenrollment after a redetermination of eligibility, and when premiums, cost sharing charges, or aggregate limits are revised, notice to beneficiaries must be in accordance with §435.905(b) of this chapter;

(2) Applicants, at the time of application;

(3) All participating providers; and

(4) The general public.

(c) Prior to submitting to the Centers for Medicare & Medicaid Services for approval a state plan amendment (SPA) to establish or substantially modify existing premiums or cost sharing, or change the consequences for non-payment, the agency must provide the public with advance notice of the SPA, specifying the amount of premiums or cost sharing and who is subject to the charges. The agency must provide a reasonable opportunity to comment on such SPAs. The agency must submit documentation with the SPA to demonstrate that these requirements were met. If premiums or cost sharing is substantially modified during the SPA approval process, the agency must provide additional public notice.

§§ 445.58 through 447.82 [Removed]

47c. Remove §§ 445.58 through 447.82.

PART 457--ALLOTMENTS AND GRANTS TO STATES

48. The authority citation for part 457 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

49. Section 457.10 is amended by adding the definitions of “Exchange appeals entity,” and “Premium Lock Out” to read as follows:

§457.10 Definitions and use of terms.

* * * * *

Exchange appeals entity has the meaning given to the term “appeals entity,” as defined in 45 CFR 155.500.

* * * * *

Premium Lock-Out is defined as a State-specified period of time not to exceed 90 days that a CHIP eligible child who has an unpaid premium or enrollment fee (as applicable) will not be permitted to reenroll for coverage in CHIP. Premium lock-out periods are not applicable to children who have paid outstanding premiums or enrollment fees.

* * * * *

50. Section 457.110 is amended by adding paragraph (a)(1) and a reserved paragraph (a)(2) to read as follows:

§457.110 Enrollment assistance and information requirements.

(a) * * *

(1) The State may provide individuals with a choice to receive notices and information required under this subpart and Subpart K of this part, in electronic format or by regular mail, provided that the State establish safeguards in accordance with § 435.918 of this chapter.

(2) [Reserved]

* * * * *

51. Section §457.340 is amended by revising paragraph (a) and adding paragraph (d)(3) to read as follows:

§457.340 Application for and enrollment in CHIP.

(a) Application and renewal assistance, availability of program information, and Internet Website. The terms of §435.905, §435.906, §435.907(h), §435.908, and §435.1200(f) of this chapter apply equally to the State in administering a separate CHIP.

* * * * *

(d) * * *

(3) In the case of individuals subject to a period of uninsurance under this part, the state must identify and implement processes to facilitate enrollment of CHIP-eligible children who have satisfied a period of uninsurance (as described under §457.805). To minimize burden on individuals, a state may not require a new application or information already provided by a family immediately preceding the beginning of a waiting period. States must also ensure that the proper safeguards are in place to prevent a disruption in coverage for children transitioning from coverage under another insurance affordability program after the completion of a period of uninsurance.

* * * * *

52. Section 457.348 is amended by adding paragraph (c)(6) to read as follows:

§457.348 Determinations of Children’s Health Insurance Program eligibility by other insurance affordability programs

* * * * *

(c)* * *

(6) Notify such program of the final determination of the individual’s eligibility or ineligibility for CHIP.

* * * * *

53. Section 457.350 is amended by revising paragraphs paragraph (i) to read as follows:

§457.350 Eligibility screening and enrollment in other insurance affordability programs.

* * * * *

(i) Applicants found potentially eligible for other insurance affordability programs. For individuals identified in paragraph (b)(3) of this section, including during a period of uninsurance imposed by the state under §457.805 , the state must—

(1) Promptly and without undue delay, consistent with the timeliness standards established under §457.340(d), transfer the electronic account to the applicable program via a secure electronic interfaces.

(2) [Reserved.]

(3) In the case of individuals subject to a period of uninsurance under this part, the state must notify such program of the date on which such period ends and the individual is eligible to enroll in CHIP.

* * * * *

54. Section 457.370 is added to read as follows:

§457.370 Alignment with Exchange initial open enrollment period.

The terms of §435.1205 apply equally to the State in administering a separate CHIP, except that the State shall make available and accept the application described in §457.330 , shall accept electronic accounts as described in §457.348, and furnish coverage in accordance with §457.340.

§457.540 [Amended]

55. In §457.540, amend paragraph (a) by removing the reference “§447.52” and by adding in its place the reference “§447.52, §447.53, or §447.54”.

56. Section 457.570 is amended by revising paragraph (c) and adding paragraph (d) to read as follows:

§457.570 Disenrollment protections.

* * * * *

(c) The State must ensure that disenrollment policies, such as policies related to non-payment of premiums, do not present barriers to the timely determination of eligibility and enrollment in coverage of an eligible child in the appropriate insurance affordability program. A State may not--

(1) Establish a premium lock-out period that exceeds 90-days in accordance with §457.10 of this part.

(2) Continue to impose a premium lock-out period after a child's past due premiums have been paid.

(3) Require the collection of past due premiums or enrollment fees as a condition of eligibility for reenrollment once the State-defined lock out period has expired, regardless of the length of the lock- out period.

(d) The State must provide the enrollee with an opportunity for an impartial review to address disenrollment from the program in accordance with §457.1130(a)(3).

57. Section 457.805 is revised to read as follows:

§457.805 State plan requirement: Procedures to address substitution under group health plans.

(a) State plan requirements. The state plan must include a description of reasonable procedures to ensure that health benefits coverage provided under the State plan does not substitute for coverage provided under group health plans as defined at §457.10.

(b) Limitations. (1) A state may not, under this section, impose a period of uninsurance which exceeds 90 days from the date a child otherwise eligible for CHIP is disenrolled from coverage under a group health plan.

(2) A waiting period may not be applied to a child following the loss of eligibility for and enrollment in Medicaid or another insurance affordability program.

(3) If a state elects to impose a period of uninsurance following the loss of coverage under a group health plan under this section, such period may not be imposed in the case of any child if:

(i) The premium paid by the family for coverage of the child under the group health plan exceeded 5 percent of household income;

(ii) The child's parent is determined eligible for advance payment of the premium tax credit for enrollment in a QHP through the Exchange because the ESI in which the family was enrolled is determined unaffordable in accordance with 26 CFR 1.36B-2(c)(3)(v).

(iii) The cost of family coverage that includes the child exceeds 9.5 percent of the household income.

(iv) The employer stopped offering coverage of dependents (or any coverage) under an employer-sponsored health insurance plan;

(v) A change in employment, including involuntary separation, resulted in the child's loss of employer-sponsored insurance (other than through full payment of the premium by the parent under COBRA);

(vi) The child has special health care needs; and

(vii) The child lost coverage due to the death or divorce of a parent.

58. Section 457.810 is amended by revising paragraph (a) to read as follows:

§457.810 Premium assistance programs: Required protections against substitution.

* * * * *

(a) Period without coverage under a group health plan. For health benefits coverage provided through premium assistance for group health plans, the following rules apply:

(1) Any waiting period imposed under the state child health plan prior to the provision of child health assistance to a targeted low-income child under the state plan shall apply to the same extent to the provision of a premium assistance subsidy for the child and shall not exceed 90 days.

(2) States must permit the same exemptions to the required waiting period for premium assistance as specified under the state plan at §457.805(a)(2), and §457.805(a)(3) for the provision of child health assistance to a targeted low-income child.

* * * * *

Title 45

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter B, as set forth below:

PART 155 --EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

59. The authority citation for part 155 is revised to read as follows:

Authority: Sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1332, 1334, 1402, 1413, 1321, 1322, 1331, 1332, 1334, 1402, 1411, 1412, 1413 of the Affordable Care Act, Pub. L 111-148, 124 Stat 199.

60. Section 155.20 is amended by revising the definitions of “Advance payments of the premium tax credit,” and adding a definition of “Catastrophic plan” to read as follows:

§155.20 Definitions.

* * * * *

Advance payments of the premium tax credit means payment of the tax credit authorized by 26 U.S.C. 36B and its implementing regulations, which are provided on an advance basis to an eligible individual enrolled in a QHP through an Exchange in accordance with section 1412 of the Affordable Care Act.

* * * * *

Catastrophic plan means a health plan described in section 1302(e) of the Affordable Care Act.

* * * * *

61. Section 155.105 is amended by revising paragraph (b)(2) to read as follows:

§155.105 Approval of a State Exchange.

* * * * *

(b) * * *

(2) The Exchange is capable of carrying out the information reporting requirements of 26 CFR 1.36B-5;

* * * * *

62. Section 155.227 is added to read as follows:

§155.227 Authorized representatives.

(a) General rule. (1) The Exchange must permit an applicant or enrollee in the individual or small group market, subject to applicable privacy and security requirements, to designate an individual person or organization to act on his or her behalf in applying for an eligibility determination or redetermination, under subpart D, G, or H of this part, and in carrying out other ongoing communications with the Exchange.

(2) Designation of an authorized representative must be in a written document signed by the applicant or enrollee, or through another legally binding format subject to applicable authentication and data security standards. If submitted, legal documentation of authority to act on behalf of an applicant or enrollee under State law, such as a court order establishing legal guardianship or a power of attorney, shall serve in the place of the applicant's or enrollee's signature.

(3) The Exchange must ensure that the authorized representative agrees to maintain, or be legally bound to maintain, the confidentiality of any information

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regarding the applicant or enrollee provided by the Exchange.

(4) The Exchange must ensure that the authorized representative is responsible for fulfilling all responsibilities encompassed within the scope of the authorized representation, as described in this section, to the same extent as the applicant or enrollee he or she represents.

(5) The Exchange must provide information both to the applicant or enrollee, and to the authorized representative, regarding the powers and duties of authorized representatives.

(b) Timing of designation. The Exchange must permit an applicant or enrollee to designate an authorized representative:

(1) At the time of application; and

(2) At other times and through methods as described in §155.405(c)(2).

(c) Duties. (1) The Exchange must permit an applicant or enrollee to authorize his or her representative to:

(i) Sign an application on the applicant or enrollee's behalf;

(ii) Submit an update or respond to a redetermination for the applicant or enrollee in accordance with §155.330 or §155.335;

(iii) Receive copies of the applicant's or enrollee's notices and other communications from the Exchange; and

(iv) Act on behalf of the applicant or enrollee in all other matters with the Exchange.

(2) The Exchange may permit an applicant or enrollee to authorize a

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representative to perform fewer than all of the activities described in paragraph (c)(1) of this section, provided that the Exchange tracks the specific permissions for each authorized representative.

(d) Duration. The Exchange must consider the designation of an authorized representative valid until:

(1) The applicant or enrollee notifies the Exchange that the representative is no longer authorized to act on his or her behalf using one of the methods available for the submission of an application, as described in §155.405(c). The Exchange must notify the authorized representative of such change; or

(2) The authorized representative informs the Exchange and the applicant or enrollee that he or she no longer is acting in such capacity. An authorized representative must notify the Exchange and the applicant or enrollee on whose behalf he or she is acting when the authorized representative no longer has legal authority to act on behalf of the applicant or enrollee.

(e) Compliance with State and Federal law. The Exchange must require an authorized representative to comply with applicable state and federal laws concerning conflicts of interest and confidentiality of information.

(f) Signature. For purposes of this section, designation of an authorized representative must be through a written document signed by the applicant or enrollee, or through another legally binding format, as described in §155.227(a)(2), and must be accepted through all of the modalities described in §155.405(c).

63. Section 155.230 is amended by revising paragraph (a) and adding paragraph

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(d) to read as follows:

§155.230 General standards for Exchange notices.

(a) General requirement. Any notice required to be sent by the Exchange to individuals or employers must be written and include:

(1) An explanation of the action reflected in the notice, including the effective date of the action.

(2) Any factual findings relevant to the action.

(3) Citations to, or identification of, the relevant regulations supporting the action.

(4) Contact information for available customer service resources.

(5) An explanation of appeal rights, if applicable.

* * * * *

(d) Electronic notices. (1) The individual market Exchange must provide required notices either through standard mail, or if an individual or employer elects, electronically, provided that the requirements for electronic notices in 42 CFR 435.918 are met, except that the individual market Exchange is not required to implement the process specified in 42 CFR 435.918(b)(1) for eligibility determinations for enrollment in a QHP through the Exchange and insurance affordability programs that are effective before January 1, 2015.

(2) The SHOP must provide required notices either through standard mail, or if an employer or employee elects, electronically, provided that the requirements for electronic notices in 42 CFR 435.918(b)(2) through (5) are met for the employer or employee.

64. Section 155.300(a) is amended by removing the definition of “Adoption taxpayer identification number” and revising the definitions of “Minimum value,”

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“Modified Adjusted Gross Income (MAGI),” and “Qualifying coverage in an eligible employer-sponsored plan” to read as follows:

§155.300 Definitions and general standards for eligibility determinations.

(a) * * *

Minimum value when used to describe coverage in an eligible employer-sponsored plan, means that the employer-sponsored plan meets the standards for coverage of the total allowed costs of benefits set forth in §156.145.

Modified Adjusted Gross Income (MAGI) has the same meaning as it does in 26 CFR 1.36B-1(e)(2).

* * * * *

Qualifying coverage in an eligible employer-sponsored plan means coverage in an eligible employer-sponsored plan that meets the affordability and minimum value standards specified in 26 CFR 1.36B-2(c)(3).

* * * * *

65. Section 155.302 is amended by revising paragraphs (a), (b), and (d) to read as follows:

§155.302 Options for conducting eligibility determinations.

(a) Options for conducting eligibility determinations. The Exchange may satisfy the requirements of this subpart—

(1) Directly or through contracting arrangements in accordance with §155.110(a), provided that any contracting arrangement for eligibility determinations for Medicaid and CHIP is subject to the standards in 42 CFR 431.10(c)(2); or

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(2) Through a combination of the approach described in paragraph (a)(1) of this section and one or both of the options described in paragraph (b) or (c) of this section, subject to the standards in paragraph (d) of this section.

(b) Medicaid and CHIP. Notwithstanding the requirements of this subpart, the Exchange may conduct an assessment of eligibility for Medicaid and CHIP, rather than an eligibility determination for Medicaid and CHIP, provided that –

(1) The Exchange makes such an assessment based on the applicable Medicaid and CHIP MAGI-based income standards and citizenship and immigration status, using verification rules and procedures consistent with 42 CFR parts 435 and 457, without regard to how such standards are implemented by the State Medicaid and CHIP agencies.

(2) Notices and other activities required in connection with an eligibility determination for Medicaid or CHIP are performed by the Exchange consistent with the standards identified in this subpart or the State Medicaid or CHIP agency consistent with applicable law.

(3) Applicants found potentially eligible for Medicaid or CHIP. When the Exchange assesses an applicant as potentially eligible for Medicaid or CHIP consistent with the standards in paragraph (b)(1) of this section, the Exchange transmits all information provided as a part of the application, update, or renewal that initiated the assessment, and any information obtained or verified by the Exchange to the State Medicaid agency or CHIP agency via secure electronic interface, promptly and without undue delay.

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(4) Applicants not found potentially eligible for Medicaid and CHIP. (i) If the Exchange conducts an assessment in accordance with paragraph (b) of this section and finds that an applicant is not potentially eligible for Medicaid or CHIP based on the applicable Medicaid and CHIP MAGI-based income standards, the Exchange must consider the applicant as ineligible for Medicaid and CHIP for purposes of determining eligibility for advance payments of the premium tax credit and cost-sharing reductions and must notify such applicant, and provide him or her with the opportunity to –

(A) Withdraw his or her application for Medicaid and CHIP, unless the Exchange has assessed the applicant as potentially eligible for Medicaid based on factors not otherwise considered in this subpart, in accordance with §155.345(b), and provided that the application will not be considered withdrawn if he or she appeals his or her eligibility determination for advance payments of the premium tax credit or cost-sharing reductions and the appeals entity described in §155.500(a) finds that the individual is potentially eligible for Medicaid or CHIP; or

(B) Request a full determination of eligibility for Medicaid and CHIP by the applicable State Medicaid and CHIP agencies.

(ii) To the extent that an applicant described in paragraph (b)(4)(i) of this section requests a full determination of eligibility for Medicaid and CHIP, the Exchange must –

(A) Transmit all information provided as a part of the application, update, or renewal that initiated the assessment, and any information obtained or verified by the Exchange to the State Medicaid agency and CHIP agency via secure electronic interface, promptly and without undue delay; and

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(B) Consider such an applicant as ineligible for Medicaid and CHIP for purposes of determining eligibility for advance payments of the premium tax credit and cost-sharing reductions until the State Medicaid or CHIP agency notifies the Exchange that the applicant is eligible for Medicaid or CHIP.

(5) The Exchange and the Exchange appeals entity adheres to the eligibility determination or appeals decision for Medicaid or CHIP made by the State Medicaid or CHIP agency, or the appeals entity for such agency.

(6) The Exchange and the State Medicaid and CHIP agencies enter into an agreement specifying their respective responsibilities in connection with eligibility determinations for Medicaid and CHIP, and provide a copy of such agreement to HHS upon request.

* * * * *

(d) Standards. To the extent that assessments of eligibility for Medicaid and CHIP based on MAGI or eligibility determinations for advance payments of the premium tax credit and cost-sharing reductions are made in accordance with paragraphs (b) or (c) of this section, the Exchange must ensure that –

(1) Eligibility processes for all insurance affordability programs are streamlined and coordinated across HHS, the Exchange, the State Medicaid agency, and the State CHIP agency, as applicable;

(2) Such arrangement does not increase administrative costs and burdens on applicants, enrollees, beneficiaries, or application filers, or increase delay; and

(3) Applicable requirements under 45 CFR 155.260, 155.270, and 155.315(i), and section 6103 of the Code for the confidentiality, disclosure, maintenance, and use of information are met.

66. Section 155.305 is amended by—

A. Revising paragraphs (f)(1)(i), (f)(1)(ii)(B), (f)(2)(ii), (f)(2)(iii), (f)(3), and (f)(5).

B. Adding paragraphs (a)(3)(v), and (h).

The revisions and additions read as follows:

§155.305 Eligibility standards.

(a) * * * *

(3) * * * *

(v) Temporary absence. The Exchange may not deny or terminate an individual's eligibility for enrollment in a QHP through the Exchange if the individual meets the standards in paragraph (a)(3) of this section but for a temporary absence from the service area of the Exchange and intends to return when the purpose of the absence has been accomplished.

* * * *

(f) * * *

(1) * * *

(i) He or she is expected to have a household income, as defined in 26 CFR 1.36B-1(e), of greater than or equal to 100 percent but not more than 400 percent of the FPL for the benefit year for which coverage is requested; and

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(ii) * * *

(B) Is not eligible for minimum essential coverage, with the exception of coverage in the individual market, in accordance with section 26 CFR 1.36B-2(a)(2) and (c).

(2) * * *

(ii) He or she is expected to have a household income, as defined in 26 CFR 1.36B-1(e) of less than 100 percent of the FPL for the benefit year for which coverage is requested; and

(iii) One or more applicants for whom the tax filer expects to claim a personal exemption deduction on his or her tax return for the benefit year, including the tax filer and his or her spouse, is a non-citizen who is lawfully present and ineligible for Medicaid by reason of immigration status, in accordance with 26 CFR 1.36B-2(b)(5).

(3) Enrollment required. The Exchange may provide advance payments of the premium tax credit on behalf of a tax filer only if one or more applicants for whom the tax filer attests that he or she expects to claim a personal exemption deduction for the benefit year, including the tax filer and his or her spouse, is enrolled in a QHP that is not a catastrophic plan, through the Exchange.

* * * * *

(5) Calculation of advance payments of the premium tax credit. The Exchange must calculate advance payments of the premium tax credit in accordance with 26 CFR 1.36B-3.

* * * * *

(h) Eligibility for enrollment through the Exchange in a QHP that is a catastrophic plan. The Exchange must determine an applicant eligible for enrollment in a QHP through the Exchange in a QHP that is a catastrophic plan as defined by section 1302(e) of the Affordable Care Act, if he or she has met the requirements for eligibility for enrollment in a QHP through the Exchange, in accordance with §155.305(a), and either--

(1) Has not attained the age of 30 before the beginning of the plan year; or

(2) Has a certification in effect for any plan year that he or she is exempt from the requirement to maintain minimum essential coverage under section 5000A of the Code by reason of --

(i) Section 5000A(e)(1) of the Code (relating to individuals without affordable coverage); or

(ii) Section 5000A(e)(5) of the Code (relating to individuals with hardships).

67. Section 155.310 is amended by—

A. Redesignating paragraph (i) as paragraph (j).

B. Adding new paragraph (i).

C. Revising newly redesignated paragraph (j).

The addition and revision read as follows:

§155.310 Eligibility process.

* * * * *

(i) Certification program for employers. As part of its determination of whether an employer has a liability under section 4980H of the Code, the Internal Revenue Service will adopt methods to certify to an employer that one or more employees has

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enrolled for one or more months during a year in a QHP for which a premium tax credit or cost-sharing reduction is allowed or paid.

(j) Duration of eligibility determinations without enrollment. To the extent that an applicant who is determined eligible for enrollment in a QHP through the Exchange does not select a QHP within his or her enrollment period, or is not eligible for an enrollment period, in accordance with subpart E, and seeks a new enrollment period prior to the date on which his or her eligibility is redetermined in accordance with §155.335, the Exchange must require the applicant to attest as to whether information affecting his or her eligibility has changed since his or her most recent eligibility determination before determining his or her eligibility for a special enrollment period, and must process any changes reported in accordance with the procedures specified in §155.330.

68. Section 155.315 is amended by revising paragraphs (b)(2), (f) introductory text, (f)(4) introductory text, and (f)(5) and by adding paragraphs (f)(6) and (j) to read as follows:

§155.315 Verification process related to eligibility for enrollment in a QHP through the Exchange.

* * * * *

(b) * * *

(2) To the extent that the Exchange is unable to validate an individual's Social Security number through the Social Security Administration, or the Social Security Administration indicates that the individual is deceased, the Exchange must follow the procedures specified in paragraph (f) of this section, except that the Exchange must

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provide the individual with a period of 90 days from the date on which the notice described in paragraph (f)(2)(i) of this section is received for the applicant to provide satisfactory documentary evidence or resolve the inconsistency with the Social Security Administration. The date on which the notice is received means 5 days after the date on the notice, unless the individual demonstrates that he or she did not receive the notice within the 5 day period.

* * * * *

(f) Inconsistencies. Except as otherwise specified in this subpart, for an applicant for whom the Exchange cannot verify information required to determine eligibility for enrollment in a QHP through the Exchange, advance payments of the premium tax credit, and cost-sharing reductions, including when electronic data is required in accordance with this subpart but data for individuals relevant to the eligibility determination are not included in such data sources or when electronic data from IRS, DHS, or SSA is required but it is not reasonably expected that data sources will be available within 1 day of the initial request to the data source, the Exchange:

* * * * *

(4) During the periods described in paragraphs (f)(1) and (f)(2)(ii) of this section, must:

* * * * *

(5) If, after the period described in paragraph (f)(2)(ii) of this section, the Exchange remains unable to verify the attestation, the Exchange must determine the applicant's eligibility based on the information available from the data sources specified

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in this subpart, unless such applicant qualifies for the exception provided under paragraph (g) of this section, and notify the applicant of such determination in accordance with the notice requirements specified in §155.310(g), including notice that the Exchange is unable to verify the attestation.

(6) When electronic data to support the verifications specified in §155.315(d) or §155.320(b) is required but it is not reasonably expected that data sources will be available within 1 day of the initial request to the data source, the Exchange must accept the applicant's attestation regarding the factor of eligibility for which the unavailable data source is relevant.

* * * * *

(j) Verification related to eligibility for enrollment through the Exchange in a QHP that is a catastrophic plan. The Exchange must verify an applicant's attestation that he or she meets the requirements of §155.305(h) by –

(1) Verifying the applicant's attestation of age as follows –

(i) Except as provided in paragraph (j)(1)(iii) of this section, accepting his or her attestation without further verification; or

(ii) Examining electronic data sources that are available to the Exchange and which have been approved by HHS for this purpose, based on evidence showing that such data sources are sufficiently current and accurate, and minimize administrative costs and burdens.

(iii) If information regarding age is not reasonably compatible with other information provided by the individual or in the records of the Exchange, the Exchange

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must examine information in data sources that are available to the Exchange and which have been approved by HHS for this purpose based on evidence showing that such data sources are sufficiently current and accurate.

(2) Verifying that an applicant has a certification of exemption in effect as described in §155.305(h)(2).

(3) To the extent that the Exchange is unable to verify the information required to determine eligibility for enrollment through the Exchange in a QHP that is a catastrophic plan as described in paragraphs (j)(1) and (2) of this section, the Exchange must follow the procedures specified in §155.315(f), except for §155.315(f)(4).

69. Section 155.320 is amended by—

A. Revising paragraphs (c)(1)(i) heading, (c)(1)(i)(A), (c)(1)(ii), (c)(3)(i)(D), (c)(3)(ii)(A), (c)(3)(iii)(A) and (B), (c)(3)(vi), (c)(3)(vii), (c)(3)(viii), and (d).

B. Adding paragraphs (c)(3)(i)(E) and (c)(3)(iii)(C).

C. Removing paragraph (e).

D. Redesignating paragraph (f) as paragraph (e).

The revisions and additions read as follows:

§155.320 Verification process related to eligibility for insurance affordability programs.

* * * * *

(c) * * *

(1) * * *

(i) Data regarding annual household income. (A) For all individuals whose

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income is counted in calculating a tax filer's household income, as defined in 26 CFR 1.36B-1(e), or an applicant's household income, calculated in accordance with 42 CFR 435.603(d), and for whom the Exchange has a Social Security number, the Exchange must request tax return data regarding MAGI and family size from the Secretary of the Treasury and data regarding Social security benefits described in 26 CFR 1.36B-1(e)(2)(iii) from the Commissioner of Social Security by transmitting identifying information specified by HHS to HHS.

* * * * *

(ii) Data regarding MAGI-based income. For all individuals whose income is counted in calculating a tax filer's household income, as defined in 26 CFR 1.36B-1(e), or an applicant's household income, calculated in accordance with 42 CFR 435.603(d), the Exchange must request data regarding MAGI-based income in accordance with 42 CFR 435.948(a).

* * * * *

(3) * * *

(i) * * *

(D) If the Exchange finds that an applicant's attestation of a tax filer's family size is not reasonably compatible with other information provided by the application filer for the family or in the records of the Exchange, with the exception of the data described in paragraph (c)(1)(i) of this section, the Exchange must utilize data obtained through other electronic data sources to verify the attestation. If such data sources are unavailable or information in such data sources is not reasonably compatible with the applicant's

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attestation, the Exchange must request additional documentation to support the attestation within the procedures specified in §155.315(f).

(E) The Exchange must verify that neither advance payments of the premium tax credit nor cost-sharing reductions are being provided on behalf of an individual using information obtained by transmitting identifying information specified by HHS to HHS.

* * * * *

(ii) * * * *

(A) The Exchange must compute annual household income for the family described in paragraph (c)(3)(i)(A) of this section based on the data described in paragraph (c)(1)(i) of this section;

* * * * *

(iii) * * *

(A) Except as specified in paragraph (c)(3)(iii)(B) and (C) of this section, if an applicant's attestation, in accordance with paragraph (c)(3)(ii)(B) of this section, indicates that a tax filer's annual household income has increased or is reasonably expected to increase from the data described in paragraph (c)(3)(ii)(A) of this section for the benefit year for which the applicant(s) in the tax filer's family are requesting coverage and the Exchange has not verified the applicant's MAGI-based income through the process specified in paragraph (c)(2)(ii) of this section to be within the applicable Medicaid or CHIP MAGI-based income standard, the Exchange must accept the applicant's attestation regarding a tax filer's annual household income without further verification.

(B) If data available to the Exchange in accordance with paragraph (c)(1)(ii) of this section indicate that a tax filer's projected annual household income is in excess of his or her attestation by a significant amount, the Exchange must proceed in accordance with §155.315(f)(1) through (4).

(C) If other information provided by the application filer indicates that a tax filer's projected annual household income is in excess of his or her attestation by a significant amount, the Exchange must utilize data available to the Exchange in accordance with paragraph (c)(1)(ii) of this section to verify the attestation. If such data is unavailable or are not reasonably compatible with the applicant's attestation, the Exchange must proceed in accordance with §155.315(f)(1) through (4).

* * * * *

(vi) Alternate verification process for decreases in annual household income and situations in which tax return data is unavailable. If a tax filer qualifies for an alternate verification process based on the requirements specified in paragraph (c)(3)(iv) of this section and the applicant's attestation to projected annual household income, as described in paragraph (c)(3)(ii)(B) of this section, is greater than ten percent below the annual household income computed in accordance with paragraph (c)(3)(ii)(A) of this section, or if data described in paragraph (c)(1)(i) of this section is unavailable, the Exchange must attempt to verify the applicant's attestation of the tax filer's projected annual household income by following the procedures specified in paragraph (c)(3)(vi)(A) through (G) of this section.

(A) Data. The Exchange must annualize data from the MAGI-based income

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sources specified in paragraph (c)(1)(ii) of this section, and obtain any data available from other electronic data sources that have been approved by HHS, based on evidence showing that such data sources are sufficiently accurate and offer less administrative complexity than paper verification.

(B) Eligibility. To the extent that the applicant's attestation indicates that the information described in paragraph (c)(3)(vi)(A) of this section represents an accurate projection of the tax filer's household income for the benefit year for which coverage is requested, the Exchange must determine the tax filer's eligibility for advance payments of the premium tax credit and cost-sharing reductions based on the household income data in paragraph (c)(3)(vi)(A) of this section.

(C) Increases in annual household income. If an applicant's attestation, in accordance with paragraph (c)(3)(ii)(B) of this section, indicates that a tax filer's annual household income has increased or is reasonably expected to increase from the data described in paragraph (c)(3)(vi)(A) of this section to the benefit year for which the applicant(s) in the tax filer's family are requesting coverage and the Exchange has not verified the applicant's MAGI-based income through the process specified in paragraph (c)(2)(ii) of this section to be within the applicable Medicaid or CHIP MAGI-based income standard, the Exchange must accept the applicant's attestation for the tax filer's family without further verification, unless the Exchange finds that an applicant's attestation of a tax filer's annual household income is not reasonably compatible with other information provided by the application filer or available to the Exchange in accordance with paragraph (c)(1)(ii) of this section, in which case the Exchange must

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request additional documentation using the procedures specified in §155.315(f).

(D) Decreases in annual household income and situations in which electronic data is unavailable. If electronic data are unavailable or an applicant's attestation to projected annual household income, as described in paragraph (c)(3)(ii)(B) of this section, is more than ten percent below the annual household income as computed using data sources described in paragraphs (c)(3)(vi)(A) of this section, the Exchange must follow the procedures specified in §155.315(f)(1) through (4).

(E) If, following the 90-day period described in paragraph (c)(3)(vi)(D) of this section, an applicant has not responded to a request for additional information from the Exchange and the data sources specified in paragraph (c)(1) of this section indicate that an applicant in the tax filer's family is eligible for Medicaid or CHIP, the Exchange must not provide the applicant with eligibility for advance payments of the premium tax credit, cost-sharing reductions, Medicaid, CHIP or the BHP, if a BHP is operating in the service area of the Exchange.

(F) If, at the conclusion of the period specified in paragraph (c)(3)(vi)(D) of this section, the Exchange remains unable to verify the applicant's attestation, the Exchange must determine the applicant's eligibility based on the information described in paragraph (c)(3)(ii)(A) of this section, notify the applicant of such determination in accordance with the notice requirements specified in §155.310(g), and implement such determination in accordance with the effective dates specified in §155.330(f).

(G) If, at the conclusion of the period specified in paragraph (c)(3)(vi)(D) of this section, the Exchange remains unable to verify the applicant's attestation for the tax filer

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and the information described in paragraph (c)(3)(ii)(A) of this section is unavailable, the Exchange must determine the tax filer ineligible for advance payments of the premium tax credit and cost-sharing reductions, notify the applicant of such determination in accordance with the notice requirement specified in §155.310(g), and discontinue any advance payments of the premium tax credit and cost-sharing reductions in accordance with the effective dates specified in §155.330(f).

(vii) For the purposes of paragraph (c)(3) of this section, “household income” means household income as specified in 26 CFR 1.36B-1(e).

(viii) For the purposes of paragraph (c)(3) of this section, “family size” means family size as specified in 26 CFR 1.36B-1(d).

* * * *

(d) Verification related to enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan. (1) General requirement. The Exchange must verify whether an applicant reasonably expects to be enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested.

(2) Data. The Exchange must –

(i) Obtain data about enrollment in and eligibility for an eligible employer-sponsored plan from any electronic data sources that are available to the Exchange and which have been approved by HHS, based on evidence showing that such data sources are sufficiently current, accurate, and minimize administrative burden.

(ii) Obtain any available data regarding enrollment in employer-sponsored

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coverage or eligibility for qualifying coverage in an eligible employer-sponsored plan based on federal employment by transmitting identifying information specified by HHS to HHS for HHS to provide the necessary verification using data obtained by HHS.

(iii) Obtain any available data from the SHOP that corresponds to the State in which the Exchange is operating.

(3) Verification procedures. (i) Except as specified in paragraphs (d)(3)(ii) or (iii) of this section, the Exchange must accept an applicant's attestation regarding the verification specified in paragraph (d) of this section without further verification.

(ii) If an applicant's attestation is not reasonably compatible with the information obtained by the Exchange as specified in paragraphs (d)(2)(i) through (iii) of this section, other information provided by the application filer, or other information in the records of the Exchange, the Exchange must follow the procedures specified in §155.315(f).

(iii) Except as specified in paragraph (d)(3)(iv) of this section, if the Exchange does not have any of the information specified in paragraphs (d)(2)(i) through (iii) of this section for an applicant, the Exchange must select a statistically significant random sample of such applicants and –

(A) Provide notice to the applicant indicating that the Exchange will be contacting any employer identified on the application for the applicant and the members of his or her household, as defined in 26 CFR 1.36B-1(d), to verify whether the applicant is enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested;

(B) Proceed with all other elements of the eligibility determination using the

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applicant's attestation, and provide eligibility for enrollment in a QHP to the extent that an applicant is otherwise qualified;

(C) Ensure that advance payments of the premium tax credit and cost-sharing reductions are provided on behalf of an applicant who is otherwise qualified for such payments and reductions, as described in §155.305, if the tax filer attests to the Exchange that he or she understands that any advance payments of the premium tax credit paid on his or her behalf are subject to reconciliation;

(D) Make reasonable attempts to contact any employer identified on the application for the applicant and the members of his or her household, as defined in 26 CFR 1.36B-1(d), to verify whether the applicant is enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested;

(E) If the Exchange receives any information from an employer relevant to the applicant's enrollment in an eligible employer-sponsored plan or eligibility for qualifying coverage in an eligible employer-sponsored plan, the Exchange must determine the applicant's eligibility based on such information and in accordance with the effective dates specified in §155.330(f), and if such information changes his or her eligibility determination, notify the applicant and his or her employer or employers of such determination in accordance with the notice requirements specified in §155.310(g) and (h);

(F) If, after a period of 90 days from the date on which the notice described in paragraph (d)(3)(iii)(A) of this section is sent to the applicant, the Exchange is unable to

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obtain the necessary information from an employer, the Exchange must determine the applicant's eligibility based on his or her attestation(s) regarding coverage provided by that employer.

(G) To carry out the process described in paragraph (d)(3)(iii) of this section, the Exchange must only disclose an individual's information to an employer to the extent necessary for the employer to identify the employee.

(iv) For eligibility determinations for advance payments of the premium tax credit and cost-sharing reductions that are effective before January 1, 2015, if the Exchange does not have any of the information specified in paragraphs (d)(2)(i) through (iii) of this section for an applicant, the Exchange may accept an applicant's attestation regarding enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested without further verification, instead of following the procedure in paragraph (d)(3)(iii) of this section.

(4) Option to rely on verification performed by HHS. For eligibility determinations for advance payments of the premium tax credit and cost-sharing reductions that are effective on or after January 1, 2015, the Exchange may satisfy the provisions of paragraph (d) of this section by relying on a verification process performed by HHS, provided that –

(i) The Exchange sends the notices described in §155.310(g) and (h);

(ii) Other activities required in connection with the verifications described in this paragraph are performed by the Exchange in accordance with the standards identified in

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this subpart or in accordance with guidance issued by the Secretary; and

(iii) The Exchange provides all relevant application information to HHS through a secure, electronic interface, promptly and without undue delay.

* * * * *

70. Section 155.330 is amended by revising paragraphs (d)(1)(ii), (e)(2), and (f), and by removing paragraph (e)(3).

The revisions read as follows:

§155.330 Eligibility redetermination during a benefit year.

* * * * *

(d) * * *

(1) * * *

(ii) For an enrollee on whose behalf advance payments of the premium tax credit or cost-sharing reductions are being provided, eligibility determinations for Medicare, Medicaid, CHIP, or the BHP, if a BHP is operating in the service area of the Exchange.

* * * * *

(e) * * *

(2) Data matching. (i) If the Exchange identifies updated information regarding death, in accordance with paragraph (d)(1)(i) of this section, or regarding any factor of eligibility not regarding income, family size, or family composition, the Exchange must –

(A) Notify the enrollee regarding the updated information, as well as the enrollee’s projected eligibility determination after considering such information.

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(B) Allow an enrollee 30 days from the date of the notice to notify the Exchange that such information is inaccurate.

(C) If the enrollee responds contesting the updated information, proceed in accordance with §155.315(f) of this part.

(D) If the enrollee does not respond within the 30-day period specified in paragraph (e)(2)(i)(B), proceed in accordance with paragraphs (e)(1)(i) and (ii) of this section.

(ii) If the Exchange identifies updated information regarding income, family size, or family composition, with the exception of information regarding death, the Exchange must --

(A) Follow procedures described in paragraph (e)(2)(i)(A) and (B) of this section; and

(B) If the enrollee responds confirming the updated information, proceed in accordance with paragraphs (e)(1)(i) and (ii) of this section.

(C) If the enrollee does not respond within the 30-day period specified in paragraph (e)(2)(i)(B) of this section, maintain the enrollee's existing eligibility determination without considering the updated information.

(D) If the enrollee provides more up-to-date information, proceed in accordance with paragraph (c)(1) of this section.

* * * * *

(f) Effective dates. (1) Except as specified in paragraphs (f)(2) through (f)(5) of this section, the Exchange must implement changes—

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(i) Resulting from a redetermination under this section on the first day of the month following the date of the notice described in paragraph (e)(1)(ii) of this section; or

(ii) Resulting from an appeal decision, on the date specified in the appeal decision; or

(iii) Affecting enrollment or premiums only, on the first day of the month following the date on which the Exchange is notified of the change;

(2) Except as specified in paragraphs (f)(3) through (5) of this section, the Exchange may determine a reasonable point in a month after which a change described in paragraph (f)(1) of this section will not be effective until the first day of the month after the month specified in paragraph (f)(1) of this section. Such reasonable point in a month must be no earlier than the 15th of the month.

(3) Except as specified in paragraphs (f)(4) and (5) of this section, the Exchange must implement a change described in paragraph (f)(1) of this section that results in a decreased amount of advance payments of the premium tax credit, or a change in the level of cost-sharing reductions, and for which the date of the notices described in paragraphs (f)(1)(i) and (ii) of this section, or the date on which the Exchange is notified in accordance with paragraph (f)(1)(iii) of this section is after the 15th of the month, on the first day of the month after the month specified in paragraph (f)(1) of this section.

(4) The Exchange must implement a change associated with the events described in §155.420(b)(2)(i) and (ii) on the coverage effective dates described in §155.420(b)(2)(i) and (ii), respectively.

(5) Notwithstanding paragraphs (f)(1) through (f)(4) of this section, the Exchange may provide the effective date of a change associated with the events described in §155.420(d)(4), (d)(5), and (d)(9) based on the specific circumstances of each situation.

71. Section 155.335 is amended by revising paragraphs (a), (b), (c), (e), (f), (g), (h), (k)(1), and (l) , and adding paragraph (m) to read as follows:

§155.335 Annual eligibility redetermination.

(a) General requirement. Except as specified in paragraphs (l) and (m) of this section, the Exchange must redetermine the eligibility of a qualified individual on an annual basis.

(b) Updated income and family size information. In the case of a qualified individual who requested an eligibility determination for insurance affordability programs in accordance with §155.310(b) of this part, the Exchange must request updated tax return information, if the qualified individual has authorized the request of such tax return information, data regarding Social Security benefits, and data regarding MAGI-based income as described in §155.320(c)(1) of this part for use in the qualified individual's eligibility redetermination.

(c) Notice to qualified individual. The Exchange must provide a qualified individual with an annual redetermination notice including the following:

(1) [Reserved]

(2) [Reserved]

(3) The qualified individual's projected eligibility determination for the following year, after considering any updated information described in paragraph (b) of this section,

including, if applicable, the amount of any advance payments of the premium tax credit and the level of any cost-sharing reductions or eligibility for Medicaid, CHIP or BHP.

* * * * *

(e) Changes reported by qualified individuals. (1) The Exchange must require a qualified individual to report any changes for the information listed in the notice described in paragraph (c) of this section within 30 days from the date of the notice.

(2) The Exchange must allow a qualified individual, or an application filer, on behalf of the qualified individual, to report changes via the channels available for the submission of an application, as described in §155.405(c)(2) .

(f) Verification of reported changes. The Exchange must verify any information reported by a qualified individual under paragraph (e) of this section using the processes specified in §155.315 and §155.320, including the relevant provisions in those sections regarding inconsistencies, prior to using such information to determine eligibility.

(g) Response to redetermination notice. (1) The Exchange must require a qualified individual, or an application filer, on behalf of the qualified individual, to sign and return the notice described in paragraph (c) of this section.

(2) To the extent that a qualified individual does not sign and return the notice described in paragraph (c) of this section within the 30-day period specified in paragraph (e) of this section, the Exchange must proceed in accordance with the procedures specified in paragraph (h)(1) of this section.

(h) Redetermination and notification of eligibility. (1) After the 30-day period specified in paragraph (e) of this section has elapsed, the Exchange must—

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(i) Redetermine the qualified individual's eligibility in accordance with the standards specified in §155.305 using the information provided to the qualified individual in the notice specified in paragraph (c) of this section, as supplemented with any information reported by the qualified individual and verified by the Exchange in accordance with paragraphs (e) and (f) of this section.

(ii) Notify the qualified individual in accordance with the requirements specified in §155.310(g).

(iii) If applicable, notify the qualified individual employer, in accordance with the requirements specified in §155.310(h).

(2) If a qualified individual reports a change for the information provided in the notice specified in paragraph (c) of this section that the Exchange has not verified as of the end of the 30-day period specified in paragraph (e) of this section, the Exchange must redetermine the qualified individual's eligibility after completing verification, as specified in paragraph (f) of this section.

* * * * *

(k) * * *

(1) The Exchange must have authorization from a qualified individual to obtain updated tax return information described in paragraph (b) of this section for purposes of conducting an annual redetermination.

* * * * *

(l) Limitation on redetermination. To the extent that a qualified individual has requested an eligibility determination for insurance affordability programs in accordance

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with §155.310(b) and the Exchange does not have an active authorization to obtain tax data as a part of the annual redetermination process, the Exchange must redetermine the qualified individual's eligibility only for enrollment in a QHP and notify the enrollee in accordance with the timing described in paragraph (d) of this section. The Exchange may not proceed with a redetermination for insurance affordability programs until such authorization has been obtained or the qualified individual continues his or her request for an eligibility determination for insurance affordability programs in accordance with §155.310(b).

(m) Special rule. The Exchange must not redetermine a qualified individual's eligibility in accordance with this section if the qualified individual's eligibility was redetermined under this section during the prior year, and the qualified individual was not enrolled in a QHP through the Exchange at the time of such redetermination, and has not enrolled in a QHP through the Exchange since such redetermination.

72. Section 155.340 is amended by revising paragraphs (b) heading, (b)(1), and (c) to read as follows:

§155.340 Administration of advance payments of the premium tax credit and cost-sharing reductions.

* * * * *

(b) Requirement to provide information related to employer responsibility. (1) In the event that the Exchange determines that an individual is eligible for advance payments of the premium tax credit or cost-sharing reductions based in part on a finding that an individual's employer does not provide minimum essential coverage, or provides

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minimum essential coverage that is unaffordable, within the standard of 26 CFR 1.36B-2(c)(3)(v), or provide minimum essential coverage that does not meet the minimum value standard of §156.145, the Exchange must transmit the individual's name and taxpayer identification number to HHS.

* * * * *

(c) Requirement to provide information related to reconciliation of advance payments of the premium tax credit. The Exchange must comply with the requirements of 26 CFR 1.36B-5 regarding reporting to the IRS and to taxpayers.

* * * * *

73. Section 155.345 is amended by—

A. Revising paragraphs (a) introductory text and (a)(2).

B. Redesignating paragraph (a)(3) as paragraph (a)(4).

C. Adding reserved paragraph (a)(3).

D. Revising paragraphs (f) introductory text, (g) introductory text, and (g)(2) through (5).

E. Adding paragraph (g)(6).

F. Redesignating paragraphs (h) and (i) as paragraphs (i) and (j).

G. Adding new paragraph (h).

The revisions and addition read as follows:

§155.345 Coordination with Medicaid, CHIP, the Basic Health Program, and the Pre-existing Condition Insurance Plan.

(a) Agreements. The Exchange must enter into agreements with agencies administering Medicaid, CHIP, and the BHP, if a BHP is operating in the service area of the Exchange, as are necessary to fulfill the requirements of this subpart and provide copies of any such agreements to HHS upon request. Such agreements must include a clear delineation of the responsibilities of each agency to –

* * * * *

(2) Ensure prompt determinations of eligibility and enrollment in the appropriate program without undue delay, based on the date the application is submitted to or redetermination is initiated by the Exchange or the agency administering Medicaid, CHIP, or the BHP;

(3) [Reserved]

(4) Ensure compliance with paragraphs (c), (d), (e), and (g) of this section.

* * * * *

(f) Special rule. If the Exchange verifies that a tax filer’s household income, as defined in 26 CFR 1.36B-1(e), is less than 100 percent of the FPL for the benefit year for which coverage is requested, determines that the tax filer is not eligible for advance payments of the premium tax credit based on §155.305(f)(2), and one or more applicants in the tax filer’s household has been determined ineligible for Medicaid and CHIP based on income, the Exchange must –

* * * * *

(g) Determination of eligibility for individuals submitting applications directly to an agency administering Medicaid, CHIP, or the BHP. The Exchange, in consultation

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with the agency or agencies administering Medicaid, CHIP, and the BHP if a BHP is operating in the service area of the Exchange, must establish procedures to ensure that an eligibility determination for enrollment in a QHP, advance payments of the premium tax credit, and cost-sharing reductions is performed when an application is submitted directly to an agency administering Medicaid, CHIP, or the BHP if a BHP is operating in the service area of the Exchange. Under such procedures, the Exchange must—

* * * * *

(2) Notify such agency of the receipt of the information described in paragraph (g)(1) of this section and final eligibility determination for enrollment in a QHP, advance payments of the premium tax credit, and cost-sharing reductions.

(3) Not duplicate any eligibility and verification findings already made by the transmitting agency, to the extent such findings are made in accordance with this part.

(4) Not request information or documentation from the individual already provided to another agency administering an insurance affordability program and included in the transmission of information provided on the application or other information transmitted from the other agency.

(5) Determine the individual's eligibility for enrollment in a QHP, advance payments of the premium tax credit, and cost-sharing reductions, promptly and without undue delay, and in accordance with this subpart.

(6) Follow a streamlined process for eligibility determinations regardless of the agency that initially received an application.

(h) Adherence to state decision regarding Medicaid and CHIP. The Exchange and the Exchange appeals entity must adhere to the eligibility determination or appeals decision for Medicaid or CHIP made by the State Medicaid or CHIP agency, or the appeals entity for such agency.

* * * * *

74. Section 155.350 is amended by revising paragraph (a)(1)(ii) to read as follows:

§155.350 Special eligibility standards and process for Indians.

(a) * * *

(1) * * *

(ii) Is expected to have a household income, as defined in 26 CFR 1.36B-1(e) that does not exceed 300 percent of the FPL for the benefit year for which coverage is requested.

* * * * *

75. Section 155.400 is amended by adding paragraph (b)(3) to read as follows:

§155.400 Enrollment of qualified individuals into QHPs.

* * * * *

(b) * * *

(3) Send updated eligibility and enrollment information to HHS promptly and without undue delay, in a manner and timeframe as specified by HHS.

* * * * *

76. Section 155.420 is amended by revising paragraphs (a), (b)(2), (b)(3), adding

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paragraph (b)(4), and revising paragraph (d) to read as follows:

§155.420 Special enrollment periods.

(a) General requirements. (1) The Exchange must provide special enrollment periods consistent with this section, during which qualified individuals may enroll in QHPs and enrollees may change QHPs.

(2) For the purpose of this section, “dependent”, has the same meaning as it does in 26 CFR 54.9801-2, referring to any individual who is or who may become eligible for coverage under the terms of a QHP because of a relationship to a qualified individual or enrollee.

(b) * * *

(2) Special effective dates. (i) In the case of birth, adoption, placement for adoption, or placement in foster care, the Exchange must ensure that coverage is effective for a qualified individual or enrollee on the date of birth, adoption, placement for adoption, or placement in foster care.

(ii) In the case of marriage, or in the case where a qualified individual loses minimum essential coverage, as described in paragraph (d)(1) of this section, the Exchange must ensure that coverage is effective for a qualified individual or enrollee on the first day of the following month.

(iii) In the case of a qualified individual or enrollee eligible for a special enrollment period as described in paragraphs (d)(4), (d)(5), or (d)(9) of this section, the Exchange must ensure that coverage is effective on an appropriate date based on the circumstances of the special enrollment period, in accordance with guidelines issued by

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HHS. Such date must be either—

(A) The date of the event that triggered the special enrollment period under (d)(4), (d)(5), or (d)(9) of this section; or

(B) In accordance with the regular effective dates specified in paragraph (b)(1) of this section.

(3) Option for earlier effective dates. Subject to the Exchange demonstrating to HHS that all of its participating QHP issuers agree to effectuate coverage in a timeframe shorter than discussed in paragraph (b)(1) or (b)(2)(ii) of this section, the Exchange may do one or both of the following for all applicable individuals:

(i) For a QHP selection received by the Exchange from a qualified individual in accordance with the dates specified in paragraph (b)(1) or (b)(2)(ii) of this section, the Exchange may provide a coverage effective date for a qualified individual earlier than specified in such paragraphs.

(ii) For a QHP selection received by the Exchange from a qualified individual on a date set by the Exchange after the fifteenth of the month, the Exchange may provide a coverage effective date of the first of the following month.

(4) Advance payments of the premium tax credit and cost-sharing reductions. Notwithstanding the standards of this section, the Exchange must ensure that advance payments of the premium tax credit and cost-sharing reductions adhere to the effective dates specified in §155.330(f).

* * * * *

(d) The Exchange must allow a qualified individual or enrollee, and, when

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specified below, his or her dependent, to enroll in or change from one QHP to another if one of the following triggering events occur:

(1) The qualified individual or his or her dependent loses minimum essential coverage:

(i) In the case of a QHP decertification, the triggering event is the date of the notice of decertification as described in §155.1080(e)(2); or

(ii) In all other cases, the triggering event is the date the individual or dependent loses eligibility for minimum essential coverage;

(2) The qualified individual gains a dependent or becomes a dependent through marriage, birth, adoption, placement for adoption, or placement in foster care.

(3) The qualified individual, or his or her dependent, which was not previously a citizen, national, or lawfully present individual gains such status;

(4) The qualified individual's or his or her dependent's, enrollment or non-enrollment in a QHP is unintentional, inadvertent, or erroneous and is the result of the error, misrepresentation, or inaction of an officer, employee, or agent of the Exchange or HHS, or its instrumentalities as evaluated and determined by the Exchange. In such cases, the Exchange may take such action as may be necessary to correct or eliminate the effects of such error, misrepresentation, or inaction;

(5) The enrollee or, his or her dependent adequately demonstrates to the Exchange that the QHP in which he or she is enrolled substantially violated a material provision of its contract in relation to the enrollee;

(6) Newly eligible or ineligible for advance payments of the premium tax credit.

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or change in eligibility for cost-sharing reductions. (i) The enrollee is determined newly eligible or newly ineligible for advance payments of the premium tax credit or has a change in eligibility for cost-sharing reductions;

(ii) The enrollee's dependent enrolled in the same QHP is determined newly eligible or newly ineligible for advance payments of the premium tax credit or has a change in eligibility for cost-sharing reductions; or

(iii) A qualified individual or his or her dependent who is enrolled in an eligible employer-sponsored plan is determined newly eligible for advance payments of the premium tax credit based in part on a finding that such individual is ineligible for qualifying coverage in an eligible-employer sponsored plan in accordance with 26 CFR 1.36B-2(c)(3), including as a result of his or her employer discontinuing or changing available coverage within the next 60 days, provided that such individual is allowed to terminate existing coverage. The Exchange must permit an individual who is enrolled in an eligible employer-sponsored plan and will lose eligibility for qualifying coverage in an eligible employer-sponsored plan within the next 60 days to access this special enrollment period prior to the end of his or her existing coverage, although he or she is not eligible for advance payments of the premium tax credit until the end of his or her coverage in an eligible employer-sponsored plan;

(7) The qualified individual or enrollee, or his or her dependent, gains access to new QHPs as a result of a permanent move;

(8) The qualified individual who is an Indian, as defined by section 4 of the Indian Health Care Improvement Act, may enroll in a QHP or change from one QHP to

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another one time per month;

(9) The qualified individual or enrollee, or his or her dependent, demonstrates to the Exchange, in accordance with guidelines issued by HHS, that the individual meets other exceptional circumstances as the Exchange may provide;

* * * *

77. Section 155.430 is amended by revising paragraphs (b)(1), (d)(1), (d)(2)(iii), (d)(2)(iv), (d)(3), and by adding paragraph (d)(7) to read as follows:

§155.430 Termination of coverage.

* * * *

(b) * * *

(1) Enrollee-initiated terminations. (i) The Exchange must permit an enrollee to terminate his or her coverage in a QHP, including as a result of the enrollee obtaining other minimum essential coverage, with appropriate notice to the Exchange or the QHP.

(ii) The Exchange must provide an opportunity at the time of plan selection for an enrollee to choose to remain enrolled in a QHP if he or she becomes eligible for other minimum essential coverage and the enrollee does not request termination in accordance with paragraph (b)(1)(i) of this section. If an enrollee does not choose to remain enrolled in a QHP in such a situation, the Exchange must initiate termination of his or her coverage upon completion of the redetermination process specified in §155.330.

* * * *

(d) * * *

(1) For purposes of this section--

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(i) Reasonable notice is defined as at least fourteen days before the requested effective date of termination; and

(ii) Changes in eligibility for advance payments of the premium tax credit and cost sharing reductions, including terminations, must adhere to the effective dates specified in §155.330(f).

(2) * * *

(iii) On a date on or after the date on which the termination is requested by the enrollee, subject to the determination of the enrollee's QHP issuer, if the enrollee's QHP issuer agrees to effectuate termination in fewer than fourteen days, and the enrollee requests an earlier termination effective date.

(iv) If the enrollee is newly eligible for Medicaid, CHIP, or the BHP, if a BHP is operating in the service area of the Exchange, the last day of QHP coverage is the day before the individual is determined eligible for Medicaid, CHIP, or the BHP.

(3) In the case of a termination in accordance with paragraph (b)(2)(i) of this section, the last day of QHP coverage is the last day of eligibility, as described in §155.330(f), unless the individual requests an earlier termination effective date per paragraph (b)(1) of this section. * * * * *

(7) In the case of a termination due to death, the last day of coverage is the date of death.

* * * * *

78. Section 155.615 is amended by revising paragraph (f)(2)(i) to read as follows:

§155.615 Verification process related to eligibility for exemptions.

* * * * *

(f) * * *

(2) * * *

(i) For any applicant who requests an exemption based on the hardship described in §155.605(g)(2), the Exchange must verify the unavailability of affordable coverage through the procedures used to determine eligibility for advance payments of the premium tax credit, as specified in subpart D of this part, including the procedures described in §155.315(c)(1), and the procedures used to verify eligibility for qualifying coverage in an eligible employer-sponsored plan, as specified in §155.320(d), except as specified in §155.615(f)(2)(ii).

* * * * *

PART 156 –HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

79. The authority citation for part 156 continues to read as follows:

Authority: Sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1324, 1334, 1341, 1342, 1343, 1402, 1413, 1321, 1322, 1331, 1332, 1334, 1341, 1342, 1343, 1401, and 1402 of the Affordable Care Act, Pub. L 111-148, 124 Stat 199.

80. Section 156.270 is amended by revising paragraph (b) to read as follows:

§156.270 Termination of coverage for qualified individuals.

* * * * *

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(b) Termination of coverage notice requirement. If a QHP issuer terminates an enrollee's coverage in accordance with §155.430(b)(1)(i), (ii), or (iii), the QHP issuer must, promptly and without undue delay:

(1) Provide the enrollee with a notice of termination of coverage that includes the termination effective date and reason for termination.

(2) [Reserved]

* * * * *

Dated: May 28, 2013.

Marilyn Tavenner,
Administrator,
Centers for Medicare & Medicaid Services.

Approved: May 31, 2013.

Kathleen Sebelius,
Secretary,
Department of Health and Human Services.

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