

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Parts 147, 155, and 156****[CMS-9980-F]****RIN 0938-AR03****Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation****AGENCY:** Department of Health and Human Services.**ACTION:** Final rule.

SUMMARY: This final rule sets forth standards for health insurance issuers consistent with title I of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, referred to collectively as the Affordable Care Act. Specifically, this final rule outlines Exchange and issuer standards related to coverage of essential health benefits and actuarial value. This rule also finalizes a timeline for qualified health plans to be accredited in Federally-facilitated Exchanges and amends regulations providing an application process for the recognition of additional accrediting entities for purposes of certification of qualified health plans.

DATES: Effective April 26, 2013.**FOR FURTHER INFORMATION CONTACT:**

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Acronym List:

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:

- AV Actuarial Value
- CHIP Children's Health Insurance Program
- CMS Centers for Medicare & Medicaid Services
- DOL U.S. Department of Labor
- EHB Essential Health Benefits
- ERISA Employee Retirement Income Security Act (29 U.S.C. section 1001, et seq.)
- FDA U.S. Food and Drug Administration
- FEDVIP Federal Employees Dental and Vision Insurance Program
- FEHBP Federal Employees Health Benefits Program
- FSA Flexible Spending Arrangement
- HEDIS Healthcare Effectiveness Data and Information Set
- HHS U.S. Department of Health and Human Services
- HIOS Health Insurance Oversight System
- HMO Health Maintenance Organization
- HRA Health Reimbursement Arrangement
- HSA Health Savings Account
- IOM Institute of Medicine
- ICR Information Collection Requirements
- IRS Internal Revenue Service
- MV Minimum Value
- NAIC National Association of Insurance Commissioners
- OMB Office of Management and Budget
- OPM U.S. Office of Personnel Management
- PHSAct Public Health Service Act
- PRA Paperwork Reduction Act
- QHP Qualified Health Plan
- SHOP Small Business Health Options Program
- SSA Social Security Administration
- The Act Social Security Act
- The Code Internal Revenue Code of 1986
- USP United States Pharmacopeia

Executive Summary: Beginning in 2014, all non-grandfathered health

insurance coverage in the individual and small group markets, Medicaid benchmark and benchmark-equivalent plans, and Basic Health Programs (if applicable) will cover essential health benefits (EHB), which include items and services in 10 statutory benefit categories, such as hospitalization, prescription drugs, and maternity and newborn care, and are equal in scope to a typical employer health plan. In addition to offering EHB, non-grandfathered health insurance plans will meet specific actuarial values (AVs): 60 percent for a bronze plan, 70 percent for a silver plan, 80 percent for a gold plan, and 90 percent for a platinum plan. These AVs, called “metal levels,” will assist consumers in comparing and selecting health plans by allowing a potential enrollee to compare the relative payment generosity of available plans. Taken together, EHB and AV will significantly increase consumers' ability to compare and make an informed choice about health plans.

The Department of Health and Human Services (HHS) has provided information on EHB and AV standards in several phases. On December 16, 2011, HHS released a bulletin¹ (the EHB Bulletin) following a report from the U.S. Department of Labor (DOL)² describing the scope of benefits typically covered under employer-sponsored coverage and an HHS-commissioned study from the Institute of Medicine (IOM)³ recommending the criteria and methods for determining and updating the EHB. The EHB Bulletin outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. Shortly thereafter, on January 25, 2012, HHS released an illustrative list of the largest three small group market products by state, which was updated on July 2, 2012.⁴ HHS further clarified the approach described in the EHB Bulletin through a series of Frequently Asked Questions (FAQs),⁵ released on

¹ “Essential Health Benefits Bulletin.” December 16, 2011. Available at: http://ccio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.

² “Selected Medical Benefits: A report from the Department of Labor to the Department of Health and Human Services.” April 15, 2011. Available at: <http://www.bls.gov/ncs/ebs/sp/selmedbensreport.pdf>.

³ Institute of Medicine, “Essential Health Benefits: Balancing Coverage and Cost.” October 6, 2011. Available at: <http://www.iom.edu/Reports/2011/Essential-Health-Benefits-Balancing-Coverage-and-Cost.aspx>.

⁴ “Essential Health Benefits: List of the Largest Three Small Group Products by State.” July 3, 2012. Available at: <http://ccio.cms.gov/resources/files/largest-smgroup-products-7-2-2012.pdf.PDF>.

⁵ “Frequently Asked Questions on Essential Health Benefits Bulletin.” February 17, 2012.

February 17, 2012. On July 20, 2012, HHS published a final rule⁶ authorizing the collection of data to be used under the intended process for states to select from among several benchmark options to define EHB.

HHS also published a bulletin⁷ outlining an intended regulatory approach to calculations of AV and implementation of cost-sharing reductions on February 24, 2012 (the AV/CSR Bulletin). Specifically, HHS outlined an intended regulatory approach for the calculation of AV, de minimis variation standards, and silver plan variations for individuals eligible for cost-sharing reductions among other topics. As described in section IB of this preamble, “Stakeholder Consultation and Input,” HHS reviewed and considered comments on both the EHB and AV/CSR bulletins in developing the notice of proposed rulemaking and this final rule.

In addition, this rule finalizes an amendment to 45 CFR 156.275, as published on July 20, 2012 (77 FR 42658), which established the first phase of an intended two-phase approach to recognizing accrediting entities. As directed under law, recognized entities will implement the standards established under the Affordable Care Act for qualified health plans (QHPs) to be accredited on the basis of local performance on a timeline established by the Exchange. The amendment to phase one included here does not alter recognition of the National Committee for Quality Assurance (NCQA) and URAC as published in the **Federal Register** notice on November 23, 2012 (77 FR 70163). The amendment provides an opportunity for additional accrediting entities meeting the conditions in listed § 156.275 to be recognized by the Secretary, until phase two is in effect. This opportunity includes an application and review process. This final rule also sets forth a timeline for the accreditation standard for the purposes of QHP certification in Federally-facilitated Exchanges.

I. Background

A. Legislative Overview

Section 1302 of the Affordable Care Act provides for the establishment of an EHB package that includes coverage of EHB (as defined by the Secretary of the Department of Health and Human Services (the Secretary)), cost-sharing limits, and AV requirements. The law directs that EHB be equal in scope to the benefits covered by a typical employer plan and cover at least the following 10 general EHB categories: Ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral⁸ and vision care. Sections 1302(b)(4)(A) through (D) of the Affordable Care Act establish that the Secretary must define EHB in a manner that (1) reflects appropriate balance among the 10 statutory EHB categories; (2) is not designed in such a way as to discriminate based on age, disability, or expected length of life; (3) takes into account the health care needs of diverse segments of the population; and (4) does not allow denials of EHB based on age, life expectancy, or disability. Sections 1302(b)(4)(E) and (F) of the Affordable Care Act further direct the Secretary to consider the provision of emergency services and dental benefits when determining whether a particular health plan covers EHB. Finally, sections 1302(b)(4)(G) and (H) of the Affordable Care Act specify that the Secretary periodically review the EHB, report the findings of such review to the Congress and to the public, and update the EHB as needed to address any gaps in access to care or advances in the relevant evidence base. Section 1311(d)(3)(B) of the Affordable Care Act establishes that states may require a QHP to cover additional benefits beyond those in the EHB, provided that the state defrays the costs of such required benefits.

As first described in Public Health Service (PHS) Act section 2711,⁹ to

determine which benefits are EHB for purposes of complying with PHS Act section 2711 and its implementing regulations, the Departments of Labor, Treasury, and HHS will consider a self-insured group health plan, a large group market health plan, or a grandfathered group health plan to have used a permissible definition of EHB under section 1302(b) of the Affordable Care Act if the definition is one that is authorized by the Secretary of HHS (including any available benchmark option, supplemented as needed to ensure coverage of all ten statutory categories). Furthermore, the Departments intend to work with those plans that make a good faith effort to apply an authorized definition of EHB to ensure there are no annual or lifetime dollar limits on EHB.

Section 1301(a)(1)(B) of the Affordable Care Act directs all issuers of QHPs to cover the EHB package described in section 1302(a) of the Affordable Care Act, including coverage of the services described in section 1302(b), adhering to the cost-sharing limits described in section 1302(c), and subject to 1302(e), meeting the AV levels established in section 1302(d). Section 2707(a) of the PHS Act extends the coverage of the EHB package to issuers of non-grandfathered individual and small group policies beginning with plan years starting on or after January 1, 2014, irrespective of whether such issuers offer coverage through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost-sharing under the plan does not exceed the limitations described in sections 1302(c)(1) and (2) of the Affordable Care Act.

Section 1302(d)(2) of the Affordable Care Act describes the levels of coverage that section 1302(a)(3) includes in the EHB package: 60 percent for a bronze plan, 70 percent for a silver plan, 80 percent for a gold plan, and 90 percent for a platinum plan. Section 1302(d)(3) directs the Secretary to develop guidelines that allow for de minimis variation in AV calculations.

Section 1311(c)(1)(D)(i) of the Affordable Care Act directs a health plan to “be accredited with respect to local performance on clinical quality measures * * * by any entity recognized by the Secretary for the accreditation of health insurance issuers or plans (so long as any such entity has transparent and rigorous methodological and scoring criteria).” Section 1311(c)(1)(D)(ii) requires that QHPs

been issued at the time of publication of the regulations implementing PHS Act section 2711.

Available at: <http://ccio.cms.gov/resources/files/Files2/02172012/ehb-faq-508.pdf>.

⁶ Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, Final Rule, 77 FR 42658–42672 (July 20, 2012) (to be codified at 45 CFR part 156).

⁷ “Actuarial Value and Cost-Sharing Reductions Bulletin.” February 24, 2012. Available at: <http://ccio.cms.gov/resources/files/Files2/02242012/Av-csr-bulletin.pdf>.

⁸ We note that the Affordable Care Act uses the terms “dental” and “oral” interchangeably when referring to the pediatric dental care category of EHB (see, e.g., section 1302(B)(1)(J), referring to pediatric oral care, and section 1311(d)(2)(B)(ii), referring to stand-alone dental benefits). Similarly, we intend for purposes of the EHB rule that these terms be used without distinction.

⁹ See 75 FR 37188, 37191 (June 28, 2010). The regulations define “essential health benefits” by cross-reference to section 1302(b) of the Affordable Care Act and applicable regulations, which had not

“receive such accreditation within a period established by an Exchange * * *”. In a final rule published on July 20, 2012 (77 FR 42658), because NCQA and URAC already met the statutory requirements, they were recognized as accrediting entities on an interim basis, subject to the submission of documentation required in 45 CFR 156.275(c)(4). This recognition is now effective as indicated in the **Federal Register** notice (77 FR 70163) published on November 23, 2012, titled “Recognition of Entities for the Accreditation of Qualified Health Plans.”

In this final rule, HHS establishes a process by which accrediting entities that are not already recognized can submit an application to be recognized and a proposed notice and final notice process for recognizing any new accrediting entities. This final rule also sets forth a timeline for the accreditation requirement in a Federally-facilitated Exchange.

B. Stakeholder Consultation and Input

HHS consulted with interested stakeholders on several policies related to EHB, AV, 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. In addition, HHS consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with states through the process of awarding and monitoring grants for the establishment of Exchanges, Medicaid consultations, and meetings with tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties.

HHS received approximately 11,000 comments in response to the EHB Bulletin. Commenters represented a wide variety of stakeholders, including health insurance issuers, consumers, health providers, states, employers, employees, and Members of Congress. In the proposed rule, we noted that these comments were considered as the policies were developed and were also discussed throughout the preamble of the proposed rule. HHS has consulted with and will continue to consult with federally recognized tribes on the provisions of this rule that impact tribes.

II. Provisions of the Regulation and Analysis of and Responses to Public Comments

The proposed rule, titled “Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation” (77 FR 70644), was published in the **Federal Register** on November 26, 2012. In that rule, we proposed to codify regulations in 45 CFR parts 147, 155, and 156. For Part 147, we proposed standards for health insurance issuers in the small group and individual markets related to health insurance reforms. For Part 155, we proposed standards for states seeking to require benefits in addition to those in EHB and outlined the proposed standards for Exchanges related to the QHP accreditation timeline. Additionally, for Part 156, we proposed standards relating to EHB and AV, as well as relating to accreditation of QHP issuers. These standards apply only in the individual and small group markets, and not to Medicaid benchmark or benchmark-equivalent plans. In a proposed rule, released on January 14, 2013, titled “Medicaid, Children’s Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefits 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,”¹⁰ CMS proposed EHB applicability to Medicaid.

We received approximately 5,798 public comments including roughly 600 total unique letters on the essential health benefit proposals, including comments from states, health plans, industry experts, health care providers, Members of Congress, consumer groups, and members of the public. Many non-unique comments concerned coverage of lactation services, medical foods, acupuncture services, maternity coverage for dependents, and cost sharing for mental health services. Many commenters expressed concern about the comprehensiveness of the proposed benchmark standard, the balance between affordability and state

flexibility, and the length of the public comment period. In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing.

The comments and our responses to general comments are set forth below.

Comment: Several commenters were concerned that the 30-day comment period was not an adequate amount of time to provide sufficient feedback on the proposed regulation. Specifically, many commenters requested a 60-day comment period, but provided no substantive comment.

Response: CMS provided a 30-day comment period, which is consistent with the Administrative Procedure Act and the policy established by the Assistant Secretary for Administration (ASA) and the Office of Management and Budget (OMB). We note that CMS previously allowed for an extended comment period on the EHB Bulletin, which outlined the intended policy in the proposed rule. CMS believes that interested stakeholders had adequate opportunity to provide comment on the policies established in this final rule.

A. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Subpart B—Requirements Relating to Health Care Access

a. Coverage of EHB (§ 147.150)

Section 2707(a) of the PHS Act, as added by the Affordable Care Act, directs health insurance issuers that offer non-grandfathered health insurance coverage in the individual or small group market to ensure that such coverage includes the EHB package, which is defined under section 1302(a) of the Affordable Care Act to include the coverage of EHB, application of cost-sharing limitations, and AV requirements (plans must be a bronze, silver, gold, or platinum plan, or a catastrophic plan).

Section 1255 of the Affordable Care Act provides that this EHB package standard applies starting the first plan year for the small group market or policy year for the individual market beginning on or after January 1, 2014. In 45 CFR 147.150(a), we implement the requirement in section 2707(a) of the PHS Act that a health insurance issuer that offers health insurance coverage in the individual or small group market—inside or outside of the Exchange—ensures that such coverage offers the EHB package.

Section 2707(b) of the PHS Act provides that a group health plan shall ensure that any cost-sharing

¹⁰ Medicaid, Children’s Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefits 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, 78 FR 4594 (proposed January 22, 2013) (to be codified at 42 CFR parts 430, 431, 433, 435, 440, 447, and 457 and 45 CFR part 155).

requirements under the plan does not exceed the limitations provided for under section 1302(c)(1), annual limitation on cost-sharing, and (c)(2), annual limitation on deductibles, of the Affordable Care Act. Section 715(a)(1) of the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) of the Internal Revenue Code (the Code) incorporate section 2707(b) of the PHS Act into ERISA and the Code. In the preamble to the proposed rule, HHS, DOL, and the Department of the Treasury state that they read section 2707(b) to apply the deductible limit described in section 1302(c)(2) of the Affordable Care Act only to plans and issuers in the small group market and not to self-insured group health plans, large group health plans, or health insurance issuers offering health insurance coverage in the large group market. However, no rules to implement that interpretation were proposed at that time and we noted that section 147.150(b) would be reserved. The three Departments intend to engage in future rulemaking to implement section 2707(b) but, in light of comments received on the interpretation of section 2707(b), are explaining in more detail here our intended approach to this provision and the application of the section 1302(c)(1) and (2) cost-sharing limits to group health plans. Section 2707(b) provides that “[a] group health plan shall ensure that any annual cost sharing imposed under the plan does not exceed the limitations provided for under paragraphs (1) and (2) of section 1302(c).” We recognize the potential ambiguity in this reference to the limitations provided under section 1302(c)(1) and (2) of the Affordable Care Act. As noted below in response to comments, we read section 2707(b) as requiring all group health plans to comply with the annual limitation on out-of-pocket maximums described in section 1302(c)(1),¹¹ annual limitation on cost-sharing. At the same time, consistent with the approach described in the preamble to the proposed rule, we continue to believe that only plans and issuers in the small group market are subject to the deductible limits described in section 1302(c)(2).

We believe there are two alternative reads of the statute that give strong textual support for this interpretation of the relationship between of section 2707(b) and section 1302(c)(2) and lead to effectively the same result. The first interpretation would implement section

2707(b)’s direction that group health plans comply with section 1302(c)(1) and (2) by substituting the term “group health plan” from section 2707(b) where the term “health plan” appears in section 1302(c)(1) and (2). The annual limitation on cost-sharing in section 1302(c)(1) applies to all “health plan[s],” and so under this interpretation that limitation would apply to all “group health plan[s].” In contrast, the annual limitation on deductibles in section 1302(c)(2) applies only to “health plan[s] offered in the small group market,” and so under this interpretation that limitation would apply only to insured small group market health plans.

Under the second interpretation we see as consistent with the statutory text, section 2707(b) could be read to require all group health plans to comply with both the annual limitation on cost-sharing in section 1302(c)(1) and the annual limitation on deductibles in section 1302(c)(2). Section 1302(c)(2)(C), however, provides that the cap on deductibles shall be applied in such a manner so as not to affect the actuarial value of the plan. If the limitation on deductibles were interpreted to apply to large and self-insured group health plans, the Departments would engage in rulemaking to implement this provision broadly, so as to provide relief to large and self-insured group health plans in cases where complying with the limit on deductibles would affect the actuarial value of those plans. We anticipate that we would develop the applicable parameters in separate rulemaking that would take into consideration the differences in applying the concept of actuarial value to large and self-insured group health plans that do not have to meet the level of coverage requirements that are part of the EHB package.

In addition, section 2707(c) of the PHS Act provides that an issuer offering any level of coverage specified under section 1302(d) of the Affordable Care Act offer coverage in that level as a plan in which the only enrollees are individuals who have not yet attained the age of 21. We codify this standard in 45 CFR 147.150(c).

Comments received regarding § 147.150(a) and (c) are addressed in other sections of this preamble that are more relevant to the substance of the comments. We also received comments addressing the suggested interpretation of section 2707(b) and how the limitations on cost-sharing should apply to all group health plans.

Comment: Some commenters requested that self-insured plans be exempt from the cost sharing limits

described in § 156.130(a). Several of these comments indicated operational concerns with applying a single annual limitation on cost sharing to EHB that are administered by separate contractors; in particular, commenters noted the practice of using a pharmacy benefit manager to administer prescription benefits separately from other medical benefits. Other commenters agreed with the legal read that cost sharing limits described in § 156.130(a) apply to all group health plans.

Response: We note that DOL also received correspondence on this issue seeking clarification of how the three Departments would interpret section 2707(b) of the PHS Act and the corresponding provisions in ERISA and the Code. As discussed in more detail above, the three Departments interpret these provisions to mean that large group market and self-insured group health plans must comply with the annual limitation on out-of-pocket maximums described in section 1302(c)(1).

Nevertheless, the Departments are concerned about the operational and timing issues raised by commenters, and find that some transitional relief is appropriate. Accordingly, the three Departments are issuing concurrent sub-regulatory guidance identifying an enforcement safe harbor for large and self-insured group health plans to address those operational concerns.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 147.150 of the proposed rule with two technical edits to paragraph (c) to conform to the underlying statutory authority, including adding to paragraph (c) the following language “as a plan in which the only enrollees are,” to clarify that the child-only coverage offered by an issuer under this section must be a plan with only child enrollees.

B. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act State-Required Benefits

Section 1311(d)(3)(B) of the Affordable Care Act explicitly permits a state, at its option, to require QHPs to offer benefits in addition to EHB, but requires the state to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional benefits. We proposed that state-required benefits enacted on or before December 31, 2011 (even if not effective

¹¹ Note that PHS Act section 2707 is not applicable to grandfathered health plans. See 26 CFR 54.9815–1251T, 29 CFR 2590.715–1251, 45 CFR 147.140.

until a later date) may be considered EHB, which would obviate the requirement for the state to defray costs for these state-required benefits. We also proposed that these state-required benefits that are not included in the benchmark would apply to QHP markets in the same way they apply in the current market. This policy regarding state-required benefits is intended to apply for at least plan years 2014 and 2015. This two year transitional period accommodates current market offerings and limits market disruption in the first years of the Exchanges.

Under the Affordable Care Act, state payment for state-required benefits only applies to QHPs. Since the Exchange is responsible for certifying QHPs, we proposed that the Exchange identify which additional state-required benefits, if any, are in excess of the EHB.

We additionally proposed that the calculations of the cost of additional benefits be made by a member of the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies. We also proposed the calculation be done prospectively to allow for the offset of an enrollee's share of premium and for purposes of calculating the premium tax credit and reduced cost sharing.¹²

The comments and our responses to § 155.170 are set forth below.

Comment: Some commenters were concerned that including all state-required benefits enacted before December 31, 2011 in EHB would increase costs for covered individuals. However, most who commented on inclusion of state-required benefits favored this policy.

Response: Research by the HHS Office of the Assistant Secretary for Planning and Evaluation found that the majority of required benefits have a negligible impact on premiums.¹³

Comment: Some commenters suggested that states should make monthly payments to only the issuer on behalf of the enrollee, and that payments to the enrollee directly should not be permitted.

Response: Section 1311(d)(3)(B) of the Affordable Care Act directs the state to

make payments either to the individual enrollee or to the issuer, and regulatory language reflects that statutory requirement. We are retaining our proposed approach as final and will permit states to either make payments to individuals or issuers, as applicable.

Comment: Some commenters suggested that we should require the state to defray any cost associated with other types of state requirements, such as rules regarding reimbursement to certain providers, anti-discrimination laws, and rules specific to benefit delivery method.

Response: As we explained in the preamble of the proposed rule, we interpret "state-required benefits" to include the care, treatment and services that an issuer must provide to its enrollees. Other state laws that do not relate to specific benefits, including those relating to providers and benefit delivery method, are not addressed in § 155.170.

Comment: In the proposed rule we requested comment on whether the state should make payments based on the statewide average cost of additional state-required benefits that are outside the scope of EHB or make payments based on each QHP issuer's actual cost. Several commenters noted that each QHP issuer's cost may vary due to differences in market share and enrollee pool, and those commenters favored payments based on actual cost. Other commenters recommended that payments should be based on the average benefit cost for the relevant geographic area.

Response: We believe that states may wish to take different approaches, basing payments on either statewide average or each issuer's actual cost. Therefore, we are not establishing a standard in this final rule but permit both options for calculating state payments, at the election of the state.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 155.170 of the proposed rule without modification.

Accreditation Timeline (§ 155.1045)

In § 155.1045, we proposed to redesignate the existing paragraph as paragraph (a) and to add a new paragraph (b) to set forth the timeline for accreditation as a QHP certification requirement in the Federally-facilitated Exchanges (including State Partnership Exchanges). This provision is consistent with § 156.275(a), in which we required that all QHP issuers must be accredited with respect to local performance of

their QHPs on the timeline established by the Exchange.

The comments and our responses to § 155.1045 are set forth below.

Comment: Several commenters supported the proposal to phase-in accreditation standards for QHP issuers participating in a Federally-facilitated Exchange. Other commenters did not support this approach and requested that QHP issuer accreditation, as defined in 45 CFR 156.275, be required for QHP issuers beginning in 2013.

Response: HHS is finalizing the accreditation timeline for QHP issuers in the Federally-facilitated Exchanges as proposed. We proposed a phased approach in order to accommodate issuers without existing accreditation and new issuers. We believe that accepting existing accreditation from an issuer's commercial, Medicaid, or Exchange products and phasing in accreditation requirements for issuers without existing accreditation will expand QHP choices available to consumers while ensuring that all QHP issuers commit to delivering high quality care. Creating a phased approach for these requirements also provides issuers and recognized accrediting entities with sufficient time to schedule and conduct accreditation reviews, which can take as long as 18 months.

Comment: Several commenters requested clarification of the requirements specified in proposed § 155.1045(b)(2) and (3) and the meaning of being accredited in accordance with § 156.275.

Response: As stated above, HHS proposed a phased approach to accreditation for the Federally-facilitated Exchanges. In paragraph (b)(2), we proposed that a QHP issuer must be accredited on their policies and procedures that are applicable to their Exchange products, or a QHP issuer must have commercial or Medicaid health plan accreditation granted by a recognized accrediting entity for the same state in which the issuer is offering Exchange coverage and the administrative policies and procedures underlying that accreditation must be the same or similar to the administrative policies and procedures used in connection with the QHP. In paragraph (b)(3), we direct issuers of QHPs to be accredited in accordance with all of the standards specified in § 156.275, including performance measurement reporting required at (a)(1)(i) and (ii) of § 156.275 and the reporting of clinical performance measures and patient experience ratings on a standardized Consumer Assessment of Health Providers and Systems® (CAHPS) survey. We are adopting this phased

¹² Section 36B(b)(3)(D) of the Code specifies that the portion of the premium allocable to required additional benefits shall not be taken into account in determining a premium tax credit. Likewise, section 1402(c) of the Affordable Care Act specifies that cost-sharing reductions do not apply to required additional benefits.

¹³ "Essential Health Benefits: Comparing Benefits in Small Group Products and State and Federal Employee Plans." ASPE Research Brief, December 2011. Available at: <http://aspe.hhs.gov/health/reports/2011/marketcomparison/rb.pdf>.

approach to accreditation to align with the earliest possible time that issuers are able to report performance data on their QHP population as part of the accreditation process. We acknowledged in earlier guidance¹⁴ that performance data on an issuer's QHP population will not be available until a full-year of data are available (for example, in 2015 based on the 2014 coverage year).

Comment: One commenter questioned if accreditation at the Exchange product type level would be methodologically sound in 2016 and requested a delay of several years in the requirement at § 155.1045(b)(3) which requires QHP issuers to be accredited in accordance with 45 CFR 156.275 as early as 2016 certification for the 2017 coverage year.

Response: We are requiring performance measurement reporting at the Exchange product type level as part of accreditation required in 2016 to align with the earliest possible time that issuers are able to report performance data on their QHP population. As finalized in 45 CFR 156.275(c)(2)(iii),¹⁵ there is an exception to the Exchange product type level accreditation requirement if the recognized accrediting entity demonstrates that the Exchange product type accreditation is not methodologically sound for a particular issuer.

Comment: One commenter suggested that State-based Exchanges should be encouraged to follow the accreditation timeline set forth for a Federally-facilitated Exchange.

Response: As specified in 45 CFR 155.1045(a), Exchanges must establish a uniform period within which a QHP issuer must become accredited. State-based Exchanges are able to align with the proposed Federally-facilitated Exchange timeline if they choose. This provision was finalized in the Exchange Establishment Final Rule.¹⁶

Comment: Some commenters urged HHS to take additional steps to monitor and oversee QHP quality, aside from accreditation.

Response: Issuers participating in Exchanges need to meet the range of standards for certification which are

included in 45 CFR part 156. As part of plan management functions, Exchanges will be responsible for managing certain types of consumer complaints about QHP issuers, examining potential QHP issuer non-compliance with applicable laws, and ensuring ongoing compliance with the QHP certification standards. We believe these requirements, including processes for issuer recertification and decertification will ensure adequate oversight of issuers participating in a Federally-facilitated Exchange. Additionally, we anticipate future rulemaking on QHP issuer quality reporting requirements, including a QHP-specific quality rating as required by section 1311(c)(3) of the Affordable Care Act.

Comment: Several commenters asked for clarification regarding how HHS will determine if an issuer has existing commercial, Medicaid, or Exchange accreditation. Several commenters noted that Medicaid managed care plans may not be licensed as "issuers." Other commenters questioned if HHS would accept accreditation from a company's Preferred Provider Organization product if it is accredited on a different legal entity than the company's Health Maintenance Organization (HMO) product.

Response: The Exchange Establishment Final Rule, at 45 CFR 155.20, defines "health insurance issuer or issuer" by cross-referencing the definition of health insurance issuer as defined in 45 CFR 144.103: A health insurance issuer means "an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a state and that is subject to state law that regulates insurance (within the meaning of section 514(b)(2) of ERISA)." This term does not include a group health plan. We consider issuers, as defined above, to have existing accreditation if they are accredited with respect to the product type at issue under the same legal entity as the one that is offering such a product in the Exchange. We plan to issue future guidance as to the process by which issuers may demonstrate how they meet the accreditation standard.

Comment: One commenter asked that HHS clarify that a federally-facilitated Exchange will accept any existing health plan accreditation on issuers' commercial or Medicaid lines of business, in the same state as the Exchange in which the issuer is seeking to offer coverage, at the overall QHP issuer level.

Response: As we stated in a previously issued rule,¹⁷ accreditation at the Exchange product type level balances capturing the QHP experience and enabling the reporting of valid and reliable performance measures. An issuer may offer multiple QHPs under the same product type, in the same Exchange; if the product type for that Exchange is accredited, each of the corresponding QHPs would be considered to be accredited.

Comment: Some commenters questioned whether an issuer would meet the standard in § 155.1045(b) if the recognized accrediting entity that had awarded the accreditation modified its accreditation standards. One commenter specifically asked whether a QHP issuer would meet the similarity standard described in § 155.1045(b)(2) if the recognized accrediting entity loses its recognition.

Response: We view these comments as pertaining to the meaning of being accredited as required in § 156.275. We would consider issuers whose recognized accrediting entity modified its requirements or lost its recognition as being accredited, provided that the accrediting entity was recognized by HHS and accredited as meeting the standards identified in § 156.275 when the accreditation was awarded. These issuers would meet the requirements in § 156.275 and, therefore, the timeliness and similarity standards described in § 155.1045(b). Further, we do not anticipate that phase one recognized accrediting entities are likely to lose their recognition because § 156.275(c)(4)(ii) requires that recognized accrediting entities provide to HHS any proposed changes or updates to the accreditation standards and requirements, processes, and measure specifications for performance measures with 60 days' notice prior to public notification.¹⁸ Therefore, HHS would have ample time to analyze the entity's changes and assess if the changes should result in the loss of recognition.

Comment: Several commenters requested that HHS exempt certain types of plans or issuers from the accreditation requirements, such as CO-OPs and Medicaid managed care plans,

¹⁴ General Guidance on Federally-facilitated Exchanges, May 16, 2012. Available at <http://ccio.cms.gov/resources/files/jfe-guidance-05-16-2012.pdf>.

¹⁵ Patient Protection and Affordable Care Act; Data Collection To Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, 77 FR 42658 (July 20, 2012).

¹⁶ "Establishment of Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; Final Rule and Interim Final Rule" (77 FR 18310 (March 27, 2012)). Available at <http://www.gpo.gov/fdsys/pkg/FR-2012-03-27/pdf/2012-6125.pdf>.

¹⁷ Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, Final Rule, 77 FR 42658, -42665-42666 (July 20, 2012) (to be codified at 45 CFR 156.275(c)(2)(iii)).

¹⁸ 45 CFR 156.275(c)(2) was finalized in the final rule, Patient Protection and Affordable Care Act; Data Collection To Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, 77 FR 42658 (July 20, 2012).

or provide a different accreditation timeline for these issuers.

Response: Under 45 CFR 155.1045(a) Exchanges are responsible for establishing a timeline for which all QHP issuers must be accredited. The timeline for accreditation must be applied consistently across QHP issuers. The phased process was developed in part to accommodate new issuers, including CO-OP, and Medicaid plans without existing accreditation.

Comment: A commenter asked for clarification on the applicability of the accreditation requirements to stand-alone dental plans.

Response: The preamble to the Exchange Establishment Final Rule specifies that to the extent that accreditation standards specific to stand-alone dental plans do not exist, then such plans would not be required to meet the accreditation requirement or the accreditation timeline required by 45 CFR 155.1045.

Comment: Several commenters made recommendations as to when in the QHP certification year a QHP issuer must be accredited in order to be considered to have met the standards proposed in 45 CFR 155.1045(b)(1), (2), and (3). One commenter recommended requiring issuers to crosswalk their existing accredited policies or procedures to their QHP products.

Response: HHS will be issuing forthcoming guidance on how the accreditation requirements will be operationalized as part of the QHP certification process in the Federally-facilitated Exchanges.

Comment: Several commenters submitted comments in regard to the U.S. Office of Personnel Management's (OPM) Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges Notice of Proposed Rulemaking, 77 FR 72582 ¹⁹ (December 5, 2012) on accreditation of multi-state plans (MSPs).

Response: HHS has determined that these comments are outside the scope of this rule. As noted in § 155.1045(a), the timeline for accreditation for multi-state plans will be set by OPM.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing § 155.1045 of the proposed rule without modification.

C. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. Subpart A—General Provisions

In § 156.20, we proposed to add the following definitions as follows:

Actuarial Value and Percentage of the Total Allowed Costs of Benefits

We proposed to define “actuarial value (AV)” as the percentage paid by a health plan of the total allowed costs of benefits. We proposed to define the “percentage of the total allowed costs of benefits” as the anticipated covered medical spending for EHB coverage (as defined in § 156.110 (a)) paid by a health plan for a standard population, computed in accordance with the health plan's cost sharing, divided by the total anticipated allowed charges for EHB coverage provided to the standard population, and expressed as a percentage.

Because section 1302(d)(2) of the Affordable Care Act refers to AV relative to coverage of the EHB for a standard population, we proposed these definitions together in order to provide that AV is the percentage that represents the total allowed costs of benefits paid by the health plan, based on the provision of EHB as defined for that plan according to § 156.115.

Benchmark Plans

Under the benchmark selection and standards proposed in §§ 156.100 and 156.110, we believe it is important to differentiate between the plan selected by a state (or through the default process in § 156.100(c)), which we proposed to call the “base-benchmark plan,” and the benchmark standard that EHB plans will need to meet, which we proposed to call the “EHB-benchmark plan.”

We proposed that “base-benchmark plan” means that the plan that is selected by a state from the options described in § 156.100(a), or a default benchmark plan, as described in § 156.100(c), prior to any adjustments made to meet the benchmark standards described in § 156.110.

We proposed that “EHB-benchmark plan” means that the standardized set of EHB that must be met by a QHP or other issuer as required by § 147.150.

We proposed that “Essential health benefits package or EHB package” means the scope of covered benefits and associated limits of a health plan offered by an issuer, as set forth in section 1302(a) of the Affordable Care Act. The EHB package provides at least the ten statutory categories of benefits, as described in 45 CFR 156.110(a);

provides benefits in the manner described in § 156.115; limits cost-sharing for such coverage as described in § 156.130; and subject to offering catastrophic plans as described in section 1302(e) of the Affordable Care Act, provides distinct levels of coverage as described in 45 CFR 156.140.

The comments and our responses to the proposed changes to § 156.20 are set forth below.

Comment: Several commenters urged HHS to provide uniform, standardized definitions for certain terms used throughout the regulation relating to cost sharing.

Response: Terms used throughout the regulation are standard terms of art that are understood in the industry, therefore we will not provide additional definitions.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.20 of the proposed rule, without substantive modifications. We note that we have made technical corrections to clarify that “EHB package” and “essential health benefits package” are the same.

2. Subpart B—EHB Package

a. State Selection of Benchmark (§ 156.100)

In § 156.100, we proposed to set forth the criteria for the selection process if a state chooses to select a benchmark plan. The EHB-benchmark plan would apply to non-grandfathered health insurance coverage offered in the individual or small group markets. The EHB-benchmark plan would serve as a reference plan, reflecting both the scope of services and limits offered by a typical employer plan in that state. This approach and benchmark selection would apply for at least the 2014 and 2015 benefit years.

Consistent with the approach outlined in the EHB Bulletin, in § 156.100(a) we proposed that the state may select its base-benchmark plan from among the following four types of health plans: (1) The largest plan by enrollment in any of the three largest small group insurance products in the state's small group market as defined in § 155.20; (2) any of the largest three state employee health benefit plans by enrollment; (3) any of the largest three national Federal Employees Health Benefits Program (FEHBP) plan options by enrollment that are open to Federal employees; or (4) the largest insured commercial non-Medicaid HMO operating in the state. Data from the first quarter two years

¹⁹ “Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges” (77 FR 72582 (December 5, 2012)). Available at: <http://www.gpo.gov/fdsys/pkg/FR-2012-12-05/pdf/2012-29118.pdf>.

prior to the coverage year would be used to determine plan enrollment. HHS also made available benefit data for the single largest Federal Employees Dental and Vision Insurance Program (FEDVIP) dental and vision plans respectively, based on enrollment.

Section 156.100(a)(1) would reflect a typical plan in the state's small group market and provides state flexibility as recommended by the IOM in its report.²⁰ The remaining proposed benchmark plan options, in § 156.100(a)(2) through (a)(4), would reflect the benchmark approach used in Medicaid, as defined in 42 CFR 440.330, and in the Children's Health Insurance Plan (CHIP), as defined in 42 CFR 457.410 and 457.420.

Because the PHS Act defines "state" to include the U.S. territories (Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands), the PHS Act requirements related to EHB, as established by section 1302 of the Affordable Care Act, apply to the territories.

At § 156.100(b), we proposed the standard for approval of a state-selected EHB-benchmark plan.

We proposed that the state's benchmark plan selection in 2012 would be applicable for at least the 2014 and 2015 benefit years and stated that we intend to revisit this policy for subsequent years. This two year transitional period accommodates current market offerings and limits market disruption in the first years of the Exchanges.

In § 156.100(c), we proposed that if a state did not make a benchmark plan selection, the default base-benchmark plan would be the largest plan by enrollment in the largest product by enrollment in the state's small group market. Each state's benchmark is specified in Appendix A with a detailed set of benefits available at www.cciio.cms.gov.

The comments and our responses to § 156.100 are set forth below.

Comment: Some commenters preferred a different benchmark plan than the selection proposed in Appendix A of the proposed rule. Commenters suggested that the proposed benchmark was inconsistent with the typical employer plan in the state, and/or the scope of benefits was not sufficiently comprehensive. Several commenters recommended that HHS have a single, uniform federal EHB

package because they are concerned that the proposed benchmark options have a large degree of variation in covered benefits which may lead to inconsistent EHB packages from state to state. We also received several comments indicating that the "top three small group products in each state" approach to the benchmark selection was not the best option for the default benchmark plan, and that FEHBP would have been a better alternative. Several commenters believed that offering plan benefit packages created for adults or families may not be considered sufficient to meet the requirement to provide child-only coverage and that we should provide child-specific benchmark plans such as states' CHIP plans as a more appropriate child-only plan option.

Response: The benchmark approach for defining EHB sought to balance the statutory ten benefit categories and affordability while providing states—the primary regulators of health insurance markets—with flexibility. The benchmark plan options for each state reflect the scope of benefits and services typically offered in the employer market in that state. This approach meets the statutory requirement that EHB reflect a typical employer plan as well as the recommendation provided by the IOM on the approach to defining EHB. Prior to the release of the proposed rule and during the comment period prior to the release of the final rule, HHS held multiple discussions with states regarding specific details of their EHB-benchmark recommendations and these selections are reflected in the finalized selections available in Appendix A. Furthermore, we believe that our general EHB requirements, along with regulatory prohibitions on benefit discrimination, ensure that plans include an appropriate range of benefits for adults and children. We will monitor these and other benefit packages to ensure regulatory compliance and assess the need for future program changes.

Comment: We received numerous comments that the largest plan in the largest product in the state was not among the options provided by HHS. HHS did not propose the largest plan in the largest product due to technical concerns with the methodology used in determining enrollment data for the list of largest plans in the largest products.

Response: The three largest products in each state's small group market were identified using enrollment data collected by HealthCare.gov. The largest plan for each of the three largest products in the small group market in each state was identified using enrollment data from the plans in each state. We recognize that there are several

different methodologies for counting enrollment that we could have chosen, and we selected the one that is most uniform across states and best represents for all states the largest plan in the largest product in the small group market. Prior to the release of the largest three products list, HHS confirmed the methodology with each state.

Comment: We received comments recommending which one of the four types of health plan benchmark options would be the most appropriate default base-benchmark plan for territories. A few commenters recommended that the territories follow the same standard as states for the default base-benchmark plan; however, there was also concern that the territories' markets are too small and unique, compared to those in the states, to use the largest small group market plan. Some commenters recommended using one consistent set of benefits, such as FEHBP, to ensure a comprehensive EHB package. Other commenters discussed that the small group market in Puerto Rico is more similar to the small group markets in the 50 states than to those in the other territories given the much larger size of its population and suggested that Puerto Rico should have the largest small group plan in the market as the default benchmark.

Response: In light of comments received, HHS has selected the largest FEHBP plan as the default base-benchmark plan for all U.S. territories, except for Puerto Rico. Benchmarks for Puerto Rico and the other territories are listed in Appendix A along with the state benchmark plans.

Comment: Several commenters expressed concern over providing enforcement authority to states and recommended a more prescriptive approach to monitoring and enforcement of this regulation. Some requested that the federal government exercise strong oversight of state efforts in monitoring and enforcing this area. Commenters also urged HHS to use 2014 and 2015 as transitional years, during which we would collect data on the plans then use those data to help update EHB annually, starting in 2016. Recommended criteria for review included but were not limited to plan comprehensiveness, affordability, and continuity of coverage. Moreover, commenters recommended that, starting in 2016, HHS adopt a comprehensive, Federal EHB standard.

Response: Enforcement of the requirement to cover EHB is governed by section 2723 of the PHS Act, which looks first to states for enforcement, then to the Secretary where a state has failed to substantially enforce.

²⁰ Institute of Medicine, "Essential Health Benefits: Balancing Coverage and Cost" (2011). Available at: <http://www.iom.edu/Reports/2011/Essential-Health-Benefits-Balancing-Coverage-and-Cost.aspx>.

Therefore, we expect states to enforce the requirement that plans must offer EHB. We are currently reviewing all options for updating EHB in 2016 and anticipate releasing additional guidance in the future on enforcement of EHB requirements and updating EHB.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.100 of the proposed rule, with the following modification: while continuing to be recognized as states, as defined under the PHS Act, the U.S. territories including Guam, American Samoa, the U.S. Virgin Islands and the Northern Mariana Islands, with exception of Puerto Rico, will use the largest FEHBP plan as the default base-benchmark plan. Like the other 50 states and the District of Columbia, Puerto Rico will use the largest plan by enrollment in the largest product by enrollment in its small group market as its default base-benchmark plan. This is reflected in Appendix A.

b. Determination of EHB for Multi-State Plans (§ 156.105)

In § 156.105, we proposed how the EHB determination would be made for Multi-State Plans offered under contract with OPM pursuant to section 1334 of the Affordable Care Act. We proposed that Multi-State Plans must meet benchmark standards set by OPM.²¹

The comments and our responses to § 156.105 are set forth below.

Comment: We received several comments requesting more information on the EHB requirement with respect to Multi-State Plans.

Response: OPM will be releasing regulations and guidance on the application of EHB to Multi-State Plans. Therefore, we are not addressing these comments in this rule.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.105 of the proposed rule without modifications.

c. EHB-Benchmark Plan Standards (§ 156.110)

To clarify the relationship between the 10 statutory EHB categories and the

EHB-benchmark plan, in paragraph (a) we proposed that the EHB-benchmark plan provide coverage of at least the following categories of benefits described in section 1302(b)(1) of the Affordable Care Act: (1) Ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) pediatric services, including oral and vision care.

We proposed to interpret “pediatric services” to mean services for individuals under the age of 19 years. We noted that states have the flexibility to extend pediatric coverage beyond the 19-year age baseline.

For those base-benchmark plan options that would not cover one or more of the 10 statutorily required EHB categories, in paragraph (b), we proposed standards for supplementing. In paragraph (b)(1), we proposed requiring that if a base-benchmark plan option does not cover any items and services within an EHB category, the base-benchmark plan would be supplemented by adding that particular category in its entirety from another base-benchmark plan option. The resulting plan, which would then cover all 10 statutory EHB categories, must also meet standards for non-discrimination and balance defined in paragraphs (d) and (e) of this section. After meeting all of these standards, it would be considered the EHB-benchmark plan.

Proposed paragraphs (b)(2) and (3) discuss two categories of benefits that may not currently be included in some major medical benefit plans but that were included in the EHB as defined in proposed § 156.110(a) and section 1302(b)(1) of the Affordable Care Act. Our review of research on employer-sponsored plan benefits, including small employer products, found that pediatric oral and vision services were not covered under the benefit packages of a number of potential benchmarks, but, rather, were often covered under stand-alone policies. We proposed targeted policy options for each of these benefit categories.

In proposed paragraph (b)(2), we proposed to provide states with two options for supplementing base-benchmark plans that do not include benefits for pediatric oral care coverage. The first option, described in paragraph (b)(2)(i), was to supplement with pediatric coverage included in the

FEDVIP dental plan with the largest enrollment. The second option, described in paragraph (b)(2)(ii), was to supplement with the benefits available under that state’s separate CHIP program, if one exists, to the eligibility group with the highest enrollment.

Similarly, in proposed paragraph (b)(3), we proposed to provide two options for states to supplement a base-benchmark plan that does not include pediatric vision services. The first option, described in (b)(3)(i), is to supplement with the pediatric vision coverage included in the FEDVIP vision plan with the largest national enrollment offered to federal employees under 5 U.S.C. 8982. The second option, described in (b)(3)(ii), is to supplement pediatric vision coverage with the state’s separate CHIP plan, if applicable.

In proposed paragraph (c), we proposed the process by which HHS will supplement a default base-benchmark plan, where necessary. Specifically, HHS would supplement the category of benefits in the default base-benchmark plan with the first of the following options that offers benefits in that particular EHB category: (1) The largest plan by enrollment in the second largest product by enrollment in the state’s small group market as defined in § 155.20; (2) the largest plan by enrollment in the third largest product by enrollment in the state’s small group market as defined in § 155.20; (3) the largest national FEHBP plan by enrollment across states that is described in and offered to Federal employees under 5 U.S.C. 8903; (4) the plan described in paragraph (b)(2)(i) to cover pediatric oral care benefits; (5) the plan described in (b)(3)(i) to cover pediatric vision care benefits; and (6) habilitative services as described in § 156.110(f) or § 156.115(a)(4).

In proposed paragraph (d), we state that the EHB-benchmark plan must not include discriminatory benefit designs. As set forth in proposed § 156.125, issuers would be prohibited from using benefit designs that discriminate on the basis of an individual’s age, expected length of life, present or predicted disability, degree of medical dependency, quality of life or other health condition. Issuers would also have to comply with non-discrimination standards applicable to QHPs under the Exchange rules. These standards would apply both to benefit designs that limit enrollment, and those that prohibit access to care for enrollees.

In proposed paragraph (e), we proposed to implement section 1302(b)(4)(A) of the Affordable Care Act by proposing to require that the EHB-benchmark plan ensure an appropriate

²¹ OPM has proposed standards for the Multi-State Plan Program in “Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges” 77 FR 72582 (December 5, 2012). Available at: <http://www.gpo.gov/fdsys/pkg/FR-2012-12-05/pdf/2012-29118.pdf>.

balance among the categories of EHB so that benefits would not be unduly weighted toward any category.

In conducting research on employer-sponsored plan benefits and state-required benefits, HHS found that many health insurance plans do not identify habilitative services as a distinct group of services.²² Accordingly, our proposed regulation proposed to include a transitional policy for coverage of habilitative services that would provide states with the opportunity to define these benefits if they were not included in the base-benchmark plan. Specifically, in paragraph (f), we proposed that, if the base-benchmark plan did not include coverage of habilitative services, the state would be permitted to determine the services included in the habilitative services category. If states did not define the habilitative services category, plans would be required to provide these benefits as defined in § 156.115(a)(4). HHS intends to carefully monitor coverage of habilitative services across the individual and small group markets, and to use this data to inform future changes to this transitional policy.

The comments and our responses to § 156.110 are set forth below.

Comment: Numerous commenters urged that the 10 EHB categories and individual services or benefits within those categories be defined in more detail. Medicaid was suggested as an appropriate model for defining the habilitation benefit, as well as pediatric dental and vision benefits.

Response: The statute directed the Secretary to define EHB to include at least the 10 identified categories, while ensuring that the scope of EHB is equal to the scope of benefits provided under a typical employer plan. However, typical employer plans differ by state. The Secretary balanced these directives, and minimized market disruption, by directing plans to offer the 10 statutory EHB categories while allowing the state to select the specific details of their EHB coverage by reference to one of a range of popularly selected plans offered in the state or as part of the FEHBP. Accordingly, the states continue to maintain their traditional role in defining the scope of insurance benefits and may exercise that authority by selecting a plan that reflects the benefit priorities of that state. With regard to habilitative and pediatric dental and vision benefits, we appreciate the

commenters' recommendation to use Medicaid plans as appropriate models. In order to maintain the states' role in defining required benefits in their markets, we will finalize the regulations to provide for state flexibility in determining how to define habilitation services and to offer other options for supplementing based-benchmark plans that do not include coverage for pediatric dental and vision services. We will continue to monitor this area to assess the need for future regulatory action.

Comment: We received a number of comments recommending that the age limit for the "pediatric services" category be raised from 19, as proposed, to 21, to better align with existing Medicaid and CHIP standards for pediatric benefits and help ensure continuity of coverage for those children who will transition between Exchange and public coverage. Commenters further asserted that the higher age limit would improve care for children with chronic or complex conditions such as cystic fibrosis by allowing continued treatment beyond the age of 19 by such children's pediatric provider, who has more expertise in these areas than adult-focused practitioners.

Response: The age of 19 as the upper limit for the definition of pediatric services is consistent with the upper age limit in the Affordable Care Act's prohibition on preexisting conditions for children as well as the age limit for eligibility to enroll in CHIP. In addition, federal Medicaid law requires that states cover children up to age 19 with family incomes up to 100 percent of the federal poverty limit as a mandatory eligibility category. States are permitted to increase this maximum age in defining pediatric services.

Comment: A number of commenters expressed concern with individual state selections for supplementing coverage categories lacking in a chosen benchmark plan, suggested that the regulation allow additional supplementation options, or suggested that states should be required to supplement inadequate coverage of individual service types within a benefit category.

Response: As stated previously, the Secretary structured the EHB regulations to maintain state flexibility in defining benefits within the categorical parameters set out by Congress. Benchmark options derive from the most popular products in each state's small group market, among others. Allowing states to supplement from this range of options allows each state to develop an EHB-benchmark

plan that reflects its state benefit priorities.

Comment: Several commenters suggested that we require balance not only across the benefit category but also within each category or across the continuum of care.

Response: The balance provision in § 156.110(e) is consistent with the section 1302(b)(4)(A) of the Affordable Care Act, which it implements. Requiring balance within each category or across the continuum of care could result in plans that are not similar in scope to a typical employer health plan as required by statute.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.110 of the proposed rule with two technical edits. We have added the words "pediatric oral" to § 156.110(b)(2) to clarify that supplementation of the pediatric dental services category in the base-benchmark plan would be with the pediatric oral benefits from a benchmark option. We have likewise added the words "pediatric vision" to § 156.110(b)(3) in place of the word "such" to clarify that supplementation of the pediatric vision services category in the base-benchmark plan would be with the pediatric vision benefits from allowable source plan and have added the words "by enrollment" to clarify that the largest product in a state's small group market is determined by enrollment.

d. Provision of EHB (§ 156.115)

In paragraph (a)(1), we proposed that plans may have limitations on coverage that differ from the limitations in the EHB-benchmark plan, but covered benefits and limitations on coverage must remain substantially equal to the benefits in the EHB-benchmark plan.

In paragraph (a)(2), we proposed that in order to satisfy the requirement to offer EHB, mental health and substance use disorder services, including behavioral health treatment services required under § 156.110(a)(5), must be provided in a manner that complies with the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).

In paragraph (a)(3), we further proposed that a plan does not provide EHB unless it meets the standards in 45 CFR 147.130.

In paragraph (a)(4), we proposed that if the EHB-benchmark plan does not include coverage for habilitative services and the state does not determine habilitative benefits, a health

²² ASPE Research Brief, "Essential Health Benefits: Comparing Benefits in Small Group Products and State and Federal Employee Plans." December 16, 2011. Available at: <http://aspe.hhs.gov/health/reports/2011/MarketComparison/rb.shtml>.

insurance issuer must either: (1) Provide parity by covering habilitative services benefits that are similar in scope, amount, and duration to benefits covered for rehabilitative services; or (2) decide which habilitative services to cover and report on that coverage to HHS.

We proposed the concept of benefit substitution consistent with what HHS outlined in the EHB Bulletin. As outlined in paragraph (b)(1)(i), we proposed that issuers may substitute benefits, or sets of benefits, that are actuarially equivalent to the benefits being replaced. We further proposed in paragraph (b)(1)(ii) that substitution could only occur within benefit categories, not between different benefit categories. In paragraph (b)(1)(iii), we clarify that our proposed benefit substitution policy does not apply to prescription drug benefits. In paragraph (b)(2), we outlined what must be submitted to demonstrate that any substituted benefit, or group thereof, is actuarially equivalent to the original benefit or benefits contained in the EHB-benchmark for that state. Lastly, in paragraph (b)(3), we proposed that actuarial equivalence of benefits be determined based on the value of the service without regard to cost-sharing, as cost sharing will be considered in the actuarial value calculation described in § 156.135. We noted that the resulting plan benefits would be subject to requirements of non-discrimination described in § 156.125. In addition, we note that under this approach, states would have the option to enforce a stricter standard on benefit substitution or prohibit it completely.

In paragraph (c), we proposed to clarify that a plan does not fail to provide EHB solely because it does not offer the services described in § 156.280(d). Here we would apply the statutory provision in section 1303(b)(1)(B)(i) of the Affordable Care Act that allows a QHP to meet the standards for EHB even if it does not offer the services described in 45 CFR § 156.280(d), to health insurance issuers that offer non-grandfathered coverage in the individual or small group market. This provision applies to all services in section 1303(b)(1)(A) of the Affordable Care Act, including pharmacological services.

In paragraph (d), we proposed that an issuer of a plan offering EHB may not include routine non-pediatric dental services, routine non-pediatric eye exam services, cosmetic orthodontia and long-term/custodial nursing home care benefits as EHB.

The comments and our responses to § 156.115 are set forth below.

Comment: Some commenters asked us to eliminate or provide additional guidance regarding the substantially equal standard.

Response: Based on the rationale we outlined in the proposed rule, we are maintaining the substantially equal standard as written to allow for flexibility of plan design.

Comment: Several commenters requested confirmation that EHB must comply with federal mental health and substance use disorder parity requirements in both the individual and the small group markets. Commenters also asked if states would have to defray the cost of adding benefits in order to comply with parity.

Response: Section 2707 of the PHS Act requires health insurance issuers in the individual and small group health insurance markets to cover the EHB package required under section 1302 of the Affordable Care Act. The Affordable Care Act grants the Secretary broad authority to define EHB. We proposed in § 156.115(a)(2) that plans are required to comply with the parity standards set forth in § 146.136 of this chapter, implementing the requirements under MHPAEA in order to satisfy the requirement to provide EHB. Section 1311(j) of the Affordable Care Act specifies that section 2726 of the PHS Act shall apply to qualified health plans in the same manner and to the same extent as such section applies to health insurance issuers and group health plans. For these reasons, we confirm that plans must comply with the parity standards applicable to mental health and substance use disorder benefits set forth in 45 CFR 146.136 in both the individual and the small group markets in order to satisfy the requirement to cover EHB. Additionally, because compliance with EHB would require compliance with the parity standards, states would not have to defray any costs associated with bringing plans into compliance because any benefits added to ensure parity would be considered part of the EHB package.

Comment: Commenters requested a federal definition of habilitative services. Many recommended that HHS adopt the NAIC definition of habilitation or use the Medicaid statute's definition of habilitation as a reference point, to highlight the importance of maintenance of function. Commenters also asked that HHS eliminate giving issuers the choice of determining their habilitative benefits.

Response: As explained in the EHB Bulletin, habilitative benefits are not well defined in the current commercial market. If habilitative services are not covered by the EHB-benchmark plan,

then states have the first opportunity to determine which habilitative benefits must be covered by their benchmark plan. States may choose to use the NAIC or Medicaid definition. If states have not chosen to define habilitative benefits, the issuers' choice remains. This is a transitional policy, and HHS intends to monitor available data regarding coverage of habilitative services.

Comment: Many commenters urged HHS to eliminate the option to substitute benefits, noting concerns that substitution may result in discrimination. Commenters also requested that HHS codify the implied option for states to limit or completely prohibit substitution.

Response: We have retained the discretion we proposed to provide for substitution within categories to provide greater choice to consumers, and promote plan innovation through coverage and design options. We also retained the requirement that any substitution must be actuarially equivalent. As the party responsible for enforcement of EHB, it is up to each state to set criteria for substitution in its state, consistent with paragraph (b) of this Section.

Comment: In the preamble to the proposed rule, we clarified that a plan may not exclude enrollees from coverage in any category except pediatric services. Many commenters recommended that CMS codify this proposal in regulation text.

Response: In response to the comments received, we have modified § 156.115(a)(2) to prohibit an EHB plan from excluding an enrollee from coverage in an EHB category except pediatric services.

Comment: Several commenters urged HHS to remove the provision at § 156.115(c) so that section 1303(b)(1)(A) of the Affordable Care Act would not extend to plans that are not QHPs. Other commenters noted that services under section 1303 of the Affordable Care Act are covered by their state benchmark plan and requested confirmation that other EHB plans will not have to offer such services.

Response: We are finalizing the regulation to include the provision to ensure parity between the Exchange and non-Exchange markets. We note that nothing in the proposed provision impedes an issuer's ability to offer 1303 services. It also does not limit a state's authority to prohibit or require these services under state law.

Comment: While some commenters objected to the exclusion of routine non-pediatric dental services, routine non-pediatric eye exam services, and long term/custodial nursing home care

benefits, from EHB, the majority of commenters agreed with the exclusion of these services because they are not typically included in medical plans offered by a typical employer.

Response: The Affordable Care Act requires EHB to be based on benefits typically offered by a typical employer plan. In contrast with the benefits covered by a typical employer health plan, these particular benefits often qualify as excepted benefits.²³ However, plan offerings are not restricted to EHB, so plans may offer additional benefits.

Comment: We received comments requesting that HHS change the reference to “cosmetic orthodontia” and define the excluded service as “non-medically necessary orthodontia” to reflect the standard that issuers typically use and to be consistent with the EHB Bulletin.

Response: Based on comments, we have changed the language in § 156.115(d) to refer to non-medically necessary orthodontia and deleted the reference to cosmetic orthodontia.

Summary of Regulatory Changes

We are finalizing the provisions proposed in § 156.115 of the proposed rule, with the following modifications: In paragraph (a) we added subparagraph (2) to clarify that an EHB plan cannot exclude an enrollee from any EHB category except pediatric services. In paragraph (b), we have added regulation text explicitly reflecting our adoption in this final rule of our proposal that states be permitted to limit or prohibit benefit substitutions that would otherwise be permissible under our regulations, and we recodified subparagraph (3) as (2)(iv). We changed the language in § 156.115(d) to use the term “non-medically necessary” instead of “cosmetic” orthodontia.

e. Prescription Drug Benefits (§ 156.122)

This subsection appeared as § 156.120 in the proposed rule, however, for technical reasons this subsection will be renumbered as § 156.122 in the final rule.

In paragraph (a)(1), we proposed that in order to comply with the requirement to cover EHB, a plan would cover 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. In paragraph (a)(2) we proposed that a QHP would have to report its drug list to the Exchange, an EHB plan operating outside of the Exchange must report its

drug list to the state, and a multi-state plan must report its drug list to OPM. In paragraph (b) we proposed to clarify that a health plan does not fail to provide EHB prescription drug benefits solely because it does not offer drugs that are § 156.280(d) services.

We proposed using the most recent version of the United States Pharmacopeia’s (USP) Model Guidelines as a common organizational tool for plans to report drug coverage. We stated that we would work with issuers, states and the NAIC to facilitate use of the USP classification system and we would provide a tool for states and issuers to count clinically distinct drugs and categorize them into the USP system.²⁴

We also proposed that drugs would be counted toward these requirements if they are chemically distinct.²⁵ For example, offering two dosage forms or strengths of the same drug would not be offering drugs that are chemically distinct. Similarly, a brand name drug and its generic equivalent are not chemically distinct.

In paragraph (c), we proposed that a plan offering EHB have procedures in place to ensure that enrollees have access to clinically appropriate drugs that are prescribed by a provider but are not included on the plan’s drug list, which is generally consistent with private plan practice today.

The comments and our responses to § 156.122 are set forth below.

Comment: Several commenters noted that the proposed rule requires plans to meet a target number of drugs within a specific class without regard to which drugs are covered. Those commenters expressed concern regarding absence of a system to review the adequacy and quality of each plan drug list.

Response: Section 156.125, regarding discrimination, applies to all EHB including prescription drug benefits. Under the prohibition on discrimination regulation we are finalizing at § 156.125 of this part, an issuer’s benefit design, or the implementation of its benefit design, may not discriminate 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. Issuers may continue to use reasonable medical management techniques that

are evidence-based in accordance with § 156.125. The states and the Exchanges will be responsible for monitoring drug lists for such compliance as part of their enforcement and certification responsibilities.

Comment: Some commenters noted that the proposed rule does not discuss how plans must address new drugs that come onto the market during the course of a plan year.

Response: While plans must offer at least the greater of one drug for each USP category and class or the number of drugs in the EHB-benchmark plan, plans are permitted to go beyond the number of drugs offered by the benchmark without exceeding EHB.

Comment: Some commenters recommended that HHS should not require coverage of at least one drug in each USP category and class, because such coverage is not similar to a typical employer plan and that certain categories and classes have limited drug options. Some commenters raised concerns about cost and that covering a drug in each USP category and class is arbitrary. Instead, they suggested HHS delete the requirement to match a specific number of drugs per benchmark plan category and class, and allow plans to determine the specific drugs covered.

Response: In response, we internally analyzed and carefully reviewed prescription drug coverage in the EHB-benchmark plans listed in Appendix A, and found that the majority of the benchmark plans already meet the EHB standard or would only have to cover one or two additional drugs to meet the standard. Therefore, we believe that, given current coverage under benchmark plans, the policy of requiring at least one drug per category and class reflects drug coverage in a typical employer plan and will have a negligible effect on premiums. We also note that this section does not require that drugs be covered on a particular tier. Additionally, we are finalizing § 156.122(a)(1) as proposed as a transition policy for the first two plan or policy years beginning in 2014 and will study and take into consideration the effects this policy, if any, have on changing typical drug coverage in the market.

Comment: Many commenters expressed concern over the use of USP as the class and category classification system.

Response: For consistency and to minimize administrative burden and barriers to market entry for health plans, specifically for issuers offering products in multiple states, we believe it is important to use only one classification system. While there was concern among

²³ For more information on excepted benefits, see 26 CFR 54.9831–1, 29 CFR 2590.732, 45 CFR 146.145, and 45 CFR 148.220.

²⁴ The requirement to use USP classification applies only to submission of formulary for review/certification. Plans may continue to use any classification system they choose in marketing and other plan materials.

²⁵ The concept of chemically distinct is also described in the Medicare Part D Manual, Chapter 6, Section 30.2.1. More information is available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf>.

commenters on the use of USP as the system, there was no universal system identified as a potential alternative. We chose the current version USP Model Guidelines (version 5) because it is publicly available and many pharmacy benefit managers are familiar with it. We believe the USP model best fits the needs for the years 2014 and 2015 during the transitional EHB policy and we have developed a crosswalk tool to count the number of drugs available in each USP category and class. We intend to work with issuers, states and the NAIC to facilitate state use of the USP Model Guidelines Version 5.0 as a classification system and as a comparison tool.

Comment: Several commenters requested additional detail regarding the requirement that a plan “must have procedures in place that allow an enrollee to request clinically appropriate drugs not covered by the health plan.”

Response: Additional guidance regarding our expectations for the required exceptions process is forthcoming in sub-regulatory guidance. We note the importance of this option for those whose medical needs require a very narrow range of pharmaceuticals, and emphasize that our research has shown that a large number of plans already offer this option in the market today. It is expected that plans that currently have such a process in place will not be expected to modify their existing process.

Comment: Many commenters suggested that HHS should clarify in § 156.120(c) (as explained above, now renumbered as § 156.122(c)) of the final regulation that plans must have procedures in place that ensure enrollees have access to clinically appropriate drugs, not just allow the enrollee to request such a drug. While the preamble of the proposed rule includes a statement of this standard, the proposed rule does not.

Response: We have added language from the proposed rule preamble to § 156.122(c) directing plans to have procedures to allow an enrollee to gain access to clinically appropriate drugs.

Comment: Commenters urged HHS to provide guidance as to which drugs are covered by § 156.280(d) so that the final rule is clear as to which drugs are actually exempted.

Response: We have revised the language to specify that we are referring to drugs approved by the U.S. Food and Drug Administration (FDA) as a § 156.280(d) service.

Summary of Regulatory Changes

We are finalizing the provisions in § 156.120 of the proposed rule (renumbered as § 156.122 in the final rule), with the following modifications: We have added language to § 156.122(c) based on the proposed rule's preamble text directing plans to have procedures to allow an enrollee to gain access to clinically appropriate drugs. We have revised the language in subparagraph (b) to specify that we are referring to drugs approved by the U.S. Food and Drug Administration (FDA) as a § 156.280(d) service.

f. Prohibition on Discrimination (§ 156.125)

Section 1302(b)(4) of the Affordable Care Act directs the Secretary to address certain standards in defining EHB, including elements related to balance, discrimination, the needs of diverse sections of the population, and denial of benefits. The proposed regulations would provide an approach to addressing discrimination that would allow states to monitor and identify discriminatory benefit designs, or the implementation thereof.

To address potentially discriminatory practices, we proposed in paragraph (a) that an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, or present or predicted disability, degree of medical dependency, quality of life, or other health conditions. In paragraph (b), we proposed that §§ 156.200 and 156.225 also apply to all issuers required to provide coverage of EHB, prohibiting discrimination based on factors including but not limited to race, gender, disability, and age as well as marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs.

These provisions would provide a framework and legal standard from which to develop analytic tools to test for discriminatory plan benefits. Such analyses could include evaluations to identify significant deviation from typical plan offerings including such as limitations for benefits with specific characteristics.

The comments and our responses to § 156.125 are set forth below.

Comment: Several commenters indicated their belief that section 1302(b)(4) of the Affordable Care Act does not prohibit discrimination in benefit implementation in the standards for providing EHBs.

Response: Section 1302(b)(4) of the Affordable Care Act specifies that EHB

not include “coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life.” We believe that this range of prohibited discrimination implicitly encompasses not just the categories of benefits included in the benefit design but also the implementation of that design.

Comment: A number of commenters recommended that we expand this section to prohibit discrimination based on sex, gender identity, sexual orientation, having a particular medical condition, and other factors.

Response: The regulation as written prohibits benefit discrimination on the grounds articulated by Congress in section 1302(b)(4) of the Affordable Care Act, as well as those in 45 CFR 156.200(e), which include race, color, national origin, disability, age, sex, gender identity and sexual orientation.

Comment: Many commenters requested that we add more detail to the regulation regarding standards of nondiscrimination, the framework for monitoring and enforcement, as well as clarification of the roles of the states and the federal government. Several commenters expressed concern that enrollees with certain health conditions might be discriminated against by an issuer's failure to include appropriate specialists in their network.

Response: Enforcement of the PHS Act provisions codified in this rule is governed by section 2723 of the PHS Act, which first looks to states and then to the Secretary where a state has does not substantially enforce. The approach to nondiscrimination will reserve flexibility for both HHS and the states to respond to new developments in benefit structure and implementation and to be responsive to varying circumstances across the states. We agree with the commenters that network adequacy is an important part of plan coverage. Compliance with network adequacy requirements is outside of the scope of this regulation.

Comment: Several commenters expressed concern over state benchmarks that they believed contained discriminatory benefit designs and worried that issuers in those states would be required to copy those designs.

Response: To the extent that a state benchmark plan includes a discriminatory benefit design, non-discrimination regulations at § 156.110(d) and § 156.125 require issuers to meet the benchmark requirements in a nondiscriminatory matter.

Comment: Many commenters expressed concern that § 156.125 would prevent issuers from employing traditional medical management techniques, with some requesting that we revise regulatory text to indicate that evidence-based techniques would not be considered discriminatory. Others expressed ongoing concern that medical management techniques were often used as nuanced mechanisms for discrimination.

Response: As we stated in the preamble to the proposed rule, and consistent with section 1563(d) of the Affordable Care Act, these EHB regulations do not prohibit issuers from applying reasonable medical management techniques. An issuer could use prior authorization, but could not implement prior authorization in a manner that discriminates on the basis of membership in a particular group based on factors such as age, disability, or expected length of life that are not based on nationally recognized, clinically appropriate standards of medical practice evidence or not medically indicated and evidence-based. For example, a reasonable medical management technique would be to require preauthorization for coverage of the zoster (shingles) vaccine in persons under 60 years of age, consistent with the recommendation of the Advisory Committee on Immunization Practices. We are adding a new paragraph (c) in § 156.125, to clarify that nothing in this section shall be construed to prevent an issuer from using reasonable medical management techniques.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.125 of the proposed rule with two modifications. Based on comments addressed below in response to proposed section § 156.130, we have deleted the reference to § 156.225 from paragraph (b) of this section, and, as described in response to the comment above, we have added a new paragraph (c), clarifying that nothing in this section shall be construed to prevent an issuer from appropriately utilizing reasonable medical management techniques.

g. Cost-Sharing Requirements (§ 156.130)

The Affordable Care Act provides several standards on cost sharing for certain health plans. Standards in § 156.130 are applicable to QHPs pursuant to section 1301(a)(1)(B), as

implemented by 45 CFR 156.200(b)(3) and 45 CFR 156.20, which require QHPs to offer the essential health benefits package described at section 1302(a) of the Affordable Care Act. Similarly, these standards would be applicable to non-grandfathered health insurance coverage offered by health insurance issuers in the individual and small group markets pursuant to section 2707(a) of the PHS Act as implemented by § 147.150(a) of these regulations.

In § 156.130(a), we proposed to codify the Affordable Care Act's limitation on cost sharing for 2014 and in subsequent years. Section 156.130(a)(1) would tie the annual limitation on cost sharing for plan years beginning in 2014, to the enrollee out-of-pocket limit for high-deductible health plans (HDHP), as calculated pursuant to section 223(c)(2)(A)(ii) of Internal Revenue Code of 1986 (the Code) based on section 1302(c)(1)(A) of the Affordable Care Act. Proposed paragraph (a)(1)(i) would address the limitation for self-only coverage and proposed paragraph (a)(1)(ii) would address the limitation for coverage other than self-only coverage; the practical effect for coverage other than self-only coverage would be that the annual limitation would be double the limitation applicable to self-only coverage. For illustrative purposes only, for the year 2013 these amounts will be \$6,250 for self-only and \$12,500 for non-self only coverage.²⁶ Amounts for 2014 are expected to be released by the IRS in the spring of 2013. In proposed § 156.130(a)(2)(i), the annual limitation on cost sharing would increase by the premium adjustment percentage, which would be set by HHS as described in § 156.130(e), in years after 2014 for self-only coverage. In proposed § 156.130(a)(2)(ii), the annual limitation on cost sharing in years after 2014 for non-self only coverage is double the annual limitation on cost sharing for self-only coverage for that year.

Sections 1302(c)(2)(A)(i) and 1302(c)(2)(A)(ii) of the Affordable Care Act define and proposed § 156.130(b) codified the annual limitation on deductibles for health plans offered in the small group market as part of the EHB package. This limitation on deductibles is imposed on QHPs by section 1301(a)(1)(B) of the Affordable Care Act and 45 CFR 156.200(b)(3). The limitation is also imposed on non-grandfathered health plans in the individual and small group markets by section 2707(a) of the PHS Act, which we proposed to implement in proposed 45 CFR 147.150(a). In proposed

§ 156.130(b)(1)(i), we proposed that the annual limitation on deductibles for the year 2014 be \$2,000 for self-only coverage and in proposed § 156.160(b)(1)(ii), \$4,000 for non self-only coverage. In proposed § 156.130(b)(2), we proposed that in years beyond 2014, the annual deductible limits for self-only plans would increase by the premium adjustment percentage described in paragraph (e) under the authority of section 1302(c)(2)(B) of the Affordable Care Act.

Section 1302(c)(2)(C) of the Affordable Care Act directs that the limit on deductibles described in section 1302(c)(2)(A) for a health plan offered in the small group market be applied so as to not affect the actuarial value of any health plan. We proposed to interpret and implement this provision through our proposal at § 156.130(b)(3) by authorizing a health insurance issuer to make adjustments to its deductible to maintain the specified actuarial value for the applicable level of coverage required under proposed § 156.140. In proposed § 156.130(b)(3), we proposed that a plan may exceed the annual deductible limit if it cannot reasonably reach a given level of coverage (metal tier) without doing so.

Section 1302(c)(2)(A) of the Affordable Care Act permits but does not require, contributions to flexible spending arrangements (FSAs) to be taken into account when determining the deductible maximum. We proposed to standardize the maximum deductible for all health plans in the small group market at \$2,000 for self-only coverage and \$4,000 for non-self-only coverage, as described in proposed § 156.130(b)(1) and potentially adjusted in proposed § 156.130(b)(3), and not increase the deductible levels by the amount available under the FSA.

In proposed § 156.130(c), we proposed a special rule for network plans. Under our proposal, cost sharing requirements for benefits from a provider outside of a plan's network would not count towards the annual limitation on cost sharing, or the annual limitation on deductibles. We considered an out-of-network provider to be a provider with whom the issuer does not have a contractual arrangement with respect to the applicable plan.

In proposed § 156.130(d), we proposed to codify sections 1302(c)(1)(B) and 1302(c)(2)(B) of the Affordable Care Act by requiring that the annual limitation on cost sharing and the annual limitation on deductibles for a plan year beginning after calendar year 2014 only increase by multiples of \$50 and must be

²⁶ <http://www.irs.gov/pub/irs-drop/rp-12-26.pdf>.

rounded to the next lowest multiple of \$50.

In proposed § 156.130(e), we proposed to codify section 1302(c)(4) of the Affordable Care Act, which specifies that the premium adjustment percentage is calculated as the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013.

In proposed § 156.130(f), we proposed to codify section 1302(c)(2)(D) of the Affordable Care Act, which states that the annual deductibles do not apply to preventive care described in § 147.130.

Proposed § 156.130(g) proposed to prohibit discriminatory cost sharing.

Proposed § 156.130(h) proposed to implement the requirements in section 1302(b)(4)(E) of the Affordable Care Act that, as part of coverage of EHB, a QHP must (1) provide coverage for emergency department services provided out-of-network without imposing any requirement under the plan for prior authorization of services or any limitation on coverage for the provision of services that is more restrictive than the requirements or limitations that apply to emergency department services received from network providers, and (2) apply the same cost sharing in the form of a copayment or coinsurance for emergency department services for an out-of-network provider—as would apply to an in-network provider.

The comments and our responses to § 156.130 are set forth below.

Comment: HHS received several comments suggesting a standard definition of the reasonableness exemption in proposed § 156.130(b)(3) for plans in the small group market that can only meet the deductible requirements as well as certain actuarial value requirements such as for a bronze plan for a very narrow range of plan designs.

Response: We intend to provide sub-regulatory guidance outlining options related to plan designs where exceeding the deductible limits described in § 156.130(b) is permissible. We reiterate that § 156.130(b) as finalized here applies only for purposes of defining a cost-sharing limitation application to issuers and QHPs that must offer the EHB package.

Comment: Several commenters expressed concerns about the protection of a health plan's ability to control costs through the use of reasonable medical management, as well as cost and administrative burdens placed on QHP issuers.

Response: We do not believe that the requirements pertaining to cost-sharing

would preclude issuers from engaging in reasonable medical management. However, in response to comments about the protection of a health plan's ability to control costs through the use of utilization management and administrative burden, we are not finalizing the policy as paragraph (g) of § 156.130 and we are relabeling the remainder of § 156.130 accordingly.

Comment: HHS received several comments requesting deductible increases for plans in the small group market based on employer FSA contributions. Other commenters preferred our approach, which prohibits these increases, because of the operational complications of determining the FSA contribution in time for plan selection.

Response: The Affordable Care Act provides the option but not the requirement to increase deductibles in the small group market based on FSA contributions. The operational implications of determining which employers are contributing to employee FSAs and matching only those employees to plan options with corresponding increases in deductibles when FSA contributions and plan selection generally occurs simultaneously is operationally infeasible. We are now finalizing our policy due to the operational complications of determining the FSA contribution in time for plan selection, although we will revisit this policy in later years. We believe this will have no impact on enrollment in small group plans for those eligible.

Comment: HHS received several comments discussing the merits of applying the cost-sharing limits to in-network services only rather than applying the annual cost sharing limits defined in § 156.130(a) to all costs including both in-network and out-of-network fees.

Response: Our research has shown that generally, health spending occurs in-network.²⁷ The IOM in its recommendation²⁸ focused on the long term balance between affordability and comprehensiveness of coverage, therefore, we have decided to apply cost-sharing limits to in-network visits only to promote health plan affordability. We note that nothing in this proposal explicitly prohibits an issuer from voluntarily establishing a maximum out-of-pocket limit applicable

to out-of-network services, or a state from requiring that issuers do so.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.130 of the proposed rule with one modification. We are not finalizing the text proposed as paragraph (g) and are relabeling the provision proposed paragraph (h) as paragraph (g) in this final rule.

h. AV Calculation for Determining Level of Coverage (§ 156.135)

The Affordable Care Act directs issuers offering non-grandfathered health insurance coverage in the individual and small group markets, including QHPs, to ensure that plans meet a level of coverage specified in section 1302(a)(3) of the Affordable Care Act and defined in § 156.140(b). Each level of coverage corresponds to an AV calculated based on the cost-sharing features of the plan. Pursuant to these statutory provisions, in paragraph (a), we proposed that an issuer would use the AV Calculator developed by HHS to determine the health plan's level of coverage as proposed in § 156.140(b), subject to the exception in paragraph (b). As part of this proposal, we solicited comment on both the AV Calculator and a methodology document that includes the logic behind the calculator and a description of the development of the standard population, represented in the calculator as tables of aggregated data called continuance tables.

Consistent with section 1302(d)(2)(A) of the Affordable Care Act that AV be calculated based on the provision of the EHB to a standard population, we proposed that the AV Calculator use one or more sets of national claims data reflecting plans of various levels of generosity as the underlying standard population. In paragraph (b), we proposed options for an issuer whose plan designs do not permit the calculator to provide an accurate summary of plan generosity. Although HHS anticipates that the vast majority of plans will be able to use the calculator in 2014 and beyond, no uniform calculator can accommodate the entire potential universe of plan designs. Therefore, we proposed to provide exceptions for plan designs not compatible with the calculator. Specifically, we proposed in paragraph (b)(1) that plans not using the AV calculator would need to submit documentation in the form of actuarial certification that they have complied with one of the methods described

²⁷ 26 U.S.C. 223(c)(2)(D)

²⁸ Institute of Medicine, "Essential Health Benefits: Balancing Coverage and Cost" (2011). Available at: <http://www.iom.edu/Reports/2011/Essential-Health-Benefits-Balancing-Coverage-and-Cost.aspx>.

below. We intend for this submission to be made to the appropriate entity (the state, HHS, the Exchange, or OPM) reviewing the health plan for compliance with AV and level of coverage standards.

In paragraph (b)(2), we proposed two options to accommodate plans with benefit designs that cannot be accommodated by the AV Calculator. In paragraph (b)(2)(i), we proposed that a health plan issuer be permitted to decide how to adjust the plan benefit design (for calculation purposes only) to fit the parameters of the calculator and then, pursuant to paragraph (b)(2)(ii), have a member of the American Academy of Actuaries certify that the methodology was fit to the parameters of the AV Calculator in accordance with generally accepted actuarial principles and methodologies. In paragraph (b)(3), we proposed a second option, that the plan may use the calculator for the plan design provisions that correspond to the parameters of the calculator and then have a member of the American Academy of Actuaries calculate appropriate adjustments to the AV as determined by the AV Calculator for plan design features that deviate substantially, in accordance with generally accepted actuarial principles and methodologies. We proposed in paragraph (b)(4) that, to align with the AV Calculator and the rules proposed here for how AV is determined, plans using one of these methods would exclude out-of-network costs when using additional calculation methods.

In paragraph (c), we proposed a standard for the treatment of small group market HDHPs offered with a health savings account (HSA) or a health plan in the small group market integrated with a health reimbursement arrangement (HRA), so that HDHP and HSAs/HRAs are integrated. Recognizing that simply calculating the AV of the HDHP based on the insurance plan alone could understate the value of coverage if the value of the employer contribution to such accounts are not included, and that employer-provided HSAs and HRAs are generally the equivalent of first dollar coverage for any cost-sharing requirements encountered by the enrollee, in paragraph (c)(1), we proposed that the annual employer contributions to HSAs and amounts newly made available under HRAs for the current year count within the plan design.

Section 1302(d)(2)(B) of the Affordable Care Act directs the Secretary to issue regulations under which employer contributions to an HSA (within the meaning of section 223 of the Code) may be taken into account

in determining the level of coverage for a plan of the employer and HHS proposed allowing for similar treatment of HRAs.

In paragraphs (c)(2)(i) and (ii), we proposed that the AV Calculator would include any current year HSA contributions or amounts newly made available under integrated HRAs for the current year as an input into the calculator that can be used to determine the AV of an employer-sponsored health benefit plan.

In paragraph (d) we proposed that in years 2015 and after, a state-specific data set may be used as the standard population (that is, in place of the HHS-issued continuance tables) for AV calculations if approved by HHS. Issuers in such a state would still use the AV Calculator logic, but the underlying data used for generating the AV would be specific to the state. In paragraphs (d)(1) through (5), we proposed and solicited comment on criteria, based on a July 2011 American Academy of Actuaries issue brief, for acceptable state claims data and their use.

In paragraph (e), we proposed that the default standard population provided by HHS, which is described in paragraph (f) and represented in the continuance tables incorporated into the regulatory proposal by reference, would be used unless the state submits its own standard population consistent with paragraphs (d) and (e). In paragraph (e), we proposed that the state data set be submitted in a format that can support the AV Calculator described in paragraph (a).

In paragraph (f), we proposed that HHS will develop the standard population to be used to calculate AV in accordance with section 1302(d)(2)(A) of the Affordable Care Act, which requires that AV be calculated using a standard population.

The comments and our responses to § 156.135 are set forth below.

Comment: Some commenters suggested a different version of the AV Calculator including a microsimulation model based calculator, a calculator with greater inputs, or no calculator at all with plans utilizing their own data to calculate an AV. Other commenters supported HHS's decision to develop an AV Calculator based on continuance tables.

Response: We elected to use a continuance table model as a methodology for determining actuarial value because in general this type of model is common, popular, and well understood by the actuarial community. We have no evidence that a microsimulation model would be more precise or would be more successful at

parsing plan designs that receive high actuarial values with this continuance table model, but would receive low actuarial values in a microsimulation model. The level of detail of the calculator inputs was thoroughly researched and tested and we concluded that adding detail did not have a material impact on actuarial value.

Comment: HHS received numerous comments in support of the development of an AV Calculator based on a single national standard population. Other commenters suggested the use of standardized plan data instead of a single data set to develop the standard population.

Response: HHS is finalizing its proposed approach to develop an AV Calculator based on a single national standardized dataset. We considered allowing issuers to use standardized plan data to determine AV levels, but in response to comments received to both the AV Bulletin and the proposed regulation, ultimately developed the AV Calculator using a single standardized dataset to best facilitate consumer comparisons so that plans with the same cost-sharing structure would have the same AVs. As described in § 156.135(d), we are also allowing for the use of state-specific standard population data beginning in 2015.

Comment: HHS received several comments urging HHS to allow states to submit their own claims data for use in the AV Calculator starting in 2014 or to account for regional variations in the AV Calculator. Other commenters recommended that HHS wait to allow the use of state data until 2017 or until an update to the AV Calculator is made.

Response: Starting in 2015, states will have the opportunity to submit state-specific claims data for the AV Calculator. In 2014, states and other stakeholders can assess the AV Calculator and determine whether geographic variation or state-specific claims data would be useful modifications starting in 2015.

Comment: Some commenters suggested that the AV Calculator should consider both in and out-of-network utilization. Other commenters supported the inclusion of only in-network utilization for the AV Calculator.

Response: HHS developed the AV Calculator and with regard to exceptions to use of the AV Calculator in § 156.135(b)(4), is finalizing the proposal to consider only in-network utilization based on empirical data indicating that only a small percentage of total costs come from out-of-network

utilization.²⁹ This approach was supported by the American Academy of Actuaries in its comments on the AV Bulletin.

Comment: Many commenters noted a variety of potential technical issues in the proposed AV Calculator. Other commenters asked HHS to provide additional detail on the development of the standard population and logic and assumptions used to convert the claims data into an AV Calculator, including that HHS provide additional detail on the specific services included in each benefit input in the calculator to facilitate calculation using one of the exceptions, as well as the services included in the unclassified category.

Response: As part of the proposed regulation, HHS released both the AV Calculator tool and a methodology document detailing the development of the standard population and AV Calculator. In developing the final version of the AV Calculator tool, HHS considered all of the technical comments received and made revisions as appropriate. In addition, the revised and final version of the methodology document considers all comments received and provides additional explanation wherever possible. In developing the publicly available methodology document, we described step by step the data and logic that the calculator uses to determine plan AVs and held ourselves to the common practice level of detail present in describing risk adjustment models for CMS as well as academic publications. The final AV Calculator and methodology document are incorporated by reference into this final rule and available at <http://ccio.cms.gov/resources/regulations/index.html#pm>.

Comment: Several commenters asked for additional guidance and clarification on when one of the exceptions in § 156.135(b) may be used to calculate AV.

Response: We intend to interpret this standard as dependent on whether the AV Calculator takes into account or accommodates all material aspects of a plan's cost-sharing structure. For example, we expect that the calculator will not be able to accommodate plan designs with multiple coinsurance rates as different levels of out-of-pocket spending are met or a multi-tier network with substantial amounts of utilization expected in tiers other than the lowest-priced tier. We have also made minor

edits to the regulation to clarify that, for a plan that cannot be accommodated by the calculator, an issuer has the option of using either exception method and that both methods require submission of an actuarial certification.

Comment: The majority of commenters noted that the AV Calculator does not address health plans with family cost-sharing features such as deductibles that accrue across members of the same family. Some commenters recommended adjustments or additional guidance for the final AV Calculator to account for these plans.

Response: The AV Calculator standard population was developed using claims data that did not include family cost-sharing information. Therefore, health plans with cost-sharing features that accrue across family members for non-self-only coverage may be treated as unique plan designs, if the family plan design has a material effect on the plan's AV. To address commenters' concerns regarding AV calculation for plans with family cost-sharing features, as a safe harbor, the AV of a plan with a deductible and/or out-of-pocket maximum that accumulates at the family level will be considered the same AV as calculated using the AV Calculator for the corresponding individual plan, so long as the deductible and/or out-of-pocket maximum do not exceed that allowed by a family multiplier set by CMS in future guidance. We note that the out-of-pocket maximum would still be constrained by the maximum permitted by § 156.130(a)(1)(ii).

Comment: Several commenters encouraged HHS to add functionality or additional benefit inputs to the AV Calculator—for example, that the calculator account for more or different benefits as separate cost-sharing inputs and that the calculator take into account service limits.

Response: The AV Calculator was developed to accommodate the vast majority of plan designs and to include as separate cost-sharing inputs those benefits that have a significant impact on a plan's AV. The AV Calculator balances the need to accommodate a wide range of plan designs, with the need to provide a tool that is accessible to the user and contains a manageable number of inputs.

Comment: Several commenters requested that the full amount of HSA and integrated HRA employer contributions be accounted for in the AV Calculator. Some of these commenters also requested that HHS allow employee contributions to count towards a plan's AV.

Response: We clarify here that the AV Calculator implements § 156.135 by treating HSA and amounts newly made available under an integrated HRA that may be used only for cost sharing the same way it treats any other plan benefits. For example, a \$1,000 HSA employer contribution is treated in the AV Calculator as if a plan with \$1,000 deductible is reduced to \$0. The \$1,000 HSA contribution does not get counted as \$1,000 in the numerator of the AV Calculator because the equation is based on total population expected spending by the total population, rather than by particular individuals. Instead the \$1,000 contribution is counted as the average dollar value it would cost to reduce a \$1,000 deductible to \$0. We note that while the AV Calculator cannot accommodate situations in which the HSA or amounts first made available under integrated HRAs that may be used only for cost sharing, exceeds the deductible, the value of the account can still be accommodated by using the alternative methods for AV calculation allowed under § 156.135(b).

Comment: Some commenters expressed concerns that a health plan issuer would not have access to information on employer contributions to HSAs and HRAs. Other commenters asked HHS to clarify how the provision on HSAs and HRAs would be operationalized.

Response: As finalized in § 156.135(c), employer contributions to an HSA or newly made available through integrated HRAs that may be used only for cost sharing, are taken into account when calculating the AV of a health plan only when the plan is offered with an HSA integrated HRAs that may only be used for cost sharing at the time of purchase. Because it is the issuer that uses the AV Calculator to determine a plan's AV, the HSA employer contribution, or the amount newly made available by the employer under an integrated HRA that may only be used for cost sharing, may be considered part of the AV calculation when the contribution is available and known to the issuer at the time the plan is purchased.

Comment: HHS received numerous comments regarding when and how to update the AV Calculator in future years. In some cases commenters expressed concern that annual updates to the AV Calculator or underlying data would require issuers to make annual updates to plan benefit designs in order to comply with AV standards.

Response: In response to these comments, we are now clarifying that HHS does not anticipate making annual changes to the AV Calculator logic or

²⁹ AHIP, Center for Policy and Research, "An Updated Survey of Health Insurance Claims Receipt and Processing Times, 2011", 2013. <http://www.ahip.org/SurveyHealthCare-January2013>.

underlying standard population. We will consider all comments received and give sufficient notice with regard to updating as we develop a strategy for updating the AV Calculator.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.135 of the proposed rule, with two modifications. First we make minor modifications to paragraph (b) to clarify that the issuer must submit an actuarial certification from an actuary as to the methodology used to determine AV when the plan design is not compatible with the AV Calculator. In paragraph (c) we clarify that, in order to count towards the AV calculation, employer contributions to HSAs and amounts made newly available under integrated HRAs that may only be used for cost sharing must be known to the issuer when the plan is purchased. Whether other types of integrated HRAs might count towards AV is being given further consideration. In this case, guidance on the treatment of HRAs will be issued and this regulation will be amended as necessary.

i. Levels of Coverage (§ 156.140)

This section describes standards for meeting the Affordable Care Act provisions directing that issuers offering QHPs or non-grandfathered health plans in the individual and small group markets offer plans that meet distinct levels of coverage.

In paragraph (a), we proposed the general requirement that the AV of a plan must be calculated according to § 156.135, within de minimis variation, in order to determine a plan's level of coverage. In paragraph (b), we proposed to codify section 1302(d)(1) of the Affordable Care Act, which requires that a bronze plan has an AV of 60 percent; a silver plan, 70 percent; a gold plan, 80 percent; and a platinum plan, 90 percent.

In paragraph (c), we proposed a de minimis variation of ± 2 percentage points for all non-grandfathered plans. For example, a silver plan could have an AV between 68 and 72 percent.

The comments and our responses to § 156.140 are set forth below.

Comment: Several commenters encouraged HHS to adopt a wider range of de minimis variation to allow for greater variation in plan design and so that more plans are able to maintain their current benefit designs in 2014 or to allow states to define their own de minimis variation. Other commenters

requested a narrower range than ± 2 percentage points.

Response: The proposed de minimis variation of ± 2 percentage points gives issuers the flexibility to set cost-sharing rates that are simple and competitive while ensuring consumers can easily compare plans of similar generosity. This approach strikes a balance between ensuring comparability of plans within each metal level and allowing plans the flexibility to use convenient cost-sharing metrics. The de minimis range also mitigates the need for annual plan redesign, allowing plans to retain the same plan design year to year and remain at the same metal level.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.140 of the proposed rule without modification.

j. Determination of Minimum Value (§ 156.145)

Section 1302(d)(2)(C) of the Affordable Care Act sets forth the rules for calculating the percentage of the total allowed costs of benefits provided under a group health plan or health insurance coverage under the PHS Act and the Code by providing that the rule adopted by the Secretary under section 1302(d)(2) include the rules for calculating the percentage of the total allowed costs of benefits provided under a group health plan or health insurance coverage. Section 36B(c)(2)(C)(ii) of the Code provides that an employer-sponsored plan provides minimum value (MV) if this percentage is no less than 60 percent. For the purpose of determining that a given plan provides MV, we proposed in paragraph (a) that the percentage of the total allowed cost of benefits will be determined using one of the main methodologies as described in Treasury Notice 2012–31, released on May 14, 2012 (“MV Notice”).³⁰ In paragraph (c), we proposed that MV for employer-sponsored self-insured group health plans and insured large group health plans will be determined using a standard population that is based on self-insured group health plans. We also proposed in the preamble that employer contributions to an HSA and amounts newly made available under an HRA will be taken into account in determining MV in accordance with the principles applied in taking such

amounts into account in determining AV.

In applying this approach to determining MV, in paragraph (a)(1), we proposed that employer-sponsored self-insured and insured group plans will be able to use the MV Calculator, which would be made available by HHS and the Internal Revenue Service. We described in preamble to the proposed rule how the MV Calculator is similar in design to the AV Calculator discussed above in connection with § 156.135. Furthermore, section 1302(d)(2)(C) of the Affordable Care Act provides that the percentage of the total allowed costs of benefits provided under a group health plan or health insurance coverage for the purposes of determining whether the plan or insurance provide minimum value will be determined using the rules contained in regulation for determining actuarial value.

As an alternative to using the MV Calculator, we proposed in paragraph (a)(2) that an employer-sponsored plan would be able to use an array of design-based safe-harbors published by HHS and the Internal Revenue Service in the form of checklists to determine whether the plan provides MV.

Third, if an employer-sponsored plan contains non-standard features that are not suitable for the use of the calculator and do not fit the safe harbor checklists, we proposed in paragraph (a)(3) to permit MV to be determined through certification by an actuary without the use of the MV Calculator. The actuary would make this determination based on the plan's benefits and coverage data and the standard population, utilization, and pricing tables available for purposes of the valuation of employer-sponsored plans. As proposed, this final option would be available only when one of the other methodologies is not applicable to the employer-sponsored plan. We proposed that the determination of MV must be made by a member of the American Academy of Actuaries, based on an analysis performed in accordance with generally accepted actuarial principles and methodologies. We intend to issue applicable guidance concerning the actuarial analysis.

In the event that a plan uses the MV Calculator and offers an EHB outside of the parameters of the MV Calculator, we proposed in paragraph (b)(1) that an actuary who is a member of the American Academy of Actuaries will be permitted to determine the value of that benefit and add it to the result derived from the MV Calculator in accordance with the generally accepted actuarial principles and methodologies. For clarity, alignment, and administrative ease, we proposed in paragraph (b)(2),

³⁰ Internal Revenue Service, “Minimum value of an employer-sponsored health plan” (2012). Available at: <http://www.irs.gov/pub/irs-drop/n-12-31.pdf>.

for purposes of determining that a group health plan provides MV, that such plans will be permitted to take into account all benefits provided by the plan that are included in any one of the EHB-benchmarks.

The comments and our responses to § 156.145 are set forth below.

Comment: We received several comments asking why the AV Calculator cannot be used to determine minimum value.

Response: The AV Calculator was designed to reflect a standard population as directed by section 1302(d)(2)(A) of the Affordable Care Act. Because it represents the individual and small group markets, the AV Calculator was designed to include data that is reflective of these anticipated populations. Similarly, the MV Calculator is intended to test whether an employer-sponsored group health plan—which is not in the individual or small group insurance markets—provides minimum value and therefore determine if an employee is eligible for a premium tax credit. Thus, we have developed an MV Calculator with similar functionality to the AV Calculator but based on claims data that better reflects typical employer-sponsored plans. In our sampling, the vast majority of plan designs that are in excess of 60 percent AV are also in excess of 60 percent MV. We are finalizing the rule with added language establishing any plan in the small group market that meets any of the levels of coverage, as described in § 156.140 of this subpart, satisfies minimum value.

Comment: We received numerous comments asking when the MV Calculator and safe-harbor checklists will be available for public use.

Response: The MV Calculator with accompanying continuance tables and the MV methodology are now available at <http://cciio.cms.gov/resources/regulations/index.html#pm> and we look forward to comments on both.

Comment: Several commenters questioned why certain benefits outside EHB would be included in the calculation of MV under paragraph (b).

Response: While employer-sponsored group health plans are not required to offer EHB unless they are health plans offered in the small group market subject to PHS Act section 2707(a), employer-sponsored group health plans that seek to offer minimum value must offer 60 percent of the total allowed cost of benefits. Under section 1302(d)(2) of the Affordable Care Act, this measurement, like AV, is based on the provision of EHB to a standard population. To calculate minimum value, employer-sponsored plans may

account for any benefits covered by the employer that are also covered in any one of the EHB-benchmark plan options in any state.

Comment: Commenters recommended using the same de minimis variation of the AV Calculator, ± 2 percentage points, when using the MV Calculator.

Response: We acknowledge the flexibility in plan design when allowing for a de minimis variation of ± 2 percentage points in the AV Calculator and the similar functionality of the MV Calculator to the AV Calculator; however, whereas the statute allows for a de minimis range with actuarial value there is no similar provision in section 36B of the Code with regard to MV.

Summary of Regulatory Changes

In general, we are finalizing the provisions of § 156.145 as proposed. To address concerns whether insurance offered in the small group market at a bronze level of coverage provides MV, we have added regulation text at § 156.145(a)(4), to clarify that if a plan in the small group market meets any of the levels of coverage described in § 156.140(b), it meets MV. We have also added § 156.145(d) to reflect the proposed preamble language that employer contributions to an HSA and amounts newly made available under integrated HRAs, specifically HRAs that may be used only for cost sharing, will be taken into account in determining MV. To provide greater clarity, we have modified § 156.145(a) to read that an employer-sponsored plan provides MV if the percentage of the total allowed costs of benefits provided under the plan is no less than 60 percent. An employer-sponsored plan may use one of the methodologies outlined in § 156.145 to determine whether the percentage of the total allowed costs of benefits provided under the plan is not less than 60 percent. Whether other types of integrated HRAs might count towards MV is being given further consideration. In this case, guidance on the treatment of HRAs will be issued and this regulation will be amended as necessary.

k. Application to Stand-alone Dental Plans inside the Exchange (§ 156.150)

In paragraph (a), we proposed that stand-alone dental plans would have a separate annual limitation on cost sharing from QHPs covering the remaining EHBs. While the annual limitation on cost-sharing for a QHP embedding pediatric dental coverage would have to be consistent with § 156.130, the annual limitation on cost sharing for a stand-alone dental plan would be considered in accordance with

this section. We proposed that the plan must demonstrate the annual limitation on cost sharing for the stand-alone dental plan is reasonable for coverage of the pediatric dental EHB. The annual limitation on cost sharing would be applicable to in-network services only, consistent with § 156.130(c).

In paragraph (b), we proposed actuarial value standards for stand-alone dental plans. The calculator developed by HHS under proposed § 156.135 would be inappropriate for stand-alone dental plans because the standard population that underlies the HHS-developed calculator could not be reasonably adapted to reflect a pediatric-only population that utilizes dental services. Accordingly, in paragraph (b)(1), we proposed that stand-alone dental plans may not use the HHS-developed AV calculator. Instead, given the unique and narrow focus of the stand-alone dental plan market, we proposed in paragraph (b)(2) that any stand-alone dental plan certified to meet an 75 percent AV, with a de minimis range of ± 2 percentage points, be considered a “low” plan and anything with an AV of 85 percent, with a de minimis range of ± 2 percentage points, be considered a “high” plan. In order to meet this standard we proposed in paragraph (b)(3) that the issuer of a stand-alone plan demonstrate that the plan meets the “high” or “low” level of coverage as certified by a member of the American Academy of Actuaries using generally accepted actuarial principles.

The comments and our responses to § 156.150 are set forth below.

Comment: Several commenters supported our proposal to allow stand-alone dental plan to have a separate out-of-pocket maximum, subject to a standard of “reasonableness” and either requested additional guidance on the “reasonable” standard or provided suggestions for how best to further define what a “reasonable” out-of-pocket maximum would be for a stand-alone dental plan. Other commenters urged HHS to include stand-alone dental plans in the overall out-of-pocket maximum and to find some method to develop a method to track and coordinate the out-of-pocket maximum between issuers.

Response: We agree with comments noting that coordination between medical and dental issuers would be administratively complex and accordingly could result in higher premiums for consumers. We therefore allow for a separate out-of-pocket maximum for stand-alone dental issuers. We clarify that it will be up to the Exchange to decide what constitutes a reasonable out-of-pocket maximum for

stand-alone dental plans and anticipate issuing further interpretive guidance for the federally-facilitated Exchanges in sub-regulatory guidance.

Comment: Several commenters supported the proposed “high” and “low” approach for the AV calculation of stand-alone dental plans, but urged HHS to decrease the “low” option from 75 percent to 70 percent as a more affordable option for consumers and to increase variation between “high” and “low” plans. Other commenters expressed concerns about the impact of a “high” and “low” approach on consumers from an affordability standpoint. Lastly, some commenters requested that stand-alone dental plans be held to the same standard as health plans.

Response: A “high” and “low” approach for the AV calculation of stand-alone dental plans simplifies the comparison between stand-alone dental plans with varying cost-sharing levels, while minimizing market disruption for dental plans. The AV levels for the “high” and “low” options are high compared to metal levels set in the statute to minimize market disruption. This permits stand-alone dental plans to maintain current benefit designs without adding deductibles or other cost-sharing features that are currently not part of those plans. We agree with commenters that 70 percent as a low level will allow for greater plan variation and are finalizing the regulation with a high/low AV requirement of 70 percent and 85 percent respectively.

Comment: The statute and regulations provide that if an Exchange offers a stand-alone dental plan offering a pediatric dental EHB benefit, medical plans are not required to offer a pediatric dental plan benefit on that Exchange. Several commenters encouraged HHS to extend the ability of a medical insurance plan to not offer the pediatric dental EHB into the non-Exchange market, in cases where a stand-alone dental plan that meet the standards to cover the pediatric dental EHB is offered.

Response: The Affordable Care Act does not provide for the exclusion of a pediatric dental EHB outside of the Exchange as it does in section 1302(b)(4)(F) of the Affordable Care Act for QHPs. Therefore, individuals enrolling in health insurance coverage not offered on an Exchange must be offered the full ten EHB categories, including the pediatric dental benefit. However, in cases in which an individual has purchased stand-alone pediatric dental coverage offered by an Exchange-certified stand-alone dental

plan off the Exchange, that individual would already be covered by the same pediatric dental benefit that is a part of EHB. When an issuer is reasonably assured that an individual has obtained such coverage through an Exchange-certified stand-alone dental plan offered outside an Exchange, the issuer would not be found non-compliant with EHB requirements if the issuer offers that individual a policy that, when combined with the Exchange-certified stand-alone dental plan, ensures full coverage of EHB. We note that the stand-alone dental plan would have to be an Exchange-certified stand-alone dental plan to ensure that it covered the pediatric dental EHB, as required for Exchange certification under section 1311(d)(2)(B)(ii) of the Affordable Care Act. However, the Exchange-certified stand-alone dental plan would not need to be purchased through an Exchange. This alternate method of compliance is at the option of the medical plan issuer, and would only apply with respect to individuals for whom the medical plan issuer is reasonably assured have obtained pediatric dental coverage through an Exchange-certified stand-alone dental plan. In addition, this option is only available for the pediatric dental EHB, and not for any other EHB, because of the unique treatment of stand-alone dental plans inside the Exchanges. With respect to other individuals seeking to enroll in the same plan, the issuer would be required to offer the same coverage generally (there would be no exception to guaranteed availability that would apply), but would have to make pediatric dental benefits available to such individuals.

Comment: HHS received comments asking whether childless adults and families with children need to purchase a stand-alone dental plan if the QHP they enroll in through an Exchange has omitted the pediatric dental EHB as allowed under section 1302(b)(4)(F) of the Affordable Care Act.

Response: Section 1302 of the Affordable Care Act outlines the requirements for health plans to cover the ten categories of the essential health benefits. The only exception permitted under 1302 of the Affordable Care Act is for QHPs to exclude coverage of the pediatric dental EHB if there is a stand-alone dental plan offered in the Exchange. Section 1311 of the Affordable Care Act requires all Exchange stand-alone dental plans to cover the pediatric dental EHB. In this way, sections 1302 and 1311 of the Affordable Care Act require that the full set of essential health benefits be offered to people purchasing coverage through

the Exchange. However, nothing in this rule requires the purchase of the full set of EHB if the purchase is made through an Exchange. Thus, in an Exchange, someone (with a child or without) can purchase a QHP that does not cover the pediatric dental EHB without purchasing a stand-alone dental plan. As noted above, outside of an Exchange, an individual or family must be offered coverage of all ten categories of EHB, either through one policy, or through a combination of a medical policy and an Exchange-certified stand-alone dental plan, as described above.

Comment: Several commenters asked how the policies in § 156.150 would affect a health insurance plan with an embedded pediatric dental EHB.

Response: In response to these questions, we are now clarifying that the policies in § 156.150 apply only to the pediatric dental EHB when offered by a stand-alone dental plan through an Exchange. When the pediatric dental benefit is embedded in a health insurance plan subject to standards set forth in §§ 156.130 and 156.140, we do not distinguish it from other benefits with respect to AV and cost-sharing requirements.

Comment: Several commenters asked whether stand-alone dental plans in the Exchange can offer family coverage in addition to the pediatric dental EHB benefit.

Response: Pursuant to section 1311(d)(2)(B)(ii) of the Affordable Care Act, a stand-alone dental plan must offer the pediatric dental EHB but may offer additional benefits, which could include non-pediatric coverage. We note that only the pediatric dental benefit, and not any non-pediatric coverage, would be subject to EHB standards, including complying with the requirement to offer benefits that are substantially equal to the benchmark and meeting AV and out-of-pocket limit requirements for stand-alone dental plans.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.150 of the proposed rule, with the following modifications: We clarify in paragraph (a) that the Exchange determines what constitutes a reasonable out-of-pocket maximum for a stand-alone dental plan. Also, in paragraph (b)(2)(i) we are changing the target AV for a “low” stand-alone dental plan from 75 percent to 70 percent. In addition, we clarify here that plans outside of the Exchange may offer EHB that exclude pediatric dental benefits if they are “reasonably

assured” that such coverage is sold only to individuals who purchase Exchange certified stand-alone dental plans.

3. Subpart C—Accreditation

Accreditation of QHP Issuers (§ 156.275)

Recognition of Accrediting Entity by HHS (§ 156.275(c)(1) and (c)(4))

In § 156.275, we proposed to amend § 156.275(c)(1) to provide an application and review process for the current (“phase one”) recognition process of accrediting entities. This would allow additional accrediting entities the opportunity to apply and demonstrate how they meet the conditions for recognition articulated in 1311(c)(1)(D) of the Affordable Care Act. We also proposed to amend § 156.275(c)(4)(i) to delete the timeframe of submitting the documentation within 60 days of publication of this final rule and require accrediting entities to provide the documentation described in § 156.275(c)(4)(i) with their application for review.

The comments and our responses to § 156.275 are set forth below.

Comment: Commenters generally supported the HHS proposal to establish an application and review process for the recognition of additional accrediting entities as part of the phase one recognition process. Several commenters requested that, to be recognized, accrediting entities be held to the same standards as were used to recognize NCQA and URAC.^{31 32} Other commenters noted specific accrediting entities that should be recognized and asked that issuers seeking QHP certification be able to select the recognized accrediting entity from which to seek accreditation. Commenters also asked HHS to clarify that Exchanges must accept accreditation from any of the recognized accrediting entities.

Response: In our notice titled, “Recognition of Entities for the Accreditation of Qualified Health Plans”, published on November 23, 2012 (77 FR 70163), we announced NCQA and URAC as recognized accrediting entities by the Secretary of HHS to provide accreditation of QHPs meeting the requirements of 45 CFR 156.275 as they have effectively met the conditions listed in § 156.275(c)(2), (c)(3), and (c)(4). Nothing in this final

rule changes that recognition. HHS will finalize our regulation text as proposed with slight technical corrections to paragraph (c)(1)(iv) to correct the verb tenses. By finalizing § 156.275(c)(1) and (4) largely as proposed, HHS will implement an application and review process by which additional accrediting entities can be recognized. This process also allows for accrediting entities that apply and are not recognized to reapply, provided that its standards are modified to meet the requirements. We concur with commenters that this process to provide other entities an opportunity to apply would provide expanded choices regarding QHP accreditation for Exchanges, states and issuers. As we stated in the proposed rule, this assessment will be the same as that underlying the recognition of NCQA and URAC. We also confirm that, for the purposes of QHP certification, issuers have the flexibility to seek accreditation from any of the HHS-recognized accrediting entities and that Exchanges must accept accreditation from any of the recognized accrediting entities for the purposes of QHP certification.

Comment: Commenters asked for clarification about when the phase two recognition process would replace phase one.

Response: As stated in the Recognition of Entities for the Accreditation of Qualified Health Plans Final Rule (July 20, 2012 77 FR 42663), the phase one recognition process is effective until it is replaced by the phase two process. HHS has not yet set a timeline for the development and implementation of phase two.

Comment: Several commenters requested that HHS modify the criteria established to evaluate accrediting entities, specified in 45 CFR 156.275, including setting minimum standards for accrediting entities, adding specific clinical measures for accrediting entities to collect as part of accreditation, and adding specific topic areas to the accreditation standards, such as evaluating an issuer’s implementation of mental health parity. Other commenters gave suggestions on items for inclusion in the phase two recognition process, including antidiscrimination, network adequacy and essential community provider standards; clinical measures applicable to specific populations, such as children, and specific measurement tools; implementing performance-based accreditation; permitting QHP issuers to have their programs or services accredited; and a process for HHS to update standards over time.

Response: HHS has established criteria for accreditation in 45 CFR 156.275 that correspond to requirements

included in section 1311(c)(1)(D) of the Affordable Care Act. We consider these requirements as minimum standards for recognized accrediting entities to review as part of the accreditation of QHPs. These requirements were finalized in 45 CFR 156.275. We will consider the above comments as we develop the phase two recognition process which may establish additional criteria for recognized accrediting entities or for the accreditation to be provided for QHPs.

Comment: Commenters supported the proposal for HHS to review applications from accrediting entities as they are received by HHS. Other commenters asked that HHS modify the proposed process by shortening the timeline to review applications from accrediting entities. Commenters also asked that the documentation required in § 156.275(c)(4) be released to the public.

Response: HHS has established a process to accept accrediting entity applications on a rolling basis in order to allow for any accrediting entity wishing to apply to do so as soon as it meets the requirements established in § 156.275(c). The process also allows for accrediting entities who apply and are not recognized to reapply. HHS maintains that a thorough review of an applicant’s documentation supporting the application specified in (c)(1)(i) and the publication of a notice in the **Federal Register** may take up to 60 days from the date of receipt. Further, HHS maintains that a minimum 30-day comment period is necessary to ensure that the public has adequate time to consider the accrediting entities being considered for recognition. HHS further maintains that no time period will be established for when the final notice is published in the **Federal Register**, as HHS must carefully review and consider comments submitted during the comment period before making a determination on whether or not an accrediting entity will be recognized. Lastly, as we proposed in (c)(1)(ii), HHS will publish a notice in the **Federal Register** that will include a summary of HHS’s analysis of whether the accrediting entity meets the criteria described in (c)(2) and (3). Other documentation submitted during the application process may be proprietary and will not be made public.

Comment: Several commenters offered suggestions for HHS to consider when implementing future quality reporting requirements for QHP issuers and Exchanges. These suggestions included: Specific quality measures for issuers to report; methods to minimize burden for reporting quality data; elements and attributes to consider in developing the QHP-specific quality

³¹ Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, Final Rule, 77 FR 42658–42672 (July 20, 2012) (to be codified at 45 CFR part 156).

³² Recognition of Entities for the Accreditation of Qualified Health Plans, 77 FR 70163 (November 23, 2012).

rating; and consulting with external stakeholders as the quality requirements are developed. Other commenters made recommendations for educating consumers about quality information as well as the types of information that should be displayed to consumers. Finally, we received comments encouraging standardized quality reporting requirements across Exchanges and expressing support for State flexibility in establishing quality requirements.

Response: While HHS appreciates the submission of these comments, they are outside the scope of this rule. We will solicit input on quality reporting requirements as part of future rulemaking.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.275(c)(1) and (4) of the proposed rule without substantive modification. We are revising the text at § 156.275(c)(1)(iv) for technical corrections to reflect that the required notice has been published since the proposed rule.

III. Collection of Information

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before an information collection request is submitted to the Office of Management and Budget (OMB) for review and approval. In order 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.

Below is a summary of the information collection requirements outlined in this regulation. Throughout this section, we assume that each data collection will occur on an annual basis unless otherwise noted. We used the Bureau of Labor Statistics (BLS) Web site to identify salary data, unless otherwise indicated. Fringe benefit estimates were taken from the BLS March 2011 Employer Costs for

Employee Compensation report. These compensation estimates were selected to align with the burden estimates for the data collections described in the final rule that published on March 27, 2012 (77 FR 18310). For purposes of presenting an estimate of paperwork burden, we reflect the operation of an Exchange in fifty states, the U.S. territories, and the District of Columbia. Similarly, we estimate the burden for issuers participating in all 50 states, the territories and the District of Columbia. Therefore, these estimates should be considered an upper bound of burden estimates. These estimates may be adjusted in future information collection requests. We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. ICRs Regarding Additional Required Benefits (§ 155.170(c))

In § 155.170(c), we direct QHP issuers to quantify and report to the Exchange the cost attributable to required benefits in addition to EHB. This is a third-party disclosure requirement. Issuers will use a uniform rate template in a revision to the Rate Increase Disclosure and Review Reporting Requirements information collection request to report this information. The burden associated with meeting this data collection is included in the Rate Review information collection request. A **Federal Register** notice (77 FR 40061),³³ in which we sought comments on this PRA package, was published on July 6, 2012.

As noted in the Rate Review information collection request, we estimate that a total of 2,010 issuers in the individual market and 1,050 issuers in the small group market will offer products and that each issuer will have an average of 2.5 submissions per year. We anticipate that it will take an actuary a total of 11 hours to complete the uniform rate template, at \$225 per hour for an actuary. The total annual cost is estimated to be \$18,933,750. Of this total amount, only a fraction can be attributable to the portion of the uniform rate template that pertains to benefits in addition to EHB for QHP issuers. We estimate that of the total 11 hours it will take an actuary to complete the uniform rate template, it will take an actuary 1 hour to complete the portion pertaining to benefits in addition to EHB. Therefore, we estimate the cost

attributable to the collection of information regarding benefits in addition to EHB to be \$1,721,250.

B. ICRs Regarding State Selection of Base-Benchmark (§ 156.100) and EHB-Benchmark Plan Standards (§ 156.110)

In § 156.100, we proposed that a state may select a base-benchmark plan to serve as a reference plan to define EHB in that state. We also proposed that if a state does not select a benchmark plan, its base-benchmark would be the largest plan by enrollment in the largest product in the state's small group market. In § 156.110, we proposed that a state-selected or default benchmark plan must offer coverage in each EHB category, as required by the Affordable Care Act. We proposed that if a base-benchmark plan does not offer coverage in a category, it must be supplemented to include those missing benefit categories.

We do not believe that this is a change to the information collection associated with state selection and submission of a benchmark plan and associated benefits and the data collection to establish default benchmark plans, including any required supplementing, which is already captured in the collection approved under OMB Control Number 0938-1174.

C. ICRs Regarding AV Calculation for Determining Level of Coverage (§ 156.135)

In § 156.135(b), we proposed to create an exception to using the AV calculator for issuers with health plans that are not designed in a way that is compatible with the AV calculator. To take advantage of this exception, issuers must submit an actuarial certification on their alternative method to the state, HHS, the Exchange, or OPM. This is a third-party disclosure requirement when the issuers submit to the state or the Exchange, and this is a reporting requirement when the issuers submit to HHS, OPM, or a Federally-facilitated Exchange. We account for this collection in the Initial Plan Data Collection to Support Qualified Health Plan Certification and Other Financial Management and Exchange Operations information collection request. A **Federal Register** notice (77 FR 40061) regarding this PRA package was published on July 6, 2012. As required by the PRA, we will publish another notice in the **Federal Register** when the aforementioned information collection request is submitted to OMB for review and approval.

In the QHP Certification PRA package, we estimate that 1,200 issuers will each offer 15 potential QHPs, for a total of

³³ "Agency Information Collection Activities: Proposed Collection; Comment Request; Webinars". (77 FR 40061) Available at <http://www.gpo.gov/fdsys/pkg/FR-2012-07-06/pdf/2012-16508.pdf>.

18,000 potential QHPs, and that the per-issuer burden will be 175 hours. We estimate the cost per issuer in the first year of operations to be \$13,475, which represents an aggregation of several staff, including actuarial staff. This information collection request includes data collections for QHP certification, risk adjustment, and reinsurance. We believe that only 5 percent of issuers will be unable to use the AV calculator, thus use the process proposed in § 156.135(b) and assume that it will take each issuer 8 of the total 175 hours to provide the requested information. We further assume that the 8 hours of work would be performed by an actuary, at \$225 per hour. Therefore, we estimate the total cost attributable to § 156.135(b) to be \$1,800 per QHP and \$1,620,000, per year.

In § 156.135(d), we proposed that beginning in 2015, a state may submit a state-specific standard population, to be used for AV calculations, so long as the criteria described in § 156.135(d)(1) through (6) are met. A state that applies must submit to HHS summary evidence that the requirements described in the proposed rule are met and the dataset is in a format that will support the use of the AV calculator. We expect that for each state choosing this option, the data submission will require 15 hours from a database administrator at \$47.70 an hour, 4 hours of actuarial work at \$225 an hour, and 1 hour of management review at \$75.15 an hour. Therefore, the total cost associated with the reporting requirement for each state choosing this option will be \$1,691. We assume that states opting to develop a state-specific standard population will provide new data every three to five years.

D. ICRs Regarding Stand-Alone Dental Plans Inside the Exchange (§ 156.150(a))

In § 156.150(a), we proposed that stand-alone dental plans covering the pediatric dental EHB under § 155.1065 must demonstrate to the Exchange that they have a reasonable annual limitation on cost sharing. This is a third-party disclosure requirement.

We account for this collection in the QHP Certification information collection request discussed earlier in this section, where we estimate that 40 issuers will each offer a stand-alone dental plan, and that the burden for certification will be 6 hours per issuer, at a total hourly billing rate of \$77, for a total cost of \$462 per issuer. We estimate that of those 6 hours, 1 will be attributable to demonstrating that the annual limitation on cost sharing is reasonable, at a cost of \$77 per plan. Therefore, across 40 plans, we estimate the total annual cost to be \$3,080.

E. ICRs Regarding Accreditation (§ 156.275)

As part of the proposed rule, titled “Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation” (77 FR 70644), published in the **Federal Register** on November 26, 2012, we also issued a 60-day **Federal Register** notice seeking comments on these ICRs. The 60-day comment period closed on January 26, 2013. We will submit a revised information collection request to OMB, under OMB Control Number 0938–1176, to account for the adjustment in the number of respondents and the corresponding adjustment to the burden. At that time, as required by the PRA, we will publish another notice in the **Federal Register** when the aforementioned information collection request is submitted to OMB for review and approval.

The comments and our responses are set forth below.

Comment: One commenter noted that the data collection proposed under the information collection request entitled “Recognized Accrediting Entities Data Collection”³⁴ requires the submission of significant amounts of sensitive, proprietary, or confidential data and may be overly burdensome to issuers.

Response: HHS disagrees that the data submission requirements for recognized accrediting entities and accrediting entities seeking recognition from HHS for the purpose of § 156.275(a) will be overly burdensome to issuers. We describe minimal data submission requirements for issuers. Issuer burden for the accreditation requirement is accounted for in the QHP Application information collection request.³⁵ All other data requirements described in the information collection request regarding accreditation will be met by recognized accrediting entities and entities applying to be recognized by HHS.

Comment: One commenter offered specific feedback on the content areas that were proposed for data collection, including what accreditation survey data is collected, how accreditation data from different accrediting entities may vary, and requesting that only specific CAHPS survey questions be required for submission by QHP issuers.

³⁴ Available at: <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10449.html>.

³⁵ Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, Final Rule, 77 FR 42658–42672 (July 20, 2012) (to be codified at 45 CFR part 156).

Response: The purpose of the ICRs regarding accreditation is to solicit feedback from stakeholders on the estimated burden associated with the proposed data collection on recognized accrediting entities. Comments in regard to specific content areas of the data collection are therefore outside of the scope. We finalized the accreditation documentation submission requirements in a final rule published on July 20, 2012.³⁶

IV. Regulatory Impact Analysis

HHS has examined the impacts of this proposed regulation under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993) and Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 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). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866—emphasizing the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any 1 year), and a “significant” regulatory action is subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a “significant regulatory action.” In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget as an economically significant regulatory action.

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. HHS will submit a

³⁶ Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans (CMS–9965–F), 77 FR 42,658 (July 20, 2012).

report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is a “major rule” as defined by 5 U.S.C. 804(2). This rule will be effective April 26, 2013, sixty days after date of publication in the **Federal Register**.

A. Summary

This final rule will implement the requirements related to EHB and AV levels of coverage, and establish the timeline according to which QHP issuers participating in Federally-facilitated Exchanges must be accredited. We note that the Exchange regulation (45 CFR 156.200) established that QHPs will cover essential health benefits, as defined by the Secretary, and that QHPs be accredited on the basis of local performance. The cost to health plans of obtaining QHP certification and participating in Exchanges is already accounted for in the regulatory impact analysis that accompanies that regulation.³⁷ Therefore, this analysis describes the incremental costs, benefits, and transfers associated with provisions in this proposed rule, for example that health plans cover the essential health benefits as specifically defined herein, and that health plans use the HHS-developed AV calculator.

This final rule also contains details relating to the establishment of a timeline by which QHPs seeking certification by Federally-facilitated Exchanges must be accredited. We do not believe that this results in incremental benefits, costs, or transfers.

HHS has finalized this regulation to implement the protections intended by the Congress in an economically efficient manner. In accordance with OMB Circular A–4, HHS has quantified the benefits, costs and transfers where possible, and has also provided a qualitative discussion of some of the benefits, costs and transfers that may stem from this proposed regulation.

B. Overview of Key Provisions in the Proposed Rule

The Affordable Care Act directs the Secretary to define EHB such that EHB includes at least and reflects an appropriate balance among 10 benefit categories, and is equal in scope to benefits offered by a typical employer plan. Non-grandfathered plans in the individual and small group markets both inside and outside of the Exchanges, including multi-state plans, Medicaid benchmark and benchmark-equivalent, and Basic Health Programs, if applicable, must cover EHB beginning in 2014. This final rule establishes how the Secretary will define EHB based on a state-specific benchmark plan and lays out standards for the EHB-benchmark plan and for issuers that cover EHB.

In addition, the Affordable Care Act directs issuers offering non-grandfathered health plans in the individual and small group markets to ensure that any offered plan meets specific AVs. The final rule outlines a process for computing plan AV using an HHS-developed AV calculator, as well as standards and flexibility for issuers in meeting the metal tiers.

C. Need for Regulatory Action

This rule finalizes standards related to EHB and AV consistent with the Affordable Care Act. HHS believes that the provisions that are included in this final rule are necessary to fulfill the Secretary's obligations under sections 1302 and 1311 of the Affordable Care Act. Establishing specific approaches for defining EHB and calculating AV will bring needed clarity for states, issuers, and other stakeholders. Absent the provisions outlined in this proposed rule, states, issuers, and consumers would face significant uncertainty about how coverage of EHB should be defined and evaluated. Similarly, failing to specify a method for calculating AV could result in significant inconsistency across states and issuers, and significant confusion for consumers. Finally, establishing a clear timeline for potential QHPs to become accredited is essential to successful issuer participation in Federally-facilitated Exchanges.

D. Summary of Impacts and Accounting Table

In accordance with OMB Circular A–4, Table IV.1 below depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this regulatory action.

HHS anticipates that the provisions of this final rule will assure consumers

that they will have health insurance coverage for EHB, and significantly increase consumers' ability to compare health plans, make an informed selection by promoting consistency across covered benefits and levels of coverage, and more efficiently purchase coverage. This final rule ensures that consumers can shop on the basis of issues that are important to them such as price, network physicians, and benefits offered, and be confident that the plan they choose does not include unexpected coverage gaps, like hidden benefit exclusions. It also allows for flexibility for plans to promote innovation in benefit design.

Insurance contracts are extremely complicated documents; therefore, many consumers may not understand the content of the contracts they purchase.³⁸ This complexity has two undesirable results. First, consumers may unknowingly purchase a product that does not meet their basic needs—the product may not cover benefits to restore or maintain good health, or may result in more financial exposure than the consumer anticipated. Second, complexity may deter consumers from market transactions, whereas a small number of meaningful choices may increase consumers' willingness to purchase coverage.³⁹

The specific approach to defining EHB in this final rule realizes the benefits of simplicity and transparency by allowing each state to choose a benchmark from a set of plans that are typical of the benefits offered by employers in that state. The final rule allows that EHB in each state reflect the choices made by employers and employees in that state today, and minimizes disruption in existing coverage in the small group market. In addition, the provisions addressing specific benefit categories, such as habilitative services and pediatric dental and vision services, will improve access to care for consumers who require these benefits.

The approach to defining AV in this final rule uses standard assumptions about utilization and prices, and, for most products, directs issuers to use an AV calculator created by the Department to compute AV. This approach will ensure that two plans with the same cost-sharing parameters

³⁷ “Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans, Exchange Standards for Employers (CMS–9989–FWP) and Standards Related to Reinsurance, Risk Corridors and Risk Adjustment (CMS–9975–F): Regulatory Impact Analysis.” Centers for Medicare & Medicaid Services. Available at: <http://ccio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf>.

³⁸ Consumers Union. (2012). “What's Behind the Door: Consumers' Difficulties Selecting Health Plans.” Available at: <http://www.consumersunion.org/pub/pdf/Consumer%20Difficulties%20Selecting%20Health%20Plans%20Jan%202012.pdf>.

³⁹ Iyengar, Sheena S.; Lepper, Mark R. Journal of Personality and Social Psychology, Vol 79(6), Dec 2000, 995–1006.

(that is, deductibles, copayments, and coinsurance features) will have the same AVs. This approach is intended to lower consumer information costs and drive competition in the market by enabling

consumers to easily compare the relative generosity of plans, knowing that the AV of each plan has been calculated in the same manner.

In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

TABLE IV.1—ACCOUNTING TABLE

Category	Estimates	Units		
		Year dollar	Dis-count rate	Period covered
Benefits				
Annualized Monetized (\$millions/year)	Not Estimated Not Estimated	2011 2011	7% 3%	2013–2016 2013–2016
Qualitative	(1) Improved coverage in benefit categories less typically available. Expanded access to coverage of benefits, particularly in the individual market, including maternity and prescription drug coverage. (2) Alignment with current consumer and employer choices. Flexibility for states; limited market disruption; allowance for health plan innovation (e.g., substitution within benefit categories; de minimis variation for AV). (3) Efficiency due to greater transparency. Increased transparency and consumer ability to compare coverage.			
Costs				
Annualized Monetized (\$millions/year)	\$3.4* \$3.1*	2011 2011	7% 3%	2013–2016 2013–2016
Qualitative	(1) Administrative costs. Insurers will incur administrative costs associated with altering benefit packages to ensure compliance with the definition of EHB established in this proposed rule. Issuers may also incur minor administrative costs related to computing AV.			
	(2) Costs due to higher service utilization. As consumers gain additional coverage for benefits that previously did not meet the standards outlined in this proposed rule (for example, pediatric dental or vision coverage), utilization, and thus costs, may increase. A portion of this increased utilization and costs may be economically inefficient.			
Transfers				
Federal Annualized Monetized (\$millions/year)	Not Estimated Not Estimated	2011 2011	7% 3%	2013–2016 2013–2016

***Note:** Administrative costs include costs associated with Information Collection Requirements as described in section III of this final rule. These costs are annualized over the analysis period of 2013–2016.

E. Methods and Limitations of Analysis

There are many provisions of the Affordable Care Act that are integral to the goal of expanding access to affordable insurance coverage, including the provisions of this proposed rule relating to EHB and AV. Because it is often difficult to isolate the effects associated with each particular provision of the Affordable Care Act, we discuss the evidence relating to the provisions of this proposed rule, as well

as related provisions of the Affordable Care Act, in this regulatory impact analysis. We present quantitative evidence where it is possible and supplement with qualitative discussion.

F. Estimated Number of Affected Entities

As discussed elsewhere in the preamble, standards relating to EHB and AV will apply to all health insurance issuers offering non-grandfathered

coverage in the individual and small group markets—both inside and outside of the Exchanges. The following sections summarize HHS's estimates of the number of entities that will be affected by this proposed regulation.

a. Issuers

For purposes of the regulatory impact analysis, we have estimated the total number of health insurance issuers that will be affected by this proposed

regulation at the company level because this is the level at which issuers currently submit their annual financial reports to the National Association of Insurance Commissioners (NAIC). Table IV.2 shows the estimated distribution of

issuers offering comprehensive major medical coverage in the individual and small group markets based on data submitted on the National Association of Insurance Commissioners' 2011 Supplemental Health Care Exhibit

(SHCE).⁴⁰ Additionally, because many issuers are licensed in more than one state, we have also included data by "licensed entity" (company/state combination) for each market.

TABLE IV.2—ESTIMATED NUMBER OF ISSUERS AND LICENSED ENTITIES AFFECTED BY THE EHB AND AV REQUIREMENTS BY MARKET, 2011

Description	Issuers ¹ offering comprehensive major medical coverage		Licensed entities ² offering comprehensive major medical coverage	
	Number	% of Total	Number	% of Total
Total Issuers Offering Comprehensive Major Medical Coverage ³	446	100.0	2,107	100.0
By Market: ⁴				
Individual Market	355	79.6	1,663	78.9
Small Group Market ⁵	366	82.1	1,039	49.3
Large Group Market	375	84.1	922	43.8
Individual and/or Small Group Markets ⁶	427	95.7	1,993	94.6
Individual Market Only	82	18.4	904	42.9
Small Group Market Only	39	8.7	117	5.6
Individual & Small Group Markets Only	29	6.5	164	7.8
All Three Markets	279	62.6	545	25.9

Notes: ¹ Issuers represents companies (for example, NAIC company codes).

² Licensed Entities represents company/state combinations.

³ Total issuers excludes data for companies that are regulated by the California Department of Managed Health Care.

⁴ To be counted as offering coverage in a particular comprehensive major medical market, the issuer must have reported non-zero premiums and claims and had at least \$1,000 in total premiums per life year for at least one state.

⁵ Small group is defined based on the current definition in the PHS Act.

⁶ Subcategories do not add to the total because other categories are not shown separately such as those entities in the large group and small group markets, but not in the individual market.

Source: ASPE analysis of 2011 NAIC Supplemental Health Care Exhibit data.

b. Individuals

Persons enrolled in non-grandfathered individual or small group market coverage inside or outside of the Exchanges beginning in 2014 will be affected by the provisions of this final rule.⁴¹

In July 2012, CBO estimated that there will be approximately 24 million enrollees in Exchange coverage by 2016.⁴² Participation rates among potential enrollees are expected to be lower in the first few years of Exchange availability as employers and individuals adjust to the features of the

Exchanges.⁴³ Additionally, the EHB and AV provisions of this final rule will also affect enrollees in non-grandfathered individual and small group coverage outside of the Exchanges.

G. Anticipated Benefits

The Affordable Care Act ensures non-grandfathered health plans offered in the individual and small group markets offer a basic package of items and services. The benefits of health insurance coverage are well documented and discussed at length in previous RIAs,⁴⁴ including

improvement in clinical outcomes and financial security.^{45 46} This final rule applies a definition to EHB and finalizes other standards that are required of health plans, as directed under the statute.

In the market today, it is difficult for consumers to make well-informed choices when selecting from among competing health plans. The benefits offered are complicated and can vary widely across plans, making it difficult for consumers to understand which benefits are covered.⁴⁷ Further, wide variation in deductibles, coinsurance,

⁴⁰ The most complete source of data on the number of entities offering fully insured, private comprehensive major medical coverage in the individual and group markets is the National Association of Insurance Commissioners (NAIC) Annual Financial Statements and Policy Experience Exhibits database. These data contain information that issuers submit to the NAIC through State insurance regulators on four different financial exhibits (the Health, Life, Property & Casualty, and Fraternal "Blanks"). The 2011 SHCE captures data on individual, small group and large group comprehensive major medical coverage at the State level in a consistent manner across all Blanks, providing more extensive information about this market than was previously available. We note that issuers electing not to offer non-grandfathered individual or small group market policies would not be affected by the proposed rule.

⁴¹ The provisions in this proposed regulation could also potentially affect some enrollees with non-grandfathered large group market coverage in States that choose to give larger employers the option of purchasing coverage through the

Exchange starting in 2017. However, the Congressional Budget Office (CBO) and Joint Committee on Taxation (JCT) "expect that few large firms would take [advantage of] that option if offered because their administrative costs would generally be lower than those of nongroup policies that would be available in the exchanges." (For more information, see Congressional Budget Office, "Letter to the Honorable Evan Bayh: An Analysis of Health Insurance Premiums under the Patient Protection and Affordable Care Act," Washington, DC, 2009.)

⁴² "CBO's February 2013 Estimate of the Effects of the Affordable Care Act on Health Insurance Coverage," Congressional Budget Office, February 2013. Available at http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900_ACAInsuranceCoverageEffects.pdf.

⁴³ Congressional Budget Office, "Letter to the Honorable Evan Bayh: An Analysis of Health Insurance Premiums under the Patient Protection and Affordable Care Act," Washington, DC 2009.

⁴⁴ Available at: <http://ccio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf>.

⁴⁵ Institute of Medicine (2001). *Coverage Matters: Insurance and Health Care*. National Academies Press: Washington, DC. Burstin HR, Swartz K, O'Neil AC, Orav EJ, Brennan TA. 1999. The effect of change of health insurance on access to care. *Inquiry*; 35: 389–97. Finkelstein A et al. 2011. The Oregon health insurance experiment: Evidence from the first year. NBER Working Paper No. 17190.

⁴⁶ Institute of Medicine (2002). *Care without coverage: too little, too late*. National Academies Press. Ayanian J, et al. "Unmet Health Needs of Uninsured Adults in the United States." *JAMA*. 284(16). 2000:2061–9. 27; Roetzheim R, et al. "Effects of Health Insurance and Race on Colorectal Cancer Treatments and Outcomes." *American Journal of Public Health* 90(11). 2000: 1746–54; Wilper, et al. "Health Insurance and Mortality in US Adults." *American Journal of Public Health*. 99(12). 2009: 2289–2295.

⁴⁷ Garnick, D.W. et al. (1993). "How well do Americans understand their health coverage?" *Health Affairs*, 12(3); 204–212.

and other cost sharing features make it difficult for consumers to understand the relative levels of financial protection they will receive under competing plans.^{48 49}

Under the provisions in this final rule, the EHB-benchmark plan will reflect both the scope of services and any limits offered by a “typical employer plan” in that state. This approach, applying for at least the 2014 and 2015 benefit years, will allow states to build on coverage that is already widely available, minimize market disruption, and provide consumers with familiar products. This should heighten consumer understanding of plan options and may facilitate consumers’ abilities to make choices that better suit their needs. In addition, by ensuring that all plans cover a core set of benefits and services that will be compared against other plans that offer the same financial protection to the consumer, this final rule is expected to improve the quality and value of the coverage that is available for EHB.

Information on AV is expected to be used by consumers to compare non-grandfathered individual and small group market plans, and provides a method for consumers to understand relative plan value. Proposing standard pricing and utilization assumptions for AV calculations for QHPs and non-grandfathered health plans in the individual and small group markets will promote transparency and simplicity in the consumer shopping experience, as well as offer issuers the flexibility to set cost-sharing rates that are simple and competitive. Without this approach, plans with the same cost-sharing provisions could have different AVs making it difficult for consumers to compare and choose among health plans. It also fosters plan competition based on price, quality, and service—rather than variations in benefit design.

H. Anticipated Costs and Transfers

In addition to the administrative costs described in the Information Collection Requirements section of this proposed rule, HHS anticipates that the provisions of this final rule could result in increased costs related to increased utilization of health care services by people receiving coverage for previously uncovered or unaffordable benefits.

States have primary enforcement authority over health insurance issuers

and this proposed rule extends this primary enforcement authority for compliance with EHB and AV requirements defined in this rule. In addition, states must defray the cost of any state-required benefits in excess of the EHB that apply to QHPs and multi-state plans offered through Exchanges. As stated earlier, we expect that this will rarely occur, if at all, in 2014 and 2015, the period coverage by the benchmark policy.

The anticipated effects on enrollees in the individual market are expected to be larger than the effects on enrollees in the small group market. Coverage in the small group market is much more likely to include EHB already and, in fact, is included in the choice of benchmark plans.⁵⁰ Second, almost all products in the group market have AV above 60 percent,⁵¹ while there are likely to be changes to products in the individual market due to the provisions of this proposed rule.

Impact on Issuers

Commonly purchased products in the small group market, state employee plans, and the FEHBP Blue Cross Blue Shield (BCBS) Standard and Basic Options and Government Employees Health Association (GEHA) plans do not differ significantly in the range of services they cover.⁵² Because one of these plans will be chosen as the reference plan for EHB, most small group plans will provide benefits that are similar to EHB, and changes in

benefits offered to comply with EHB provisions will be relatively minor.

Notwithstanding this general conclusion, there are four types of benefits where changes are expected in the small group market: Mental health and substance use disorder, habilitative services, pediatric dental care, and pediatric vision services. In addition, individual health plans are less likely than small group health plans to cover all of the 10 statutory EHB categories. Below we discuss two categories of benefits and services that are less likely to be covered in the market today: mental health and substance use disorder services, and habilitative services.

Coverage of additional benefits results in a transfer from out-of-pocket payments to premium payments. Increased access to insurance coverage for previously excluded benefits will make medical care for those benefit categories more affordable for consumers by covering a portion of the costs of those services. While out-of-pocket costs would decline, consumers could purchase benefits and services inefficiently—that is, purchase more than the efficient amount of the previously excluded benefits and services. However, studies of the Medicare program suggest that the costs of this inefficiency are likely more than offset by the benefits of risk reduction.⁵³ The introduction of the Medicare program resulted largely in changes from uninsured to insured—research suggests that only 25 percent of seniors had private hospital insurance before the introduction of the program.⁵⁴ In contrast, this final rule will likely result in incremental gains in access, rather than changes in status from uninsured to insured. Accordingly, CMS expects that the tradeoff between the costs of inefficiency and the benefits of risk reduction will be as or more favorable as the results observed in studies of the Medicare program. As discussed previously, many other provisions of the Affordable Care Act, including healthier risk pools, greater administrative efficiencies, premium tax credits, and the transitional reinsurance program will lower premiums in the individual market and Exchanges.

⁴⁸ Consumers Union. (2012). “What’s Behind the Door: Consumers’ Difficulties Selecting Health Plans.” Available at: <http://www.consumersunion.org/pub/pdf/Consumer%20Difficulties%20Selecting%20Health%20Plans%20Jan%202012.pdf>.

⁴⁹ Isaacs, S.L. (2006). Consumer’s information needs: results of a national survey. *Health Affairs*, 15(4): 31–41.

⁵⁰ A study conducted by the Assistant Secretary for Planning and Evaluation (ASPE) found that commonly purchased products in the small group market, state employee plans, and federal employee plans do not differ significantly in the range of services they cover. Because one of these plans will be chosen as the reference plan for EHB, most small group plans will provide benefits that are similar to EHB. (ASPE Issue Brief (2011). “EHB: Comparing Benefits in Small Group Products and State and Federal Employee Plans.” U.S. Department of Health & Human Services.) In contrast, another ASPE study found that many current subscribers in the individual market lack coverage for some EHB benefits and services, such as maternity care and prescription drugs. (ASPE Research Brief (2011). “EHB: Individual Market Coverage” U.S. Department of Health & Human Services.)

⁵¹ ASPE Research Brief (2011). “AV and Employer Sponsored Insurance,” available at: <http://aspe.hhs.gov/health/reports/2011/AV-ESI/rb.pdf>. Similar results were found in a recent study by Gabel and colleagues. Jon R. Gabel, Ryan Lore, Roland D. McDevitt, Jeremy D. Pickreign, Heidi Whitmore, Michael Slover and Ethan Levy-Forsythe, “More Than Half Of Individual Health Plans Offer Coverage That Falls Short Of What Can Be Sold Through Exchanges As Of 2014,” *Health Affairs*, (2012), available at: <http://content.healthaffairs.org/content/early/2012/05/22/hlthaff.2011.1082.full.pdf+html>.

⁵² ASPE Issue Brief (2011). “EHB: Comparing Benefits in Small Group Products and State and Federal Employee Plans.” U.S. Department of Health & Human Services (2011).

⁵³ Finkelstein A, McKnight R: “What Did Medicare Do (And Was It Worth It)?” *Journal of Public Economics* 2008, 92:1644–1669; and Finkelstein, A, “The Aggregate Effects of Health Insurance: Evidence from the Introduction of Medicare,” *National Bureau of Economic Research. Working Paper No. 11619*, Sept, 2005.

⁵⁴ Finkelstein, A, “The Aggregate Effects of Health Insurance: Evidence from the Introduction of Medicare,” *National Bureau of Economic Research. Working Paper No. 11619*, Sept, 2005.

The statute requires that all plans covering EHB offer mental health and substance use disorder service benefits, including behavioral health treatment and services. The preamble of this rule provides that coverage of EHB must provide parity in treatment limitations between medical and surgical benefits and the mental health and substance use disorder benefits required to be covered as EHB in both the individual and small group markets. Many states^{55 56} have already added some form of mental health parity in some or all insured markets.⁵⁷ About 95 percent of those with coverage through the three largest small group products in each state had substance use disorder and mental health benefits.⁵⁸ Additionally, a study of implementation of parity in the FEHBP plans⁵⁹ as well as research into state-passed mental health parity laws⁶⁰ have shown little or no increase in utilization of mental health services, but found that parity reduced out-of-pocket spending among those who used mental health and substance abuse services.

As indicated in the preamble, many health insurance plans do not identify habilitative services as a distinct group of services.⁶¹ By implementing a transitional policy for coverage of habilitative services, this rule allows issuers time for review and development of policy in this area, and to gain experience to define these benefits. To the extent that states exercise the option to define habilitative services, small group market issuers may incur administrative and contracting costs associated with bringing their products into compliance

with a state's definition. However, because it is not yet clear which states will exercise this option or how any such states will define habilitative services, HHS cannot estimate these costs at this time.

With respect to AV and MV, research indicates that the overwhelming majority of employer-sponsored health plans meets and exceeds an AV of 60 percent.⁶² Combining both small group and large group, an estimated 1.6 percent to 2.0 percent of people covered by employer-sponsored insurance are enrolled in plans with an AV of less than 60 percent.

To keep premium costs low, the Affordable Care Act allows certain individuals (adults under age 30 and people who otherwise have unaffordable coverage) to purchase catastrophic coverage, which still guarantees first dollar coverage of preventive services and primary care check-ups but has higher deductibles and lower AVs.

Costs to States

State governments are generally responsible for health insurance enforcement in the individual and small group markets, with the federal government assuming that role in connection with federal law requirements if a state does not do so. While HHS expects that states may need additional resources to enforce the requirements that non-grandfathered plans in the individual and small group market provide EHB, and that these plans offer coverage with an AV equal to one of the four metal levels, these costs will be relatively minor.

If a state requires issuers to cover benefits in excess of EHB, the Affordable Care Act directs the state to defray the costs of these benefits in QHPs. States may include as part of their benchmark plan state benefit requirements that were enacted before December 31, 2011, avoiding costs associated with these provisions.

Costs to Health Insurance Issuers

Issuers will incur administrative costs to modify existing offerings to meet EHB and AV standards as defined in this

final rule. For example, issuers that do not currently meet the standards for prescription drug coverage will incur contracting and one-time administrative costs to bring their pharmacy benefits into compliance. Issuers may also incur minor administrative costs related to AV standards and computing AV. However, because EHB will be based on a benchmark plan that is typical of what is offered in the market in each state currently, the modifications in benefits are expected to be relatively minor for most issuers. Further, issuers have extensive experience in offering products with various levels of cost sharing, and HHS expects that following the process for computing AV outlined in this proposed rule will not demand many additional resources.

I. Regulatory Alternatives

In addition to the regulatory approach outlined in the Essential Health Bulletin issued on December 16, 2011, HHS considered several alternatives when developing policy around defining EHBs and calculating AV.

Definition of EHBs

At the request of some commenters, HHS considered one national definition of EHB that would have applicable issuers offer a uniform list of benefits. However, this approach would not allow for state flexibility and issuer innovation in benefit design, would require a burdensome overhaul for issuers, and would disrupt the market.

HHS also considered codifying the 10 statutorily required categories without additional definition and allowing issuers to adjust their benefit packages accordingly. However, this approach would have allowed extremely wide variation across plans in the benefits offered, would not have assured consumers that they would have coverage for basic benefits, and would not have improved the ability of consumers to make comparisons among plans.

HHS believes the benchmark approach best strikes the balance between comprehensiveness, affordability, and state flexibility. Additionally, HHS believes that the benchmark approach, supplemented when necessary, best addresses the statutory requirements that EHBs reflect a typical employer plan and encompass at least the 10 statutory EHB categories of items and services outlined in the statute.

⁵⁵ Kaiser State Health Facts. *State mandated benefits in small group private health insurance: Mandated coverage in mental health, as of January 2010*. Available at: <http://www.statehealthfacts.org/comparereport.jsp?rep=2&cat=7>.

⁵⁶ Health Insurance Mandates in the States 2010, Council for Affordable Health Insurance, available at: http://www.cahi.org/cahi_contents/resources/pdf/MandatesintheStates2010ExecSummary.pdf.

⁵⁷ Health Insurance Mandates in the States 2010, Council for Affordable Health Insurance, available at: http://www.cahi.org/cahi_contents/resources/pdf/MandatesintheStates2010ExecSummary.pdf.

⁵⁸ ASPE Issue Brief, "EHB: Comparing Benefits in Small Group Products and State and Federal Employee Plans, U.S. Department of Health & Human Services (2011).

⁵⁹ Goldman HH, et al. 2006. Behavioral health insurance parity for federal employees. *New Engl J Med*;354 1378–86.

⁶⁰ Barry CL, Busch SH. 2007. Effects of state parity laws on the family financial burden of children with mental health care needs. *Health Serv Res*; 42: 1061–84. Ma CA, McGuire TG. 1998. Cost and incentives in a behavioral health carve-out. *Health Affairs*;17: 56–67.

⁶¹ ASPE Research Brief (2011). "EHB: Comparing Benefits in Small Group Products and State and Federal Employee Plans." Available at: <http://aspe.hhs.gov/health/reports/2011/MarketComparison/rb.shtml>.

⁶² ASPE Research Brief (2011). "AV and Employer Sponsored Insurance," available at: <http://aspe.hhs.gov/health/reports/2011/AV-ESI/rb.pdf>. Similar results were found in a recent study by Gabel and colleagues. Jon R. Gabel, Ryan Lore, Roland D. McDevitt, Jeremy D. Pickreign, Heidi Whitmore, Michael Slover and Ethan Levy-Forsythe, "More Than Half Of Individual Health Plans Offer Coverage That Falls Short Of What Can Be Sold Through Exchanges As Of 2014," *Health Affairs*, (2012), available at: <http://content.healthaffairs.org/content/early/2012/05/22/hlthaff.2011.1082.full.pdf+html>.

Calculation of AV

In the calculation of AV, the statute specifies the use of a standard population. As described in the AV/CSR Bulletin, HHS considered allowing issuers to use their own utilization and pricing data in connection with an HHS-defined standard population (that is, HHS-set demographics for the standard population) to calculate a standard population. However, this would not have allowed for consumer transparency and would not have increased competition. The approach in this final rule instead reduces issuer burden while allowing consumers to compare more easily among plans.

The comments and our responses to the RIA are set forth below.

Comment: A few commenters stated that the RIA included in the proposed rule was insufficiently quantitative; failed to address specific potential impacts of the regulation, such as access to previously uncovered benefits and premium costs associated with induced utilization; and did not adequately describe other regulatory alternatives considered by HHS.

Response: HHS published the Establishment of Exchanges Final Rule on March 27, 2012. In the regulatory impact analysis associated with that final rule, HHS codified standards related to coverage of EHB, compliance with AV levels, and accreditation of QHPs. The costs, benefits, and other impacts associated with those standards are described in the RIA associated with CMS-9989-F. This final rule builds upon CMS-9989-F by establishing a specific definition of EHB and AV, and detailing a timeline for issuers to obtain accreditation. Accordingly, the RIA associated with this final rule assesses only the costs and benefits of applying that specific definition and timeline (that is, adopting a benchmark-based approach to defining EHB and a calculator-based approach to computing AV). HHS provided quantitative estimates of the costs and benefits associated with the specific provisions of this regulation where possible, and supplemented those estimates with qualitative discussion. HHS and OMB

reviewed the RIA to confirm that it addressed all critical components required by Executive Orders 12866 and 13563, including a description of regulatory alternatives that HHS considered.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) requires agencies to analyze options for regulatory relief of small businesses if a proposed rule has a significant 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.

This final rule is necessary to implement standards related to the EHB, AV, cost-sharing limitations, and quality, as authorized by the Affordable Care Act. For purposes of the Regulatory Flexibility Analysis, we expect the following types of entities to be affected by this final rule: (1) Issuers; (2) employers; and (3) providers.

We believe that health insurers would be classified under the North American Industry Classification System (NAICS) Code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$7 million or less would be considered small entities for this NAICS code. Health issuers could possibly also be classified in NAICS Code 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$10 million or less.

As discussed in the Web Portal interim final rule (75 FR 24481), HHS examined the health insurance industry in depth in the Regulatory Impact Analysis we prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866,

August 3, 2004). 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).⁶³

In the proposed rule, we noted that HHS used 2011 National Association of Insurance Commissioners (NAIC) Supplemental Health Care Exhibit data to develop an updated estimate of the number of small entities that offer comprehensive major medical coverage in the individual and small group markets. HHS used total Accident and Health (A&H) earned premiums as a proxy for annual receipts. Table IV.3 shows that HHS estimates that there were 35 small entities with less than \$7 million in accident and health earned premiums offering individual or small group comprehensive major medical (CMM) coverage; however, this estimate may overstate the actual number of small health insurance issuers offering such coverage, since it does not include receipts from these companies’ other lines of business.

HHS estimates that 83 percent of these small issuers are subsidiaries of larger carriers, and 71 percent also offer large group or other types of A&H coverage. On average, HHS estimates that individual and small group CMM coverage accounts for approximately 45 percent of total A&H earned premiums for these small issuers. HHS estimates that 75 percent of these small issuers only offer individual and small group CMM coverage in a single state. Additionally, HHS estimates that approximately a third (11) of these small issuers only offer individual market CMM coverage.

⁶³ “Table of Size Standards Matched to North American Industry Classification System Codes,” effective November 5, 2010, U.S. Small Business Administration, available at <http://www.sba.gov>.

TABLE IV.3—DESCRIPTION OF ISSUERS OFFERING INDIVIDUAL OR SMALL GROUP COMPREHENSIVE MAJOR MEDICAL (CMM) COVERAGE BY SIZE, 2011

Total earned premiums for accident and health coverage	Total issuers offering individual or small group market CMM coverage	Percent of issuers that are part of larger carriers	Average number of States in which individual or small group CMM coverage is offered	Percent of issuers only offering individual or small group CMM coverage in a single State	Individual & small group CMM premiums as a percent of total A&H premiums	Percent of issuers also offering large group CMM or other A&H coverage	Number of issuers only offering individual market CMM coverage
Less Than \$7 Million	35	82.9	2.3	74.3	45.0	71.4	11
\$7 million to \$99 million	93	68.8	4.5	62.4	37.2	66.7	6
\$100 million to \$999 million	184	87.0	5.2	65.8	27.0	84.8	11
\$1 billion or more	115	87.8	4.8	69.6	24.0	93.9	1
Total	427	82.9	4.7	66.7	24.5	82.2	29

Notes: (1) Issuers represents companies (for example, NAIC company codes). (2) Licensed Entities represents company/state combinations. (3) Total issuers excludes data for companies that are regulated by the California Department of Managed Health Care. (4) To be counted as offering coverage in a particular comprehensive major medical market, the issuer must have reported positive premiums, non-zero claims and had at least \$1,000 in total premiums per life year for at least one state. (5) Small group is defined based on the current definition in the PHS Act.

Sources: ASPE analysis of 2011 NAIC Supplemental Health Care Exhibit data.

This rule finalizes standards related to EHB, AV, and accreditation of QHPs (specifically, by establishing a timeline for accreditation for QHPs seeking certification in Federally-facilitated Exchanges and recognition of accrediting entities). These standards may impose some additional costs on issuers offering coverage that is affected by these provisions. For example, as discussed earlier, issuers are likely to experience some administrative costs associated with reconfiguring existing non-grandfathered plans to meet EHB and AV metal level standards as defined in this final rule. However, these costs will vary depending on a number of factors, including the extent to which an issuer offers coverage in multiple states or is a subsidiary of a larger carrier, and the variation between these standards and current practice. Further, some of the changes that standardize coverage may reduce administrative costs.

As discussed in the regulatory impact analysis for the Establishment of Exchanges Final Rule, the cost of participating in an Exchange is an investment for QHP issuers, with benefits expected to accrue to QHP issuers because of access to new markets where consumers may receive tax credits to purchase insurance.

This final rule also establishes standards that will affect employers participating in the small group market, including those that choose to participate in a SHOP. As discussed in the Summary of Regulatory Impact Analysis for the Establishment of Exchanges Final Rule, the SHOP is limited by statute to employers with at least one but not more than 100 employees. For this reason, we expect that many affected employers would meet the SBA standard for small

entities. However, the standards outlined in this proposed rule apply to issuers of small group market health insurance coverage, and not to any small employers that elect to purchase such coverage on behalf of their employees (that is, the final rule impacts what coverage is available to be purchased). We anticipate that the essential health benefits, coupled with the ability to compare plans based on metal level, will lead to greater transparency and reduce transaction costs for small employers.

HHS anticipates that the provisions in this proposed rule will have a positive effect on providers—particularly those offering services in areas where many individual market enrollees previously did not have coverage for these services, and those who serve a substantial share of the low-income population. HHS anticipates that small providers will also experience positive effects relating to the provisions of this proposed rule.

Therefore, the Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities. We welcomed comments on the analysis described in this section and on HHS's conclusion.

VII. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any final rule that includes a federal mandate that could result in expenditure in any one year by state, local or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In early 2013, that threshold level is approximately \$139 million.

UMRA does not address the total cost of a final rule. Rather, it focuses on certain categories of cost, mainly those “Federal mandate” costs resulting from: (1) Imposing enforceable duties on state, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs.

Because states are not required to set up an Exchange, and because grants are available for funding of the establishment of an Exchange by a state, we anticipate that this final rule would not impose costs above that threshold on state, local, or Tribal governments. In addition, because states largely already collect information on plan rates and benefits to license them, we believe that the burden on states is limited. However, because these costs have not been estimated, HHS sought comments on any additional burdens.

Under the final rule, issuers will provide coverage of certain benefits. While some issuers may not currently offer benefit packages that meet the standards outlined in the final rule, we anticipate that the administrative costs associated with compliance will fall below the threshold. We anticipate that such administrative costs will be concentrated in the initial year, with costs significantly tapering off during subsequent years.

The benchmark-based approach to defining EHB ensures that EHB will reflect the scope of services offered by a “typical employer plan.” Accordingly, we anticipate that many small group market plans meet or are close to meeting the coverage requirements for EHB and will not need to incur significant administrative costs to bring

currently available plans into compliance. Individual market plans are somewhat less likely to cover all statutorily required benefits and services as described in this final rule; however, many such plans are offered by issuers with diverse portfolios that may include small and large group products or other individual market products that do include the required services. Accordingly, we do not anticipate that the provisions related to the EHB package outlined in the final rule impose costs greater than \$139 million on the private sector.

Consistent with policy embodied in UMRA, this final rule has been designed to be a low-burden alternative for state, local and tribal governments, and the private sector while achieving the objectives of the Affordable Care Act.

VIII. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications.

States regulate health insurance coverage. States would continue to apply state laws regarding health insurance coverage. However, if any state law or requirement prevents the application of a federal standard, then that particular state law or requirement would be preempted. State requirements that are more stringent than the federal requirements would not be preempted by this proposed rule unless such requirements prevent the application of federal law. Accordingly, states have significant latitude to impose requirements with respect to health insurance coverage that are more consumer-protective than the Federal law.

In the view of HHS, this final rule does not impose substantial direct costs on state and local governments. However, we believe that this final rule has federalism implications due to direct effects on the distribution of power and responsibilities among the state and Federal governments relating to determining standards for health insurance coverage that is offered in the individual and small group markets. Each state would adhere to the federal standards outlined in this final rule for purposes of determining whether non-grandfathered individual and small group market health insurance coverage includes the EHB package, or have HHS enforce these policies.

HHS expects that the federalism implications, if any, are substantially

mitigated for a number of reasons. First, the final rule affords discretion to states to select an EHB-benchmark plan. States also can choose to be responsible for evaluating the selected benchmark and making adjustments as needed, and for determining whether non-grandfathered individual and small group market health insurance coverage meets the standards outlined in this final rule. While this final rule establishes new federal standards for certain health insurance coverage, states will retain their traditional regulatory roles. Further, if a state elects not to substantially enforce the standards outlined in the final rule, the federal government will assume responsibility for these standards.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policymaking discretion of the states, HHS has made efforts to consult with and work cooperatively with states as evidenced by continued communication through weekly calls and listening sessions.

HHS initiated weekly calls with key stakeholders from states in April 2010 as a way for HHS and states to have a regular means of communication about the Affordable Care Act. The audience for the call is "State Government Implementers of the Affordable Care Act" which often includes Governors' office staff, state Medicaid Directors' staff, Insurance Commissioners' staff, state high risk pool staff, Exchange grantees, health reform coordinators, and other state staff. National intergovernmental organizations are also invited to participate. Regular participants also include representatives from the following intergovernmental organizations:

- National Governors Association
- National Conference of State Legislatures
- National Association of Medicaid Directors
- National Association of Insurance Commissioners
- American Public Human Services Association
- The Council of State Governments
- National Academy for State Health Policy
- National Association of Counties

These calls, in addition to listening sessions specifically related to EHB, have helped HHS understand states' major questions about implementation of the Affordable Care Act. Ongoing communication with states allowed HHS to develop policy that addressed two central issues: Flexibility and state-

required benefits. The benchmark approach allows states to select a benchmark option that offer benefit packages that reflect the needs of their populations and maintain state-required benefits that were enacted before December 31, 2011. This approach minimizes state burden while increasing access to quality health care.

List of Subjects

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

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.

Department of Health and Human Services

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 147, 155, and 156 as set forth below:

Subchapter B—Requirements Relating to Health Care Access

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

- 1. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

■ 2. Section 147.150 is added to read as follows:

§ 147.150 Coverage of essential health benefits.

(a) *Requirement to cover the essential health benefits package.* A health insurance issuer offering health insurance coverage in the individual or small group market must ensure that such coverage includes the essential health benefits package as defined in section 1302(a) of the Affordable Care Act effective for plan or policy years beginning on or after January 1, 2014.

(b) *Cost-sharing under group health plans.* [Reserved.]

(c) *Child-only plans.* If a health insurance issuer offers health insurance coverage in any level of coverage specified under section 1302(d)(1) of the Affordable Care Act, the issuer must offer coverage in that level as a plan in which the only enrollees are individuals who, as of the beginning of a plan year, have not attained the age of 21.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 3. The authority citation for part 155 is revised to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1334, 1402, 1411, 1412, 1413, Pub. L. 111-148, 124 Stat. 119 [42 U.S.C. 18021-18024, 18031-18033, 18041-18042, 18051, 18054, 18071, and 18081-18083].

■ 4. Section 155.170 is added to subpart B to read as follows:

§ 155.170 Additional required benefits.

(a) *Additional required benefits.* (1) A State may require a QHP to offer benefits in addition to the essential health benefits.

(2) A State-required benefit enacted on or before December 31, 2011 is not considered in addition to the essential health benefits.

(3) The Exchange shall identify which state-required benefits are in excess of EHB.

(b) *Payments.* The State must make payments to defray the cost of additional required benefits specified in paragraph (a) of this section to one of the following:

(1) To an enrollee, as defined in § 155.20 of this subchapter; or

(2) Directly to the QHP issuer on behalf of the individual described in paragraph (b)(1) of this section.

(c) *Cost of additional required benefits.* (1) Each QHP issuer in the State shall quantify cost attributable to each additional required benefit specified in paragraph (a) of this section.

(2) A QHP issuer's calculation shall be:

(i) Based on an analysis performed in accordance with generally accepted actuarial principles and methodologies;

(ii) Conducted by a member of the American Academy of Actuaries; and

(iii) Reported to the Exchange.

■ 5. Revise § 155.1045 to read as follows:

§ 155.1045 Accreditation timeline.

(a) *Timeline.* The Exchange must establish a uniform period following certification of a QHP within which a QHP issuer that is not already accredited must become accredited as required by § 156.275 of this subchapter, except for multi-state plans. The U.S. Office of Personnel Management will establish the accreditation period for multi-state plans.

(b) *Federally-facilitated Exchange.* The accreditation timeline used in federally-facilitated Exchanges follows:

(1) During certification for an issuer's initial year of QHP certification (for example, in 2013 for the 2014 coverage year), a QHP issuer without existing commercial, Medicaid, or Exchange health plan accreditation granted by a recognized accrediting entity for the same State in which the issuer is applying to offer coverage must have scheduled or plan to schedule a review of QHP policies and procedures of the applying QHP issuer with a recognized accrediting entity.

(2) Prior to a QHP issuer's second year and third year of QHP certification (for example, in 2014 for the 2015 coverage year and 2015 for the 2016 coverage year), a QHP issuer must be accredited by a recognized accrediting entity on the policies and procedures that are applicable to their Exchange products, or a QHP issuer must have commercial or Medicaid health plan accreditation granted by a recognized accrediting entity for the same State in which the issuer is offering Exchange coverage and the administrative policies and procedures underlying that accreditation must be the same or similar to the administrative policies and procedures used in connection with the QHP.

(3) Prior to the QHP issuer's fourth year of QHP certification and in every subsequent year of certification (for example, in 2016 for the 2017 coverage year and forward), a QHP issuer must be

accredited in accordance with § 156.275 of this subchapter.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 6. The authority citation for part 156 is revised to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301-1304, 1311-1312, 1321-1322, 1324, 1334, 1342-1343, and 1401-1402, Pub. L. 111-148, 124 Stat. 119 [42 U.S.C. 18021-18024, 18031-18032, 18041-18042, 18044, 18054, 18061, 18063, 18071, and 26 U.S.C. 36B].

■ 7. Section 156.20 is amended by adding new definitions for “Actuarial value (AV),” “Base-benchmark plan,” “EHB-benchmark plan,” “Essential health benefits package or EHB package,” and “Percentage of the total allowed costs of benefits” in alphabetical order to read as follows:

§ 156.20 Definitions.

Actuarial value (AV) means the percentage paid by a health plan of the percentage of the total allowed costs of benefits.

* * * * *

Base-benchmark plan means the plan that is selected by a State from the options described in § 156.100(a) of this subchapter, or a default benchmark plan, as described in § 156.100(c) of this subchapter, prior to any adjustments made pursuant to the benchmark standards described in § 156.110 of this subchapter.

* * * * *

EHB-benchmark plan means the standardized set of essential health benefits that must be met by a QHP, as defined in § 155.20 of this section, or other issuer as required by § 147.150 of this subchapter.

Essential health benefits package or EHB package means the scope of covered benefits and associated limits of a health plan offered by an issuer that provides at least the ten statutory categories of benefits, as described in § 156.110(a) of this subchapter; provides the benefits in the manner described in § 156.115 of this subchapter; limits cost sharing for such coverage as described in § 156.130; and subject to offering catastrophic plans as described in section 1302(e) of the Affordable Care Act, provides distinct levels of coverage as described in § 156.140 of this subchapter.

* * * * *

Percentage of the total allowed costs of benefits means the anticipated

covered medical spending for EHB coverage (as defined in § 156.110(a) of this subchapter) paid by a health plan for a standard population, computed in accordance with the plan's cost-sharing, divided by the total anticipated allowed charges for EHB coverage provided to a standard population, and expressed as a percentage.

* * * * *

■ 8. Subpart B is revised to read as follows:

Subpart B—Essential Health Benefits Package

Sec.

- 156.100 State selection of benchmark.
- 156.105 Determination of EHB for multi-state plans.
- 156.110 EHB-benchmark plan standards.
- 156.115 Provision of EHB.
- 156.122 Prescription drug benefits.
- 156.125 Prohibition on discrimination.
- 156.130 Cost-sharing requirements.
- 156.135 AV calculation for determining level of coverage.
- 156.140 Levels of coverage.
- 156.145 Determination of minimum value.
- 156.150 Application to stand-alone dental plans inside the Exchange.

Subpart B—Essential Health Benefits Package

§ 156.100 State selection of benchmark.

Each State may identify a single EHB-benchmark plan according to the selection criteria described below:

(a) *State selection of base-benchmark plan.* The options from which a base-benchmark plan may be selected by the State are the following:

(1) *Small group market health plan.* The largest health plan by enrollment in any of the three largest small group insurance products by enrollment, as defined in § 159.110 of this subpart, in the State's small group market as defined in § 155.20 of this subchapter.

(2) *State employee health benefit plan.* Any of the largest three employee health benefit plan options by enrollment offered and generally available to State employees in the State involved.

(3) *FEHBP plan.* Any of the largest three national Federal Employees Health Benefits Program (FEHBP) plan options by aggregate enrollment that is offered to all health-benefits-eligible federal employees under 5 USC 8903.

(4) *HMO.* The coverage plan with the largest insured commercial non-Medicaid enrollment offered by a health maintenance organization operating in the State.

(b) *EHB-benchmark selection standards.* In order to become an EHB-benchmark plan as defined in § 156.20 of this subchapter, a state-selected base-benchmark plan must meet the

requirements for coverage of benefits and limits described in § 156.110 of this subpart; and

(c) *Default base-benchmark plan.* If a State does not make a selection using the process defined in § 156.100 of this section, the default base-benchmark plan will be the largest plan by enrollment in the largest product by enrollment in the State's small group market. If Guam, the U.S. Virgin Islands, American Samoa, or the Northern Mariana Islands do not make a benchmark selection, the default base-benchmark plan will be the largest FEHBP plan by enrollment.

§ 156.105 Determination of EHB for multi-state plans.

A multi-state plan must meet benchmark standards set by the U.S. Office of Personnel Management.

§ 156.110 EHB-benchmark plan standards.

An EHB-benchmark plan must meet the following standards:

(a) *EHB coverage.* Provide coverage of at least the following categories of benefits:

- (1) Ambulatory patient services.
- (2) Emergency services.
- (3) Hospitalization.
- (4) Maternity and newborn care.
- (5) Mental health and substance use disorder services, including behavioral health treatment.
- (6) Prescription drugs.
- (7) Rehabilitative and habilitative services and devices.
- (8) Laboratory services.
- (9) Preventive and wellness services and chronic disease management.
- (10) Pediatric services, including oral and vision care.

(b) *Coverage in each benefit category.* A base-benchmark plan not providing any coverage in one or more of the categories described in paragraph (a) of this section, must be supplemented as follows:

(1) *General supplementation methodology.* A base-benchmark plan that does not include items or services within one or more of the categories described in paragraph (a) of this section must be supplemented by the addition of the entire category of such benefits offered under any other benchmark plan option described in § 156.100(a) of this subpart unless otherwise described in this subsection.

(2) *Supplementing pediatric oral services.* A base-benchmark plan lacking the category of pediatric oral services must be supplemented by the addition of the entire category of pediatric oral benefits from one of the following:

(i) The FEDVIP dental plan with the largest national enrollment that is

described in and offered to federal employees under 5 U.S.C. 8952; or

(ii) The benefits available under that State's separate CHIP plan, if a separate CHIP plan exists, to the eligibility group with the highest enrollment.

(3) *Supplementing pediatric vision services.* A base-benchmark plan lacking the category of pediatric vision services must be supplemented by the addition of the entire category of pediatric vision benefits from one of the following:

(i) The FEDVIP vision plan with the largest national enrollment that is offered to federal employees under 5 USC 8982; or

(ii) The benefits available under the State's separate CHIP plan, if a separate CHIP plan exists, to the eligibility group with the highest enrollment.

(c) *Supplementing the default base-benchmark plan.* A default base-benchmark plan as defined in § 156.100(c) of this subpart that lacks any categories of essential health benefits will be supplemented by HHS in the following order, to the extent that any of the plans offer benefits in the missing EHB category:

(1) The largest plan by enrollment in the second largest product by enrollment in the State's small group market, as defined in § 155.20 of this subchapter (except for pediatric oral and vision benefits);

(2) The largest plan by enrollment in the third largest product by enrollment in the State's small group market, as defined in § 155.20 of this subchapter (except for pediatric oral and vision benefits);

(3) The largest national FEHBP plan by enrollment across States that is offered to federal employees under 5 USC 8903 (except for pediatric oral and vision benefits);

(4) The plan described in paragraph (b)(2)(i) of this section with respect to pediatric oral care benefits;

(5) The plan described in paragraph (b)(3)(i) of this section with respect to pediatric vision care benefits; and

(6) A habilitative benefit determined by the plan as described in § 156.115(a)(5) of this subpart or by the State as described in paragraph (f) of this section.

(d) *Non-discrimination.* Not include discriminatory benefit designs that contravene the non-discrimination standards defined in § 156.125 of this subpart.

(e) *Balance.* Ensure an appropriate balance among the EHB categories to ensure that benefits are not unduly weighted toward any category.

(f) *Determining habilitative services.* If the base-benchmark plan does not include coverage for habilitative

services, the State may determine which services are included in that category.

§ 156.115 Provision of EHB.

(a) Provision of EHB means that a health plan provides benefits that—

(1) Are substantially equal to the EHB-benchmark plan including:

(i) Covered benefits;

(ii) Limitations on coverage including coverage of benefit amount, duration, and scope; and

(iii) Prescription drug benefits that meet the requirements of § 156.122 of this subpart;

(2) With the exception of the EHB category of coverage for pediatric services, do not exclude an enrollee from coverage in an EHB category.

(3) With respect to the mental health and substance use disorder services, including behavioral health treatment services, required under § 156.110(a)(5) of this subpart, comply with the requirements of § 146.136 of this subchapter.

(4) Include preventive health services described in § 147.130 of this subchapter.

(5) If the EHB-benchmark plan does not include coverage for habilitative services, as described in § 156.110(f) of this subpart, include habilitative services in a manner that meets one of the following—

(i) Provides parity by covering habilitative services benefits that are similar in scope, amount, and duration to benefits covered for rehabilitative services; or

(ii) Is determined by the issuer and reported to HHS.

(b) Unless prohibited by applicable State requirements, an issuer of a plan offering EHB may substitute benefits if the issuer meets the following conditions—

(1) Substitutes a benefit that:

(i) Is actuarially equivalent to the benefit that is being replaced as determined in paragraph (b)(2) of this section;

(ii) Is made only within the same essential health benefit category; and

(iii) Is not a prescription drug benefit.

(2) Submits evidence of actuarial equivalence that is:

(i) Certified by a member of the American Academy of Actuaries;

(ii) Based on an analysis performed in accordance with generally accepted actuarial principles and methodologies;

(iii) Based on a standardized plan population; and

(iv) Determined regardless of cost-sharing.

(c) A health plan does not fail to provide EHB solely because it does not offer the services described in § 156.280(d) of this subchapter.

(d) An issuer of a plan offering EHB may not include routine non-pediatric dental services, routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia as EHB.

§ 156.122 Prescription drug benefits.

(a) A health plan does not provide essential health benefits unless it:

(1) Subject to the exception in paragraph (b) of this section, covers at least the greater of:

(i) One drug in every United States Pharmacopeia (USP) category and class; or

(ii) The same number of prescription drugs in each category and class as the EHB-benchmark plan; and

(2) Submits its drug list to the Exchange, the State, or OPM.

(b) A health plan does not fail to provide EHB prescription drug benefits solely because it does not offer drugs approved by the Food and Drug Administration as a service described in § 156.280(d) of this subchapter.

(c) A health plan providing essential health benefits must have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the health plan.

§ 156.125 Prohibition on discrimination.

(a) An issuer does not provide EHB if its benefit design, or the implementation of its benefit design, 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.

(b) An issuer providing EHB must comply with the requirements of § 156.200(e) of this subchapter; and

(c) Nothing in this section shall be construed to prevent an issuer from appropriately utilizing reasonable medical management techniques.

§ 156.130 Cost-sharing requirements.

(a) *Annual limitation on cost sharing.*

(1) For a plan year beginning in the calendar year 2014, cost sharing may not exceed the following:

(i) For self-only coverage—the annual dollar limit as described in section 223(c)(2)(A)(ii)(I) of the Internal Revenue Code of 1986 as amended, for self-only coverage that is in effect for 2014; or

(ii) For other than self-only coverage—the annual dollar limit in section 223(c)(2)(A)(ii)(II) of the Internal Revenue Code of 1986 as amended, for non-self-only coverage that is in effect for 2014.

(2) For a plan year beginning in a calendar year after 2014, cost sharing may not exceed the following:

(i) For self-only coverage—the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage, as defined in paragraph (e) of this section.

(ii) For other than self-only coverage—twice the dollar limit for self-only coverage described in paragraph (a)(2)(i) of this section.

(b) *Annual limitation on deductibles for plans in the small group market.* (1) For a plan year beginning in calendar year 2014, the annual deductible for a health plan in the small group market may not exceed the following:

(i) For self-only coverage—\$2,000; or

(ii) For coverage other than self-only—\$4,000.

(2) For a plan year beginning in a calendar year after 2014, the annual deductible for a health plan in the small group market may not exceed the following:

(i) For self-only coverage—the annual limitation on deductibles for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage as defined in paragraph (e) of this section; and

(ii) For other than self-only coverage—twice the annual deductible limit for self-only coverage described in paragraph (b)(2)(i) of this section.

(3) A health plan's annual deductible may exceed the annual deductible limit if that plan may not reasonably reach the actuarial value of a given level of coverage as defined in § 156.140 of this subpart without exceeding the annual deductible limit.

(c) *Special rule for network plans.* In the case of a plan using a network of providers, cost-sharing paid by, or on behalf of, an enrollee for benefits provided outside of such network shall not count towards the annual limitation on cost-sharing (as defined in paragraph (a) of this section), or the annual limitation on deductibles (as defined in paragraph (b) of this section).

(d) *Increase annual dollar limits in multiples of 50.* For a plan year beginning in a calendar year after 2014, any increase in the annual dollar limits described in paragraphs (a) and (b) of this section that do not result in a multiple of 50 dollars must be rounded to the next lowest multiple of 50 dollars.

(e) *Premium adjustment percentage.* The premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013. HHS will publish the annual premium adjustment percentage in the

annual HHS notice of benefits and payment parameters.

(f) *Coordination with preventive limits.* Nothing in this subpart is in derogation of the requirements of § 147.130 of this subchapter.

(g) *Coverage of emergency department services.* Emergency department services must be provided as follows:

(1) Without imposing any requirement under the plan for prior authorization of services or any limitation on coverage where the provider of services is out of network that is more restrictive than the requirements or limitations that apply to emergency department services received in network; and

(2) If such services are provided out-of-network, cost-sharing must be limited as provided in § 147.138(b)(3) of this subchapter.

§ 156.135 AV calculation for determining level of coverage.

(a) *Calculation of AV.* Subject to paragraph (b) of this section, to calculate the AV of a health plan, the issuer must use the AV Calculator developed and made available by HHS.

(b) *Exception to the use of the AV Calculator.* If a health plan's design is not compatible with the AV Calculator, the issuer must meet the following:

(1) Submit the actuarial certification from an actuary, who is a member of the American Academy of Actuaries, on the chosen methodology identified in paragraphs (b)(2) and (b)(3) of this section:

(2) Calculate the plan's AV by:

(i) Estimating a fit of its plan design into the parameters of the AV Calculator; and

(ii) Having an actuary, who is a member of the American Academy of Actuaries, certify that the plan design was fit appropriately in accordance with generally accepted actuarial principles and methodologies; or

(3) Use the AV Calculator to determine the AV for the plan provisions that fit within the calculator parameters and have an actuary, who is a member of the American Academy of Actuaries calculate and certify, in accordance with generally accepted actuarial principles and methodologies, appropriate adjustments to the AV identified by the calculator, for plan design features that deviate substantially from the parameters of the AV Calculator.

(4) The calculation methods described in paragraphs (b)(2) and (3) of this section may include only in-network cost-sharing, including multi-tier networks.

(c) *Employer contributions to health savings accounts and amounts made*

available under certain health reimbursement arrangements. For plans other than those in the individual market that at the time of purchase are offered in conjunction with an HSA or with integrated HRAs that may be used only for cost-sharing, annual employer contributions to HSAs and amounts newly made available under such HRAs for the current year are:

(1) Counted towards the total anticipated medical spending of the standard population that is paid by the health plan; and

(2) Adjusted to reflect the expected spending for health care costs in a benefit year so that:

(i) Any current year HSA contributions are accounted for; and

(ii) The amounts newly made available under such integrated HRAs for the current year are accounted for.

(d) *Use of state-specific standard population for the calculation of AV.* Beginning in 2015, if submitted by the State and approved by HHS, a state-specific data set will be used as the standard population to calculate AV in accordance with paragraph (a) of this section. The data set may be approved by HHS if it is submitted in accordance with paragraph (e) of this section and:

(1) Supports the calculation of AVs for the full range of health plans available in the market;

(2) Is derived from a non-elderly population and estimates those likely to be covered by private health plans on or after January 1, 2014;

(3) Is large enough that: (i) The demographic and spending patterns are stable over time; and (ii) Includes a substantial majority of the State's insured population, subject to the requirement in paragraph (d)(2) of this section;

(4) Is a statistically reliable and stable basis for area-specific calculations; and

(5) Contains claims data on health care services typically offered in the then-current market.

(e) *Submission of state-specific data.*

AV will be calculated using the default standard population described in paragraph (f) of this section, unless a data set in a format specified by HHS that can support the use of the AV Calculator as described in paragraph (a) of this section is submitted by a State and approved by HHS consistent with paragraph (d) of this section by a date specified by HHS.

(f) *Default standard population.* The default standard population for AV calculation will be developed and summary statistics, such as in

continuation tables, will be provided by HHS in a format that supports the

calculation of AV as described in paragraph (a) of this section.

§ 156.140 Levels of coverage.

(a) *General requirement for levels of coverage.* AV, calculated as described in § 156.135 of this subpart, and within a de minimis variation as defined in paragraph (c) of this section, determines whether a health plan offers a bronze, silver, gold, or platinum level of coverage.

(b) *The levels of coverage are:*

(1) A bronze health plan is a health plan that has an AV of 60 percent.

(2) A silver health plan is a health plan that has an AV of 70 percent.

(3) A gold health plan is a health plan that has an AV of 80 percent.

(4) A platinum health plan is a health plan that has an AV of 90 percent.

(c) *De minimis variation.* The allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan is ± 2 percentage points.

§ 156.145 Determination of minimum value.

(a) *Acceptable methods for determining MV.* An employer-sponsored plan provides minimum value (MV) if the percentage of the total allowed costs of benefits provided under the plan is no less than 60 percent. An employer-sponsored plan may use one of the following methods to determine whether the percentage of the total allowed costs of benefits provided under the plan is not less than 60 percent.

(1) The MV Calculator to be made available by HHS and the Internal Revenue Service. The result derived from the calculator may be modified under the rules in paragraph (b) of this section.

(2) Any safe harbor established by HHS and the Internal Revenue Service.

(3) A group health plan may seek certification by an actuary to determine MV if the plan contains non-standard features that are not suitable for either of the methods described in paragraphs (a)(1) or (2) of this section. The determination of MV must be made by a member of the American Academy of Actuaries, based on an analysis performed in accordance with generally accepted actuarial principles and methodologies.

(4) Any plan in the small group market that meets any of the levels of coverage, as described in § 156.140 of this subpart, satisfies minimum value.

(b) *Benefits that may be counted towards the determination of MV.* (1) In the event that a group health plan uses the MV Calculator and offers an EHB

outside of the parameters of the MV Calculator, the plan may seek an actuary, who is a member of the American Academy of Actuaries, to determine the value of that benefit and adjust the result derived from the MV Calculator to reflect that value.

(2) For the purposes of applying the options described in paragraph (a) of this section in determining MV, a group health plan will be permitted to take into account all benefits provided by the plan that are included in any one of the EHB-benchmarks.

(c) *Standard population.* The standard population for MV determinations described in paragraph (a) of this section is the standard population developed by HHS for such use and described through summary statistics issued by HHS. The standard population for MV must reflect the population covered by self-insured group health plans.

(d) *Employer contributions to health savings accounts and amounts made available under certain health reimbursement arrangements.* For employer-sponsored self-insured group health plans and insured group health plans that at the time of purchase are offered in conjunction with an HSA or with integrated HRAs that may be used only for cost-sharing, annual employer contributions to HSAs and amounts newly made available under such HRAs for the current year are:

(1) Counted towards the total anticipated medical spending of the standard population that is paid by the health plan; and

(2) Adjusted to reflect the expected spending for health care costs in a benefit year so that:

(i) Any current year HSA contributions are accounted for; and

(ii) The amounts newly made available under such integrated HRAs for the current year are accounted for.

§ 156.150 Application to stand-alone dental plans inside the Exchange.

(a) *Annual limitation on cost-sharing.* A stand-alone dental plan covering the pediatric dental EHB under § 155.1065 of this subchapter must demonstrate that it has a reasonable annual limitation on cost-sharing as determined by the Exchange. Such annual limit is calculated without regard to EHBs provided by the QHP and without regard to out-of-network services.

(b) *Calculation of AV.* A stand-alone dental plan:

(1) May not use the AV calculator in § 156.135 of this subpart;

(2) Must demonstrate that the stand-alone dental plan offers the pediatric dental essential health benefit at either:

(i) A low level of coverage with an AV of 70 percent; or

(ii) A high level of coverage with an AV of 85 percent; and

(iii) Within a de minimis variation of ± 2 percentage points of the level of coverage in paragraphs (b)(2)(i) or (ii) of this section.

(3) The level of coverage as defined in paragraph (b)(2) of this section must be certified by a member of the American Academy of Actuaries using generally accepted actuarial principles.

■ 9. Section 156.275 is amended by revising paragraphs (c)(1), (c)(4) introductory text, and (c)(4)(i) to read as follows:

§ 156.275 Accreditation of QHP issuers.

* * * * *

(c) * * *

(1) *Recognition of accrediting entity by HHS—(i) Application.* An accrediting entity may apply to HHS for recognition. An application must include the documentation described in paragraph (c)(4) of this section and demonstrate, in a concise and organized fashion how the accrediting entity meets the requirements of paragraphs (c)(2) and (3) of this section.

(ii) *Proposed notice.* Within 60 days of receiving a complete application as described in paragraph (c)(1)(i) of this section, HHS will publish a notice in the **Federal Register** identifying the accrediting entity making the request, summarizing HHS's analysis of whether the accrediting entity meets the criteria described in paragraphs (c)(2) and (3) of this section, and providing no less than a 30-day public comment period about whether HHS should recognize the accrediting entity.

(iii) *Final notice.* After the close of the comment period described in paragraph (c)(1)(ii) of this section, HHS will notify the public in the **Federal Register** of the names of the accrediting entities recognized and those not recognized as accrediting entities by the Secretary of HHS to provide accreditation of QHPs.

(iv) *Other recognition.* Upon completion of conditions listed in paragraphs (c)(2), (3), and (4) of this section, HHS recognized, and provided

notice to the public in the **Federal Register**, the National Committee for Quality Assurance (NCQA) and URAC as accrediting entities by the Secretary of HHS to provide accreditation of QHPs meeting the requirement of this section.

* * * * *

(4) *Documentation.* An accrediting entity applying to be recognized under the process described in (c)(1) of this section must provide the following documentation:

(i) To be recognized, an accrediting entity must provide current accreditation standards and requirements, processes and measure specifications for performance measures to demonstrate that it meets the conditions described in paragraphs (c)(2) and (3) of this section to HHS.

* * * * *

Dated: February 12, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: February 14, 2013.

Kathleen Sebelius,

Secretary.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix A: List of Essential Health Benefits Benchmarks

The purpose of this appendix is to list the EHB-benchmark plans for the 50 States, the U.S. territories (Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands) and the District of Columbia. As described in § 156.100 of this regulation, each State may select a benchmark plan to serve as the standard for plans required to offer EHB in the State.⁶⁴ HHS has also stated that the default base-benchmark plan for States, Puerto Rico and the District of Columbia that do not exercise the option to select a benchmark health plan would be the largest plan by enrollment in the largest product by enrollment in the State's small group market. The default base-benchmark plan for the territories other than Puerto Rico is the largest FEHBP plan by enrollment. As described in § 156.110, an EHB-benchmark plan must offer coverage in each of the 10 statutory benefit categories. In the summary table that follows, we list the EHB-benchmark plans. Additional information on the specific benefits, limits, and prescription drug categories and classes covered by the EHB-benchmark plans, and state-required benefits, is provided on the Center for Consumer Information and Insurance Oversight (CCIIO) Web site (<http://cciio.cms.gov/resources/data/ehb.html>).

⁶⁴ Non-grandfathered plans in the individual and small group markets both inside and outside of the Exchanges along with certain other types of plans

must cover EHBs beginning in 2014. Self-insured group health plans, health insurance coverage offered in the large group market, and grandfathered

health plans are not required to cover the essential health benefits.

State	Plan type	Issuer and plan name	Supplemented categories	Supplementary plan type	Habilitative services
Alabama	Largest small group product.	Blue Cross Blue Shield of Alabama PPO 320 Plan.	Pediatric oral	FEDVIP	Yes.
Alaska	Largest small group product.	Premiera Blue Cross Blue Shield of Alaska Heritage Select Envoy PPO.	Pediatric vision	FEDVIP.	Yes.
			Mental health and substance use disorder services, including behavioral health treatment.	Largest FEHBP.	
			Pediatric oral	O="xl"< FEDVIP..	
			Pediatric vision	FEDVIP.	
American Samoa	Largest National FEHBP	Blue Cross Blue Shield Standard Option PPO.	Pediatric vision	FEDVIP	Yes.
Arizona	Largest State employee plan.	Arizona Benefit Options EPO Plan, administered by United HealthCare.	Pediatric oral	FEDVIP	No.
			Pediatric vision	FEDVIP.	
Arkansas	Plan from third largest small group product.	HMO Partners, Inc. Open Access POS, 13262 AR001.	Mental health and substance use disorder services, including behavioral health treatment.	2nd Largest FEHBP.	No.
			Pediatric oral	CHIP.	
			Pediatric vision	CHIP.	
California	Plan from largest small group product.	Kaiser Foundation Health Plan, Inc. Small Group HMO 30 ID 40513CA035.	Pediatric oral	CHIP	Yes.
			Pediatric vision	FEDVIP.	
Colorado	Plan from largest small group product.	Kaiser Foundation Health Plan of Colorado Ded HMO 1200D.	Pediatric oral	CHIP	No.
Connecticut	Largest State non-Medicaid HMO.	ConnectiCare HMO	Pediatric oral	CHIP	No.
			Pediatric vision	FEDVIP.	
Delaware	Plan from second largest small group product.	Highmark Blue Cross Blue Shield Delaware Simply Blue EPO 100 500.	Pediatric oral	CHIP	No.
			Pediatric vision	FEDVIP.	
District of Columbia	Plan from largest small group product.	Group Hospitalization and Medical Services, Inc. BluePreferred PPO.	Pediatric oral	FEDVIP	Yes.
			Pediatric vision	FEDVIP.	
Florida	Plan from largest small group product.	Blue Cross Blue Shield of Florida, Inc. BlueOptions PPO.	Pediatric oral	FEDVIP	No.
			Pediatric vision	FEDVIP.	
Georgia	Plan from largest small group product.	Blue Cross Blue Shield of Georgia HMO Urgent Care 60 Copay.	Pediatric oral	FEDVIP	Yes.
			Pediatric vision	FEDVIP.	
Guam	Largest National FEHBP	Blue Cross Blue Shield Standard Option PPO.	Pediatric vision	FEDVIP	Yes.
Hawaii	Plan from largest small group product.	Hawaii Medical Service Association Preferred Provider Plan 2010.	Pediatric oral	CHIP	No.
			Pediatric vision	FEDVIP.	
Idaho	Plan from largest small group product.	Blue Cross of Idaho Health Service, Inc. Preferred Blue PPO.	Pediatric oral	FEDVIP	Yes.
			Pediatric vision	FEDVIP.	
Illinois	Plan from largest small group product.	Blue Cross and Blue Shield of Illinois BlueAdvantage PPO.	Pediatric oral	CHIP	Yes.
			Pediatric vision	FEDVIP.	
Indiana	Plan from largest small group product.	Anthem Blue Cross and Blue Shield of Indiana Blue 5 Blue Access PPO Medical Option 6 Rx Option G.	Pediatric oral	FEDVIP	Yes.
			Pediatric vision	FEDVIP.	
Iowa	Plan from largest small group product.	Wellmark Inc. Alliance Select Copayment Plus PPO.	Pediatric oral	FEDVIP	Yes.
			Pediatric vision	FEDVIP.	
Kansas	Plan from largest small group product.	Blue Cross and Blue Shield of Kansas Comprehensive Major Medical Blue Choice PPO GF 500 deductible with Blue Rx card.	Pediatric oral	CHIP	No.
			Pediatric vision	CHIP.	
Kentucky	Plan from largest small group product.	Anthem Health Plans of Kentucky, Inc. PPO.	Pediatric oral	CHIP	Yes.
			Pediatric vision	CHIP.	
Louisiana	Plan from largest small group product.	Blue Cross and Blue Shield of Louisiana GroupCare PPO.	Pediatric oral	FEDVIP	Yes.
			Pediatric vision	FEDVIP.	

State	Plan type	Issuer and plan name	Supplemented categories	Supplementary plan type	Habilitative services
Maine	Plan from largest small group product.	Anthem Health Plans of Maine Blue Choice 20 PPO with RX 10 30 50 50.	Pediatric oral	FEDVIP	Yes.
Maryland	Plan from largest small group product.	BlueChoice 20 with RX 10 30 50 50.	Pediatric oral	CHIP	Yes.
Massachusetts	Plan from largest small group product.	Blue Cross Blue Shield of Massachusetts, Inc. HMO Blue 2000 Deductible.	Pediatric vision	FEDVIP.	
			Pediatric oral	CHIP	Yes.
Michigan	Largest State non-Medicaid HMO.	Priority Health PriorityHMO 100 Percent Hospital Services Plan.	Pediatric oral	CHIP	No.
			Pediatric vision	FEDVIP.	
Minnesota	Plan from largest small group product.	HealthPartners 500 25 Open Access PPO.	Pediatric oral	FEDVIP	Yes.
			Pediatric vision	FEDVIP.	
Mississippi	Plan from largest small group product.	Blue Cross and Blue Shield of Mississippi Network Blue PPO.	Pediatric oral	CHIP	Yes.
			Pediatric vision	CHIP.	
Missouri	Plan from largest small group product.	Healthy Alliance Life Insurance Co. (Anthem BCBS) Blue 5 Blue Access PPO Medical Option 4 Rx Option D.	Pediatric oral	FEDVIP	Yes.
			Pediatric vision	FEDVIP.	
Montana	Plan from largest small group product.	Blue Cross and Blue Shield of Montana Blue Dimensions PPO.	Pediatric oral	FEDVIP	Yes.
			Pediatric vision	FEDVIP.	
Nebraska	Plan from largest small group product.	Blue Cross and Blue Shield of Nebraska BluePride PPO.	Pediatric oral	FEDVIP	Yes.
			Pediatric vision	FEDVIP.	
Nevada	Plan from largest small group product.	HPN POS Group 1 c XV 500 HCR.	Pediatric oral	CHIP	Yes.
			Pediatric vision	FEDVIP.	
New Hampshire	Plan from second largest small group product.	Matthew Thornton Health Plan (Anthem BCBS) HMO.	Pediatric oral	FEDVIP	Yes.
			Pediatric vision	FEDVIP.	
New Jersey	Plan from largest small group product.	Horizon HMO Access HSA Compatible.	Pediatric oral	CHIP	Yes.
			Pediatric vision	FEDVIP.	
New Mexico	Plan from largest small group product.	Lovelace Insurance Company Classic PPO.	Pediatric oral	CHIP	Yes.
			Pediatric vision	CHIP.	
New York	Plan from largest small group product.	Oxford Health Insurance, Inc. Oxford EPO.	Pediatric oral	CHIP	No.
			Pediatric vision	CHIP.	
North Carolina	Plan from largest small group product.	Blue Cross and Blue Shield of North Carolina Blue Options PPO.	Pediatric oral	FEDVIP	No.
			Pediatric vision	FEDVIP.	
North Dakota	Largest State non-Medicaid HMO.	Sanford Health Plan HMO ..	Pediatric oral	CHIP	No.
			Pediatric vision	CHIP.	
Northern Mariana Islands	Largest National FEHBP	Blue Cross Blue Shield Standard Option PPO.	Pediatric vision	FEDVIP	Yes.
Ohio	Plan from largest small group product.	Community Insurance Company (Anthem BCBS) Blue 6 Blue Access PPO Medical Option D4 Rx Option G.	Pediatric oral	FEDVIP	No.
			Pediatric vision	FEDVIP.	
Oklahoma	Plan from largest small group product.	Blue Cross and Blue Shield of Oklahoma BlueOptions PPO RYB05.	Pediatric oral	CHIP	Yes.
			Pediatric vision	FEDVIP.	
Oregon	Plan from third largest small group product.	PacificSource Health Plans PPO Preferred CoDeduct Value 3000 35 70.	Pediatric oral	CHIP	No.
			Pediatric vision	FEDVIP.	
Pennsylvania	Plan from largest small group product.	Aetna Health, Inc. PA POS Cost Sharing 34 1500 Ded.	Pediatric oral	FEDVIP	No.
Puerto Rico	Plan from largest small group product.	Triple-S Salud, Inc. Óptimo Plus (Plan de Salud PG-OP 2008).	Pediatric oral	FEDVIP	No.
			Pediatric vision	FEDVIP.	
Rhode Island	Plan from largest small group product.	Blue Cross and Blue Shield of Rhode Island Vantage Blue PPO.	Pediatric oral	FEDVIP	No.
			Pediatric vision	FEDVIP.	
South Carolina	Plan from largest small group product.	Blue Cross Blue Shield of South Carolina Business Blue Complete PPO.	Pediatric oral	FEDVIP	No.
			Pediatric vision	FEDVIP.	
South Dakota	Plan from largest small group product.	Wellmark of South Dakota Blue Select PPO.	Pediatric oral	FEDVIP	Yes.
			Pediatric vision	FEDVIP.	
Tennessee	Plan from largest small group product.	Blue Cross Blue Shield of Tennessee PPO.	Pediatric oral	FEDVIP	Yes.
			Pediatric vision	FEDVIP.	

State	Plan type	Issuer and plan name	Supplemented categories	Supplementary plan type	Habilitative services
Texas	Plan from largest small group product.	Blue Cross Blue Shield of Texas BestChoice PPO RS26.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
Utah	Plan from third largest State employee plan.	Public Employee's Health Program Utah Basic Plus.	None	None	Yes.
Vermont	Plan from largest small group product.	The Vermont Health Plan, LLC, CDHP-HMO.	Pediatric oral Pediatric vision	CHIP FEDVIP.	No.
Virginia	Plan from largest small group product.	Anthem Health Plans of VA PPO KeyCare 30 with KC30 Rx plan 10 30 50 OR 20.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
Virgin Islands	Largest National FEHBP	Blue Cross Blue Shield Standard Option PPO.	Pediatric vision	FEDVIP	Yes.
Washington	Plan from largest small group product.	Regence BlueShield non-grandfathered small group product.	Pediatric oral Pediatric vision	CHIP FEDVIP.	Yes.
West Virginia	Plan from largest small group product.	Highmark Blue Cross Blue Shield West Virginia Super Blue PPO Plus 2000 1000 Ded.	Pediatric oral Pediatric vision	CHIP FEDVIP.	No.
Wisconsin	Plan from largest small group product.	UnitedHealthcare Insurance Company Choice Plus Definity HSA Plan A92NS.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	No.
Wyoming	Plan from largest small group product.	Blue Cross Blue Shield of Wyoming Blue Choice Business 1000 80 20.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	No.

Appendix B: Largest FEDVIP Dental and Vision Plan Options, as of March 31, 2012

Section 156.110(b)(2)–(3) directs States to supplement base-benchmark plans that lack pediatric oral or vision services with benefits drawn from either the Federal Employees

Dental and Vision Program (FEDVIP) or a State's separate CHIP program. Specifically, States may select benefits from either: (1) The FEDVIP dental or vision plans with the largest national enrollments, or (2) the State's separate CHIP program's dental or vision benefits, where they exist, which offer benefits to the eligibility group with the

highest enrollment. To assist States with this process, we collected information about the benefits provided in the FEDVIP dental and vision plans with the highest national enrollments, as issued by MetLife and FED Blue, respectively. Below, we provide a chart with a summary of the benefits offered by these plans.

LARGEST FEDVIP DENTAL AND VISION PLAN OPTIONS, AS OF MARCH 31, 2012 *

Issuer name	Plan name	Additional information
MetLife (dental)	MetLife Federal Dental Plan—High	2012 Plan Benefit Brochure: http://www.opm.gov/insure/health/planinfo/2012/brochures/MetLife.pdf
BCBS Association (vision)	FEP BlueVision—High	2012 Plan Benefit Brochure: http://www.opm.gov/insure/health/planinfo/2012/brochures/FEPBlueVi.pdf

Source: U.S. Office of Personnel Management.

*Please note that this information will be updated with the latest data when released.