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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 156

[CMS-9965-F]

RIN 0938-AR36

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

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This final rule establishes data collection standards necessary to implement aspects of section 1302 of the Patient Protection and Affordable Care Act (Affordable Care Act), which directs the Secretary of Health and Human Services to define essential health benefits. This final rule outlines the data on applicable plans to be collected from certain issuers to support the definition of essential health benefits. This final rule also establishes a process for the recognition of accrediting entities for purposes of certification of qualified health plans.

EFFECTIVE DATE: These regulations are effective on [OFR: Insert 30 days from date of publication].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Executive Summary:

Beginning in 2014, all non-grandfathered health plans in the individual and small group

market, and other plans will cover the essential health benefits (EHB), as defined by the Secretary of Health and Human Services (the Secretary). The Affordable Care Act directs that the EHB reflect the scope of benefits covered by a typical employer plan and cover at least the following 10 general categories of items and services: 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 oral and vision care. EHB will promote predictability for consumers who purchase coverage in these markets, facilitate comparison across health plans, and ensure that individual and small group subscribers have the same access to the same scope of benefits provided under a typical employer plan.

This final rule includes data reporting standards for health plans that represent potential State-specific benchmark plans. Specifically, the final rule establishes that issuers of the largest three small group market products in each state report information on covered benefits.

In addition, this rule establishes the first phase of a two-phased approach for recognizing accrediting entities to implement the standards established under the Affordable Care Act for qualified health plans (QHPs) to be accredited on the basis of local performance by an accrediting entity recognized by the Secretary on a timeline established by the Exchange and addresses some data sharing and performance requirements of the recognized accrediting entities. In phase one, the National Committee for Quality Assurance (NCQA) and URAC are recognized as accrediting entities on an interim basis. In phase two, a criteria-based review process will be adopted through future rulemaking.

I. Background

Section 2707 of the Public Health Service Act, as added by section 1201 of the Affordable Care Act, directs that, for plan years beginning on or after January 1, 2014, health insurance issuers offering non-grandfathered plans in the individual or small group market ensure such coverage includes EHB as described in section 1302(a) of the Affordable Care Act. Section 1302 of the Affordable Care Act provides for the establishment of EHB, to be defined by the Secretary. The law also directs that EHB reflect the scope of benefits covered by a typical employer plan and cover at least the 10 general categories of items and services previously listed. Section 1302(b)(4) of the Affordable Care Act further establishes that the Secretary define EHB such that it:

- Sets an appropriate balance among the 10 general categories;
- Does not discriminate based on age, disability, or expected length of life;
- Takes into account the health care needs of diverse segments of the population; and
- Does not allow denials of essential benefits based on age, life expectancy, disability, or degree of medical dependency and quality of life.

Section 1302(b)(4) of the Affordable Care Act further directs the Secretary to consider the provision of emergency services and dental benefits when determining whether a particular health plan covers the EHB. Finally, sections 1302(b)(4)(G) and (H) of the Affordable Care Act direct the Secretary to periodically review the EHB, report the findings of the review to the Congress and to the public, and update the EHB as needed. A bulletin on HHS's intended benchmark approach to defining essential health benefits was made available for comment on December 16, 2011 (EHB Bulletin).¹

¹ Available at: http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.

Section 1311(c)(1)(D)(i) of the Affordable Care Act provides that in order to be certified as a QHP and operate in an Exchange, a health plan must be accredited by a recognized accrediting entity on a uniform timeline established by the applicable Exchange. In a separate rule titled “Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers” (Exchange Rule) published in the March 27, 2012 Federal Register (77 FR 18310), HHS finalized 45 CFR 156.275, specifying that a QHP issuer must be accredited by an entity recognized by HHS.

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

The Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans proposed rule was published in the Federal Register on June 5, 2012 and the comment period closed on July 5, 2012 (77 FR 33133). In total, we received 80 public comments on the proposed regulation.

We received numerous comments on the EHB data collection portion of the proposed rule. Commenters represented a variety of stakeholders, including issuers, states, consumer groups, and others interested parties. We received a number of comments in support of the proposed data collection, including the required submission of data on treatment limitations, prescription drug coverage, and other descriptive information for small group plans.

Commenters also recommended specific uses of the data we proposed to collect, for example that consumers and states have access to the data. Several commenters urged HHS to use the data for specific purposes, such as to ensure that certain services are covered, that plans are not discriminatory, that prescription drug coverage is comparable to a typical employer plan and that benefit limits do not reduce actuarial value (AV). We note that the purpose of the data collection in this final rule is to collect benefit and coverage information from potential

benchmark plans. Accordingly, we addressed comments on potential uses of the data collected to the extent that they are related to the development of benchmark plans.

We received a number of comments that fall outside of the scope of this regulation, which is specific to data collection from certain issuers to support the definition of essential health benefits. Because we intend to publish additional rules on EHB standards in the future, we do not specifically address these comments in this final rule.

We also received numerous comments on the proposed rule regarding recognition of accrediting entities. Commenters represented a diverse set of stakeholders including but not limited to accrediting entities, healthcare provider organizations, consumer groups, health plans, industry experts, and members of the public. The vast majority of commenters supported the recognition of NCQA and URAC for the accreditation of QHPs in the interim phase one and agreed with the proposed provisions that we outlined in the NPRM. We received a number of comments on the timeline, financial and operational requirements for accreditation, the Federally Facilitated Exchange (FFE), the broader quality requirements in the Affordable Care Act, network adequacy and access standards for QHPs, coordination of quality requirements inside and outside Exchanges, and Exchange requirements. We have not addressed such comments and others that are outside the scope of this final rule. HHS will be releasing future rulemaking and guidance on these other topics. Several commenters requested clarifications regarding the future recognition process for accrediting entities, clinical quality measures criteria, accreditation standards related to network adequacy and access, documentation and data sharing requirements. In this final rule, we have responded to comments submitted in response to the recognition of entities for the accreditation of QHPs within the scope of the proposal and this final rule.

A. Collection of Essential Health Benefits Data (§156.120)

1. Definitions

Under §156.120(a), we proposed definitions for terms that are used throughout the section. For the most part, the definitions presented in §156.120(a) were taken from existing regulations.

We proposed to define “health benefits” as “benefits for medical care, as defined at §144.103 of this chapter, that may be delivered through the purchase of insurance or otherwise.” This proposed definition is adapted from the definition of health benefits finalized in the Early Retiree Reinsurance Program regulation at 45 CFR 149.2.

We proposed that for the purposes of this data collection “health plan” has the meaning given to the term “portal plan” in §159.110 of this chapter, which is the discrete pairing of a package of benefits and a particular cost sharing option (not including premium rates or premium quotes). We note that a “portal plan” is collected as a unique combination of benefits, which may include optional benefits available for an additional premium (often referred to as “riders”) as well as benefits that are legally considered riders but are not optional for consumers (“mandatory riders”), if those benefits are part of the most commonly purchased set of benefits within the product by enrollment.

We proposed that “health insurance product” has the meaning given to the term at §159.110 of this chapter, which is a package of benefits that an issuer offers that is reported to state regulators in an insurance filing. We proposed that “small group market” has the meaning given to the term in §155.20 of this chapter, which is the meaning in section 1304(a)(3) of the Affordable Care Act. We also proposed that “State” has the meaning given at §155.20. We noted that the Public Health Service Act definition of “State” that would apply to section 2707(a) is broader than the definition in section 1304 of the Affordable Care Act.

We proposed that “treatment limitations” have the meaning found in §146.136 of this chapter, which includes both quantitative and nonquantitative limits on benefits. Examples of quantitative limits include limits based on the frequency of treatment, days of coverage, or other similar limits on the scope and duration of treatment. Examples of nonquantitative limits include prior authorization and step therapy requirements. In response to comments received on this proposal, we are changing the definition of “treatment limitations” for the purpose of this final rule to include only quantitative limits.

Additionally, throughout the proposed rule we referred to “issuers,” which is defined in previous rulemaking at 45 CFR 156.20.

Comment: We received several comments on the treatment of riders, or optional benefits available for an additional premium, under proposed §156.120. Commenters requested that HHS clarify the treatment of riders with respect to EHB; specifically some commenters recommended that HHS collect information on riders made available as part of a plan and stated that benefits offered through riders be considered part of EHB. Another commenter expressed concern that the definition of “health insurance product” included in the final rule could make it difficult for issuers and states to identify the largest plan within that product as a benchmark option.

Response: In response to these comments, we now use the term portal plan defined in §159.110 for this identification in the final rule, which as described above may include riders. The issuers subject to this reporting requirement will submit the requested benefit data on the largest plan by enrollment within that product. By using the “portal plan” definition for this data collection, the largest plan by enrollment will be comprised of the most commonly purchased unique set of benefits, which may include riders.

2. Required Information (§156.120(b))

In §156.120(b), we proposed that certain issuers of applicable plans described in paragraph (c) of this section submit certain benefit and enrollment information to HHS. We stated that this information could be used by HHS and eventually states, Exchanges, and issuers to define, evaluate, and provide the EHB.

First, at §156.120(b)(1), we proposed that the relevant issuers would submit administrative data necessary to identify their health plan. Since an issuer may offer multiple similar plans within a product, this information is critical to the identification of a single, uniquely identified benchmark plan.

At §156.120(b)(2), we proposed that the relevant issuers would submit data and descriptive information on the plans identified in paragraph (d) in four areas. Additional detail describing the specific data elements that issuers would submit can be found in the revision of the currently approved Health Insurance Web Portal information collection request (ICR). The ICR is approved under OCN: 0938-1086, and is available to the public under a notice and comment period separate from the notice of proposed rulemaking. That notice and comment period is ongoing until August 5, 2012. Section 156.120(b)(2)(i) proposed that certain issuers submit information on covered health benefits in the applicable plans to be used to define certain benchmark plan options.

In section 156.120(b)(2)(ii), we proposed to collect from issuers data on treatment limitations imposed on coverage, if applicable. For example, a quantitative scope and duration treatment limitation might limit a physical therapy benefit to 10 physical therapy visits per year.

At §156.120(b)(2)(iii), we proposed to collect data on drug coverage. This would include a list of covered drugs and whether each drug is subject to prior authorization and/or step therapy. In response to comments received on this proposal, we no longer intend to collect data

on prior authorization and/or step therapy for drug coverage.

At §156.120(b)(2)(iv) we proposed to collect plan enrollment data, which is discussed in more detail in the “Plans Impacted” section below.

Comment: Many commenters requested that HHS collect data in addition to the elements listed in the proposed rule, such as data on exclusions, medical necessity, habilitative services, cost-sharing (including premiums and co-pays), additional drug data, additional data on treatment limits, and a more extensive list of benefits.

Response: We believe the data collection proposed balances a minimal data collection burden on issuers while being sufficient to support the establishment of a potential benchmark for each state. Therefore, we are not requiring issuers to report any additional data elements in this final rule.

Comment: Some commenters expressed concern with the data collection of treatment limitations, particularly with regard to nonquantitative treatment limits, stating that the data elements are related to product design as opposed to benefit coverage and that the data are not necessary to establish EHB standards. Others expressed concern with the collection of prescription drug formularies.

Response: We believe that the data collection described in the proposed rule reflects the appropriate balance between the need to collect data that are sufficiently specific to establish benchmark plans while minimizing the burden on issuers. However, we agree with the commenters that the data on nonquantitative limits are not necessary for benchmark plan purposes and are therefore amending our definition of treatment limitations and data collection to include only quantitative limits. We encourage commenters to continue to submit comments on the PRA package associated with this rule.

Comment: Two commenters expressed concern that the proposed data collection asks for information that is proprietary and confidential.

Response: The data HHS intends to collect are part of the contract agreement between the issuer and enrollees in the plan and available to every enrollee. Therefore, we believe issuers will not experience adverse commercial effects as a result of reporting the data.

Comment: Some commenters recommended that HHS leverage data already collected by states and by HealthCare.gov for purposes of establishing default benchmark plans and urged HHS to synchronize the collection of data described in the proposed rule with data collection to support HealthCare.gov.

Response: The benefit data are consistent with the data collected to support HealthCare.gov. We believe it is necessary to collect additional information related to treatment limitations and drug coverage to establish the definition of essential health benefits. We also note that the data we intend to collect to establish potential benchmark plans are more recent and at a plan level.

Comment: Several commenters requested that HHS clarify specific data elements of the proposed data collection, for example that HHS describe the level of specificity and establish the format for data submission. One commenter recommended that HHS modify the language in its data collection on drugs to from “drug coverage” to “formulary” and urged HHS to ensure a flexible prescription drug benefit.

Response: We refer commenters to the relevant parts of the PRA package associated with the NPRM and available at <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1247405.html>.

The PRA package includes additional information on the data HHS intends to collect with regard

to treatment limitations, as well as a list of the data elements.

3. Issuers Who Will Report (§156.120(c))

Section 156.120(c) of the proposed regulation specified that these reporting requirements would apply only to certain issuers. Specifically, we proposed to collect data from the issuers in each state that offer the three largest health insurance products, by enrollment, in that state's small group market. We proposed that enrollment data submitted to www.HealthCare.gov would be the source of product enrollment and therefore, the products eligible to be benchmarks based on enrollment (described in part 159 of this title) on March 31, 2012, the date set forth in the December 16, 2011 EHB bulletin. State data may vary from www.HealthCare.gov data, and we requested comment on whether states should be permitted to use an alternative data source for determining the enrollment in the small group market. We also solicited comment on whether closed block products or association products should be included as options in the selection of the largest three products.

Under the approach outlined in the EHB bulletin, states would be permitted to select their own benchmark plans from a set of options. State submissions of these selections are information collections under the PRA. As part of the PRA package, we requested comment on the draft instructions for states to submit benefits for their selected benchmark plan.

Comment: Several commenters made recommendations with respect to which plans should be available as benchmark plan options. Some commenters recommended that HHS exclude association plans and plans closed to new enrollment as benchmark plan options. In contrast, a few commenters stated that plans closed to new enrollment should be available as benchmark plan options.

Response: As described in the EHB Bulletin, HHS intends to propose that EHB be defined in reference to one of four benchmark plan options. With respect to potential default benchmark plans, we refer commenters to the guidance published on July 2, 2012, titled “Essential Health Benefits: List of the Largest Three Small Group Products by State,”² which provides a state-by-state list of small group market products available for selection as benchmark plans.

Comment: Several commenters expressed concern that HHS is only collecting data on the small group market benchmark options.

Response: We note that this regulation is narrow in scope and collects data in order to establish potential default benchmark plans in each state. As stated in the EHB Bulletin, the default benchmark plan in each state is the largest small group market plan within the largest small group market product by enrollment, supplemented to reflect coverage in the 10 statutory benefit categories.

Comment: Several commenters recommended that HHS consider additional data to establish EHB, such as national claims data or data from Medicaid.

Response: Our proposed data collection from issuers is consistent with the benchmark approach described in the EHB bulletin, which uses a typical employer plan as a reference to define EHB.

4. Plans Affected (§156.120(d))

In §156.120(d), we proposed that issuers of the largest three products in each state provide information based on the plan with the highest enrollment within the product. For purposes of identifying the benchmark plan, we proposed to identify the plan following the definition of “portal plan” in §159.110 of this chapter.

² Available at: <http://cciio.cms.gov/resources/files/largest-smgroup-products-7-2-2012.pdf>.PDF.

We stated in the proposed rule that issuers may use their own data to determine which plan within each product has the highest enrollment, although we expect that for many products, the benefits will be the same across plans within the product. We also specified that enrollment data should reflect a plan's entire service area and to the extent possible should align with the timing of the www.HealthCare.gov data collection (reflecting enrollment as of March 31, 2012). We requested comment on the necessity of plan-level specificity.

Comment: Several commenters offered feedback on the enrollment data used to identify the plans eligible for benchmark consideration. Several comments supported the use of the HealthCare.gov for determining enrollment. Commenters also urged HHS to allow states to use their own enrollment data and recommended that if state enrollment data conflict with HealthCare.gov data, the state data should be considered. In contrast, one commenter recommended that if state enrollment data are permitted, states should be required to demonstrate that the state data are more accurate.

Response: The guidance published on July 2, 2012, titled "Essential Health Benefits: List of the Largest Three Small Group Products by State,"³ clarifies the small group market products that are available for benchmark plan consideration in each state. In developing this list, HHS worked with states to reconcile enrollment data from HealthCare.gov with state data when necessary.

5. Reporting Requirements (§156.120(e))

Finally, §156.120(e) proposed that issuers described in subparagraph (c) submit the information described in subparagraph (b) to HHS in a form and manner to be determined by HHS. We stated that we intend to make information on final state selections of benchmarks publicly available as soon as possible so that issuers can use it for benefit design and rate setting

³ Available at: <http://cciio.cms.gov/resources/files/largest-smgroup-products-7-2-2012.pdf>.PDF.

for 2014. We intend to publish the State-specific benchmarks for notice and comment and then finalize those benchmarks, as approved by the Secretary. We welcomed public comment on this approach.

Comment: Several commenters requested additional guidance on the schedule for collecting data pursuant to this final rule.

Response: We clarify in this final rule that the submission window for applicable issuers will open upon the effective date of this final regulation and remain open until September 4, 2012. Issuers will use the Health Insurance Oversight system to make these submissions.

Comment: Several commenters urged HHS to make the data collected pursuant to this final rule, including data on benefits, treatment limits, and prescription drugs, publicly available to all stakeholders. Several commenters urged HHS to release these data as soon as possible. In addition, some commenters recommended that HHS establish a federal oversight role in the evaluation and approval of state-specific EHB packages.

Response: HHS intends to publish State-specific benchmarks for notice and comment.

B. Voluntary Data Collection from Stand-alone Dental Plans

Section 1302(b) of the Affordable Care Act outlines the ten statutory benefit categories, including pediatric oral care, which must be covered by applicable plans. Section 1302(b)(4)(F) allows QHPs in an Exchange in a state to choose not to offer coverage for pediatric oral services provided that a stand-alone dental benefit plan that covers pediatric oral services is offered through the same Exchange. In order for QHPs to know whether their plan design must include pediatric oral services, issuers need to know if stand-alone dental plans would be offered through their Exchange. To facilitate and streamline the communication of this information, we proposed to collect, on a voluntary basis, information from likely stand-alone dental issuers to

find out whether various Exchanges are likely to have stand-alone plans as options.

Comment: One commenter expressed concern that the data collection from stand-alone dental plans described in the proposed rule would be voluntary, and recommended that HHS require QHPs to offer pediatric dental benefits unless there is confirmation that a stand-alone dental plan will be offered.

Response: We appreciate the commenter's concern and note that the goal of this data collection is to begin the process of identifying which issuers intend to offer stand-alone dental coverage in Exchanges. We believe that a requirement is not necessary and this voluntary collection was only proposed to facilitate the most efficient exchange of information between issuers.

C. Accreditation of QHP Issuers (§156.275)

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

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).” HHS has determined that recognizing entities through an interim phase one process is necessary to meet the timeline for Exchange QHP certification activities and may include the accreditation requirement, depending on the uniform timeline established by an Exchange. In the proposed rule, we stated that after a survey of the market, to HHS's knowledge, only two entities that accredit health plans meet or plan to meet the statutory requirements this year. We proposed recognition of the National Committee for Quality Assurance (NCQA) and URAC on an interim basis for the purpose of accreditation of QHPs, subject to the conditions specified in paragraphs

(c)(2), (c)(3), and (c)(4) of §156.275 of the proposed rule. As such, we proposed for this recognition to be effective once these conditions are met, at which time HHS would provide notification in the Federal Register. We requested comment on whether or not there are other accrediting entities that meet or would meet the statutory requirements this year.

In addition, we proposed certain data sharing and performance standards for the recognized accrediting entities.

We are making a technical correction in this final rule to clarify that both NCQA and URAC currently meet certain statutory requirements for accreditation. At the time the proposed rule was published, we did not include the fact that URAC had already released its Health Plan Accreditation Program Version 7 effective January 3, 2012, which includes reporting on a CAHPS survey and a set of clinical performance measures which are statutorily required to be considered as part of accreditation. Here, we clarify that both entities have already issued health plan accreditation standards that meet the conditions for recognition as detailed in paragraphs (c)(2)(ii), (c)(2)(iv) and (c)(3) of this rule.

Comment: The vast majority of commenters expressed support for recognizing NCQA and URAC in phase one of the process to recognize accrediting entities. Commenters agreed with provisions to identify these two entities in this interim phase and encouraged HHS to finalize its recognition of NCQA and URAC as soon as possible.

Response: We intend to provide notification in the Federal Register to make this recognition effective once the documentation requirements in (c)(4) are satisfied.

Comment: One commenter stated that the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC) should be recognized as an accrediting entity for the purposes of QHP certification in addition to the NCQA and URAC in the phase one recognition process.

The commenter contends that AAAHC meets the requirements for the phase one recognized accrediting entities.

Response: Upon review of the AAAHC's accreditation processes and standards, we believe that, currently, the AAAHC does not meet the statutory requirements necessary to be recognized for phase one. Our review indicates that the AAAHC does not currently score clinical quality and CAHPS data from health plans as part of accreditation in a standardized, comparable way across health plans using transparent and rigorous methodological and scoring criteria, as directed by section 1311(c)(1)(D)(i) of the Affordable Care Act and 45 CFR 156.275(c)(3), which is finalized in this rule. We believe that the methodology and scoring criteria for accreditation by recognized accrediting entities is a significant requirement that contributes to the strength and validity of the accreditation of QHPs. For these reasons, the statutory accreditation requirements for QHP issuers would not be met if AAAHC were recognized as an accrediting entity as part of the phase one recognition process. In the final rule, we are maintaining the proposed recognition of the NCQA and URAC in the interim phase one process of recognizing accrediting entities. We encourage entities that would like to be recognized as accrediting entities for the purposes of fulfilling the accreditation requirement for QHPs in the future to prepare and plan to apply for the phase two recognition process. We anticipate that the future recognition process will, at a minimum, require accreditation on local performance in the nine categories specified in 45 CFR 156.275 (a)(1) and clinical measures that span a broad range of conditions and domains.

Comment: Two commenters requested that CMS establish an accreditation recognition process that enables New York and other states with rigorous issuer regulation, state licensing and quality monitoring requirements to be recognized as accrediting entities in phase one such

that accreditation by entities such as NCQA and URAC is unnecessary if QHP issuers are licensed in such states. The commenters state that the licensing and oversight processes and standards in New York exceed those of NCQA and URAC.

Response: The standards described by commenters are currently for state licensing and oversight requirements and not for accreditation of health plans. However, the statute specifically directs that QHPs be accredited and that the Secretary recognize accrediting entities. In the final rule, we are maintaining the proposed recognition of the NCQA and URAC in the interim phase one process of recognizing accrediting entities. However, we will consider the role of states in the phase two recognition process for accrediting entities.

Comment: One commenter requested a specific public deadline for URAC to obtain full approval as a recognized accrediting entity so that QHPs may confidently choose their accreditation provider and begin their accreditation process immediately. The commenter suggests that if URAC does not meet full approval for being a recognized accrediting entity by a specified deadline, that the accreditation requirement be delayed until sufficient accrediting entity choices are available.

Response: As noted, we have made a technical correction to the proposed rule to accurately state that URAC has already released its Health Plan Accreditation Program Version 7 which includes reporting on a CAHPS survey and a set of clinical performance measures. We intend to recognize both URAC and the NCQA as recognized accrediting entities for the interim phase one recognition process once both entities fulfill the documentation requirements finalized in §156.275 (c)(4).

Comment: One commenter requested clarification regarding which health plan accreditation program URAC is proposing because there are multiple materials referenced

including Health Plan Accreditation Program 7.0, Health Insurance Exchange Version 7.1 and measures Version 1.3

Response: We clarify that URAC's publicly released Health Plan Accreditation Program Version 7 includes the standards that meet the statutory requirements to be recognized as an accrediting entity of QHPs and has been effective since January 3, 2012.

Comment: Several commenters expressed concern that NCQA or URAC accreditation is not the best measure of the quality and effectiveness of Consumer Operated and Oriented Plans (CO-OP). The commenters are concerned that the accreditation processes of NCQA and URAC do not adequately address many of the key goals established for CO-OPs under the Affordable Care Act, including member control, consumer focus and benefit delivery innovation. Commenters proposed that the accrediting entities modify their accreditation processes to include a focus on the unique nature of CO-OPs.

Response: Pursuant to 45 CFR 156.520(e)(2), CO-OPs must meet the same accreditation standards as other QHPs. We maintain, in this final rule, the recognition of accrediting entities for phase one. We will consider the unique goals established for all QHPs including CO-OP plans as we develop the requirements for the phase two recognition process.

2. Phased Recognition Process for Accrediting Entities (§156.275(c)(1))

We proposed that the recognition as an approved entity for accreditation of QHPs is effective until it is rescinded or this interim phase one process is replaced by the process that we intend to identify in future rulemaking. We proposed for the future phase two recognition process to include an application procedure, standards for recognition, criteria-based review of applications, public participation, and public notice of the recognition for entities seeking to

become a recognized accrediting entity. We welcomed comments to inform this future rulemaking.

Comment: A few commenters stated that recognized accrediting entities' accreditation processes should be equally rigorous, include comparable accreditation results and use consistent standards. One commenter urged CMS to establish standards as part of the phase two recognition process, then compare these standards with the phase two accrediting entities' standards to recognize them as accrediting entities for the purposes of QHP accreditation.

Response: We agree that recognized accrediting entities should have rigorous, comparable processes and standards. We will consider the commenter's suggestion regarding use of a crosswalk to compare and ensure that each recognized accrediting entity meet the standards for the phase two recognition process. We will be establishing these standards in future rulemaking and will replace the phase one process codified in §156.275(c)(1).

Comment: One commenter requested clarification and public transparency of a timeline for moving from phase one to phase two of recognizing accrediting entities. The commenter questioned whether the proposed phases will align with the phased approach also being planned for new quality reporting and display requirements. The commenter recommended that HHS consider the different timelines across Exchanges for requiring accreditation of QHP issuers.

Response: We intend to establish through future rulemaking the recognition process of accrediting entities to align with the timeframe of other quality reporting requirements, including establishing a quality rating system. We recognize that it is important to coordinate these requirements for effective quality reporting and minimal burden on issuers. We will consider commenters' recommendations regarding the phase two recognition process as we develop future rulemaking.

Comment: One commenter requested clarification that the recognized accrediting entities from phase one would need to go through the full application process proposed for phase two rather than be grandfathered into phase two recognition.

Response: As we stated in the proposed rule, we maintain that the recognition of accrediting entities in phase one is effective until it is rescinded or this interim phase one process is replaced by the phase two process. We are clarifying that a phase one recognized accrediting entity must complete the application to be recognized for the phase two recognition process that we intend to identify in future rulemaking. We intend to propose in future rulemaking that the accreditation that is obtained from NCQA or URAC would be recognized for the purposes of QHP certification until this accreditation expired, regardless of whether NCQA or URAC continue to be recognized as accrediting entities in the future phase two recognition process.

Comment: A few commenters requested HHS to clearly distinguish the broader quality requirements on Exchanges and health insurance issuers and stated that accreditation should not be considered a permanent substitute for such requirements.

Response: We acknowledge that accreditation is not a substitute for the broader quality requirements included in the Affordable Care Act. We intend to issue rulemaking and welcome future public comment and stakeholder input regarding the quality requirements on Exchanges and health insurance issuers.

Comment: One commenter recommended that HHS monitor fees that accrediting entities charge and to potentially place a limit on fees that may not be included in the medical loss ratio (MLR) calculation. The commenter recommended that the criteria for review in the phase two recognition process for accrediting entities include full transparency in pricing.

Response: Accreditation user fees are part of the quality improvement component of MLR under 45 CFR 158.150(b)(2)(i)(5). We believe more entities will apply to meet the standards that we will be issuing for the phase two recognition process for accrediting entities, increasing competition.

3. Clinical Quality Measure Standards (§156.275(c)(2)(ii))

We proposed that the first condition of recognition is based on section 1311(c)(1)(D)(i) of the Affordable Care Act, which requires accreditation on local performance in nine categories, which are codified in 45 CFR 156.275(a)(1):

- Clinical quality measures such as the Healthcare Effectiveness Data and Information Set (HEDIS);
- Patient experience ratings on a standardized Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey;
- Consumer access;
- Utilization management;
- Quality Assurance;
- Provider credentialing;
- Complaints and appeals;
- Network adequacy and access; and
- Patient information programs.

We proposed in §156.275 (c)(2)(ii) that the clinical quality measures meet certain criteria in order for the accreditation to meet the requirements outlined in section 1311(c)(1)(D) of the Affordable Care Act and 45 CFR 156.275(a)(1)(i). These criteria were chosen based on

stakeholder input and to ensure that the clinical quality measures used in accreditation are applicable to the Exchange enrollee population.

We proposed that the clinical quality measure set must:

- Span a breadth of conditions and domains, including, but not limited to, preventive care, mental health and substance abuse disorders, chronic care, and acute care;
- Include measures that are applicable to adults and separate measures that are applicable to children;
- Align with the priorities of the National Strategy for Quality Improvement in Health Care issued by the Secretary and submitted to Congress on March 12, 2011 (see <http://www.healthcare.gov/law/resources/reports/quality03212011a.html>) and the National Quality Strategy: 2012 Annual Progress Report released by HHS on April 30, 2012 (see <http://www.healthcare.gov/news/factsheets/2012/04/national-quality-strategy04302012a.html>);
- Only include measures that are either developed or adopted by a voluntary consensus standards setting body (such as those described in the National Technology and Transfer Advancement of Act of 1995 (NTTAA) and Office of Management and Budget (OMB) Circular A-119 (1998)) or, where appropriate endorsed measures are unavailable, are in common use for health plan quality measurement and meet health plan industry standards; and,
- Be evidence based.

We solicited comments on these standards for clinical quality measures, including whether additional standards for such measures should be included, the standards for using endorsed and non-endorsed measures, and whether HHS should require entities seeking recognition as accrediting entities to review specific clinical measures as part of accreditation and if so, which ones.

Comment: One commenter recommended additional criteria for clinical quality measures to include domains such as outcomes and process apart from access and patient satisfaction, be risk-adjusted when appropriate, be scientifically sound and be periodically updated for use within the accreditation standards. A few commenters recommended prioritizing measures that are being used concurrently by public and private sector purchasers and payers. Commenters also suggested that HHS require accrediting entities to review health plan processes including marketing practices, member privacy, language access services and health plan efforts to reduce health care disparities and to provide culturally competent services.

Response: Much of the recommended criteria for clinical quality measures are already current components of accreditation standards and processes of the accrediting entities being recognized in the interim phase one. In this final rule, we are maintaining the standards that we proposed for clinical quality measure sets but will consider the additional suggested criteria in future rulemaking on phase two.

Comment: Several commenters expressed concern that clinical quality measure standards used by current accrediting entities and the CAHPS survey process do not include people with disabilities. Several commenters recommended that phase two recognition process requirements for recognized accrediting entities should include standards for clinical quality measures that address the needs of people with disabilities and that specifically address persons in need of habilitative and rehabilitative services and devices. Commenters suggested that the accreditation process should address habilitative and rehabilitative related quality measures, the evaluation of quality of life beyond that represented by the typical quality indicators and network adequacy.

Response: As part of future rulemaking on the phase two recognition process, we will

consider these standards.

Comment: One commenter requested clarification regarding which CAHPS survey will be used to measure patient experience or whether a future CAHPS survey will be developed. The commenter opposed the use of instruments such as the CAHPS Surgical Care Survey and the Clinician/Group CAHPS as proposed measure tools and recommended inclusion of all types of providers such as advanced practice registered nurses and certified registered nurse anesthetists in any measurement tools developed to adequately capture the patient and caregiver experience.

Response: We are finalizing the requirement that the recognized accrediting entities require accreditation on local performance in patient experience ratings on a standardized CAHPS survey. We are not specifying which CAHPS surveys that the recognized accrediting entities must use as part of accreditation but expect that the recognized accrediting entities will use health plan CAHPS surveys and will not use the surgical care and/or Clinician/Group CAHPS surveys.

Comment: Several commenters expressed support that accreditation include, to the extent possible, measures that are already developed or endorsed by recognized consensus standards setting bodies. A few commenters stated that measures should be based on national standards such as National Quality Forum (NQF) endorsed measures. One commenter requested clarification regarding the language related to measures that are developed or adopted by a voluntary consensus standards setting body. This commenter recommended that CMS specify that measure sets used for QHP accreditation only include measures that are endorsed by the entity with a contract with the Secretary, which is currently only the National Quality Forum (NQF).

Response: We agree that NQF plays a significant role in endorsing quality measures. However, we do not require clinical quality measures to either be endorsed by NQF or submitted for review to NQF since recognized accrediting entities may use a diverse measurement set. We maintain the criteria we proposed for the clinical quality measure set. We will consider the commenter's recommendations as we set the measurement standards as part of the future rulemaking on phase two.

Comment: One commenter suggested that the clinical quality measure requirements for recognized accrediting entities include measures that reflect patients' and families' perspectives and measures that advance primary care services and medical homes.

Response: We believe that the patient perspective is captured by the requirement that accreditation include patient experience ratings on a standardized CAHPS survey in 45 CFR 156.275(a)(1). We also maintain in this final rule that clinical quality measures be aligned with priorities of the National Strategy for Quality Improvement in Health Care ("the National Strategy"). The National Strategy includes as core principles, person-centeredness and family engagement, and strengthening primary care using models such as patient-centered medical homes.

Comment: A few commenters recommended requiring independent auditing of results as an additional criterion for clinical quality measures considered as part of accreditation to ensure the accuracy and comparability of results, to provide an important feedback loop for plans, and to instill support among all stakeholders.

Response: While independent auditing of results could be an effective way to assure accuracy and comparability and provide useful verification information to issuers and

stakeholders, we maintain in the final rule the criteria we proposed in §156.275(c)(2)(ii), which was based on diverse stakeholder input.

Comment: One commenter suggested that the phase two recognition process should include clinical measures, such as those from Minnesota Community Measurement, which address health outcomes for patients rather than process measures concerning the kind of care or tests that patients receive. Another commenter suggested that HHS examine and consider adoption of the uSPEQ measurement tool, which incorporates both consumer and employee satisfaction as primary factors in assessing the success of a program and that has been used to evaluate programs from a consumer perspective.

Response: Many of the quality measures currently used by the recognized accrediting entities address patients' health outcomes and patient experience. We will consider clinical health outcomes measures from organizations such as the Minnesota Community Measurement and measurement tools such as uSPEQ when we propose rules on phase two.

Comment: One commenter recommended that recognized accrediting entities require qualified health plans seeking accreditation to submit data on HIV quality measures to ensure that the care supported by qualified health plans can be effectively monitored and evaluated. The commenter suggested that, at a minimum, plans should be required to submit data for HIV measures proposed for Stage II Meaningful Use and to select from measures that are being used by Medicare, Medicaid and the HIV/AIDS Bureau.

Response: The recognized accrediting entities do not currently use an HIV-related quality measure in their accreditation scoring. However, there are such measures under development for accreditation standards. We maintain in the final rule that measures selected should be developed or adopted by a voluntary consensus standards setting body, appropriately endorsed

whenever possible and span a breadth of conditions. We support the alignment of measures with existing public and private measurement initiatives and intend to consider other measures during rulemaking for phase two.

Comment: One commenter endorsed HHS's recognition of URAC as an accrediting entity largely because it supports data collection requirements URAC has already implemented to help ensure QHP issuers seeking accreditation are currently complying with the Paul Wellstone-Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). The commenter encouraged HHS to require that as a condition of becoming a QHP accrediting entity, NCQA, as well as other possible future QHP accrediting entities, data collection of MHPAEA compliance as part of each QHP's local performance in the nine categories, including utilization management.

Response: We will consider the commenter's suggestion to include data collection related to MHPAEA compliance when we develop standards for the phase two process for recognizing accrediting entities in future rulemaking.

4. Product Type Level of Accreditation §156.275(c)(2)(iii)

In §156.275(c)(2)(iii), we proposed that recognized accrediting entities provide separate accreditation determinations for each product type offered by a QHP issuer in each Exchange (for example, Exchange HMO, Exchange point of service (POS) plans, and Exchange preferred provider organization (PPO) plans), based on data submitted by the issuer that are representative of the population of each QHP in that Exchange product type. We believe that the product type is the appropriate level for accreditation as it would balance 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. We solicited comments on the proposed level of accreditation. We also solicited comments on circumstances under which an exception should be made to the accreditation determination being made at the Exchange product type level.

Comment: A few commenters opposed requiring accreditation at the Exchange product type level due to their belief that product type level accreditation is not current market practice and potential challenges of inadequate sample size if accreditation moves to more granular levels. Several commenters expressed support for product type level accreditation to facilitate comparisons based on quality and transparency. One commenter recommended that states should have the responsibility to dictate the product level requiring accreditation because implementation of federally-defined product types would disrupt states' existing regulatory classifications and accreditation requirements for insurance products.

Response: We maintain in the final rule that recognized accrediting entities provide separate accreditation determinations for each Exchange product type since QHP issuers must be accredited on the basis of local performance per §156.275(a)(1). We believe that accreditation at the overall QHP issuer level would not adequately meet the requirement that QHP issuers be accredited on the basis of local performance. We believe that accreditation at the plan or metal-level would also be unreasonable because of the likely inadequate sample size for reliable performance data reporting.

Comment: One commenter stated that although NCQA generally accredits by product type, which combines product line (that is, Commercial, Medicare, Medicaid or Exchange) with product (that is, HMO, POS or PPO), there are some exceptions. For example, with NCQA approval, issuers can combine HMO and PPO or POS and PPO (or all three) products for HEDIS

reporting purposes or they can combine the same product across contiguous states for statistically valid HEDIS and CAHPS results.

Response: We understand that there may be some necessary exceptions to product type level accreditation for methodological reasons. We maintain that recognized accrediting entities provide separate accreditation determinations for each QHP product type offered in an Exchange (for example, Exchange HMO or Exchange PPO). However, we agree that in some instances, such as when sample sizes are inadequate to provide statistically valid results at the Exchange product type level, an exception to Exchange product level accreditation would then be reasonable. In the final rule, we are modifying the requirement that recognized accrediting entities provide accreditation at the Exchange product type level to permit an exception when this Exchange product type level accreditation is not methodologically sound. In such cases, the recognized accrediting entity must demonstrate that the Exchange product type level accreditation is not methodologically sound as a condition of the Exchange granting an exception such as authorizing Exchange product type combinations across contiguous states (for example, Exchange HMO in New York and Exchange HMO in New Jersey). We encourage Exchanges to collaborate and consult with state Departments of Insurance and other state regulatory and licensing bodies in granting the exception.

Comment: One commenter requested clarification on whether NCQA and URAC will be responsible for accrediting dental plans. The commenter suggested that designated accrediting entities use specific clinical quality measures developed by the Dental Quality Alliance (DQA) to accredit dental plans.

Response: We are not currently requiring that recognized accrediting entities accredit stand-alone dental plans. The Exchange final rule specifies that to the extent that accreditation

standards specific to stand-alone dental plans do not exist⁴, then such plans would not be required to meet the accreditation timeline required by 45 CFR 155.1045.

Comment: A few commenters recommended allowing plans to meet Exchange-specific requirements as part of their current accreditation instead of undergoing a separate accreditation process solely for Exchanges. One commenter recommended that at a minimum, issuer-level accreditation on policies and procedures should apply across product types offered within Exchanges.

Response: We agree with commenters and clarify our interpretation of this final rule that the recognized accrediting entities may review policies and procedures at the issuer level, provided that the same policies and procedures apply across an issuer's product lines and product types. We maintain that the recognized accrediting entity must provide accreditation at the Exchange product type level but we do not require recognized accrediting entities to duplicate valid and applicable work or reviews conducted in connection with accreditations provided at a different level for the same issuer.

5. Network Adequacy and Access in Accreditation Standards (§156.275(c)(2)(iv))

As part of our proposal that recognized accrediting entities include network adequacy and access in the accreditation standards, we proposed in subparagraph (c)(2)(iv) that the network adequacy and access standards outlined in section 1311(c)(1)(D) of the Affordable Care Act and 45 CFR 156.275(a)(1)(viii) must, at a minimum, be consistent with the general requirements for network adequacy standards for QHP issuers codified in §156.230(a). We solicited comments on this proposed requirement.

Comment: We received one comment that the current accreditation standards relating to network adequacy in use by NCQA are not fully consistent with the general requirements for

⁴ Exchange Final Rule published in 77 FR 18310 at 18412 (March 27, 2012).

network adequacy standards in §156.230(a) because NCQA does not currently address the inclusion of essential community providers in their network adequacy assessment. However, in its comment on the proposed rule, NCQA stated willingness to work with CMS to address this in their accreditation standards in the future.

Response: We acknowledge that NCQA does not currently capture information regarding essential community providers as part of its current accreditation standards. Because the direction to cover essential community providers is included as a separate provision defined in §156.235, we are finalizing the rule for the phase one recognition process such that network adequacy and access accreditation standards must be consistent with §156.230(a)(2) and §156.230 (a)(3) only. A review of the inclusion of essential community providers as part of accreditation standards will not be required in the interim phase one recognition process. This change does not affect the QHP certification standard that QHPs demonstrate essential community provider network adequacy. We will consider proposing that accreditation standards be fully consistent with all general requirements of network adequacy in §156.230(a) in future rulemaking on phase two.

Comment: One commenter expressed concerns about making network adequacy a part of the accreditation process and stated that it should not be delegated to private accreditors. The commenter believes that this is inherently a regulatory function and should be retained by a regulatory body. One commenter recommends that HHS clearly specify and distinguish the network adequacy responsibilities of Exchanges, QHP issuers, and recognized accrediting entities to ensure that consumers' access and rights are protected and information on provider networks is accurate.

Response: Section 1311(c)(1)(D)(i) of the Affordable Care Act and 45 CFR 156.275

(c)(2)(iv) direct that recognized accrediting entities include network adequacy and access in the accreditation standards. We clarify in the final rule that for the phase one recognition process, network adequacy and access accreditation standards should be consistent with §156.230(a)(2) and §156.230 (a)(3), including maintaining a network that is sufficient in number and types of providers to assure that all services will be accessible without unreasonable delay and is consistent with the network adequacy provisions of section 2702(c) of the PHS Act.

6. Methodological and Scoring Criteria Requirements (§156.275(c)(3))

In §156.275(c)(3), we proposed that each recognized accrediting entity must use transparent and rigorous methodological and scoring criteria, as required by section 1311(c)(1)(D)(i) of the Affordable Care Act. . We did not receive comments on this section and are finalizing the provisions as proposed.

7. Documentation Requirements (§156.275(c)(4))

In §156.275(c)(4), we proposed that each accrediting entity recognized by the Secretary, as a condition of gaining and maintaining recognition, provide to HHS its current accreditation processes to demonstrate that the entity meets the conditions described in §§156.275(c)(2) and 156.275(c)(3). Documentation should include accreditation standards and requirements, processes, and measure specifications for performance measures. We proposed that the initial submission of documentation be made at a time specified by HHS. We solicited comment on this timing requirement, specifically whether NCQA and URAC may only be recognized if this documentation is provided within a certain number of days of the final rule.

Recognized accrediting entities must also submit any proposed changes or updates to the accreditation and measurement process with 60 days notice prior to implementation such that HHS has ample opportunity to review and comment on whether these changes or updates are

significant enough to mean that the conditions in §§156.275(c)(2) and 156.275(c)(3) would no longer be met. We solicited comments on these documentation standards.

Comment: One commenter recommended a timeframe of ninety days for submission of required documentation by accrediting entities. The accrediting entities being recognized in phase one stated no opposition to submitting documentation within a timeframe specified by HHS; one commented that it would provide documentation at any time it is required. And we received numerous comments in support of the proposed 60 day timeframe for changes and updates.

Response: We only received one comment regarding a specific timeframe for documentation submission. We finalize in this rule that the documentation from recognized accrediting entities, due under § 156.275(c)(4) be provided within 60 days of the publication of this final rule. We believe that 60 days is a reasonable time for accrediting entities to submit their current accreditation processes, standards, and requirements.

Comment: A few commenters requested clarification regarding providing notice on updates or changes to the accreditation and measurement process and providing health plans with adequate time to implement the proposed changes. We received numerous comments in support of the proposed 60 day timeframe for changes and updates. The commenters' recommended that HHS clarify that issuers should be provided with a one year advance notice of changes in accreditation and measurement process. One commenter recommended that regulations should permit accrediting entities to address any errors found in technical specifications within a shorter timeframe. One commenter recommended that HHS seek input from affected stakeholders to determine whether any proposed changes are significant enough to mean that the conditions in §§156.275(c)(2) and 156.275(c)(2) would no longer be met. The commenter also requested

clarification regarding HHS's turnaround time to review and comment on accrediting entities' planned changes and updates.

Response: In the rule, we finalize this standard to state that recognized accrediting entities submit to HHS any proposed changes or updates to the accreditation and measurement process with 60 days prior to public notice. HHS does not intend to interfere with current practices of accrediting entities to provide advance notice to health plans and agree with commenters that health plans should have adequate time to implement any proposed changes. We also agree with the commenter's recommendation that accrediting entities should correct any errors to technical specifications within a shorter time period. We clarify that recognized accrediting entities do not have to provide advance notice to CMS of non-substantive error corrections. We intend to seek diverse stakeholder input if conditions in §§156.275(c)(2) and 156.275(c)(2) are no longer met. We intend to be expeditious during our review of any changes and updates of accreditation and measurement process.

8. Authorization of Data Sharing by Accrediting Entities to the Exchange and HHS

(§156.275(a)(2))

As codified in §156.275(a)(2), a QHP issuer must authorize the accrediting entity that accredits its QHPs to release to the Exchange and HHS certain materials related to QHP accreditation. In accordance, we proposed that when authorized by an accredited QHP issuer, recognized accrediting entities provide the following accreditation survey data elements to the Exchange in which the issuer plans to operate one or more QHPs:

- The name, address, Health Insurance Oversight System (HIOS) issuer identifier⁵, and unique accreditation identifier(s) of the QHP issuer.

⁵ We expect the QHP issuer will provide the accrediting entity with the HIOS identifiers.

- The QHP issuer's accredited product line(s) (that is, Commercial, Medicaid, Exchange) and type(s) which have been released;
- For each of the QHP issuer's accredited product type(s), HIOS product identifier (if applicable); accreditation status, survey type or level (if applicable); accreditation score; expiration date of accreditation; and clinical quality measure results and adult and child CAHPS measure survey results (and corresponding expiration dates of these data) at the level specified by the Exchange (for example, QHP product or plan level).

Such disclosure was proposed to occur on the following occasions: during the annual certification period or as changes occur to these data throughout the coverage year. We solicited comment, including whether fewer or more categories of information should be included.

The proposed rule would permit Exchanges to arrange additional data sharing agreements with the recognized accrediting entities if they choose, such as information on the QHP issuer's policies and procedures. We solicited comments as to whether recognized accrediting entities must provide this additional information upon request from an Exchange.

Comment: Several commenters recommended that recognized accrediting entities provide the Exchange a copy of the most recent accreditation survey for each accredited product as well as any corrective action plans and summaries of findings or other similar written comments or analysis that is provided to each insurer by the accrediting entities. A few commenters expressed concern regarding the release of proprietary health plan data and data containing sensitive personal health information. The commenters recommended that data sharing should be limited to quality measures and CAHPS survey results that will be displayed and not include the full accreditation survey or additional information that would undermine the accreditation process. One commenter requested that data be shared with state quality

improvement organizations for additional oversight.

Response: 45 CFR 156.275(a)(2) directs QHP issuers to authorize the accrediting entity to release to the Exchanges survey-related information such as corrective action plans or summaries of findings. However, we maintain in the final rule that the recognized accrediting entity provide data through data sharing agreements to an Exchange. We interpret this regulation to permit an Exchange the flexibility, through data sharing agreements, to request additional information or to engage in data sharing with another entity, such as a state quality improvement organization. We did not propose the requirement in this rule that recognized accrediting entities share additional data not identified in §156.275(a)(2) or §156.275(c)(5) with Exchanges. We agree with the commenters' recommendations that this qualitative information may provide useful insight to an Exchange. We are modifying the data sharing requirements between the recognized accrediting entities and Exchanges to expressly exclude personally identifiable data.

Comment: One commenter requested more information regarding the process for recognized accrediting entities to provide data to Exchanges.

Response: We will be working closely with the recognized accrediting entities to further clarify the process including definitions of data elements.

Comment: One commenter requested clarification on whether accreditation data must be provided on non-Exchange products during early years of the Exchange and whether a recognized accrediting entity can collect authorizations from issuers to release data elements to an Exchange.

Response: Because it will take time for QHP product type specific accreditation to be available, consistent with the proposed rule, recognized accrediting entities will provide accreditation data from a QHP issuer's existing accreditation on non-Exchange products (for

example, commercial and Medicaid) if these data are requested by an Exchange, once the QHP issuer authorizes the release of these data. As codified in §156.275(a)(2), QHP issuers will authorize the release of their accreditation survey data as part of QHP certification.

Comment: One commenter requested clarification regarding what clinical quality and CAHPS measure results data must be reported (for example, numerators and denominators only or more detailed data like member-level survey results).

Response: The clinical quality measure results and adult and child CAHPS measure survey results specified in the final rule refer to only those measure results attained through a QHP issuer's accreditation from a recognized accrediting entity. To allow Exchanges the flexibility to specify the level of detail that is appropriate and reasonable for the QHPs, we are not further defining the level of reporting of these data for each Exchange.

Comment: One commenter requested clarification regarding what is meant by providing clinical or CAHPS data at the level specified by the Exchange. The commenter stated that there should be sufficient numbers for valid data collection by issuers, but not necessarily at the metal (Bronze, Silver, Gold or Platinum) level.

Response: We recognize that adequate sample size for valid data collection is a critical element of accreditation. We maintain that Exchanges should have the flexibility to request clinical and CAHPS data at the QHP product or plan level if there are adequate sample sizes to capture the QHP experience and enable reporting of valid and reliable performance measures.

Comment: One commenter recommended that CMS collect accrediting entity data on plan performance and scoring information of network adequacy requirements to support CMS' network adequacy review and to minimize documentation requirements.

Response: We agree that these data could support the Exchange in the review of network adequacy standards as part of QHP certification; however, at this time, we are not requiring recognized accrediting entities to provide accreditation survey data elements relating to network adequacy requirements, that are in excess of the disclosure required under § 156.275(a)(2), to the Exchange.

III. Provisions of the Final Regulations

This final rule incorporates the provisions of the proposed rule with some substantive modifications, along with additional non-substantive changes to improve clarity, not noted here. Those provisions of the final rule that differ from the proposed rule are as follows:

Changes to §156.120(a)

- Changes the definition of treatment limitations to include only quantitative limits, which also removes the requirement to provide data on nonquantitative limits for purposes of this final rule.

Changes to §156.120(e)

- Establishes a submission deadline for applicable issuers. Issuer submissions are due on September 4, 2012.

Changes to §156.275(c)(2)(iii)

- Establishes exception authority to the product type level accreditation requirement when the product type level of accreditation is not methodologically sound. In such cases, the recognized accrediting entity must demonstrate that the Exchange product type level accreditation is not methodologically sound as a condition of the Exchange granting an exception to authorize accreditation at an aggregated level.

Changes to §156.275(c)(2)(iv)

- Removes inclusion of essential community providers under the network adequacy standards for accreditation.
- Maintains that network adequacy standards for accreditation be, at a minimum, consistent with general requirements for network adequacy for QHP issuers codified in §156.230(a)(2) and (a)(3).

Changes to §156.275(c)(4)(i)

- Establishes timeframe of within 60 days of publication of the final rule that an accrediting entity must provide current accreditation standards and requirements, processes, and measure specifications for performance measures to demonstrate that each entity meets the conditions specified.

Changes to §156.275(c)(4)(ii)

- Clarifies that recognized accrediting entities must provide to HHS any proposed changes or updates to accreditation standards, processes and measure specifications for performance measures with 60 days prior to public notification.

Changes to §156.275(c)(5)

- Adds an exception to protect personally identifiable information.

IV. Collection of Information Requirements

As part of the proposed rule, and in accordance with the Paperwork Reduction Act, we sought comment on the information collection requests (ICRs) associated with the proposed rule. This included the of EHB data (§156.120) information collections. We received some comments on this section, which are discussed below. As described above, we finalize §156.120 as it was proposed, with the addition of a deadline for the reporting requirement in §156.120(e). On June

5, 2012, we issued a 60-day Federal Register notice (77 FR 33221) seeking comments on the revision to the information collection request (ICR), “Health Care Reform Insurance Web Portal Requirements.”⁶

In the proposed rule and the June 5, 2012 60-day Federal Register Notice, we also sought comment on ICRs that are not discussed in the regulations text contained in this document, including the state selection of a benchmark and the voluntary data collection from standalone dental plans. We received some comments related to these ICRs, which we will consider before submitting the ICR to the Office of Management and Budget for review and approval. We plan to finalize the ICR on benchmark data collection and stand-alone dental separately from the other portions of the “Health Care Reform Insurance Web Portal Requirements” ICR. The comment period for this package remains open through August 5, 2012, and we encourage interested parties to submit comments.

In the proposed rule, we also sought comment on ICRs for recognized accrediting entities (§156.275). We did not receive comments on the accrediting entities ICRs described in the proposed rule. As described above, although we made some changes to §156.275 in this final rule, the ICRs are unchanged. We also issued a 60-day Federal Register notice seeking comments on these ICRs.⁷ That comment period closes on August 1, 2012, and we encourage interested parties to submit comments. Following close of the 60-day comment period, we will submit the accrediting entities ICR to OMB for approval.

What follows is a discussion of comments received on the ICRs related to the EHB data (§ 156.120).

6 Available at: <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1247405.html>.

7 Available at: <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/cms-10435.html>.

Section 156.120 states that issuers that offer the three largest health insurance products by enrollment in each state's small group market, as determined by HHS based on data submitted in accordance with part 159 of this title for March 31, 2012, must provide the data described in paragraph (b) for the health plan with the highest enrollment within that product. This data collection mirrors the benefit data fields currently collected under the Health Insurance Web Portal PRA package (OCN: 0938–1086) and also includes: The administrative data necessary to identify the health plan, data on covered benefits, any treatment limitations on those benefits, data on drug coverage, and enrollment.

We estimate that it will take four hours for a health insurance issuer to meet this reporting requirement, including data collection, submission, and validation. This estimate is based on current industry surveys collected to monitor the burden of submission of similar data in the Medicare Advantage and Prescription Drug Programs. Given that the three health insurance issuers with the largest products by enrollment in each state (including the District of Columbia) would submit this information, the total burden is estimated to be 612 hours. We anticipate that the reporting requirement would require four hours for one employee at a cost of \$77.00 an hour, based on the hourly cost reported by industry in responses to a CMS survey of Medicare Advantage and Prescription Drug Programs which requires employees with similar technical expertise, for a total cost of \$308.00 a year per issuer. The total number of respondents required to report would be 153, the largest three issuers/products in each state and the District of Columbia by enrollment, for a total burden of \$47,124. Issuers would provide HHS with the data collection requirements through an online tool that we would make available to them.

Comment: We received some comments expressing concern that HHS's burden estimates related to the proposed data collection were too low.

Response: We appreciate these concerns, but for the reasons discussed above, believe that our estimates accurately reflect the burden of reporting.

Comment: One commenter recommended that HHS avoid collection of an “other” benefit category because the category is somewhat ambiguous.

Response: HHS included the “other” category to allow for full reporting of the benefits, including benefits that do not fall into the set of categories provided under HealthCare.gov.

V. Regulatory Impact Analysis

We have examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993) and Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any one year).

It is HHS’s belief that this rule does not reach this economic threshold and thus is not considered a major rule. This rule consists of a data collection from a limited number of health insurance issuers and a data submission by two accrediting entities to HHS. Because of the very limited scope of this final rule, we do not anticipate that there would be any costs associated with this rulemaking in addition to those costs, as outlined below. We derived the costs outlined below from the labor costs as outlined in the Collection of Information section above. The data collection from issuers only applies to the issuers of the three largest products by enrollment in each state’s small group market, which would result in a minor economic burden to an estimated

153 issuers, at a total cost across all issuers of \$47,124. Additionally, the PRA package that accompanied the proposed rule requested that issuers that wish to offer stand-alone dental plans in an Exchange notify HHS of their intent to participate. We estimate that 20 dental issuers would voluntarily respond, at a total cost across all responding issuers of \$770. The two entities which we are recognizing as accrediting entities already meet most of the conditions for phase one of the recognition process, and we anticipate that any required changes to their accreditation processes would be minor and result economic burden that we have estimated at \$48,625.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) (RFA) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule would not have a significant economic impact on a substantial number of small entities. The RFA 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 percent.

The 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. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Small businesses are those with sizes below thresholds established by the Small Business Administration (SBA).

As discussed above, this final rule is necessary to implement certain standards related to the establishment of essential health benefits and recognition of accrediting entities as authorized by the Affordable Care Act. Specifically, this rule outlines collecting data from issuers that offer the three largest small group products in each state and from NCQA and URAC, which are the phase one recognized accrediting entities. For the purposes of the regulatory flexibility analysis, we expect the following types of entities to be affected by this final rule--(1) QHP issuers (2) and NCQA and URAC.

As discussed in the Medical Loss Ratio interim final rule (75 FR 74918), few, if any, issuers are small enough to fall below the size thresholds for small business established by the SBA. In that rule, we used a data set created from 2009 National Association of Insurance Commissioners (NAIC) Health and Life Blank annual financial statement data to develop an updated estimate of the number of small entities that offer comprehensive major medical coverage in the individual and group markets. For purposes of that analysis, the Department used total Accident and Health earned premiums as a proxy for annual receipts. We estimated that there are 28 small entities with less than \$7 million in accident and health earned premiums offering individual or group comprehensive major medical coverage. However, this estimate may overstate the actual number of small health insurance issuers offering such coverage, since it does not include receipts from these companies' other lines of business.⁸ We further estimate that any issuers that would be considered small businesses are likely to be subsidiaries of larger issuers that are not small businesses.

This rule also directs two accrediting entities, NCQA and URAC, to submit documentation to HHS. The RFA, as noted previously, considers a non-profit entity that is not

⁸ According to the Small Business Administration size standards, entities with average annual receipts of \$7 million or less would be considered small entities for North American Industry Classification System (NAICS) Code 524114 (Direct Health and Medical Insurance Carriers) (for more information, see "Table of Size Standards Matched To North American Industry Classification System Codes," effective March 26, 2012, U.S. Small Business Administration, available at <http://www.sba.gov>).

dominant in its field to be a small entity. We selected both NCQA and URAC because they are the two most dominant actors in the field of health plan accreditation. NCQA is a not-for-profit entity that has been in existence since 1990 and is widely recognized as a national leader in developing health care performance measures and quality standards. NCQA has accredited health plans covering over 70 percent of all Americans.⁹ URAC is also a not-for-profit entity that was formed over 20 years ago. URAC accredits plans in every state and, according to its Web site, is the largest accrediting body for health care.¹⁰ Finally, based on their dominant role in accrediting health plans, we believe that NCQA and URAC are both likely to have total annual receipts exceeding the Small Business Administration size standard.¹¹

Based on the foregoing, we are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule would not have a significant economic impact on a substantial number of small entities.

VII. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold is approximately \$139 million. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of costs, 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

⁹ See “About NCQA,” NCQA Web site. Available at <http://www.ncqa.org/tabid/675/Default.aspx>.

¹⁰ See “Frequently Asked Questions” URAC Web site. Available at: <https://www.urac.org/about/faqs.aspx#General>.

¹¹ According to the Small Business Administration size standards, entities with average annual receipts of \$7 million or less would be considered small entities for North American Industry Classification System (NAICS) Code 524298 (All Other Insurance Related Activities) (for more information, see “Table of Size Standards Matched To North American Industry Classification System Codes,” effective March 26, 2012, U.S. Small Business Administration, available at <http://www.sba.gov>).

conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs.

This final rule does not place any financial mandates on state, local, or Tribal governments. This rule authorizes a narrow data collection from an estimated 153 issuers, and the only costs associated with this reporting are labor costs, which we anticipate to total \$47,124, which is significantly less than the threshold of \$139 million. States may, at their option, select a benchmark plan and submit this information to HHS. We anticipate that it would take each state five hours of labor to complete and submit this information and that the per hour labor cost would be similar to that for the issuer data submission, which is \$77 per hour. We cannot reasonably anticipate how many states will respond. However, assuming for the sake of argument that all states respond, the total cost would still be under \$20,000, which is well below the \$139 million threshold. The rule also sets standards for two accrediting entities to submit documentation to HHS as specified in the rule. We expect the cost to the two accrediting entities to be \$48,898.

VIII. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has Federalism implications. This final regulation, as it relates to the recognition of accrediting entities, does not impose any costs on state or local governments. However, this regulation includes reporting requirements if a state selects a benchmark plan.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion

of the states, HHS has engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners (NAIC), and consulting with state insurance officials on an individual basis. We believe that this final rule does not impose substantial direct costs on state and local governments, preempt state law, or otherwise have federalism implications. We note that states that choose to select a benchmark plan would be required to submit their benchmark plan selection to HHS, and provide information on the benchmark plan in the same format that is used by issuers. However, we anticipate that the administrative costs related to this requirement are likely to be minimal because the states are likely to obtain this information from the issuers.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this regulation, the Department of Health and Human Services certifies that CMS has complied with the requirements of Executive Order 13132 for the attached regulation in a meaningful and timely manner.

List of Subjects in 45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory Committees, Brokers, Conflict of interest, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, Safety, state and local governments, Sunshine Act, Technical assistance, Women, and Youth.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter B, as set forth below:

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

1. 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, 1341–1343, and 1401–1402, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18042).

2. Add subpart B to part 156 to read as follows:

Subpart B -- Standards for Essential Health Benefits, Actuarial Value, and Cost Sharing

§156.120 Collection of data from certain issuers to define essential health benefits.

(a) Definitions. The following definitions apply to this section, unless the context indicates otherwise:

Health benefits means benefits for medical care, as defined at §144.103 of this chapter, which may be delivered through the purchase of insurance or otherwise.

Health insurance product has the meaning given to the term in §159.110 of this chapter.

Health plan has the meaning given to the term, “Portal Plan” in §159.110 of this chapter.

Small group market has the meaning given to the term in §155.20 of this chapter.

State has the meaning given to the term in §155.20 of this chapter.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment.

Treatment limitations include only quantitative treatment limitations. A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation.

(b) Required information. The issuers described in paragraph (c) of this section must provide the following information for the health plans described in paragraph (d) of this section in accordance with the standards in paragraph (e) of this section:

- (1) Administrative data necessary to identify the health plan;
- (2) Data and descriptive information for each plan on the following items:
 - (i) All health benefits in the plan;
 - (ii) Treatment limitations;
 - (iii) Drug coverage; and
 - (iv) Enrollment;

(c) Issuers required to report. The issuers that offer the three largest health insurance products by enrollment, as of March 31, 2012 (enrollment is determined by HHS based on data submitted in accordance with part 159 of this title) in each state's small group market must provide the information in paragraph (b) of this section.

(d) Plans affected. The issuers described in paragraph (c) of this section must provide the information described in paragraph (b) of this section for the health plan with the highest enrollment (as determined by the issuer) within the products described in paragraph (c) of this section.

(e) Reporting requirement. To ensure consistency in reporting, an issuer described in paragraph (c) of this section must submit, in a form and manner to be determined by HHS, the information described in paragraph (b) of this section to HHS no later than September 4, 2012.

3. Amend §156.275 by adding paragraph (c) to read as follows:

§156.275 Accreditation of QHP issuers.

* * * * *

(c) Accreditation -- (1) Recognition of accrediting entity by HHS. Effective upon completion of conditions listed in paragraphs (c)(2), (c)(3), and (c)(4) of this section, at which time HHS will notify the public in the Federal Register, the National Committee for Quality Assurance (NCQA) and URAC are recognized as accrediting entities by the Secretary of HHS to provide accreditation of QHPs meeting the requirement of this section.

(2)(i) Scope of accreditation. Subject to paragraphs (c)(2)(ii), (iii), and (iv) of this section, recognized accrediting entities must provide accreditation within the categories identified in paragraphs (a)(1) of this section.

(ii) Clinical quality measures. Recognized accrediting entities must include a clinical quality measure set in their accreditation standards for health plans that:

(A) Spans a breadth of conditions and domains, including, but not limited to, preventive care, mental health and substance abuse disorders, chronic care, and acute care.

(B) Includes measures that are applicable to adults and measures that are applicable to children.

(C) Aligns with the priorities of the National Strategy for Quality Improvement in Health Care issued by the Secretary of HHS and submitted to Congress on March 12, 2011;

(D) Only includes measures that are either developed or adopted by a voluntary consensus standards setting body (such as those described in the National Technology and Transfer Advancement of Act of 1995 (NTTAA) and Office of Management and Budget (OMB) Circular A-119 (1998)) or, where appropriate endorsed measures are unavailable, are in common use for health plan quality measurement and meet health plan industry standards; and

(E) Is evidence-based.

(iii) Level of accreditation. Recognized accrediting entities must provide accreditation at the Exchange product type level unless the product type level of accreditation is not methodologically sound. In such cases, the recognized accrediting entity must demonstrate that the Exchange product type level accreditation is not methodologically sound as a condition of the Exchange granting an exception to authorize accreditation at an aggregated level.

(iv) Network adequacy. The network adequacy standards for accreditation used by the recognized accrediting entities must, at a minimum, be consistent with the general requirements for network adequacy for QHP issuers codified in §156.230(a)(2) and (a)(3).

(3) Methodological and scoring criteria for accreditation. Recognized accrediting entities must use transparent and rigorous methodological and scoring criteria.

(4) Documentation. An accrediting entity 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 each entity meets the conditions described in paragraphs (c)(2), and (c)(3) of this section to HHS within 60 days of the publication date of this final rule.

(ii) Recognized accrediting entities must 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.

(5) Data sharing requirements between the recognized accrediting entities and Exchanges. When authorized by an accredited QHP issuer pursuant to paragraph (a)(2) of this section, recognized accrediting entities must provide the following QHP issuer's accreditation survey data elements to the Exchange, other than personally identifiable information (as

described in OMB Memorandum M-07-16), in which the issuer plans to operate one or more QHPs during the annual certification period or as changes occur to these data throughout the coverage year -- the name, address, Health Insurance Oversight System (HIOS) issuer identifier, and unique accreditation identifier(s) of the QHP issuer and its accredited product line(s) and type(s) which have been released; and for each accredited product type:

- (i) HIOS product identifier (if applicable);
- (ii) Accreditation status, survey type, or level (if applicable);
- (iii) Accreditation score;
- (iv) Expiration date of accreditation; and
- (v) Clinical quality measure results and adult and child CAHPS measure survey results

(and corresponding expiration dates of these data) at the level specified by the Exchange.

Dated: July 16, 2012

Marilyn Tavenner,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved: July 16, 2012

Kathleen Sebelius,

Secretary.

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