DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 156

[CMS–9965–P]

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: Proposed rule.

SUMMARY: This proposed rule would establish data collection standards necessary to implement aspects 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 proposed rule outlines the data on applicable plans to be collected from certain issuers to support the definition of essential health benefits. A bulletin on HHS' intended benchmark approach to defining essential health benefits was published for comment on December 16, 2011, and we intend to pursue comprehensive rulemaking on essential health benefits in the future. This proposed rule would also establish a process for the recognition of accrediting entities for purposes of certification of qualified health plans.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Standard Time (EST) on July 5, 2012.

ADDRESSES: In commenting, please refer to file code CMS–9965–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9965–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9965–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Adam Block at (301) 492–4392, for matters related to essential health benefits data collection. Deborah Greene at (301) 492–4293, for matters related to accreditation of qualified health plans.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on issues set forth in this proposed rule to assist us in fully considering issues and developing policies. Comments will be most useful if they are organized by the paragraph of the proposed rule to which they apply. You can assist us by referencing the file code CMS–9965–P, and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Executive Summary

Beginning in 2014, all non-grandfathered health plans in the individual and small group market, Medicaid benchmark and benchmark-equivalent plans, and Basic Health Programs, where applicable, 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 ten 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.

The Department of Health and Human Services (HHS) has provided the public with information about EHB in several phases:

- On December 16, 2011, HHS released a bulletin, following the report from the Department of Labor describing the scope of benefits covered under employer-sponsored coverage and an HHS commissioned study from the Institute of Medicine (IOM) that

recommended criteria and methods for determining and updating essential health benefits, outlining its intended regulatory approach for defining EHB. The bulletin considered an intended approach in which EHB would be defined by a benchmark plan selected by each State. This State-specific benchmark plan would serve as a reference plan, reflecting both the scope of services and any limits offered by a ''typical employer plan'' in that State as required by section 1302(b)(2)(A) of the Affordable Care Act. In the December 16, 2011, bulletin, we laid out four potential benchmark plan types for 2014 and 2015. They are: (1) The largest plan by enrollment in any of the three largest small group insurance products in the State's small group market, (2) any of the largest three State employee health benefit plans by enrollment, (3) any of the largest three national Federal Employees Health Benefits Program plan options by enrollment, and (4) the largest insured commercial non-Medicaid health maintenance organization (HMO) operating in the State. We intend to propose these options in comprehensive rulemaking on EHB in the future. Health insurance issuers could adopt the scope of services and limits of the State benchmark, or vary it within defined parameters.

- On January 25, 2012, HHS released an illustrative list of the largest three small group market products by State.
- On February 17, 2012, HHS further clarified the approach described in the bulletin through a series of Frequently Asked Questions.

This proposed rule includes data reporting standards for health plans that represent potential State-specific EHB benchmarks, as described in the bulletin released on December 16, 2011. Specifically, the proposed rule would establish that issuers of the largest three small group market products in each State must report information on covered benefits.

In addition, this rule proposes 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. In phase one, the National Committee for Quality Assurance (NCQA) and URAC would be recognized as accrediting entities on an interim basis. In phase two, a criteria-based review process would be adopted through future rulemaking.

II. Background

A. Legislative Overview

Section 1302 of the Affordable Care Act provides for the establishment of EHB, to be defined by the Secretary and included in QHPs offered through an Exchange. In addition, section 2707 of the Public Health Service Act, as added by section 1201 of the Affordable Care Act, directs that on and 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. The law also directs that EHB reflect the scope of benefits covered by a typical employer plan and cover at least the following ten 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. Section 1302(b)(4) of the Affordable Care Act establishes that the Secretary must define the EHB such that it:

- Sets an appropriate balance among the ten 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.

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. 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.

B. Stakeholder Consultation and Input

HHS has consulted with a wide range interested stakeholders on policies related to EHB. First, the Department of Labor issued a report on April 15, 2011, describing the scope of benefits offered under employer-sponsored coverage. Second, the IOM issued a consensus report on October 7, 2011, providing its recommendations for the process HHS should use to define EHB.

Following the release of the IOM's recommendations, HHS held a number of listening sessions with consumers, providers, employers, health plans, and State representatives to gather public input. These sessions were held throughout the country.

HHS also released several documents for public review and comment. On December 16, 2011, HHS released a bulletin outlining its intended regulatory approach to defining EHB. HHS received approximately 11,000 comments in response to the bulletin. Commenters represented a wide variety of stakeholders, including health insurance issuers, consumers, health providers, States, employers, and Members of Congress. Among other topics, many commenters requested additional information on potential EHB benchmark plans, and urged HHS to publish the benefit designs of the selected benchmark plans as soon as possible. In particular, issuers emphasized that timely access to the benefits included in the benchmark is necessary to design health plans.

HHS considered the comments received on the bulletin in developing the policies in this proposed rule. HHS will continue to review the comments on the bulletin as we develop future policy related to EHB.

Regarding the recognition of accrediting entities, HHS received comments in response to the Exchange Rule. In addition, HHS conducted a review of the entities conducting health plan accreditation in the U.S. and found that substantially all issuers that have health plan accreditation are accredited by NCQA and/or URAC.[1]

C. Structure of the Proposed Rule

The regulations outlined in this proposed rule would be codified in 45 CFR part 156. The provision in part 156 outlines the standards for health insurance issuers with respect to

[1] See *http://www.ncqa.org/tabid/135/Default.aspx.* Accessed April 24, 2012. See also *https://www.urac.org/accreditation/* Accessed April 24, 2012.

participation in an Exchange, including the minimum certification requirements for QHPs. The provision in § 156.120 proposes data collection from certain issuers of applicable plans to define benchmark options for EHB.

Additional standards and guidance on the EHB package and phase two of the recognition of accrediting entities would be addressed in future rulemaking. Consistent standards related to the accrediting entities that would fulfill the accreditation requirements for multi-State plans would also be addressed in future rulemaking implementing section 1334 of the Affordable Care Act promulgated by the U.S. Office of Personnel Management.

III. Provisions of the Proposed Regulation

Beginning in 2014, individuals and small businesses would be able to purchase private health insurance through competitive marketplaces called Affordable Insurance Exchanges (Exchanges). Exchanges would facilitate the purchase of insurance coverage by qualified individuals from QHPs and assist qualified employers in the enrollment of their employees into QHPs. See Affordable Care Act § 1311(b).

Beginning in 2014, non-grandfathered health insurance plans offered in the individual or small group market would offer EHB. See Affordable Care Act § 1301(a)(1)(B); Public Health Service Act § 2707(a).[2] Section 1302(b) of the Affordable Care Act directs the Secretary to define EHB in a way that includes at least the ten general categories of benefits described in the statute, and that is equal in scope to the benefits provided under a typical employer plan. Section 1321(a)(1) authorizes the Secretary to issue regulations setting standards for meeting the requirements of title I of the Affordable Care Act, including section 1302, as the Secretary determines appropriate.

The bulletin outlining HHS' intended regulatory approach stated that we are considering an approach whereby EHB would be defined by a benchmark plan selected by each State.[3] The selected benchmark plan would serve as a reference plan, reflecting both the scope of benefits and any limits contained in the plan, as required by section 1302(b)(2)(A) of the Affordable Care Act. If a State does not exercise the option to select a benchmark health plan, we intend to propose in future rulemaking that the default benchmark plan for that State would be the largest plan by enrollment in the largest product in the State's small group market. Under this approach, the specific set of benchmark benefits defined using the data collected in 2012 would apply for plan years 2014 and 2015.[4] We intend to revisit this approach for plan years starting in 2016 and would provide additional information through subsequent rulemaking.

The purpose of this proposed rule is to collect sufficient information on potential benchmark plans' benefits to enable plans seeking to offer coverage in the individual or small group market in 2014 to know what benefits will be included in the EHB benchmark. This proposed rule would add new regulation text at 45 CFR 156.120.

Finally, to implement the accreditation provisions of the Affordable Care Act relating to QHPs, we are proposing the first phase of a two-phased approach for recognizing accrediting entities. In this rule, we propose to recognize, on an interim basis, those entities that best meet the requirements stipulated in section 1311(c)(1)(D)(i) of the Affordable Care Act. In phase two, we currently plan to adopt, through future rulemaking, a recognition process that includes an application procedure, standards for recognition, a criteria-based review of applications, public participation, and public notice of the recognition. At this time, we have determined that recognizing entities through the phase one process outlined above is necessary to meet the timeline for Exchange QHP certification activities which must commence in early 2013. Exchanges may include the accreditation requirements as early as 2013 certification, for the 2014 plan year.

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

1. Definitions

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

We propose 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 propose that ''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 propose 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 propose 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 propose that ''State'' has the meaning given at § 155.20. We note 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 propose that ''treatment limitations'' have the meaning found in § 146.136 of this chapter, which includes both quantitative and non-quantitative 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 non-quantitative limits include prior authorization and step therapy requirements.

Additionally, throughout this proposed rule we refer to ''issuers'' which is defined in previous rulemaking at 45 CFR 156.20.

2. Required Information (§ 156.120(b))

In § 156.120(b), this rule proposes that certain issuers of applicable plans described in paragraph (c) of this section submit certain benefit and enrollment information to HHS. This information would be used by HHS and eventually States, Exchanges, and issuers to define, evaluate, and provide the EHB.

First, at § 156.120(b)(1), we propose 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 propose that the relevant issuers would submit data and descriptive information on the

[2] 45 CFR 147.140(a) defines grandfathered health coverage.

[3] See ''Essential Health Benefits Bulletin,'' Center for Consumer Information and Insurance Oversight. December 16, 2011. Available at: *http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.*

[4] See ''Frequently Asked Questions on Essential Health Benefits Bulletin,'' Center for Consumer Information and Insurance Oversight. February 17, 2012. Available at: *http://cciio.cms.gov/resources/files/Files2/02172012/ehb-faq-508.pdf.*

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 would be made available to the public under a notice and comment period separate from this notice of proposed rulemaking. Section 156.120(b)(2)(i) proposes that certain issuers submit information on covered health benefits in the applicable plans. This information is needed to define certain benchmark plan options.

Section 156.120(b)(2)(ii) proposes to collect from issuers data on any 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 propose to collect data on drug coverage. This would include a list of covered drugs and information on whether each drug is subject to prior authorization and/or step therapy.

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

We are soliciting comment on other data elements that may be necessary to ensure that health plans offer EHB.

3. Issuers Required to Report (§ 156.120(c))

Section 156.120(c) of this proposed regulation specifies that these reporting requirements would apply only to certain issuers. Specifically, we propose 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 propose 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 bulletin. State data may vary from *www.HealthCare.gov* data, and we request comment on whether States should be permitted to use an alternative data source for determining the enrollment in the small group market. We are also soliciting 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 December 16, 2011 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 noted below, we seek comment on the draft instructions for States to submit benefits for their selected benchmark plan.

4. Plans Impacted (§ 156.120(d))

In § 156.120(d), we propose 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 identify the plan following the definition of ''portal plan'' in § 159.110 of this chapter.

Issuers may use their own data to determine which plan within each product has the highest enrollment, although we expect for many products, the benefits will be the same across plans within the product. 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 seek comment on the necessity of plan-level specificity.

5. Reporting Requirements (§ 156.120(e))

Finally, § 156.120(e) proposes 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 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 for 2014. We welcome public comment on this approach. See below for more information on how to comment on the data collection, in addition to the draft approach to how and when plans should submit the data.

B. Voluntary Data Collection From Stand-Alone Dental Plans

Beginning in 2014, QHPs and other non-grandfathered health insurance plans in the individual and small group market will offer the EHB. Section 1302(b) of the Affordable Care Act outlines the ten statutory benefit categories, including pediatric oral care, which must be included by those 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 propose 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. Therefore, we are requesting that issuers that intend to offer stand-alone dental plans in any Exchange notify HHS of their intent to participate. We intend to provide further guidance that explains the format and date by which stand-alone dental issuers can begin to submit this information.

C. Accreditation of QHP Issuers (§ 156.275)

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).'' At this time, HHS has determined that recognizing entities through an interim phase one process is necessary to meet the timeline for Exchange QHP certification activities, which must commence in early 2013 and may include the accreditation requirement, depending on the uniform timeline established by an Exchange. 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 propose 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) through (4) of § 156.275 of this proposed rule. We propose for this recognition to be effective once these conditions are met, at which time HHS would provide notification in the **Federal Register**. This 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 § 156.275(c)(1)(ii) in future rulemaking. We intend for the future recognition process to include an application procedure, standards for recognition, a criteria-based review of applications, public participation, and public notice of the recognition for entities seeking to become a recognized accrediting entity. We solicit comments to inform this future rulemaking. We request comment

on whether or not there are other accrediting entities that meet or would meet the statutory requirements this year.

We propose recognition of NCQA and URAC as accrediting entities because our review indicates that these accrediting entities currently issue or plan to issue health plan accreditation that meets the conditions for recognition as detailed in paragraphs (c)(2) through (4) of this proposed rule. The majority of people currently enrolled in private health plans are in health plans accredited by these two entities.[5] We solicit comment on our proposal to recognize accrediting entities on this basis and whether or not there are other entities that accredit health plans that meet the requirements of section 1311(c)(1)(D)(i) of the Affordable Care Act.

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.

In § 156.275(c)(2)(ii) through (iv), we propose requirements to interpret and further implement the statutory accreditation requirements. We solicit comments on each of these three additional provisions.

We propose 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 propose 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 solicit 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.

We are aware that URAC does not currently include clinical quality measures or patient experience ratings on a CAHPS survey in its accreditation standards for health plans. Based on URAC's recent press release and whitepaper,[6] URAC plans to release the Health Plan Accreditation Program 7.0, which includes reporting on a CAHPS survey and a set of clinical performance measures, and would allow for the flexibility to add additional clinical measure requirements specified for Exchanges. Because our proposal is to recognize NCQA and URAC on the condition that accreditation be provided consistent with § 156.275(c)(2), recognition of URAC would depend on URAC's implementation of this plan and our review and approval of its new accreditation measures.

In § 156.275(c)(2)(iii), we propose 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), and Exchange PPO), based on data submitted by the issuer that is 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, but if the product type for that Exchange is accredited, each of the corresponding QHPs would be considered to be accredited. We solicit comments on the proposed level of accreditation. We also solicit comments on circumstances under which an exception should be made to the accreditation determination being made at the Exchange product type level.

As part of our proposal that recognized accrediting entities include network adequacy and access in the accreditation standards, we propose 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 solicit comments on this proposed requirement.

In § 156.275(c)(3), we propose that each recognized accrediting entity must use transparent and rigorous methodological and scoring criteria. This requirement is taken from section 1311(c)(1)(D)(i) of the Affordable Care Act.

In § 156.275(c)(4), we propose 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 (3). Documentation should include accreditation standards and requirements, processes, and measure specifications for performance measures. We propose that the initial submission of documentation be made at a time specified by HHS. We solicit comment on this timing requirement, specifically whether NCQA and URAC may only be recognized if this required 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

[5] See *http://www.ncqa.org/tabid/135/Default.aspx.* Accessed April 24, 2012.

[6] URAC Health Plan Accreditation for Health Insurance Exchanges: *A Symbol of Excellence, Quality, and Value* available at: *https://www.urac.org/Whitepaper/Value.pdf,* accessed March 2, 2012.

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 (3) would no longer be met. We are soliciting comments on these documentation requirements.

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 with this requirement, we propose 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 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,[7] and unique accreditation identifier(s) of the QHP issuer.
- 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, 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).

We solicit comment, including whether fewer or more categories of information should be required for HHS to continue recognition of these entities.

Our proposal would permit Exchanges to arrange additional data sharing agreements with the recognized accrediting entities if they choose to require additional information, such as information on the QHP issuer's policies and procedures. We are soliciting comments on these data sharing requirements. We solicit comment whether to incorporate a requirement that recognized accrediting entities must provide this additional information upon request from an Exchange.

[7] The QHP issuer will provide the accrediting entity with this identifier.

IV. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

B. Requirements in Regulation Text

1. ICRs Regarding Collection of Essential Health Benefits Data (§ 156.120)

Proposed § 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. This information would have to be submitted to HHS in a form and manner determined by HHS. The burden associated with meeting this requirement includes the time and effort needed by the issuer to compile the benefit coverage information and submit the information to HHS in a form and manner determined by HHS. Adding the limit data collection needed to establish EHB benchmarks to the benefit data already collected and updated on a regular basis would maximize issuers' ability to leverage current business systems and processes. We estimate that it would take 4 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. The data elements on which issuers would report are listed in the ICR released concurrently with this notice of proposed rulemaking. Issuers would provide HHS with the data collection requirements through an online tool that we would make available to them.

2. ICRs Regarding Data Collection From Recognized Accrediting Entities (§ 156.275)

Proposed § 156.275(c)(4) requires recognized accrediting entities to submit documentation to HHS as a condition of gaining and maintaining recognition. This documentation includes accreditation standards and requirements, processes, and measure specifications for performance measures. The burden associated with meeting this requirement is for an analyst level employee at the recognized accrediting entity to compile the documentation and electronically transmit it to HHS. It is assumed that these accreditation standards and requirements, processes, and measure specifications for performance measures would not be changed more than once per year. We estimate 2 burden hours in

1 year for each of the accrediting entities at a cost of $110 for a total of $220.[8]

Proposed § 156.275(c)(5) also requires recognized accrediting entities to share accreditation survey data with the Exchange once the release of these data have been authorized by the QHP issuer. To comply with this information collection, the recognized accrediting entities would need to collect the Health Insurance Oversight System (HIOS) issuer identification from each issuer offering an Exchange QHP and seeking accreditation from the recognized accrediting entity. We estimate that the burden associated with meeting this requirement would be in revising the contract language with the issuer and then inputting the HIOS issuer identification into the accrediting entities' database once the HIOS issuer ID has been provided by the issuer. To fulfill this requirement, we are estimating approximately 17 hours of work for an analyst at each accrediting entity with the vast majority of that time used to input the data. The cost burden associated with this requirement is estimated to be $940. Second, the accrediting entity would need to organize its accreditation data elements specified in proposed § 156.275(c)(5) to match the data template provided by each Exchange. We are assuming 51 State-based Exchanges and we are assuming that this will require five hours of labor per Exchange for a total of 255 burden hours for an operations analyst at each accrediting entity. The cost burden associated with this is $14,025. Third, each accrediting entity would need to supply the data elements to each Exchange once per month as these data are updated. We are estimating that this process would take one hour per Exchange each month for a total hour burden of 612 hours and a cost burden of $33,660 per year.

In total, the hour burden for each accrediting entity is 884 hours and the total cost burden per accrediting entity is $48,625. For both of the accrediting entities, the hour burden is 1772 and the cost burden is $97,470.

C. Additional Information Collection Requirements

This proposed rule imposes collection of information requirements as outlined in the regulation text and specified above. However, this proposed rule also makes reference to several associated information collection requirements that are not discussed in the regulations text contained in this document. The following is a discussion of these requirements.

1. State Selection of Benchmark Plan

We request that States indicate to HHS their benchmark plan selection and provide information on this plan in the format that issuers are required to use, which leverages the current data collection for the Health Insurance Web Portal, as described above at the same time CMS collects benefit information from the three largest small group market plan issuers in each State. However, if a State selects as its benchmark one of the three largest small group market benchmark options, for which HHS proposes to collect data to establish default benchmarks, the State may choose to rely on the issuer submission and provide HHS with only the name of the plan and other necessary identifying information. If the State relies solely on issuer data, HHS would review the data to ensure benefits in all ten categories, required by statute are offered. We further note that States may voluntarily provide information on State benefit mandates. We estimate that it would take each State that selects a benchmark five hours to make a benchmark determination, compile the data, and submit the information in the required format to HHS. If a State selects one of the top three small group market plans and chooses to identify its selection by name only, we believe the burden would be less than five hours. At this time we do not have any way to accurately estimate how many States would opt to select a benchmark. We will accept comments on this issue.

2. Data Collection from Stand-Alone Dental Plans

We request that issuers that intend to offer stand-alone dental plans in any State Exchange or in the Federally-facilitated Exchange voluntarily notify HHS of their intent to participate. This collection, which would also be a revision of the Health Insurance Web Portal PRA package (OCN: 0938–1086), includes data on whether the issuer intends to offer stand-alone coverage, the anticipated Exchange market in which coverage would be offered, and the State and service area in which the issuer intends to offer coverage in the Exchange.

The burden associated with this voluntary submission includes the time and effort needed by the issuer to report on whether it intends to offer stand-alone dental coverage. We estimate that it would take 0.5 hours for a health insurance issuer to submit this information. We estimate that approximately 20 issuers would respond to this data collection. Therefore, the total burden is estimated to be 10 hours. We anticipate that the reporting would require one employee at a cost of $77.00 an hour for a total cost of $38.50 a year per issuer. The total number of respondents is estimated to be approximately 20, for a total burden of $770.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS–9965–P]
Fax: (202) 395–6974; or
Email: OIRA_submission@omb.eop.gov

V. Regulatory Impact Analysis

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993) and Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 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 proposed 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 Information Collection 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. The PRA package that accompanies this proposed rule requests that issuers that

[8] Wage data in this section are taken from the Bureau of Labor Statistics available at *http://www.bls.gov/oes/current/oes_dc.htm.*

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 proposing to recognize as accrediting entities already meet most of the conditions for recognition, 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 proposed 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 proposes collecting data from issuers that offer the three largest small group products in each state and from NCQA and URAC, which are the Phase I recognized accrediting entities. For the purposes of the regulatory flexibility analysis, we expect the following types of entities to be affected by this proposed 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.[9] 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 proposed rule also requires two accrediting entities, NCQA and URAC, to submit documentation to HHS. The RFA, as noted previously, considers a non-profit entity that is not 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.[10] 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.[11] 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.[12]

Based on the foregoing, we are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed 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 proposed rule (and subsequent 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 conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

This proposed 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 would 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 proposes to have two

[9] 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*).

[10] See ''About NCQA,'' NCQA Web site. Available at *http://www.ncqa.org/tabid/675Default.aspx.*

[11] See ''Frequently Asked Questions'' URAC Web site. Available at: *https://www.urac.org/about/faqs.aspx#General.*

[12] 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*).

accrediting entities 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 proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed regulation, as it relates to the recognition of accrediting entities, does not impose any costs on State or local governments. However, this proposed 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 proposed 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 proposed 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 proposes to amend 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 continues 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. Amend part 156 by adding subpart B, consisting of § 156.120, 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, that 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 has the meaning given to the term in § 146.136 of this chapter.

(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 impacted.* 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.

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

§ 156.275 Accreditation of QHP issuers.

* * * * *

(c)(1) *Recognition of accrediting entity by HHS.* (i) Effective upon completion of conditions listed in paragraphs (c)(2) through (4) of this section, at which time HHS will notify the public in the **Federal Register** that 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. Such recognition is effective until rescinded or recognition is required to be made by the process identified in paragraph (c)(1)(ii) of this section.

(ii) [Reserved]

(2)(i) *Scope of accreditation.* Subject to paragraphs (c)(2)(ii) through (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.

(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).

(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 (3) of this section to HHS at a time period specified by HHS.

(ii) Recognized accrediting entities must provide any proposed changes or updates to the accreditation standards and requirements, processes, and measure specifications for performance measures with 60 days notice prior to implementation.

(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 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: May 23, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May 23, 2012.

Kathleen Sebelius,

Secretary.

[FR Doc. 2012–13489 Filed 6–1–12; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2010–0049; 4500030113]

RIN 1018–AX89

Endangered and Threatened Wildlife and Plants; 12-Month Petition Finding and Proposed Listing of *Arctostaphylos franciscana* as Endangered

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the public comment period on our September 8, 2011, combined 12-month petition finding and proposed rule to list *Arctostaphylos franciscana* (Franciscan manzanita) as endangered and designate critical habitat under the Endangered species Act of 1973, as amended (Act). In the proposed rule, we found that critical habitat was not determinable at the time because we did not have sufficient information on what physical and biological features would be essential to the conservation of the species, or what other areas outside the known occupied site may be essential for the conservation of the species. The Service seeks data and comments from the public on this proposed listing rule and whether the designation of critical habitat for the species is prudent and determinable. We are reopening the comment period to allow all interested parties an additional opportunity to comment on the proposed rule and to submit information on the status of the species. Comments previously submitted need not be resubmitted, as they will be fully considered in preparation of the final rule.

DATES: We will accept comments received or postmarked on or before June 20, 2012. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section, below) must be received by 11:59 p.m. Eastern Time on the closing date.

ADDRESSES: *Document availability:* You may obtain copies of the proposed rule on the Internet at *http://www.regulations.gov* at Docket Number FWS–R8–ES–2010–0049, or by mail from the Sacramento Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Comment submission: You may submit written comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R8–ES–2010–0049, which is the docket number for this rulemaking. Then, on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document and submit a comment.

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R8–ES–2010–0049; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We request that you send comments only by the methods described above. We will post all information received on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

FOR FURTHER INFORMATION CONTACT: Karen Leyse, Listing Coordinator, Sacramento Fish and Wildlife Office, 2800 Cottage Way, Room W–2605, Sacramento, CA 95825; by telephone at 916–414–6600; or by facsimile at 916–414–6712. If you use a telecommunications device for the deaf (TDD), please call the Federal