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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3288–NC]

Patient Protection and Affordable Care Act; Exchanges and Qualified Health Plans, Quality Rating System (QRS), Framework Measures and Methodology

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

ACTION: Notice with comment.

SUMMARY: This notice with comment describes the overall Quality Rating System (QRS) framework for rating Qualified Health Plans (QHPs) offered through an Exchange. The purpose of this notice is to solicit comments on the list of proposed QRS quality measures that QHP issuers would be required to collect and report, the hierarchical structure of the measure sets and the elements of the QRS rating methodology. In addition, this notice solicits comments on ways to ensure the integrity of QRS ratings, and on priority areas for future QRS measure enhancement and development.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 21, 2014.

ADDRESSES: In commenting, refer to file code CMS–3288–NC. 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–3288–NC, P.O. Box 8016, Baltimore, MD 21244–8016.

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–3288–NC, 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 only to the following addresses:

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: Nidhi Singh Shah, (301) 492–5110, for general information. Elizabeth Flow-Delwiche, (410) 786–1718, for matters relating to the Quality Rating System.

SUPPLEMENTARY INFORMATION: *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. Background

A. Legislative Background

The Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–309) (collectively referred to as the Affordable Care Act) establish Affordable Insurance Exchange or Exchange (also known as a Health Insurance Marketplace or Marketplace) within each state. Qualified individuals and qualified employers in each state will be able to shop for affordable health insurance through Exchanges.

The Department of Health and Human Services (the Secretary) holds primary responsibility for establishing the standards and guidelines for the Exchanges. The Affordable Care Act provides States with the flexibility to establish and operate their own Exchange (State-based Exchange). However, if a state elects not to establish a State-based Exchange or if a state will not have an Exchange that is operational by January 1, 2014, pursuant to section 1321(c)(1) of the Affordable Care Act, the Secretary will establish and operate a Federally-facilitated Exchange in those states. The Affordable Care Act and applicable Exchange regulations establish that health plans offered through an Exchange must meet specific standards to be certified as QHPs and to offer coverage in an Exchange beginning in January 2014.

The Affordable Care Act also requires the Secretary to develop a number of reporting requirements to support the delivery of quality health care coverage offered in the Exchanges. Specifically, sections 1311(c)(3) and (c)(4) of the Affordable Care Act direct the Secretary to develop—(1) a system that rates qualified health plans (QHPs) based on the relative quality and price; and (2) an enrollee satisfaction survey system that assesses the level of enrollee experience (that is, consumer experience) with QHPs. Because we believe that QHP consumer experience is an important part of rating the overall quality of a QHP, we intend to use some of the information collected from the Enrollee

Satisfaction Survey in the Quality Rating System (QRS).

In addition to consumer experience, we believe that the QRS should provide ratings of QHPs based on health care quality, health outcomes, and cost of care. We intend for all QHP issuers to report data at the product level for the initial years of QRS implementation (for example, at the Health Maintenance Organization level or Preferred Provider Organization level). We expect QHPs to provide product-level quality performance data for the QRS in general topics, such as clinical effectiveness of care, patient safety, care coordination, prevention of disease and illness, access to care, member experience, plan services and efficiency, and cost reduction. The QRS ratings should demonstrate sound, reliable, and meaningful information on the performance of QHPs to ultimately support informed decisions by consumers.

We have already promulgated regulations at 45 CFR 155.200(d) that direct Exchanges to oversee implementation of the QRS, and 45 CFR 156.200(b)(5) [1] that directs QHP issuers to report health care quality information to an Exchange. In this notice, we describe the overall QRS framework and the factors that guided the development of the QRS. We solicit comments on the QRS measure sets for QHPs offered to adult individuals and families, (QRS) and for child-only QHPs (Child QRS), the hierarchical structure of the measure sets, and the elements of the rating methodology. We also solicit comments on ways to ensure the integrity of QRS ratings, and the identification of priority areas for future QRS measure enhancement and development.

In future rulemaking, we intend to propose requirements for QHPs and Exchanges regarding the collection and submission of specific quality-related information. In addition, we intend to provide future technical guidance for QHP issuers and Exchanges related to the QRS measure specifications, detailed rating methodology guidelines, and data reporting and procedures.

B. QRS Goals and Principles

We believe that the overarching goal of the QRS is based on two fundamental tenets: (1) Providing comparable and useful information regarding the quality of QHPs offered through the Exchanges to inform consumer and employer choice; and (2) facilitating regulatory oversight of QHPs with regard to the quality standards set forth in the Affordable Care Act. Consequently, we believe that the QRS should provide QHP ratings based on health care quality and outcomes, consumer experience, and cost. We developed the following five general QRS principles to guide the design of the QRS:

- The QRS should produce QHP quality performance information to encourage the delivery of higher-quality health care services, expand access to care, and improve health outcomes for QHP enrollees.
- The QRS should provide sound, reliable, and meaningful quality-related QHP information, which could be used by consumers when comparing health plans, by QHPs for quality improvement, as well as by Exchanges and CMS for QHP certification and regulatory oversight activities.
- The QRS should reflect the goals of the National Strategy for Quality Improvement in Health Care priorities,[2] which includes reporting cross-cutting performance areas (that is, patient safety, prevention, population health, patient engagement, patient experience, and efficient resource use). The QRS should also facilitate reporting on conditions or procedures of significant prevalence and importance (for example, heart disease or breast cancer screening).
- The QRS measures set should be evidence-based and align, to the maximum extent possible, with priority measures currently implemented in federal, state, and private sector programs to minimize QHP issuer burden. We have drawn on our experience administering the Medicare Advantage 5-star rating system in developing this framework, and intend that the development and evolution of the QRS should be public and transparent and should allow for flexibility to incorporate changes in measures and methodologies as medical treatments and technology evolve and the Exchanges mature.

C. QRS Framework

We have developed a framework for creating, implementing, maintaining and revising the QRS. The overall framework consists of the following components that are guided by the QRS goals and principles:

- Performance Information
- Rating Methodology

In total, there are ten associated elements that further clarify the Performance Information and Rating Methodology components (see Table 1 below).

[1] Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers, 77 FR 18310 (Mar. 27, 2012) (to be codified at 45 CFR parts 155, 156, & 157).

[2] See Report to Congress: National Strategy for Quality Improvement in Health Care available at *http://www.ahrq.gov/workingforquality/nqs/nqs2013annlrpt.htm.*

Table 1: QRS Framework

	QRS Component	Element
Goals and Principles	Performance Information	Measures Selection
		Hierarchical Structure
		Organization of Measures
		Data Strategy
	Rating Methodology	Aggregation Rules
		Sampling and Attribution
		Scoring
		Performance Classification Values
		Population and Other Adjustments
		Peer Groups

The goals and principles for the QRS serve as the common thread throughout the QRS framework. The Performance Information component consists of four elements: (1) Measures Selection; (2) Hierarchical Structure; (3) Organization of Measures; and (4) Data Strategy. The Measures Selection element represents the process for selecting and evaluating the measure sets of the QRS. The Hierarchical Structure element establishes how the QRS measure sets are organized for scoring, rating, and reporting purposes. The Organization of Measures element establishes the approach to create composites, domains, and summary indicators ratings. The Data Strategy element, which is discussed in section IV, refers to the procedures for how the measures data will be collected, calculated, submitted and will help to inform how data will be displayed.

The Rating Methodology component aims to define how QHPs will be scored and compared, and as proposed, consists of six elements:

- *Aggregation Rules* would be used to determine how measures should be combined to create useful quality information on health care areas such as diabetes care or preventive health care.
- *Sampling and Attribution* would establish the selection criteria for determining appropriate population samples that yield reliable and valid information.
- *Scoring* would be the process used to convert the raw QRS measures data to points or percentiles on a common numeric scale.
- *Performance Classification* would be used to assign values to the QHP scores; these values would then be used to categorize the QHP's performance.
- *Population and other adjustments* would refer to changes made to raw data or measures to remove potential bias introduced by factors that are not modifiable by the QHP.
- *Peer Groups* would be used to establish a benchmark dataset for comparison of the individual QHP in the performance classification work, most often based on the geographic and time period considerations (for example, current annual distribution of all plans nationally).

II. Performance Information Component

A. Measures Selection

The process used to select the QRS measure sets included a review of existing health plan measures, so that the QRS measures promote consistency and harmonization across State, Federal government entities (for example, CMS) and private-sector efforts. Our review included national measure sets that were relevant to the intended purpose of the QRS and incorporate health plan measures such as the Initial Adult Medicaid Core Set of Health Care Quality Measures, Initial Core Set of Children's Health Care Quality Measures, Clinical Quality Measures for Eligible Professionals, and Medicare Part C and Part D Reporting Requirements, as well as a variety of other quality measurement programs, including health plan accreditation programs.[3] We believe it's important that measures, in the initial years, be specified for health plans (rather than specified for health care providers) to ensure reliable data, reduce QHP burden and facilitate consumer use and comprehension.

Measures selection and measure set evaluation criteria were developed using the National Quality Forum (NQF) Measure Evaluation Criteria and the Measures Application Partnership (MAP) Measure-Selection Criteria.[4] [5]

[3] In addition to the programs and measure sets mentioned above, CMS included the following program measure sets in the environmental scan: eValue8, Consumer Reports Health Plan Rankings, Office of Personnel Management Federal Employee Health Benefit Program; Health Plan Accreditation programs: URAC, National Committee for Quality Assurance, Accreditation Association for Ambulatory Health Care; State Health Monitoring Programs: Maryland HealthChoice Consumer Report Card, California Healthcare Quality Report Card, NY Electronic Quality Assurance Reporting Requirements, Maryland Health Plan Report Card, California Medi-CAL Health Plan Quality Ratings; State Based Exchanges: Oregon Health Insurance Exchange, New York State Health Benefit Exchange California Health benefits Exchange

[4] National Quality Forum. ''Measure Evaluation Criteria, November 2012.'' accessed January 23,

The measure selection criteria, which represent industry-tested criteria and were supported as measure inclusion criteria based on discussions with stakeholders and public comment received in response to a Request for Information (RFI),[6] focuses on the following areas:

- *Importance:* the extent to which the measure is important to making significant gains in health care quality, improving health outcomes, has a high impact (high priority) and is relevant to the Exchange population and benefits covered by QHPs.
- *Performance Gap:* the extent to which the measure demonstrates opportunities for performance improvement based on variation in current health plan performance.
- *Reliability and Validity:* the extent to which the measure produces consistent (reliable) and credible (valid) results.
- *Feasibility:* the extent to which the data related to the measure are readily available or could be captured without undue burden and can be implemented by QHPs.
- *Alignment:* the extent to which the measure is included in one or more existing federal, state or private sector health plan quality reporting programs.

The QRS measure set evaluation criteria were applied to identify measurement gaps in the QRS measure sets and helped to ensure that the proposed QRS measure sets as a whole would best meet the needs of consumers and the Exchanges.

The draft QRS measure sets were evaluated to determine the extent to which the measures were NQF-endorsed and aligned with the NQS priorities. Relevance to the Exchange consumer was evaluated by assessing whether the measure set addressed clinical conditions of moderate or high prevalence or high disease burden (applicable only to the clinical care measures) and whether the measure sets identified the needs of the consumer related to health-plan operations and satisfaction. Relevance of the QRS measure sets to QHPs was evaluated by assessing how well each of the sets addressed the benefit categories required of QHPs as part of the Affordable Care Act essential health benefits requirement;[7] and if the sets complemented other information used by the Exchange to support consumer comparison of health plans or to assist with QHP certification and plan monitoring. The comprehensiveness of the draft QRS measure sets were assessed by examining the measures and ensuring that, to the extent possible based on the availability of health-plan specified measures, the sets included an appropriate mix of clinical care measure types, such as structure, process and outcome measures; experience of care measures; and measures that assess cost/resource use/appropriateness of care and plan management. The draft QRS measure sets were evaluated for the degree to which they promoted equitable access and treatment by considering healthcare disparities, and ways in which the measure sets can capture data to promote strategies that address variations in care. In addition, the draft QRS measure sets were evaluated based on the percentage of measures that demonstrated parsimony, an efficient use of resources, including—(1) the ready availability of automated data (available through existing claims, administrative, survey, and health plan management databases); or (2) whether the measures are publicly reported or currently in use as contractual performance standards between plans and public/private purchasers or between plans and provider organizations or as in accordance with statutory or regulatory requirements.

The draft measure sets were revised and the proposed QRS measure sets were created following this evaluation. The proposed QRS measure sets were also evaluated and reviewed internally by CMS, externally by industry and stakeholders and in a field test using available health plan data. Listening sessions were also conducted for insurers, states and consumer groups.

Although the measures contained in the QRS are consistent with the state-of-science for measuring health care quality, science and technology do not yet allow us to measure or represent the quality of all care delivered through the QHPs. Therefore, the QRS measure set should not be viewed as representative of all care delivered by QHPs.

B. Individual Measures for QRS and Child-Only QRS

QHPs offered in the Exchange may provide family/adult self-only coverage or child-only coverage (child-only QHPs) and therefore, there are two proposed measure sets; the QRS measure set (for family and adult self-only coverage) and a Child-only QRS measure set. Both measure sets were selected based on the above described key criteria. We solicit comments on the proposed measures in the QRS and Child-only QRS listed below in Table 2. The proposed QRS measure set for family/adult self-only coverage consists of a total of 42 measures—29 clinical measures, which encompass health care topics of clinical effectiveness, prevention, access and efficiency; and 13 Consumer Assessment of Healthcare Providers and Systems® (CAHPS) survey measures, which encompass topics such as member experiences with the QHP, providers and health care services, including preventive care. The QRS measure set addresses the essential health benefits for which health plan measures are currently available. The majority (76 percent) of the measures are presently NQF-endorsed and address all six National Quality Strategy priorities. Approximately, 83 percent of the QRS measures are included in at least one of the reviewed Federally-established measure sets (for example, Office of Personnel Management Federal Employee Health Benefit (OPM FEHB), CMS Medicare Stars, CMS Adult Medicaid Core Set,[8] CMS Initial Children's Core Set,[9] Medicare Part C&D Plan Reporting). The remaining measures are used in other state based and private sector health plan reporting programs such as Consumer Reports Health Plan Rankings [10] or through accreditation. QHPs offering family or adult self-only coverage would be required to report on all 42 measures in the QRS measure set.

The Child-only QRS measure set consists of a total of 25 measures—15 clinical measures and 10 CAHPS measures. The Child-only measure set includes a combination of process and outcome measures. The Child-only QRS measure set addresses many of the essential health benefits. The majority of the measures (84 percent) are NQF-endorsed and largely address the six National Quality Strategy priorities. Approximately 80 percent of the measures are included in either the OPM FEHB Set or the CMS Initial Children's Core Set. As with the QRS measure set, the remaining measures in

2013, *http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx.*

[5] Measure Applications Partnership. ''MAP Working Measure Selection Criteria and Working Guide.'' National Quality Forum, December 2012.

[6] Request for Information Regarding Health Care Quality for Exchanges: *http://www.gpo.gov/fdsys/pkg/FR–2012–11–27/pdf/2012–28473.pdf.*

[7] Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; Final Rule 78 FR 12834 (Feb. 25, 2013) (to be codified at 45 CFR parts 147, 155 and 156).

[8] Initial Core Set of Health Care Quality Measures for Adults Enrolled in Medicaid (Medicaid Adult Core Set). February 2013.

[9] SHO: #13–002. Letter to State Health Official and State Medicaid Director. Re: 2013 Children's Core Set of Health Care Quality Measures. January 24, 2013.

[10] *http://www.consumerreports.org/health/insurance/health-insurance-plans.htm.*

the child-only set are used state based and private sector health plan reporting programs. Child-only QHPs would be required to report on all 25 measures in the Child-only QRS measure set.

TABLE 2—PROPOSED MEASURE SETS FOR THE QRS AND CHILD-ONLY QRS

Measure title	NQF ID [11]	QRS	Child-only QRS
Adolescent Well-Care Visits	Not currently endorsed	X	X
Adult BMI Assessment	Not currently endorsed	X	
Adults' Access to Preventive and Ambulatory Health Services	Not currently endorsed	X	
Annual Dental Visit	1388	X	X
Annual Monitoring for Patients on Persistent Medications	Not currently endorsed	X	
Antidepressant Medication Management	0105	X	
Appropriate Testing for Children With Pharyngitis	0002	X	X
Appropriate Treatment for Children With Upper Respiratory Infection.	0069		X
Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis	0058	X	
Breast Cancer Screening	Not currently endorsed	X	
CAHPS—Aspirin Use and Discussion	Not currently endorsed	X	
CAHPS—Coordination of Members' Health Care Services	Not currently endorsed [12]	X	X
CAHPS—Cultural Competency	Not currently endorsed [13]	X	X
CAHPS—Customer Service	0006	X	X
CAHPS—Flu Shots for Adults	0039	X	
CAHPS—Getting Care Quickly	0006	X	X
CAHPS—Getting Needed Care	0006	X	X
CAHPS—Global Rating of Health Plan	0006	X	X
CAHPS—Medical Assistance With Smoking and Tobacco Use Cessation.	0027	X	
CAHPS—Plan Information on Costs	0006	X	X
CAHPS—Rating of All Health Care	0006	X	X
CAHPS—Rating of Personal Doctor	0006	X	X
CAHPS—Rating of Specialist Seen Most Often	0006	X	X
Cervical Cancer Screening	0032	X	
Child and Adolescent Access to PCPs	Not currently endorsed		X
Childhood Immunization Status	0038	X	X
Chlamydia Screening in Women (Ages 16–20)	0033		X
Cholesterol Management for Patients With Cardiovascular Conditions: LDL–C Control (<100 mg/Dl).	Not currently endorsed	X	
Cholesterol Management for Patients With Cardiovascular Conditions: LDL–C Screening.	Not currently endorsed	X	
Colorectal Cancer Screening	0034	X	
Controlling High Blood Pressure	0018	X	
Diabetes Care: Eye Exam (Retinal) Performed	0055	X	
Diabetes Care: Hemoglobin A1c (HbA1c) Control <8.0%	0575	X	
Follow-Up After Hospitalization for Mental Illness: 7 days	0576 [14]	X	
Follow-Up Care for Children Prescribed ADHD Medication: Initiation Phase.	0108 [15]	X	X
Follow-Up Care for Children Prescribed ADHD Medication: Continuation and Maintenance Phase.	0108		X
HPV Vaccination for Female Adolescents	1959		X
Immunizations for Adolescents	1407	X	X
Medication Management for People With Asthma	1799	X	
Medication Management for People With Asthma (Ages 5–18)	1799		X
Plan All—Cause Readmissions	1768	X	
Prenatal and Postpartum Care: Postpartum Care	1517	X	
Prenatal and Postpartum Care: Timeliness of Prenatal Care	1517	X	
Relative Resource Use for People with Cardiovascular Conditions—Inpatient Facility Index.	1558	X	
Relative Resource Use for People with Diabetes—Inpatient Facility Index.	1557	X	
Use of Imaging Studies for Low Back Pain	0052	X	
Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents.	0024		X
Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents: BMI Percentile Documentation.	0024 [16]	X	
Well-Child Visits in the First 15 Months of Life	1392		X
Well-Child Visits in the Third, Fourth, Fifth, and Sixth Years of Life	1516	X	X

C. Organization and Hierarchical Structure of the QRS Measures

The Performance Information component of the QRS framework guided the proposed structure and hierarchy, as well as the measures that will be included within each level of the hierarchy. In order to be most useful to consumers, rating systems that can present a large collection of measures must be organized into a hierarchical structure. We considered organizing the measures in a manner to maximize the approachability and understandability of the information provided by the QRS. We are proposing hierarchical structures for the QRS and Child-only QRS that allow consumers to easily use information from the QRS in their health plan comparisons for selection of a QHP in the Exchange. We solicit comments on the proposed hierarchical structures outlined in Tables 3 and 4 below.

The fundamental building block of the QRS structure is the individual indicator or measure. The hierarchical structures include composites, which represent the combination of two or more individual indicators or measures that result in a single score. Measures are grouped into composites so large amounts of information can be streamlined and reported in formats that are easy for consumers to comprehend. Grouping measures into composites also helps to reduce random variability, differentiate performance across health plans and provide meaningful information to the consumer. Not all measures in the QRS are part of a composite. Table 3 provides the organization of the proposed QRS measure set for family/adult self-only coverage. The QRS organizes measures and composites into a set of eight domains that represent unique and important aspects of quality: (1) Clinical Effectiveness, (2) Patient Safety, (3) Care Coordination, (4) Prevention, (5) Access, (6) Doctor and Care, (7) Efficiency and Affordability (8) Plan Services. The domains are grouped into three summary indicators which align with CMS priority areas: (1) Clinical Quality Management; (2) Member Experience; and (3) Plan Efficiency, Affordability and Management. The summary indicators organize the domains into broad categories that the consumer may use when evaluating health plan options. All three summary indicators would then be grouped into a single Global Rating. The Global Rating is a score that summarizes all measures, composites and domains in the hierarchical structure of the QRS.

TABLE 3—PROPOSED QRS STRUCTURE

QRS summary indicator	QRS domain	QRS composite	Measure title
Clinical Quality Management	Care Coordination	No Composite	CAHPS—Coordination of Members' Health Care Services.
	Clinical Effectiveness	No Composite	Medication Management for People With Asthma.
		Behavioral Health	Antidepressant Medication Management.
			Follow-Up After Hospitalization for Mental Illness: 7 days.
			Follow-Up Care for Children Prescribed ADHD Medication: Initiation Phase.
		Cardiovascular Care	Cholesterol Management for Patients With Cardiovascular Conditions: LDL–C screening.
			Cholesterol Management for Patients With Cardiovascular Conditions: LDL–C control (<100 mg/Dl).
			Controlling High Blood Pressure.
		Diabetes Care	Diabetes Care: Eye Exam (Retinal) Performed.
			Diabetes Care: Hemoglobin A1c (HbA1c) Control <8.0%.
	Patient Safety	No Composite	Annual Monitoring for Patients on Persistent Medications.
			Plan All-Cause Readmissions.
	Prevention	Checking for Cancer	Breast Cancer Screening.
			Cervical Cancer Screening.
			Colorectal Cancer Screening.
		Maternal Health	Prenatal and Postpartum Care: Postpartum Care.
			Prenatal and Postpartum Care: Timeliness of Prenatal Care.
		Staying Healthy Adult	Adult BMI Assessment.
			CAHPS—Aspirin Use and Discussion.
			CAHPS—Flu Shots for Adults.
			CAHPS—Medical Assistance With Smoking and Tobacco Use Cessation.
		Staying Healthy Child	Annual Dental Visit.
			Childhood Immunization Status.
			Immunizations for Adolescents.
			Weight Assessment and Counseling for Children and Adolescents: BMI Percentile Documentation.
Member Experience	Access	Access Preventive Visits	Adolescent Well-Care Visits.
			Adults' Access to Preventive and Ambulatory Health Services.

[11] Definitions of NQF endorsed measures can be found here: *http://www.qualityforum.org/Home.aspx.*

[12] Only one question within the CAHPS Coordination of Members' Health Care Services composite is currently endorsed (#0007): ''Did your personal doctor seem informed and up-to-date about the medical care you got?''. The remaining questions in the composite are new and have not yet been endorsed.

[13] One of the questions within this CAHPS composite was modified from CAHPS Clinician and Group 2.0, Adult Supplemental (NQF #1904) and the other question is new.

[14] Measure includes only one indicator of the NQF-endorsed measure.

[15] Measure includes only one indicator of the NQF-endorsed measure for the child-only QRS.

[16] Measure includes only one indicator of the NQF-endorsed measure.

TABLE 3—PROPOSED QRS STRUCTURE—Continued

QRS summary indicator	QRS domain	QRS composite	Measure title
			Well-Child Visits in the Third, Fourth, Fifth, and Sixth Years of Life.
		Access to Care	CAHPS—Getting Care Quickly.
			CAHPS—Getting Needed Care.
	Doctor and Care	Doctor and Care	CAHPS—Cultural Competency.
			CAHPS—Rating of All Health Care.
			CAHPS—Rating of Personal Doctor.
			CAHPS—Rating of Specialist Seen Most Often.
Plan Efficiency, Affordability and Management.	Efficiency and Affordability	Efficient Care	Appropriate Testing for Children With Pharyngitis.
			Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis.
			Relative Resource Use for People with Cardiovascular Conditions—Inpatient Facility Index.
			Relative Resource Use for People with Diabetes—Inpatient Facility Index.
			Use of Imaging Studies for Low Back Pain.
	Plan Service	Member Experience with Health Plan.	CAHPS—Customer Service.
			CAHPS—Global Rating of Health Plan.
			CAHPS—Plan Information on Costs.

The hierarchical structure for the proposed Child-only QRS is similar to the proposed QRS. The 25 measures of the Child-only QRS provide the basic foundation of the structure. Not all measures in the Child-only QRS are part of a composite. Table 4 below provides the organization of the proposed Child-only QRS measure set. The Child-only QRS organizes measures and composites into a set of seven domains: (1) Care Coordination, (2) Clinical Effectiveness, (3) Prevention, (4) Access, (5) Doctor and Care, (6) Efficiency and Affordability (7), and Plan Service. The domains are grouped into the same three summary indicators as the QRS: (1) Clinical Quality Management; (2) Member Experience; and (3) Plan Efficiency, Affordability and Management. All three summary indicators would then be grouped into a single Global Child-only Rating.

TABLE 4—PROPOSED CHILD-ONLY QRS STRUCTURE

Child-only summary indicator	Child-only domain	Child-only composite	Measure title
Clinical Quality Management	Care Coordination	No Composite	CAHPS—Coordination of Members' Health Care Services.
	Clinical Effectiveness	No Composite	Medication Management for People With Asthma (Ages 5–18).
		Behavioral Health Child	Follow-Up Care for Children Prescribed ADHD Medication: Initiation Phase
			Follow-Up Care for Children Prescribed ADHD Medication: Continuation and Maintenance (C and M) Phase.
	Prevention	Staying Healthy Child	Annual Dental Visit.
			Childhood Immunization Status.
			Chlamydia Screening in Women (Ages 16–20).
			Immunizations for Adolescents.
			Weight Assessment and Counseling for Children and Adolescents.
			HPV Vaccination for Female Adolescents.
Member Experience	Access	Access Preventive Visits Child.	Adolescent Well-Care Visits.
			Child and Adolescent Access to PCPs.
			Well-Child Visits in the First 15 Months of Life.
			Well-Child Visits in the Third, Fourth, Fifth, and Sixth Years of Life.
		Access to Care	CAHPS—Getting Care Quickly.
			CAHPS—Getting Needed Care.
	Doctor and Care	Doctor and Care	CAHPS—Rating of All Health Care.
			CAHPS—Rating of Personal Doctor.
			CAHPS—Rating of Specialist Seen Most Often.
			CAHPS—Cultural Competency.
Plan Efficiency, Affordability and Management.	Efficiency and Affordability	Efficient Care Child	Appropriate Testing for Children With Pharyngitis.
			Appropriate Treatment for Children With Upper Respiratory Infection.
	Plan Service	Member Experience with Health Plan.	CAHPS—Customer Service.
			CAHPS—Global Rating of Health Plan.

TABLE 4—PROPOSED CHILD-ONLY QRS STRUCTURE—Continued

Child-only summary indicator	Child-only domain	Child-only composite	Measure title
			CAHPS—Plan Information on Costs.

III. QRS Rating Methodology Component

Once the QRS measures are organized and the hierarchical structure is established, the QRS rating methodology would combine health plan measure scores into performance ratings using a set of rules and formulae. We solicit comments on the proposed six elements of the Rating Methodology component that will guide the calculation of the ratings (refer to Section I for the definitions of the elements of the Rating Methodology component). The six elements of the proposed Rating Methodology are grouped within three broad categories (Measure Scoring Rules, Aggregation Rules, and Reference Standards). See Table 5.

TABLE 5—RATING METHODOLOGY CATEGORIES OF ELEMENTS

Category	Rating category elements
Measure scoring rules	Sampling and Attribution. Scoring.
Aggregation Rules	Aggregation Rules.
Reference Standards	Performance Classification values. Population and Other Adjustments. Peer Groups.

Measure Scoring Rules will standardize the individual measure scores so that scores are on the same scale (for example, all percentiles) and can be combined meaningfully. Aggregation Rules will be used to combine measures to create quality constructs, such as diabetes care or preventive health. Reference Standards will determine how scores are converted to categorical ratings (for example, star groups on a scale of one to five) that can be easily understood, compared, and used by consumers. We intend to publish, for review and comment, technical guidance that identifies further details regarding the Rating Methodology component, elements and measure specifications.

IV. QRS Data Strategy

The QRS data strategy refers to how QRS data are collected, calculated, and submitted and will help to inform how data is displayed. We intend to develop a data strategy that would facilitate consistent data collection and calculation across QHPs; and help to ensure the integrity and accuracy of QRS ratings. We solicit comments on potential ways to enhance the QRS data strategy for QHP issuers. We intend to direct QHP issuers to submit validated data to ensure that QRS data displayed for public reporting are accurate, valid and comparable, and to allow consumers objective and meaningful comparisons of the QHPs' quality data. We believe that the ratings assigned must reflect true differences in quality. We intend to display Global Ratings using a five-star scale. While it is our intention for all QHPs in Exchanges to have publicly available ratings, some QHPs may have missing data due to data quality issues or low enrollment in the initial years.

We plan to use a full-scale rule at the global and summary indicator levels, so that these scores are true representations of what they are intended to represent. This method allows the consumer to compare Global Ratings with the important concepts at highest levels of the hierarchy represented (refer to Table 3 for proposed QRS structure). Therefore, we are considering that, for QHPs that are missing any of the domain ratings used for creating the Member Experience or Plan Efficiency, Cost Reduction and Management summary indicators would not have an associated summary indicator rating publically displayed. For the Clinical Quality Management indicator, QHPs must have the Care Coordination, Clinical Effectiveness, and Prevention domains present to have the summary indicator rating publically displayed. We have conducted preliminary testing that demonstrates that a Clinical Quality summary indicator can be reported as long as Care Coordination, Clinical Effectiveness, and Prevention domains are present even if the Patient Safety domain is not reportable because this domain did not impact QHP comparability. We believe that Patient Safety is important to measure and it is a CMS priority. We plan to further develop this domain of the QRS as more health-plan patient safety measures become available. We are also proposing that a Global Rating will be displayed only when all three summary indicator ratings are available. For the lower levels of the hierarchy, the half-scale rule would be applied, meaning that at a minimum, half of the components of the domain or composite must be present for the rating to be displayed. Thus, if a domain is composed of three composites, two would have to be present for it to be displayed or if a composite is composed of two measures at least one would have to be present for it to be displayed. Specifically, we solicit comment to inform future technical guidance regarding the full-scale and half-scale rules described as well as any additional ways to address data quality issues or potential low enrollment in QHPs in the initial years.

V. Future Considerations

We solicit comments to inform future technical guidance on priority areas for additional measure enhancements and development of the QRS. We intend to continually monitor the QRS and make necessary adjustments to ensure that the methodology and measures remain consistent with the intended goals and principles of the QRS. As advancements in health plan quality measurement and reporting are made, we will consider ways in which the QRS may evolve (such as the potential selection of measures that are reportable through disease registries or all-payer claims databases). In addition, we will consider potential factors for the retirement of measures.

As the Exchanges mature and enrollment in QHPs expands, we will consider reporting the QRS at more granular levels (that is, QHP metal levels as defined in section 1302(d)(1) of the Affordable Care Act). We will also consider the development of a quality rating system applicable to other Exchange offerings, such as stand-alone dental plans, catastrophic plans and health care saving accounts.

VI. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. However, it does make reference to an information collection activity. The aforementioned Enrollee Satisfaction Survey is currently seeking OMB approval via notice and comment periods separate from this proposed notice. The 60-day **Federal Register** notice published on June 28, 2013. Additionally, in future rulemaking, we will identify information collection requirements associated with the QRS and solicit public comment at that time.

Dated: November 6, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–27649 Filed 11–14–13; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request: NIH NCI Central Institutional Review Board (CIRB) Initiative (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 22, 2013, Vol. 78, P. 52204 and allowed 60-days for public comment. There were no public comments received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: CAPT Michael Montello, Pharm. D., MBA, Cancer Therapy Evaluation Program, Operations and Informatics Branch, 9609 Medical Center Drive, Rockville, MD 20850 or call non-toll-free number 240–276–6080 or Email your request, including your address to: *mike.montello@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: NIH NCI Central Institutional Review Board (CIRB) Initiative (NCI), 0925–0625, Expiration Date 1/31/2014, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute (NCI) Central Institutional Review Board (CIRB) provides a centralized approach to human subject protection and provides a cost efficient approach avoiding duplication of effort at each institution. The CIRB provides the services of a fully constituted IRB and provides a comprehensive and efficient mechanism to meet regulatory requirements pertaining to human subject protections including: initial reviews, continuing reviews, review of amendments, and adverse events. The Initiative consists of three central IRBs: Adult CIRB—late phase emphasis, Adult CIRB—early phase emphasis, and Pediatric CIRB. CIRB membership includes oncology physicians, surgeons, nurses, patient advocates, ethicists, statisticians, pharmacists, attorneys and other health professionals. The benefits of the CIRB Initiative reaches research participants, investigators and research staff, Institutional Review Boards (IRB), and Institutions. Benefits include: study participants having dedicated review of NCI-sponsored trials for participant protections, access to more trials more quickly and access to trials for rare diseases, accrual to trials begin more rapidly, ease of opening trials, elimination of need to submit study materials to local IRBs, and elimination of the need for a full board review. The benefits to the National Clinical Trials Network and Experimental Therapy-Clinical Trials Network include a cost efficient approach that avoids duplication of efforts at each institution. A variety of information collection tools are needed to support NCI's CIRB activities which include: worksheets, forms and a survey that is provided to all customers contacting the CIRB helpdesk.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,199.

ESTIMATES OF ANNUAL BURDEN HOURS

Form name	Type of respondents	Number of respondents	Frequency of responses per respondent	Average burden per response (in hours)	Total annual burden hours
CIRB Customer Satisfaction Survey	Participants/Board Members.	1,500	1	10/60	250
Request for 30 Day Website Access Form	Participants	25	1	10/60	4
Authorization Agreement and Division of Responsibilities between the NCI CIRB and Signatory Institution.	Participants	340	1	30/60	170
NCI CIRB Signatory Enrollment Form	Participants	40	1	4	160
IRB Staff at Signatory Institution's IRB	Participants	25	1	10/60	4
Investigator at Signatory Institution	Participants	65	1	10/60	11
Research Staff at Signatory Institution	Participants	65	1	10/60	11