DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3276–NC]

Medicare Program; Request for Information on the Use of Clinical Quality Measures (CQMs) Reported Under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program, and Other Reporting Programs

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

ACTION: Request for information.

SUMMARY: This request for information solicits ways in which an eligible professional (EP) might use the clinical quality measures (CQM) data reported to specialty boards, specialty societies, regional health care quality organizations or other non-federal reporting programs to also report under the Physician Quality Reporting System (PQRS), as well as the Electronic Health Record (EHR) Incentive Program. It also solicits ways by which the entities already collecting CQM data for other reporting programs to submit this data on behalf of EPs and group practices for reporting under the PQRS and the EHR Incentive Program. It also requests information regarding section 601(b) of the American Taxpayer Relief Act of 2012 which provides for treating an EP as satisfactorily reporting data on quality measures if the EP is satisfactorily participating in a qualified clinical data registry. We are requesting information from medical specialty societies, boards, and registries, other third party registry vendors, eligible professionals using registries to report quality measures, and any other party interested in providing information on this request for information.

DATES: The information solicited in this notice must be received at the address provided below, no later than 5 p.m. eastern standard time (e.s.t) April 8, 2013.

ADDRESSES: In commenting, refer to file code CMS–3276–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–3276–NC, P.O. Box 8013, Baltimore, MD 21244–8013.

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–3276–NC, Mail Stop S3–02–01, 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:

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: Christine Estella, 410–786–0485.

SUPPLEMENTARY INFORMATION:

I. Background

A. Maintenance of Certification

Twenty-four member boards of the American Board of Medical Specialties (ABMS) currently recertify physician specialists through the ABMS Maintenance of Certification (MOC) process.[1] The MOC assesses physicians' commitment to lifelong learning according to the following six core competencies for quality patient care: (1) Patient care; (2) medical knowledge; (3) practice-based learning and improvement; (4) interpersonal and communications skills; (5) professionalism; and (6) systems-based practice. Generally speaking, the MOC incorporates these six core competencies through a four-part process:

- Part I: Licensure and Professional Standing
- Part II: Lifelong Learning and Self-Assessment
- Part III: Cognitive Expertise
- Part IV: Practice Performance Assessment [2]

Within this four-part process, particularly in Part IV, certain member boards require the reporting of quality measures data using a registry or other method associated with a member board. More information on the ABMS MOC can be found at *http://www.abms.org/Maintenance_of_Certification/ABMS_MOC.aspx.*

A. The Physician Quality Reporting System

The Physician Quality Reporting System (PQRS), as set forth in subsections (a), (k) and (m) of section 1848 of the Social Security Act (the Act) and as amended by section 601(b) of the American Taxpayer Relief Act of 2012, is a quality pay-for-reporting program that provides incentive payments through 2014, and beginning in 2015, payment adjustments to eligible professionals (EPs) based on whether or not they satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period. The PQRS (formerly the Physician Quality Reporting Initiative or PQRI) was first implemented in 2007 pursuant to the Tax Relief and Health Care Act (TRHCA) of 2006. Although the PQRS is a quality pay-for-reporting program, the PQRS is currently used as the basis for other CMS programs that measure performance. For example, the application of the Value-Based Payment Modifier in 2015 will be dependent on the group practice's participation in the PQRS in 2013. (For additional information, see the Calendar Year (CY) 2013 Medicare Physician Fee Schedule (PFS) final rule with comment period (77 FR 69306).).

[1] *http://www.abms.org/Maintenance_of_Certification/ABMS_MOC.aspx.*

[2] *http://www.abms.org/Maintenance_of_Certification/ABMS_MOC.aspx.*

The claims-based reporting mechanism was the only reporting mechanism available for reporting PQRS individual quality measures data under the 2007 PQRS. However, the PQRS has evolved to offer multiple reporting mechanisms, reporting periods, and criteria for satisfactory reporting for purposes of reporting PQRS quality measures data.

In 2008, the PQRS introduced use of the registry-based reporting mechanism. The registry-based reporting mechanism has proven to be popular among eligible professionals, and the number of eligible professionals that participate in PQRS via registry reporting continues to increase. According to the 2010 PQRS and e-Prescribing (eRx) Experience Report, in 2008, 31 of 32 qualified registries submitted data on behalf of nearly 12,000 eligible professionals. The number of eligible professionals for which data was submitted by a registry increased to 33,411 in 2009 (from 69 of 74 qualified registries) and to 56,214 in 2010 (from 89 of the 96 qualified registries). Historically, eligible professionals using the registry-based reporting mechanism have been more successful at meeting the criteria for satisfactory reporting of the PQRS data than through the claims-based reporting mechanism.

1. Qualification Requirement for Registries Submitting PQRS Quality Measures Data on Behalf of Eligible Professionals and Group Practices

The PQRS requires every registry that wishes to submit data on PQRS quality measures on behalf of its eligible professionals to become ''qualified'' under the PQRS. The final qualification process for registries that wish to become qualified to submit PQRS quality measures data for 2013 and subsequent years can be found in the CY 2013 Medicare PFS final rule with comment period (77 FR 69178). Generally, the registry qualification process for 2013 and subsequent years requires a registry to possess certain characteristics and submit a self-nomination statement that indicates that the registry has these characteristics and of the registry's intent to submit PQRS CQMs data on behalf of its eligible professionals for the respective year.

2. Registries Classified as EHR Data Submission Vendors

In lieu of serving as a registry under the PQRS, registries that have access to an EHR system may instead serve as an EHR data submission vendor. Beginning in 2014, a registry acting as an EHR data submission vendor must have its EHR system certified under the program established by the Office of the National Coordinator for Health Information Technology (ONC) as certified EHR technology (CEHRT). (For more information see the CY 2013 Medicare PFS final rule with comment period (77 FR 69185).)

3. PQRS Reporting Options Using the Registry-Based Reporting Mechanism

Since the inception of the registry-based reporting mechanism in 2008, we have developed multiple criteria for satisfactory reporting for individual eligible professionals, and, beginning in 2013, group practices participating in the group practice reporting option (GPRO), using the registry-based reporting mechanism to report PQRS quality measures data. For example, we previously have adopted criteria for satisfactory reporting using qualified registries in which eligible professionals or group practices must report data on a minimum of three measures or, for individual eligible professionals only, one measures group, a certain percentage or number of cases. Eligible professionals or group practices using registries that serve as EHR data submission vendors may, for 2013, either report a minimum of 3 measures for at least 80 percent of cases, or use the reporting criterion that aligns with the EHR Incentive Program. To meet the criteria for satisfactory reporting using an EHR data submission vendor for the 2014 PQRS incentive, eligible professionals or group practices must use the criteria that align with the EHR Incentive Program. (For more detailed information see the CY 2013 Medicare PFS final rule with comment period (77 FR 69188).

4. Participation in a Qualified Clinical Data Registry

Section 601(b) of the recently enacted American Taxpayer Relief Act of 2012 amended section 1848(m)(3) of the Act to allow eligible professionals to be treated as satisfactorily submitting data on quality measures for covered professional services if the eligible professional satisfactorily participates in a qualified clinical data registry. For 2014 and subsequent years, the Secretary is required to treat an eligible professional as satisfactorily submitting data on quality measures under the PQRS program if, in lieu of reporting PQRS quality measures the eligible professional is satisfactorily participating, as determined by the Secretary, in a qualified clinical data registry for the year.

The Secretary is required to establish requirements for an entity to be considered a qualified clinical data registry, including a requirement that the entity provide information, at such time and in such manner, as the Secretary determines necessary. In establishing these requirements, the Secretary must consider whether an entity: Has mechanisms for transparency of data, risk models, and measures; requires submission of data with respect to multiple payers; provides timely performance reports to participants at the individual level; and supports quality improvement initiatives. The pre-rulemaking process established in sections 1890 and 1890A of the Social Security Act does not apply to measures used by a qualified registry and registries may use NQF-endorsed measures. The Secretary is required to establish a process to determine whether an entity meets the requirements to be a qualified clinical data registry. The process can involve a determination by the Secretary or the Secretary can designate one or more independent organizations to make such determination, or both approaches can be used.

B. The EHR Incentive Program

The Health Information Technology for Economic and Clinical Health Act (the ''HITECH Act'') is included in the American Recovery and Reinvestment Act of 2009 (the ''Recovery Act''). The HITECH Act authorized incentive payments under Medicare and Medicaid for eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) that adopt, implement, upgrade, or demonstrate meaningful use of certified EHR technology (CEHRT), and beginning in 2015, payment adjustments under Medicare for failing to demonstrate meaningful use. Certified EHR technology may include EHR modules that calculate and report clinical quality measures data. These EHR modules can be part of the EP's CEHRT and used by registries and other data submission vendors to report clinical quality measures on behalf of EPs.

The EHR Incentive Program will be implemented in three stages. For CYs 2011, 2012, and 2013, EPs are required to select and report from a list of 44 CQMs subject to the reporting criteria established for those years. (For more information see the July 28, 2010 EHR Incentive Program final rule (75 FR 44409 through 44411) and the September 4, 2012 EHR Incentive Program Stage 2 final rule (77 FR 54057).) Beginning in 2014, EPs must select and report from a list of 64 CQMs that are contained in the 6 domains of quality of care established in the National Quality Strategy. The six

domains are: (1) Patient and Family Engagement; (2) Patient Safety; (3) Care Coordination; (4) Population and Community Health; (5) Efficient Use of Healthcare Resources; and (6) Clinical Processes/Effectiveness. In order to satisfy the CQM component of the EHR Incentive Program beginning in 2014, EPs must report nine CQMs covering at least three domains. (For more information see the September 4, 2012 EHR Incentive Program Stage 2 final rule (77 FR 54058).)

C. Maintenance of Certification

Twenty-four member boards of the American Board of Medical Specialties (ABMS) currently recertify physician specialists through the ABMS Maintenance of Certification (MOC) process.[3] The MOC assesses physicians' commitment to lifelong learning according to the following six core competencies for quality patient care: (1) patient care; (2) medical knowledge; (3) practice-based learning and improvement; (4) interpersonal and communications skills; (5) professionalism; and (6) systems-based practice. Generally speaking, the MOC incorporates these six core competencies through a four-part process:

- Part I: Licensure and Professional Standing
- Part II: Lifelong Learning and Self-Assessment
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- Part IV: Practice Performance Assessment [4]

Within this four-part process, particularly in Part IV, certain member boards require the reporting of quality measures data using a registry or other method associated with a member board. More information on the ABMS MOC can be found at *http://www.abms.org/Maintenance_of_Certification/ABMS_MOC.aspx*.

D. Other Quality Reporting Programs

Several quality reporting programs exist within private industry as well. For example the Society of Thoracic Surgeons (STS) established a national database in 1989 as an initiative for quality improvement and patient safety among cardiothoracic surgeons. [5] Similarly, the American College of Cardiology (ACC) has developed and partnered with other organizations to create numerous quality initiatives to assist cardiovascular professionals to bridge the gap between science and practice and to ensure patient access to high-quality, appropriate and cost-effective care.[6]

These programs are a small sampling of quality reporting programs occurring throughout the nation that provide distinct reporting criteria for program participation.

II. Request for Information

We are seeking input from the public on ways in which an eligible professional might use the CQM data reported to medical boards, specialty societies, regional health care quality organizations or other non-federal reporting programs to fulfill requirements of PQRS, and, although we are not seeking to change the requirements we established for the EHR Incentive Program in 2014, the EHR Incentive Program. We are seeking input on how alignment of certain requirements present in both federal and non-federal CQM reporting programs could reduce the burden for eligible professionals and accelerate quality improvement. We are also seeking input on the amendments made by section 601(b) of the American Taxpayer Relief Act of 2012. Therefore, we are soliciting comment on the following questions:

- High level questions:

++ How are the current reporting requirements for the PQRS and and the reporting requirements in 2014 for the EHR Incentive Program similar to the reporting requirements already established for the ABMS boards or to other non-federal quality reporting programs? How are they different? In what ways are these reporting requirements duplicative and can these reporting programs be integrated to reduce reporting burden on eligible professionals?

++ Are there examples of other non-federal programs under which eligible professionals report quality measures data?

++ What would be the benefits and shortcomings involved with allowing third-party entities to report quality data to CMS on behalf of physicians and other eligible professionals?

++ What entities have the capacity to report quality data similar to those reported under the PQRS, Value-based Payment Modifier, and/or EHR Incentive programs? If these entities were to report such data to CMS, what requirements should we include in the reporting system used by such entities, including requirements to ensure high quality data?

++ How should our quality reporting programs change/evolve to reduce reporting burden on eligible professionals, while still receiving robust data on clinical quality?

- Questions regarding reporting requirements for entities that report via a registry under the PQRS for 2014 and subsequent years or the EHR Incentive Program if registry reporting is established as a reporting method for that program in future years:

++ What types of entities should be eligible to submit quality measures data on behalf of eligible professionals for PQRS and the EHR Incentive Program? Examples might include medical board registries, specialty society registries, regional quality collaboratives or other entities. What qualification requirements should be applicable to such entities?

++ What functionalities should entities qualified to submit PQRS quality measures data possess? For example, for CQMs that can be electronically submitted and reported under PQRS and the EHR Incentive Program, should an entity's qualification to submit such measures be based on whether they have technology certified to ONC's certification criteria for CQM calculation and/or electronic submission?

++ What criteria should we require of entities submitting quality measures data to us on behalf of eligible professionals? Examples might include transparency of measures available to EPs, specific frequency of feedback reports, tools to guide improvement efforts for EPs, ability to report aggregate data, agreement to data audits if requested, etc.

++ Should reporting entities be required to publicly post performance data?

++ Should we require an entity to submit a yearly self-nomination statement to participate in PQRS?

++ What should be included in the data validation plan for these reporting entities?

++ If CMS provided a reporting option for PQRS and/or the EHR Incentive Program through such entities, what specification should CMS use to receive the quality data information (for example, Quality Reporting Document Architecture [QRDA] 1 or 3, XML, other)?

++ Should data submission timelines for these reporting entities be modified so that the submission timeframes for these quality reporting programs are aligned? For example, PQRS qualified

[3] *http://www.abms.org/Maintenance_of_Certification/ABMS_MOC.aspx.*

[4] *http://www.abms.org/Maintenance_of_Certification/ABMS_MOC.aspx.*

[5] *http://www.sts.org/national-database.*

[6] *http://www.cardiosource.org/Science-And-Quality/Quality-Programs.aspx.*

registries are required to submit quality measures data once, within 2 months following the reporting period. How much time are reporting entities outside of PQRS afforded to submit quality measures data? What challenges do reporting entities face in reporting data according to current timeframes?

++ What oversight (for example, checks or audits) should be in place to ensure that data is submitted and calculated properly by entities?

• Questions regarding selection of measures related to registry reporting under PQRS for 2014 and subsequent years and for the EHR Incentive Program if registry reporting is established as a reporting method for that program in future years:

++ Should we require that a certain proportion of submitted measures have particular characteristics such as being NQF-endorsed or outcome-based?

++ Should we require that the quality measures data submitted cover a certain number of the six national quality strategy domains?

++ To what extent would third-party entities struggle to meet reporting for measures currently available under PQRS and EHR Incentive Program?

• Questions regarding registry measures reporting criteria:

++ If we propose revised criteria for satisfactory reporting under PQRS and for meeting the CQM component of meaningful use under the EHR Incentive Program, how many measures should an eligible professional be required to report to collect meaningful quality data? For example, for reporting periods occurring in 2014, eligible professionals using CEHRT must report 9 measures covering at least 3 domains to meet the criteria for satisfactory reporting for the 2014 PQRS incentive and meet the CQM component of achieving meaningful use for the EHR Incentive Program. (For more information see the EHR Incentive Program Stage 2 final rule (77 FR 54058) and the CY 2013 Medicare PFS final rule with comment period (77 FR 69192).) If we were to align reporting criteria with reporting requirements for other non-federal reporting programs, in future years, should we propose to require reporting on a different number of measures than what is currently required for the PQRS in 2013 and the EHR Incentive Program under the Stage 2 final rule or should the non-federal reporting programs align with CMS criteria?

++ For PQRS, should eligible professionals still be required to report quality measures data on a certain percentage of their applicable patients, such as 80 percent, for 2014 and subsequent years? Or, should we require that eligible professionals report on a certain minimum number of patients, such as 20, rather than a percentage?

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 9, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–02703 Filed 2–4–13; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Request for Nominations for Voting Members on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee, certain device panels of the Medical Devices Advisory Committee, the National Mammography Quality Assurance Advisory Committee, and the Technical Electronic Products Radiation Safety Standards Committee in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and those that will or may occur through December 31, 2013.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees, and therefore encourages nominations of appropriately qualified candidates from these groups.

DATES: Because scheduled vacancies occur on various dates throughout each year, no cutoff date is established for the receipt of nominations. However, when possible, nominations should be received at least 6 months before the date of scheduled vacancies for each year, as indicated in this notice.

ADDRESSES: All nominations for membership should be sent electronically to *cv@oc.fda.gov*, or by mail to Advisory Committee Oversight & Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member on a FDA advisory committee can also be obtained by visiting FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: For specific Committee/Panel questions, contact the following persons listed in table 1 of this document.

TABLE 1

Contact person	Committee/certain device panels of the medical devices advisory committee
LCDR Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993, 301–796–7046, email: *Sara.Anderson@fda.hhs.gov*.	National Mammography Quality Assurance Advisory Committee. Dental Products Panel. Hematology and Pathology Devices Panel. Orthopaedic and Rehabilitation Devices Panel.
Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1613, Silver Spring, MD 20993, 301–796–6639, email: *Shanika.Craig@fda.hhs.gov*.	Technical Electronic Product Radiation Safety Standards Committee. Anesthesiology and Respiratory Therapy Devices Panel. Gastroenterology and Urology Devices Panel. Microbiology Devices Panel. Obstetrics and Gynecology Devices Panel. Radiological Devices Panel.
Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993, 301–796–5290, email: *Natasha.Facey@fda.hhs.gov*.	Device Good Manufacturing Practice Advisory Committee. General Hospital and Personal Use Devices Panel. Immunology Devices Panel. Ophthalmic Devices Panel. Neurological Devices Panel.