2015 PHYSICIAN QUALITY REPORTING SYSTEM (PQRS): QUALIFIED CLINICAL DATA REGISTRY (QCDR) CRITERIA

01/14/2015; Revised 6/17/2015, 09/25/2015

Physician Quality Reporting System

Physician Quality Reporting System (PQRS) is a quality reporting program that uses payment adjustments to promote the reporting of quality information by eligible professionals (EPs). A qualified clinical data registry (QCDR) is one of the reporting mechanisms available within PQRS. The collection and submission of PQRS quality measures data on behalf of EPs are the functions a traditional "qualified registry" currently performs under PQRS for purposes of EPs' satisfactorily reporting. CMS believes that a QCDR should serve additional roles that foster quality improvement in addition to the collection and submission of quality measures data. For 2015, a QCDR is defined for PQRS as a CMS-approved entity that has self-nominated and successfully completed a qualification process that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. Entities that may not meet the definition and requirements of a QCDR solely on its own, but in conjunction with another entity, may be able to meet the requirements of a QCDR and therefore be eligible for qualification. EPs who satisfactorily participate in PQRS through a QCDR may avoid the 2017 PQRS payment adjustment (-2.0%).

Additional information on the PQRS can be found on the Physician Quality Reporting System section of the CMS Web site.

Medicare Electronic Health Record Incentive Program

The Medicare Electronic Health Record (EHR) Incentive Program provided incentive payments to EPs, eligible hospitals, and critical access hospitals (CAHs) if they adopted, implemented, upgraded or demonstrated meaningful use of certified EHR technology (CEHRT). Payment reductions will begin in 2015 for those who are eligible but choose not to participate. Individual EPs are able to satisfactorily participate in a QCDR for purposes of meeting the electronic clinical quality measure (eCQM) reporting component of meaningful use for the Medicare EHR Incentive Program beginning in 2014.

Additional information regarding the Medicare EHR Incentive Program can be found on the EHR Incentive Program section of the CMS website.

Value-based Payment Modifier

The Value-based Payment Modifier (VM) provides for differential payment to a physician or group of physicians under the Medicare Physician Fee Schedule (MPFS) based upon the quality of care furnished compared to cost during a performance period. The 2017 VM will apply to solo practitioners and groups of physicians with two or more EPs.

Additional information regarding VM can be found on the Value-based Payment Modifier section of the CMS website.

QCDR Criteria

The requirements and associated timelines to become a QCDR for the 2015 program year are listed below. In order to become a QCDR, entities must complete all of the requirements prior to the due dates listed below. Entities that do not meet the definition and requirements of a QCDR solely on its own, but in conjunction with another entity, must also complete the requirements prior to the due dates below.

January 31, 2015

1. Self-Nomination for PQRS

   By **January 31, 2015**, prospective QCDRs must submit a self-nomination statement indicating intent to participate in PQRS as a QCDR. The self-nomination statement must contain the following information:

   - The name of the entity seeking to become a QCDR.

- The entity's contact information, including phone number, email, and mailing address.
- A point of contact, including the contact's email address and phone number, to notify the entity of the status of its request to be considered a QCDR.
- The entity must attest that they meet all of the following QCDR criteria:
  - Have been in existence as of **January 1, 2014**, to be eligible to participate for purposes of data collected in 2015.
  - An entity that uses an external organization for purposes of data collection, calculation or transmission may meet the definition of a QCDR so long as the entity has a signed, written agreement that specifically details the relationship and responsibilities of the entity with the external organizations effective as of January 1 the year prior to the year for which the entity seeks to become a QCDR (for example, January 1, 2014, to be eligible to participate for purposes of data collected in 2015).
  - Have at least 50 QCDR participants by **January 1, 2014**, to be eligible to participate under the program with regard to data collected in 2015. Please note that not all participants would be required to participate in PQRS.
  - Not be owned or managed by an individual, locally-owned, single-specialty group (for example, single-specialty practices with only 1 practice location or solo practitioner practices would be precluded from becoming a QCDR).
  - Enter into and maintain with its participating professionals an appropriate Business Associate Agreement that provides for the QCDR's receipt of patient-specific data from the EPs, as well as the QCDR's public disclosure of quality measure results.
  - Obtain and keep on file for at least 7 years signed documentation that each holder of an NPI whose data are submitted to the QCDR has authorized the QCDR to submit quality measure results and numerator and denominator data and/or patient-specific data on beneficiaries to CMS for the purpose of PQRS participation. This documentation would be required to be obtained at the time the EP signs up with the QCDR to submit quality measures data to the QCDR and would be required to meet any applicable laws, regulations, and contractual business associate agreements.
  - Provide CMS a signed, written attestation statement via e-mail which states that the quality measure results and any and all data, including numerator and denominator data, provided to CMS are accurate and complete.
  - Provide information on how the entity collects quality measurement data.
  - Submit quality measures data or results to CMS for purposes of demonstrating that, for a reporting period, its EPs have satisfactorily participated in PQRS. A QCDR must have in place mechanisms for the transparency of data elements and specifications, risk models, and measures.
  - Be compliant with applicable privacy and security laws and regulations, by describing its plan to maintain Data Privacy and Security for data transmission, storage and reporting.
  - Report on behalf of its individual EP participants a set of measures from one or more of the following categories: CG-CAHPS; NQF-endorsed measures (information available at http://www.qualityforum.org/Home.aspx); current PQRS measures (registry measures, measures group only measures, eCQMs, and ACO/GPRO web interface measures); measures used by boards or specialty societies; and measures used in regional quality collaboratives.
  - Be able to collect all needed data elements for at least 9 individual measures covering at least 3 of the National Quality Strategy (NQS) domains.

- Report on behalf of its individual EP participants the results of at least two outcomes-based measures.
  - If 2 outcome measures are not available, report on 1 outcome measure and 1 of the following types of measures – resource use, patient experience of care, efficiency/appropriate use or patient safety.
- Upon request and for oversight purposes, provide CMS access to the QCDR's database to review the beneficiary data on which the QCDR-based submissions are based or provide to CMS a copy of the actual data.
  Make available to CMS samples of patient- level data to audit the entity for purposes of validating the data submitted to CMS by the QCDR, if determined to be necessary.

2. Self-Nomination for the Medicare EHR Incentive Program

   QCDRs who wish to report the eCQM reporting component of meaningful use for the Medicare EHR Incentive Program in 2015 must indicate intent on their Self-Nomination Statement for PQRS. In addition to the criteria established for PQRS above, QCDRs intending to submit eCQM data for purposes of meeting the eCQM reporting component of meaningful use for the Medicare EHR Incentive Program must satisfy the following criteria:

   - Use Certified Electronic Health Record Technology (CEHRT) that meets all of the certification criteria required for eCQMs as required under the Medicare EHR Incentive Program.
   - Report eCQMs included in the Stage 2 final rule and use the same electronic specifications established for the EHR Incentive Program.

   Submit the eCQM data in a quality data reporting architecture (QRDA) category III format.

3. Measure Information

   By **January 31, 2015**, prospective QCDRs must submit measure information indicating which measures (PQRS and non-PQRS) they intend to support for PY 2015. The measure information must contain the following information:

   - If reporting PQRS measures, an entity must indicate which measures they intend to report.
   - If reporting non-PQRS measures, the entity must provide the high-level information for the measures including; measure title, measure description, denominator, numerator, and, when applicable, denominator exceptions and denominator exclusions of the measure, the rationale for the measure, as well as supporting evidence, and NQF number (if NQF-endorsed).
     Please note that the full detailed measure specification must be sent to CMS by **March 31, 2015**.

4. Where to Send the Self-Nomination Statements and Measure Information

   Self-nomination statements and measure information must be sent via e-mail to the QualityNet Help Desk at Qnetsupport@hcqis.org by **5:00 PM ET on January 31, 2015**. The e-mail subject should be *PY2015 PQRS QCDR Self-Nomination or PY2015 PQRS QCDR Measure Information*. A sample self-nomination statement can be found in Appendix 1.

March 31, 2015

1. Non-PQRS Measure Specification Submission

   By **March 31, 2015,** QCDRs must submit the complete specification for the non-PQRS quality measures they intend to support within their QCDR. CMS is providing QCDRs flexibility with regard to choosing the quality measures as the QCDRs should know best what measures should be reported to achieve the goal of improving the quality of care furnished by their EPs. CMS defines a non-PQRS measure as either a measure

that is not contained in the PQRS measure set for the applicable reporting period, or a measure that may be in the PQRS measure set (or measures group) but has substantive differences in the manner it is reported by the QCDR. Measure terminology and definitions can be found in Appendix 2.

- The non-PQRS measure specifications must include measure title, measure description, denominator, numerator, and when applicable, denominator exceptions and denominator exclusions of the measure, rationale, supported evidence, and NQF number, if NQF-endorsed.
- CMS is limiting the number of non-PQRS measures a QCDR may submit on to no more than 30 measures. QCDRs may submit quality measures data on any or all PQRS measures.
- A QCDR must have at least 2 outcome measures available for reporting or if 2 outcome measures are not available, report on 1 outcome measure and 1 of the following types of measures – resource use, patient experience of care, efficiency/appropriate use or patient safety.
- The outcome and process measures reported must contain denominator data, numerator data, denominator exceptions, and denominator exclusions (although not all measures have denominator exceptions and exclusions).
- The entity must demonstrate that it has a plan to risk adjust the quality measures data for which it collects and intends to transmit to CMS. This must be integrated with the complete measure specifications.

Once the Non-PQRS Measure Specifications are approved by CMS, the QCDR has 15 days to publicly post the final measure specifications and notify CMS of the location for inclusion on the 2015 QCDR list.

2. Validation Strategy

   By **March 31, 2015**, the QCDR must submit an acceptable "validation strategy" to CMS. A validation strategy details how the QCDR will determine whether EPs satisfactorily reported measures and that the data submitted to the QCDR is true, accurate and complete. Acceptable validation strategies often include such provisions as the entity being able to conduct random sampling of their participant's data, but may also be based on other credible means of verifying the accuracy of data content and completeness of reporting or adherence to a required sampling method. The template for data validation and integrity and requirements for certification of an EHR product by the Office of the National Coordinator for Health Information Technology (ONC) should also be reviewed if a QCDR is planning to support the EHR Incentive Program.

3. Where to Send the Non-PQRS Measure Specifications and Validation Strategy

   The non-PQRS measure specifications and validation strategy must be sent via e-mail to the QualityNet Help Desk at Qnetsupport@hcqis.org by **5:00 PM ET on March 31, 2015**. The e-mail subject should be *PY2015 QCDR Non-PQRS Measure Specification or PY2015 QCDR Validation Strategy*.

Spring 2015

1. Test Submission

   In **spring 2015**, QCDRs have the opportunity to complete CMS-sponsored submission testing. CMS strongly encourages that QCDRs perform the file testing for the aggregate XML file and/or QRDA category III file as it will help QCDRs to understand what components are required and alleviate issues with the file format and submission that may occur when submitting the quality measure data in early 2016. An Individuals Authorized Access to the CMS Computer Services (IACS) account will be needed to gain access to the Submission Engine Validation Tool (SEVT) and Physician and Other Health Care Professionals Quality Reporting Portal (Portal), prior to July 11, 2015. Individuals who wish to begin testing on or after July 13, 2015

will need an Enterprise Identity Management (EIDM) account. Quick Reference Guides can be accessed on the Portal.

- The Implementation Guide for the 2015 QRDA category III file format is currently posted on the eCQM Library page of the EHR Incentive Program website.
- The 2015 QCDR XML Specifications will be posted on the Qualified Clinical Data Registry Reporting page of the PQRS website in early 2015.

May 30, 2015

1. QCDR Posting

   By **May 30, 2015**, CMS will post a list of QCDRs on the Qualified Clinical Data Registry Reporting page of the CMS PQRS website. The QCDR posting includes the vendor name, contact information, the program(s) being supported, measures being supported, and cost information for the services they provide to clients. Prior to posting, the QCDR must:

   - Verify the information contained on the list (includes names, contact information, measures, cost, etc.) is accurate and **agree to furnish/support all of the services listed on the list** to eligible professionals who may want to use the QCDR to participate in PQRS (and other CMS quality programs).
   - Provide to CMS the cost that the QCDR charges EPs to submit their data to CMS.

December 31, 2015

1. Feedback Reports

   By **December 31, 2015**, QCDRs must have provided feedback, at least four times, on the measures at the individual participant level for which the QCDR collects data on behalf of the EP for purposes of the individual EP's satisfactory participation in the QCDR.

   - QCDRs may have feedback reports that are readily available via the web or by a different communication mechanism that allows EPs to generate reports on demand in order to fulfill this requirement.

February 29, 2016 / March 31, 2016

1. Data Submission

   By **February 29, 2016**, QCDRs must submit data on behalf of their EPs who want to participate in PQRS and the EHR Incentive Program. QCDRs must submit the quality measure data in a Quality Reporting Data Architecture (QRDA) Category III file to CMS on behalf of these participants. QRDA III files will **not** be accepted after February 29, 2016. Data Submitted after February 29, 2016 will not be processed for the EHR Incentive Program.

   - Only eCQMs are able to be submitted in the QRDA I or QRDA III files.

   By **March 31, 2016**, QCDRs must submit data on behalf of their EPs who only want to participate in PQRS. QCDRs must submit the quality measure data in a QCDR XML files to CMS on behalf of these participants. Only QCDR XML files will be accepted from March 1 – March 31, 2016.

   - The PQRS and non-PQRS measures can be submitted via the QCDR XML file.
     - PQRS Measures include registry measures, measures group only measures, eCQMs, and ACO/GPRO Web Interface measures.

   In order to submit data, QCDRs must:

   - Obtain an Enterprise Identity Management (EIDM) account to gain access to the Portal.

- Be able to collect all needed data elements and transmit the data on quality measures to CMS in one of two formats, either via a CMS-approved XML format or via the QRDA category III format.
    - The CMS-approved QCDR XML format must be used when submitting PQRS specified measures or non-PQRS specified measures for purposes of PQRS participation. This data will not be processed for the EHR Incentive Program
    - The QRDA category III format must only be used when submitting the eCQMs for purposes of PQRS and EHR Incentive Program participation. Please note that the correct version of eCQM specifications must be used.
- Submit to CMS, for purposes of demonstrating satisfactory participation, quality measures data on multiple payers, not just Medicare patients.
- Comply with a CMS-specified secure method for quality data submission.
- The entity must report, on behalf of its individual EP participants, a minimum of 9 measures that cross 3 NQS domains.
- The entity must report at least 2 outcome measures or if 2 outcome measures are not available, report on 1 outcome measure and 1 of the following types of measures – resource use, patient experience of care, efficiency/appropriate use or patient safety.
- Possess benchmarking capability that enables the QCDR to compare the quality of care an EP provides to his or her patients to other EPs performing the same or similar functions and provide to CMS benchmarking information for each measure reported by the QCDR.

2. QCDR Audit and Disqualification Process

    After data submission concludes, CMS will analyze the data submitted by QCDRs. If inaccurate data is found, CMS has the ability to audit and disqualify QCDRs. A disqualified QCDR will not be allowed to submit quality measures data on behalf of its EPs for purposes of participating in PQRS for the following year. A disqualified entity must become re-qualified as a QCDR before it will be allowed to submit quality measures data on behalf of its EPs for purposes of participating in PQRS. In addition, inaccurate data collected may be discounted for purposes of an individual EP meeting the criteria for satisfactory participation in a QCDR.

June 30, 2016

1. Data Validation Execution Report

    By **June 30, 2016**, QCDRS must perform the validation outlined in the validation strategy and send the results to CMS for the data collected for the 2015 reporting period.

2. Where to Send the Data Validation Execution Report

    The data validation execution report must be sent via e-mail to the QualityNet Help Desk at Qnetsupport@hcqis.org by **5:00 PM ET on June 30, 2016**. The e-mail subject should be *PY2015 QCDR Data Validation Execution Report.*

Late 2016

1. Posting Data on Physician Compare Website

    CMS will publicly report QCDR data (both PQRS and non-PQRS measures) at the individual EP level. CMS will not publicly report any newly available measures (measures that are being reported to PQRS for the first time). CMS will review all data prior to public reporting to ensure that the non-PQRS measures included meet the same standards as the PQRS measures being publicly reported, and that PQRS measures reported via a QCDR are comparable to PQRS measures reported via other mechanisms. Only those measures deemed

accurate, valid, and reliable will be publicly reported. Although all QCDR measures are available for public reporting on Physician Compare, not all measures will be included on individual EP profile pages. Only those measures that meet all public reporting criteria and resonate with consumers will be included. QCDRs are not required to also publicly report measures on their own websites

Help Desk Support

Questions regarding any of the information contained in this document can be directed to the QualityNet Help Desk:

Available: Monday–Friday 7:00 AM–7:00 PM CT
Phone: 1-866-288-8912 TTY: 1-877-715-6222
Email: Qnetsupport@hcqis.org

Questions regarding the Medicare EHR Incentive Program can be directed to the EHR Incentive Program EHR Information Center:

Available: Monday–Friday 7:30 AM–6:30 PM CT
Phone: 1-888-734-6433

Appendix 1: Sample Self-Nomination Statement

NOTE - This is a sample Self Nomination Letter. As with all documents of this nature, legal counsel review before use would be prudent. No additional information (e.g., Validation Plans, Attestation Statements) should be included in the Self Nomination Letter.

E-mail Subject: *PY2015 PQRS QCDR Self-Nomination*

ABC QCDR
123 QCDR Avenue
Sample, MD 12345
Tel: 123-456-7890
Email: abcqcdr@abcqcdr.org
January 15, 2015[1]

Dear PQRS Nomination Committee,

Please accept this submission as the Self Nomination of ABC QCDR[2] for inclusion in the 2015 Physician Quality Reporting System (PQRS) Qualified Clinical Data Registry reporting mechanism. The ABC QCDR hereby attests that we meet all of the detailed requirements listed in the 2015 Medicare Physician Fee Schedule Final Rule and the Qualified Clinical Data Registry Criteria For Submission Of 2015 Physician Quality Reporting System Data document that is posted on the Qualified Clinical Data Registry webpage on the CMS PQRS website.

ABC QCDR collects data utilizing a collaboration of an EHR and a web-based tool[3]. ABC QCDR intends to submit clinical quality measure data for PQRS and the EHR Incentive Program[4] on behalf of their eligible professionals for the 2015 reporting period starting on January 1, 2015 and ending on December 31, 2015[5].

Please address any questions to our program representative Jon Doe (123-456-7891 / jdoe@abcqcdr.org), our clinical representative Susie Smith (123-456-7892 / ssmith@abcqcdr.org), and our technical representative Dan Jones (123-456-7893 / djones@abcqcdr.org)[6].

Thanks
Joe Smith
Joe Smith
ABC QCDR

[1] Letter must be received no later than **5 p.m. ET on January 31, 2015.**
[2] Specify your Sponsoring Organization name and QCDR name if the two are different.
[3] Specify your data collection method (e.g., EHR, practice management system, web-based tool).
[4] Specify participation in the PQRS and EHR Incentive Program, if applicable.
[5] Specify the program year and the reporting period start and end date.
[6] Specify the appropriate individuals to contact when beginning the vetting processes. Provide a phone and an email address for a program, clinical, and technical representative. A minimum of two representatives need to be provided.

Appendix 2: Measure Related Definitions

Measure Terminology	Definition
Denominator Data	The lower portion of a fraction used to calculate a rate, proportion, or ratio. The denominator must describe the population eligible (or episodes of care) to be evaluated by the measure. This should indicate age, condition, setting, and timeframe (when applicable). For example, "Patients aged 18 through 75 years with a diagnosis of diabetes."
Denominator Exceptions	Conditions that should remove a patient, procedure or unit of measurement from the denominator of the performance rate only if the numerator criteria are not met. Denominator exceptions allow for adjustment of the calculated score for those providers with higher risk populations. Denominator exceptions allow for the exercise of clinical judgment and should be specifically defined where capturing the information in a structured manner fits the clinical workflow. Generic denominator exception reasons used in measures fall into three general categories: medical, patient, or system reasons.
Denominator Exclusions	Patients with conditions who should be removed from the measure population and denominator before determining if numerator criteria are met. (For example, patients with bilateral lower extremity amputations would be listed as a denominator exclusion for a measure requiring foot exams.)
Non-PQRS Measure	A measure that is not contained in the PQRS measure set for the applicable reporting period, or a measure that may be in the PQRS measure set (or measures group) but has substantive differences in the manner it is reported by the QCDR.
Numerator Data	The upper portion of a fraction used to calculate a rate, proportion, or ratio. The numerator must detail the quality clinical action expected that satisfies the condition(s) and is the focus of the measurement for each patient, procedure, or other unit of measurement established by the denominator (that is, patients who received a particular service or providers that completed a specific outcome/process).
Outcome Measure	A measure that assesses the results of health care that are experienced by patients (that is, patients' clinical events; patients' recovery and health status [end result of care of procedure]; patients' experiences in the health system; and efficiency/cost).
Process Measure	A measure that focuses on a process which leads to a certain outcome, meaning that a scientific basis exists for believing that the process, when executed well, will increase the probability of achieving a desired outcome.
Risk Adjustment	A corrective tool used to level the playing field regarding the reporting of patient outcomes, adjusting for the differences in risk among specific patients (http://www.sts.org/patient- information/what-risk-adjustment). Risk adjustment also makes it possible to compare performance fairly. For example, if an 86-year old female with diabetes undergoes bypass surgery, there is less chance for a good outcome when compared with a healthy 40-year old male undergoing the same procedure. To take factors into account which influence outcomes, for example, advanced age, emergency operation, or previous heart surgery, a risk adjusted model is used to report surgery results.

Measure Terminology	Definition
Substantive Measure Change	A measure that may be in the PQRS measure set but has substantive differences in the manner it is reported by the QCDR. For example, PQRS measure 319 is reportable only via the GPRO web interface. A QCDR wishes to report this measure on behalf of its eligible professionals. However, as CMS has only extracted the data collected from this quality measure using the GPRO web interface, in which CMS utilizes a claims-based assignment and sampling methodology to inform the groups on which patients they are to report, the reporting of this measure would require changes to the way that the measure is calculated and reported to CMS via a QCDR instead of through the GPRO web interface. Therefore, due to the substantive changes needed to report this measure via a QCDR, PQRS measure 319 would be considered a non-PQRS measure.