

**2014 PHYSICIAN QUALITY REPORTING SYSTEM:
QUALIFIED CLINICAL DATA REGISTRY DATA
SUBMISSION CRITERIA**

12/23/2013

Physician Quality Reporting System

Physician Quality Reporting System (PQRS) is a pay-for-reporting program that uses a combination of incentive payments and payment adjustments to promote 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 2014, a QCDR is defined for purposes under 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. EPs who satisfactorily participate in PQRS through a QCDR may earn the 2014 incentive payment (0.5%) and avoid the 2016 payment adjustment (2.0%).

Additional information on the PQRS can be found on the Physician Quality Reporting System section of the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS>.

Medicare Electronic Health Record Incentive Program

The Medicare Electronic Health Record (EHR) Incentive Program provides incentive payments to EPs, eligible hospitals, and critical access hospitals (CAHs) as they adopt, implement, upgrade or demonstrate meaningful use of certified EHR technology. 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 at <http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/>.

Value-based Payment Modifier

The Value-based Payment Modifier (VM) provides for differential payment to an EP or group practice under the Medicare Physician Fee Schedule (PFS) based upon the quality of care furnished compared to cost during a performance period. The 2016 VM will apply to groups of physicians with 10 or more EPs. Groups with 10-99 EPs will not be subject to any downward payment adjustments under quality-tiering in 2016.

Additional information regarding VM can be found on the Value-based Payment Modifier section of the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html>.

QCDR Criteria

The requirements and associated timelines to become a QCDR for the 2014 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.

January 31, 2014

1. Self-Nomination for PQRS

By January 31, 2014, 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.
- If supporting PQRS measures, an entity must indicate which measures they intend to support.
- If supporting non-PQRS measures, an entity must indicate the high level information around the measures. Including: 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. Please note that the full detailed measure specification must be sent to CMS by March 31, 2014.
- The entity must attest that they meet all of the following QCDR criteria:
 - Be in existence as of **January 1, 2013**, to be eligible to participate for purposes of data collected in 2014.
 - Have at least 50 QCDR participants by **January 1, 2013**, to be eligible to participate under the program with regard to data collected in 2014. 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, if requested.
 - 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 of which is available at <http://www.qualityforum.org/Home.aspx>); current PQRS 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 at least one outcomes-based measure.
- 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 eQCM reporting component of meaningful use for the Medicare EHR Incentive Program in 2014 must indicate intent on their Self-Nomination Statement for PQRS. In addition to the criteria established for PQRS above, QCDRs intending to submit eQCM data for purposes of meeting the eQCM 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 eQCMs as required under the Medicare EHR Incentive Program.
- Report eQCMs included in the Stage 2 final rule and use the same electronic specifications established for the EHR Incentive Program.
- Submit the eQCM data in a quality data reporting architecture (QRDA) category III format.

3. Where to Send the Self-Nomination Statements

Self-nomination statements must be sent via e-mail to the QualityNet Help Desk at Qnetsupport@sdps.org by **5:00 PM EST on January 31, 2014**. The e-mail subject should be *PY2014 PQRS QCDR Self-Nomination*. A sample self-nomination statement can be found in Appendix 1.

March 31, 2014

1. Non-PQRS Measure Specification Submission

By **March 31, 2014**, QCDRs must submit the complete specification for the quality measures they intend to support within their QCDR to CMS. 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. The 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-endorsed¹.

- CMS is limiting the number of non-PQRS measures a QCDR may submit on to no more than 20 measures. QCDRs may submit quality measures data on any or all PQRS measures.

¹ Definitions and additional information regarding these measure components can be found in Appendix 2.

- A QCDR must have at least 1 outcome measure available for reporting.
- A QCDR may report on process measures.
- The outcome and process measures reported must contain denominator data, numerator data, denominator exceptions, and denominator 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.

2. Measure Specification Publication

By **March 31, 2014**, the QCDR must publically post (on the entity's website or other publication available to the public) the detailed specifications (measure titles, descriptions, denominators, numerators, and when applicable, denominator exceptions and denominator exclusions, rationales, supported evidence, and NQF numbers, if NQF-endorsed) of the quality measures it collects to ensure transparency of information to the public.

3. Validation Strategy

By **March 31, 2014**, the QCDR must submit an acceptable "validation strategy" to CMS. A validation strategy details how the QCDR will determine whether EPs succeed in reporting measures or 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. For a template for data validation and integrity, please also see the requirements for certification of an EHR product by the Office of the National Coordinator for Health Information Technology (ONC) that are explained at <http://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method>.

4. 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@sdps.org by **5:00 PM EST on March 31, 2014**. The e-mail subject should be *PY2014 QCDR Non-PQRS Measure Specification or PY2014 QCDR Validation Strategy*.

May 30, 2014

1. QCDR Posting

By **May 30, 2014**, 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 programs 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.
- Provide to CMS the cost that the QCDR charges to submit data to CMS.

Summer / Fall 2014

1. Test Submission

In **summer / fall 2014**, 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.

December 31, 2014

1. Feedback Reports

By **December 31, 2014**, QCDRs must have provided feedback, at least four times, on the measures at the individual participant level for which the QCDR reports on the EP's behalf 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 other communication mechanism that allows EPs to generate reports on demand in order to fulfill this requirement.

February 27, 2015

1. Data Submission

By **February 27, 2015**, QCDRs must submit the quality measure data in the proper format to CMS on behalf of their participants. In order to submit data, QCDRs must:

- 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 XML format must be used when submitting PQRS-specified measures or QCDR-specified measures for purposes of PQRS participation.
 - The QRDA category III format must only be used when submitting the eQCMs for purposes of PQRS and EHR Incentive Program participation. Please note that the correct version of eQCM 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.
- Possess benchmarking capacity that measures the quality of care an EP provides compared to other EPs performing the same or similar functions and provide to CMS benchmarks for each measure.

2. QCDR Audit and Disqualification Process

After data submission concludes on **February 27, 2015**, 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 meeting the criteria for satisfactory participation for the following year. Disqualified entities must become requalified as a QCDR before it may submit quality measures data on behalf of its EPs for purposes of the individual EP participants meeting the criteria for satisfactory participation under PQRS. In addition, inaccurate data collected will be discounted for purposes of an individual EP meeting the criteria for satisfactory participation in a QCDR.

June 30, 2015

1. Data Validation Execution Report

By **June 30, 2015**, QCDRS must perform the validation outlined in the validation strategy and send evidence of successful results to CMS for data collected in the reporting periods occurring in 2014.

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@sdps.org by **5:00 PM EST on March 31, 2014**. The e-mail subject should be *PY2014 QCDR Data Validation Execution Report*.

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@sdps.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: PY2014 PQRS QCDR Self-Nomination

ABC QCDR
123 QCDR Avenue
Sample, MD 12345
Tel: 123-456-7890
Email: abcqcdr@abcqcdr.org
January 15, 2014²

Dear PQRS Nomination Committee,

Please accept this submission as the Self Nomination of ABC QCDR³ for possible inclusion in the 2014 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 2014 Medicare Physician Fee Schedule Final Rule and the Qualified Clinical Data Registry Criteria For Submission Of 2014 Physician Quality Reporting System Data document dated 12/23/2013 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.⁴ ABC QCDR intends to submit clinical quality measure data for PQRS and the EHR Incentive Program⁵ on behalf of their eligible professionals for the 2014 reporting period starting on January 1, 2014 and ending on December 31, 2014⁶. ABC QCDR intends to become qualified to submit the PQRS individual Measures #1: Diabetes Mellitus: Hemoglobin A1c Poor Control - Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0%.....⁷

Please address any questions to our program representative Jon Doe (123-456-7891 / jdoe@abcqcdr.org), our clinical representative Susie Nurse (123-456-7892 / snurse@abcqcdr.org), and our technical representative Dan Jones (123-456-7893 / djones@abcqcdr.org)⁸.

Thanks

Joe Smith
Joe Smith
ABC QCDR

² Letter must be received no later than **5 p.m. ET on January 31, 2014.**

³ Specify your Sponsoring Organization name and QCDR name if the two are different.

⁴ Specify your data collection method (e.g., EHR, practice management system, web-based tool).

⁵ Specify participation in the PQRS and EHR Incentive Program, if applicable.

⁶ Specify the program year and the reporting period start and end date.

⁷ Specify what measures your QCDR intends to report. If reporting PQRS specified measures, identify the measure numbers and titles you intend to support. If reporting non-PQRS specified measures, identify the measure title, description, denominator, numerator, and when applicable, denominator exceptions and denominator exclusions, rationale, supported evidence, and NQF number, if NQF-endorsed.

⁸ 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
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.
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."
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).
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.)
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.