Physician Quality Reporting System (PQRS):

2016 Qualified Clinical Data Registry (QCDR) Criteria

February 2017

Background

The Physician Quality Reporting System (PQRS) is a voluntary quality reporting program that promotes the reporting of quality information by eligible professionals (EPs) and group practices. The program applies a downward payment adjustment to practices with EPs (identified on claims by their individual National Provider Identifier [NPI] and Tax Identification Number [TIN]) or group practices participating via the group practice reporting option (GPRO), referred to as PQRS group practices, who do not satisfactorily report data on quality measures for covered Medicare Physician Fee Schedule (Medicare PFS) services furnished to Medicare Part B Fee-for-Service (FFS) beneficiaries (including Railroad Retirement Board and Medicare Secondary Payer). Those who satisfactorily report for the 2016 program year will avoid the 2018 PQRS downward payment adjustment (-2.0%).

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

Defining a Qualified Clinical Data Registry

CMS believes that a QCDR should foster quality improvement, in addition to the collection and submission of PQRS quality measures data. A QCDR is defined as a CMS-approved entity 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. Prospective QCDRs must self-nominate and successfully complete a qualification process to become a 2016 QCDR. An entity that does not meet the definition and requirements of a QCDR on its own may be able to meet these requirements in conjunction with another entity; thus eligible to self-nominate and participate together as one QCDR. EPs and PQRS group practices who satisfactorily participate in PQRS through a QCDR may avoid the 2018 downward PQRS payment adjustment (-2.0%).

Additional information on the QCDRs can be found on the Qualified Clinical Data Registry Reporting page of the Physician Quality Reporting System section of the CMS website.

Disclaimer: *If reporting for PQRS through another Centers for Medicare & Medicaid Services' (CMS) program (such as the Medicare Shared Savings Program, Comprehensive Primary Care Initiative, Pioneer Accountable Care Organizations (ACO)), please check the program's requirements for information on how to avoid the PQRS payment adjustment. Please note, although CMS has attempted to align or adopt similar reporting requirements across programs, EPs and group practices should look to the respective quality program to ensure they satisfy*

the PQRS, Medicare Electronic Health Record (EHR) Incentive Program, Value-based Payment Modifier, etc. requirements of each of these programs.

Purpose

This document applies to entities interested in participating as a QCDR in 2016 PQRS by supporting EPs and/or PQRS group practices. In order to become a QCDR, entities must meet the definition of a QCDR, meet all of the requirements, and meet all of the deadlines prior to the due dates listed below.

2016 Updates for QCDR

This section will contain 2016 updates to the QCDR requirements and qualification process in an effort to simplify the process for 2015 QCDRs to re-nominate as a 2016 QCDR.

2016 QCDR Self-Nomination Toolkit

For 2016, CMS has posted a 2016 QCDR Self-Nomination Toolkit in lieu of the QCDR Criteria Document format used in years past. This toolkit will contain the QCDR Criteria and the Data Validation Plan Criteria.

2016 Self-Nomination via JIRA

In an attempt to streamline the process and better track the progress of interested entities, the self-nomination, PQRS measures options, non-PQRS measures and data validation plans will be built into a self-nomination form in the JIRA system. The data validation plan can either be populated into the pre-formulated question fields in JIRA or uploaded as an attachment in JIRA. Please note that if both the pre-formulated questions and upload attachment options are utilized for the submission of a QCDR's data validation plan, CMS will only review the information populated in the pre-formulated fields for purposes of satisfying the data validation plan requirement. For additional information, regarding the process to submit deliverables via JIRA, please review the 2016 Self-Nomination User Guide located in the 2016 QCDR Self-Nomination Toolkit.

2016 Self-Nomination Deadline

For 2016, CMS will require prospective QCDRs to submit their self-nomination statement, PQRS measures, non-PQRS measures specifications, and the data validation plan prior to the January 31, 2016 deadline in order to self-nominate as a 2016 QCDR. Acceptable versions of all of these deliverables must be received by the deadline to be considered for the qualification process.

An entity that uses an external organization for purposes of data collection, calculation or transmission may meet the definition of a QCDR as 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, 2016.

Failure to Meet Requirements and Deadlines

In the past, CMS has been flexible with delinquent and/or insufficient deliverables. To encourage prospective QCDRs to meet the requirements and deadlines set forth, CMS will be

more stringent with the requirements and deadlines. Failure to meet the requirements finalized by the Medicare PFS final rule or these deadlines within the qualification process may result in removal of your vendor information from the qualified posting and/or affect your status as a QCDR in the current or future program years. By adhering to the posted deadlines, it is CMS' intention to be able to more timely post the QCDRs vendors for the EP and GPRO stakeholder community who select QCDR reporting as their method of submission of PQRS data. By adhering to the posted deadlines, it is CMS' intention to be able to more timely post the qualified vendors for the EP and PQRS group practice community who select QCDR reporting as their method of submission of PQRS data.

Ability to Support Group Practices Participating via GPRO

For 2016, CMS is allowing the QCDRs to support group practices participating via GPRO, called PQRS group practices. QCDRs wishing to support PQRS group practices should review the requirements for the GPRO as there are differences between the GPRO and individual EP reporting options. For example, GPRO data is submitted at this TIN level rather than TIN/NPI level; NPIs should not be included in the GPRO data.

Additional information on the GPRO can be found on the Physician Quality Reporting System section of the CMS website.

Electronic Attestation Statements

For 2016, QCDRs will attest at the time of data submission that the quality measure results and any and all data including numerator and denominator data provided to CMS will be accurate and complete using a web-based check box mechanism in the Physicians and Other Healthcare Professionals Quality Reporting Portal (Portal). QCDRs will no longer submit this attestation statement as a separate deliverable via email.

Auditing of Entities Submitting PQRS Quality Measures Data

CMS is in the process of validating data reported by PQRS participants, including vendors who submit quality measures data. It is essential for QCDRs to cooperate with this validation process. In order to ensure that CMS has adequate information to perform a data check of QCDRs, CMS is requiring any QCDR submitting quality measures data for the PQRS comply with the following requirements:

- Make available to CMS the contact information of each EP on behalf of whom it submits data. The contact information will include, at a minimum, the EP practice's phone number, address, and, if applicable email.
- The vendor must retain all data submitted to CMS for the PQRS program for a minimum of seven years.

QCDR Required Deliverables

CMS requires that entities submit the following deliverables by the deadline listed. Failure to meet these deadlines may result in removal of your vendor information from the qualified posting and/or affect your status as a QCDR in the current or future program years.

- Self-Nomination Statement due 01/31/2016
- Public Reporting Declaration due 01/31/2016

- PQRS Measures due 01/31/2016
- Non-PQRS Measures Specifications due 01/31/2016
- Data Validation Plan due 01/31/2016
- Qualified Posting Sign-Off due 02/29/2016
- PQRS & EHR Incentive Program Data Submission using QRDA III format due 03/31/2017
- PQRS Data Submission using XML format due 03/31/2017

QCDR Self-Nomination

For 2016, prospective QCDRs must submit a nomination containing their self-nomination, measures information, and data validation plan.

- **Self-Nomination: December 1, 2015 – January 31, 2016**

By **5:00 p.m. Eastern Time (ET) on January 31, 2016**, prospective QCDRs must complete the self-nomination form electronically using the self-nomination form on JIRA**.** By completing and submitting the self-nomination form, prospective QCDRs are attesting that they meet the following requirements:

- Have been in existence as of January 1, 2016, to be eligible to participate for purposes of data collected in 2016.
- Have a signed, written agreement that specifically details the relationship and responsibilities of the entity with the external organizations effective as of January 1, 2016 to be eligible to participate for purposes of data collected in 2016.
- Have at least 50 QCDR participants by January 1, 2016, to be eligible to participate under the program with regard to data collected in 2016. Please note that not all participants are 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).
- Participate in QCDR support conference calls hosted by CMS.
- 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 participating EPs and PQRS group practices, as well as the QCDR's disclosure of patient-specific data on behalf of EPs and PQRS group practices who wish to participate in PQRS.
- Obtain and keep on file for at least 7 years signed documentation that each holder of an NPI 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 must be obtained at the time the EP or PQRS group practice signs up with the QCDR for purposes of PQRS participation and must meet any applicable laws, regulations, and contractual business associate agreements.
- Possess benchmarking capability that enables the QCDR to compare the quality of care an EP and PQRS group practice provides to his or her patients to other EPs and PQRS group practices performing the same or similar functions and provide to CMS benchmarking information for each non-PQRS measure reported by the QCDR. QCDRs are able to provide benchmarking methodology as available.
- Retain all data submitted to CMS for the PQRS program for a minimum of 7 years.

- Provide information on how the entity collects quality measurement data.
- Submit quality measures data or results to CMS for purposes of demonstrating that, for the reporting period, its EPs or PQRS group practices 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 participants a set of measures from one or more of the following categories: Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS); National Quality Forum (NQF) endorsed measures; current PQRS measures (registry measures, measures group only measures, electronic clinical quality 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, calculate and transmit quality measure data to CMS at the TIN/NPI level for at least 9 individual measures covering at least 3 of the NQS domains for submission of data on behalf of individual EPs.
- Be able to collect, calculate and transmit quality measure data to CMS at the TIN level for at least 9 individual measures covering at least 3 of the NQS domains for submission of data on behalf of PQRS group practices.
- Be able to collect, calculate and transmit data for at least 2 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, including 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. Also, make available to CMS the contact information of each EP on behalf of whom it submits data. The contact information will include, at a minimum, the EP practice's phone number, address, and, if applicable email.
- QCDRs who wish to report the eCQM reporting component of meaningful use for the Medicare EHR Incentive Program in 2016 must indicate intent on their self-nomination 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.

- **QCDR Public Reporting Declaration: December 1, 2016 – January 31, 2016**

By **5:00 p.m. ET on January 31, 2016**, QCDRs must declare a public reporting location within the self-nomination form in JIRA. CMS will publicly report QCDR data (both PQRS and non-PQRS measures) at the individual EP and group practice level. The QCDR is required to declare if they plan to post data on their own website and allow Physician Compare to link to it or if they will provide data to CMS for public reporting on Physician Compare. CMS will not publicly report any first year 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 public reporting standards as the PQRS measures being publicly reported, and that PQRS measures reported via a QCDR are comparable to PQRS measures reported via other reporting mechanisms. Only those measures deemed accurate, valid, reliable, and comparable 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 or group practice 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 if they have elected for measures to be publicly reported on Physician Compare. If the QCDR does not specifically declare, measures will be considered available for Physician Compare to publicly report.

- **Measures Information: December 1, 2015 – January 31, 2016**

By **5:00 p.m. ET on January 31, 2016**, prospective QCDRs must provide the following information about the measures (PQRS and non-PQRS) they intend to support. Once the PQRS and Non-PQRS measures are approved and posted, CMS will require the QCDR to support any EP or PQRS group practice who wishes to report data for those specific measures or measures groups.

  - PQRS Measures List
    - If reporting PQRS measures, an entity must indicate which measures they intend to report using the JIRA PQRS measures section within the JIRA self-nomination form.
  - Non-PQRS Measures Specifications
    - If reporting non-PQRS measures, QCDRs must submit the complete specification for the non-PQRS quality measures they intend to support within their QCDR using the JIRA system under the "sub-task" functionality. 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.
      - The non-PQRS measure specifications must include the following: measure title, measure description, NQS Domain, numerator, denominator, exceptions and exclusions of the measure (if applicable), measure type (process/outcome), NQF number (if NQF endorsed), eCQM number (if applicable), rationale, data source, steward, number of multiple performance rates (if applicable), inverse measure (yes/no), proportion measure scoring (yes/no), continuous measure scoring (yes/no), and risk adjustment (yes/no).
      - 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.

- 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 by way of the JIRA system of the location for inclusion on the 2016 QCDR list.

- **Data Validation Plan: December 1, 2015 – January 31, 2016**

By **5:00 p.m. ET on January 31, 2016**, prospective QCDRs must submit an acceptable data validation plan or validation strategy to CMS. An acceptable validation strategy details how the QCDR will determine whether EPs and/or PQRS group practices have submitted data accurately and satisfactorily on the minimum number of their eligible patients, visits, procedures, or episodes for a given measure. Acceptable validation strategies often include such provisions as the QCDR being able to and actually 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.

Prospective QCDRs should review the *Data Validation Plan Criteria* document located in the 2016 QCDR Self-Nomination Toolkit for additional information on the data validation plans.

Qualified Posting

- **QCDR Qualified Posting Sign-Off: February 22, 2016 – February 29, 2016**

By **February 29, 2016,** QCDRs must sign-off on the content listed in their section of the qualified posting. In order to be posted, the QCDR must:

- Verify the information contained on the list (includes names, contact information, measures, cost, public reporting location, etc.) is accurate and agree to furnish/support all of the services specified on the list to EPs 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 and PQRS group practices to submit their data to CMS.

- **QCDR Qualified Posting: March 1, 2016 – March 31, 2016**

By **March 31, 2016**, 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.

Submission Engine Validation Tool (SEVT) Testing

- **QCDR Test Submission: April 30, 2016 – December 31, 2016**

In **2016**, 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 2017. The Submission Engine Validation Tool (SEVT) is available on the Physician and Other Healthcare Professionals Quality Reporting Portal (Portal) for test submission. An Enterprise Identity Management (EIDM) account will be needed to obtain access to the Portal.

- An Enterprise Identity Management (EIDM) account will be needed to obtain access to the Portal. Additional information on EIDM accounts can be found on the Portal.
- The QRDA Category III file format is used to submit eCQM data for the PQRS and the Medicare EHR Incentive Program. The *Implementation Guide for the 2016 QRDA* category III file format is currently posted on the eCQM Library page of the EHR Incentive Program website.
- The 2016 QCDR XML file format is used to submit QCDR data. The *2016 QCDR XML Specifications* will be posted on the Qualified Clinical Data Registry Reporting page of the PQRS website in early 2016.

Feedback Reports

- **Feedback Reports: January 1, 2016 – March 31, 2017**

By **March 31, 2017**, QCDRs must have provided feedback, at least four times, on the measures for which the QCDR collects and submits data on behalf of the EPs and PQRS group practices.

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

Data Submission

- **Data Submission for PQRS and Medicare EHR Incentive Program: January 3, 2017 – March 31, 2017**

By **March 31, 2017**, QCDRs must submit data on behalf of their EPs or PQRS group practices who want to participate in PQRS and the Medicare EHR Incentive Program using QRDA III format. QRDA III files will not be accepted after March 13, 2017.

- Please note that QCDRs can only submit eCQMs through the QRDA III file format.

- **Data Submission for PQRS: January 3, 2017 – March 31, 2017**

By **March 31, 2017**, QCDRs must submit data on behalf of their EPs or PQRS group practices 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, 2017.

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

In order to submit data via QCDR XML or QRDA Category III, 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 Quality Reporting Data Architecture (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.
- 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.

CMS 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 or PQRS group practices to CMS in 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 or PQRS group practices for participation purposes. In addition, inaccurate data collected may be discounted for purposes of an individual EP and PQRS group practice meeting the criteria for satisfactory participation in a QCDR.

Report Once for Multiple CMS Programs

EPs and PQRS group practices will be able to report quality measures data once and receive credit for more than one Medicare quality reporting program. For guidance on how to report once across Medicare quality reporting programs (PQRS, Medicare EHR Incentive Program, Value-based Payment Modifier, and Accountable Care Organizations), please see the *How to Report Once for 2016 Medicare Quality Reporting Programs* that is posted on the How to Get Started page of the CMS PQRS website.

Additional Information

- For more information on 2016 QCDR reporting mechanism, go to the Qualified Clinical Data Registry page of the CMS PQRS website.
- For more information on the PQRS, go to the Physician Quality Reporting System page of the CMS PQRS website.
- For more information on the EHR Incentive Program, go to the EHR Incentive Program section of the CMS website.
- For more information on the VM, go to the Value-Based Payment Modifier page of the Medicare FFS Physician Feedback Program/Value-Based Payment Modifier website.

- For more information on Physician Compare, go to the Physician Compare Initiative page or contact the Physician Compare Support team at PhysicianCompare@Westat.com.
- For additional assistance regarding PQRS, contact the **QualityNet Help Desk** at **1-866-288-8912 (TTY 1-877-715-6222)** from 7:00 a.m. to 7:00 p.m. Central Time (CT) Monday through Friday, or via e-mail. To avoid security violations, do **not** include personal identifying information, such as Social Security Number or TIN, in email inquiries to the QualityNet Help Desk.