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MACRA NPRM

Establishment of an Entity Seeking to Qualify as Qualified Clinical Data Registry (QCDR)

Summary

Background:

The qualified clinical data registry (QCDR) **reporting mechanism** was introduced for the Physician Quality Reporting System (PQRS) beginning in 2014. A QCDR completes the collection and submission of PQRS quality measures data on behalf of individual eligible professionals (EPs) and PQRS group practices. For 2016, a QCDR is 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. To be considered a QCDR for purposes of PQRS, an entity must self-nominate and successfully complete a qualification process. A similar process is proposed in the MACRA rule.

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Qualified-Clinical-Data-Registry-Reporting.html

MACRA Rule:

- CMS encourages MIPS eligible clinicians to report on applicable measures under the quality performance category through the use of QCDR.
- CMS allows **one bonus point** under the quality performance category score, up to a maximum of 5 percent of the denominator of the quality performance category score if:
    - The MIPS eligible clinician exports and transmits data electronically to a third party;
    - QCDR uses automated software to aggregate measure data, calculate measures, perform any filtering of measurement data, and submit the data electronically to CMS via Web Interface.
    - These requirements are referred to as “end-to-end electronic reporting”.
- This bonus would be in addition to the high priority bonus.
- The data submission deadline for the qualified registry or QDCR would be March 31st following the close of the performance period. The submission period would begin on January 2nd following the close of the performance period.

Qualifications:

- The QCDR must have at least 25 participants by January 1 of the performance period. These participants do not need to be using the QCDR to report MIPS data to CMS; rather, they need to be submitting data to the QCDR for quality improvement.
- Having qualified as a QCDR in a prior year does not automatically qualify the entity to participate in MIPS as QCDR in subsequent performance years.

- Annual self-nomination process is the best process to ensure accurate information is conveyed to MIPS eligible clinicians and accurate data is submitted to MIPS.
- If an entity becomes qualified as QCDR, CMS will require the entity to sign a statement about the services to be performed for MIPS. This information will then be posted on the CMS website, and the entity will be held accountable to perform those services.
- CMS allows collaboration of entities to become a QCDR based on our experience with the qualifying entities wishing to become QCDRs for performance periods.

Self-Nomination Period:

- For the 2017 performance period, a self-nomination period is from November 15, 2016 through January 15, 2017.
- For future years, the self-nomination period is from September 1 through November 1 of the prior year.

Information Required at the Time of Self-Nomination:

- Organization name
- **MIPS Performance Categories (For example, Quality, Advancing Care Information (meaningful use - use of E.H.R.), and/or Clinical Practice Improvement Activities, CPIA [i.e., care coordination, beneficiary engagement, patient safety])**
- Performance period
- Vendor Type (for example, qualified clinical data registry)
- Provide the methods by which the entity obtains data from its customers for each performance category for which it is approved: claims, web-based tool, practice management system, certified E.H.R. technology, other (please explain). If combination of methods is used, the entity should state which methods are utilized to collect data (for example, performance numerator and denominator).
- Indicate the method the entity will use to verify the accuracy of each TIN/NPI it is intending to submit (for example, National Plan and Provider Enumeration System (NPPES), CMS claims, tax documentation).
- Describe the method the entity will use to accurately calculate performance rates for quality measures based on the appropriate measure type and specification. The entity should be able to report to CMS a calculated composite measure rate if applicable.
- Describe the method that the entity will use to accurately calculate performance data for CPIA and advancing care information based on the appropriate parameters or activities.
- Describe the process that the entity will use for completion of a *randomized audit* of a subset of data prior to the submission to CMS (for all performance categories the QCDR is submitting data on, that is, quality, CPIA, and advancing care information, as applicable). Periodic examinations may be completed to compare patient record data with submitted data and/or ensure MIPS quality measures or other performance category (CPIA, advancing care information) activities

were accurately reported and performance calculated based on the appropriate measure specifications (that is, accuracy of numerator, denominator, and exclusion criteria) or performance category requirements.

- Provide information on the entity's *process for data validation* for both individual MIPS eligible clinicians and groups within a data validation plan. For example, for individuals it is encouraged that 3 percent of the TIN/NPIs submitted to CMS by the QCDR be sampled with a minimum sample of 10 TIN/NPIs or a maximum sample of 50 TIN/NPIs. For each TIN/NPI sampled, it is encouraged that 25 percent of the TIN/NPI's patients (with a minimum sample of five patients or a maximum sample of 50 patients) should be reviewed for all measures applicable to the patient.
- Provide the results of the *executed data validation plan by May 31 of the year following the performance period.* If the results indicate the QCDR's validation reveals inaccuracy or low compliance provide to CMS an improvement plan. Failure to implement improvements may result in the QCDR being placed in a probationary status or disqualification from future participation.
- For *non-MIPS quality measures*, if the measure is risk-adjusted, the QCDR is required to provide details to CMS on their risk adjustment methodology (risk adjustment variables, and applicable calculation formula) at the time of the QCDR's self-nomination. The QCDR must submit the risk adjusted results to CMS when submitting a risk-adjusted measure on behalf of the QCDR's MIPS eligible clinicians for the performance period.

QCDR Requirements for Data Submission:

- For measures under the quality performance category, if the data is derived from certified EHR technology, the QCDR must be able to indicate this data source.
- QCDRs must provide complete quality measure specifications including data elements to CMS for non-MIPS quality measures intended for reporting from certified EHR technology.
- QCDRs must provide a plan to risk adjust (if appropriate for the measure) the non-MIPS quality measures data for which it collects and intends to transmit to CMS and must submit the risk-adjusted results (not the non-risk adjusted rates), to CMS.
- QCDRs submitting MIPS quality measures that are risk-adjusted (and have the risk-adjusted variables and methodology listed in the measure specifications) must submit the risk-adjusted measure results to CMS when submitting the data for these measures.
- Submit quality, advancing care information, or CPIA data and results to CMS in the applicable MIPS performance categories for which the QCDR is providing data.
- A QCDR must have in place mechanisms for the *transparency of data elements* and specifications, risk models, and measures. That is, we expect that the non-MIPS measures and their data elements (that is, specifications) comprising these measures be listed on the QCDR's website unless the measure is a MIPS measure, in which case the specifications will be posted by CMS.
- Submit to CMS data on measures, activities, and objectives for all patients, not just Medicare patients.
- Provide timely feedback, at least 6 times a year, on all of the MIPS performance categories that the QCDR will report to CMS.

- Possess benchmarking capacity (for non-MIPS quality measures) that compares the quality of care a MIPS eligible clinician provides with other MIPS eligible clinicians performing the same quality measures.
- For non-MIPS measures the QCDR must provide CMS, if available, data from years prior (for example, 2015 data for the 2017 MIPS performance period) before the start of the performance period.
- QCDRs must comply with any request by CMS to review the data submitted by the QCDR for purposes of MIPS in accordance with applicable law. Specifically, data requested would be limited to the minimum necessary for CMS to carry out, for example, health care operations or health oversight activities.
- Mandatory participation in ongoing support conference calls hosted by CMS (approximately one call per month), including an in-person QCDR kick-off meeting (if held) at CMS headquarters in Baltimore, MD. More than one unexcused absence could result in the QCDR being precluded from participation in the program for that year. If a QCDR is precluded from participation in MIPS, the individual MIPS eligible clinician or group would need to find another QCDR or utilize another data submission mechanism to submit their MIPS data.
- Agree that data inaccuracies including (but not limited to) TIN/NPI mismatches, formatting issues, calculation errors, data audit discrepancies affecting in excess of 3 percent of the total number of MIPS eligible clinicians submitted by the QCDR may result in notations on our qualified QCDR posting of low data quality and would place the QCDR on probation (if they decide to self-nominate for the next program year).
- Be able to submit results for at least six (6) quality measures including one cross-cutting measure and one outcome measure. If an outcome measure is not available, be able to submit results for at least one other high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures). If no outcome measure is available, then the QCDR must provide a justification for not including an outcome measure.
- QCDRs may request to report on up to 30 quality measures not in the annual list of MIPS quality measures. Full specifications will need to be provided to us at the time of self-nomination. CMS will review the quality measures and determine if they are appropriate for QCDR reporting.
- Enter into and maintain with its participating clinicians an appropriate Business Associate agreement that provides for the QCDR's receipt of patient-specific data from an individual MIPS eligible clinician or group, as well as the QCDR's disclosure of quality measure results and numerator and denominator data and/or patient specific data on Medicare and non-Medicare beneficiaries on behalf of MIPS eligible clinicians and groups.
- Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the QCDR, has authorized the QCDR to submit quality measure results, CPIA measure and activity results, advancing care information objective results and numerator and denominator data and/or patient-specific data on Medicare and non-Medicare beneficiaries to CMS for the purpose of MIPS participation. This documentation must be obtained at the time the MIPS eligible clinician or group signs up with the QCDR to submit MIPS data to the QCDR and must meet the requirements of any applicable laws, regulations, and contractual business associate agreements.
- Not be owned and managed by an individual locally owned single specialty group (for example, single specialty practices with only one practice location or solo practitioner practices are prohibited from self-nominating to become a qualified QCDR).
- **Be able to separate out and report on all payers including Medicare Part B FFS patients and non-Medicare patients.**

- Provide the measure numbers for the MIPS quality measures on which the QCDR is reporting.
- Provide the measure title for the MIPS quality measures and CPIAs (if applicable) on which the QCDR is reporting.
- Report the number of eligible instances (reporting denominator).
- Report the number of instances a quality service is performed (performance numerator).
- Report the number of performance exclusions, meaning the quality action was not performed for a valid reason as defined by the measure specification.
- Comply with a CMS-specified secure method for data submission, such as submitting the QCDR's data in an XML file.
- For purposes of distributing feedback reports to MIPS eligible clinicians, collect a MIPS eligible clinician's email addresses and have documentation from the MIPS eligible clinician authorizing the release of his or her email address.
- Must provide attestation statements during the data submission period that all of the data (quality measures, CPIAs, and advancing care information measures and objectives, if applicable) and results are accurate and complete.
- Be able to calculate and submit measure-level reporting rates or, upon request, the data elements needed to calculate the reporting and performance rates by TIN/NPI and/or TIN.
- Be able to calculate and submit, by TIN/NPI and/or TIN, a performance rate (that is the percentage of a defined population who receive a particular process of care or achieves a particular outcome based on a calculation of the measures' numerator and denominator specifications) for each measure on which the TIN/NPI and/or TIN reports or, upon request the Medicare beneficiary data elements needed to calculate the performance rates.
    - ✓ Provide the performance period start date the QCDR will cover.
    - ✓ Provide the performance period end date the QCDR will cover.
    - ✓ Report the number of reported instances, performance not met, meaning the quality actions was not performed for no valid reason as defined by the measure specification.

- For data validation purposes, provide information on the entity's sampling methodology. For example, it is encouraged that 3 percent of the MIPS eligible clinicians be sampled with a minimum sample of 10 MIPS eligible clinicians or a maximum sample of 50 MIPS eligible clinicians. For each MIPS eligible clinicians sampled, it is encouraged that 25 percent of the MIPS eligible clinicians' patients (with a minimum sample of five patients or a maximum sample of 50 patients) should be reviewed for all measures applicable to the patient.
- Submit all of the measures (MIPS measures and non-MIPS measures) including specifications for the non-MIPS measures to CMS on a designated webpage. The measures must address a gap in care. Outcome or other high priority types of measures are preferred. Simple documentation or "check box" measures are discouraged.

QCDR Measure Specifications Requirements:

- A QCDR must provide specifications for each measure, activity, or objective the QCDR intends to submit to CMS.
- Provide descriptions and narrative specifications for each measure activity, or objective for which it will submit to CMS by no later than January 15 of the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (CPIA and advancing care information) data. For subsequent years, the submission due date is November 1.

- For non-MIPS quality measures, the quality measure specifications must include: name/title of measures, NQF number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. The narrative specifications provided must be similar to the narrative specifications we provide in our measures list. CMS will consider all non-MIPS measures submitted by the QCDR but the measures must address a gap in care and outcome or other high priority measures are preferred. Documentation or "check box" measures are discouraged. Measures that have very high performance rates already or address extremely rare gaps in care (thereby allowing for little or no quality distinction between MIPS eligible clinicians) are also unlikely to be approved for inclusion.
- For MIPS measures, the QCDR only needs to submit the MIPS measure numbers and/or the specialty-specific measure sets (if applicable).
- The QCDR must publicly post the measure specifications (no later than 15 days following our approval of these measure specifications) for each non-MIPS quality measure it intends to submit for MIPS. The QCDR may use any public format it prefers. Immediately following posting of the measures specification information, the QCDR must provide CMS with the link to where this information is posted. CMS will then post this information when it provides its list of QCDRs for the year.

Identifying Non-MIPS Measures:

- To clarify the definition of a non-MIPS quality measures for purposes of QCDRs submitting data for the MIPS quality performance category, we propose to consider the following types of quality measures to be non-MIPS quality measures:
    - ✓ A measure that is not contained in the annual list of MIPS quality measures for the applicable performance period.
    - ✓ A measure that may be in the annual list of MIPS quality measures but has substantive differences in the manner it is submitted by the QCDR. For example, if a MIPS quality measure is only reportable via the CMS Web Interface and a QCDR wishes to report this quality measure on behalf of its MIPS eligible clinicians, the quality measure would be considered a non-MIPS quality measure.

- In addition, the CAHPS for MIPS survey currently could be submitted only using a CMS-approved survey vendor. Although the CAHPS for MIPS survey is proposed for inclusion in the MIPS measure set, we consider the changes that will need to be made available for reporting by individual MIPS eligible clinicians (and not as a part of a group) significant enough as to treat the CAHPS for MIPS survey as a non-MIPS quality measure for purposes of reporting the CAHPS for MIPS survey via a QCDR.

Qualified Registries:

CMS proposes to define a qualified registry as a medical registry, a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties or other data intermediary that, with respect to a particular performance period, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the MIPS qualification requirements specified by CMS for that performance period. The registry must have the requisite legal authority to submit MIPS data (as specified by CMS) on behalf of a MIPS eligible clinician or group to CMS. In addition, CMS is proposing to expand a qualified registry's capabilities by allowing qualified

registries to submit data on measures, activities, or objectives for any of the following MIPS performance categories:
(i) Quality;
(ii) CPIA; or
(iii) Advancing care information, if the MIPS eligible clinician or group is using certified EHR technology.