Information in this document is a summary only, and readers are requested to refer to official CMS materials and the MACRA Final Rule itself for specific and complete requirements.

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Introduction

NQRN contributed to PCPI’s public comments\(^1\) on the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Proposed Rule.

NQRN has conducted a review of the MACRA Final Rule\(^2\). Below is a summary of key CMS statements, public comments, CMS’ response to public comments, and NQRN clarifying notes (highlighted in grey in this document only), if any. Information in this document was selected for inclusion based on its potential for relevance to the clinical registry/QCDR, measure development and performance improvement communities, with a particular focus on the QCDR. Previous NQRN and PCPI work was referenced where appropriate\(^3\).
# Table of Contents

**Front Matter** ................................................................................................................................. 1
- Acknowledgements .......................................................................................................................... 2
- Introduction ....................................................................................................................................... 2

**MACRA Deep Dive** ....................................................................................................................... 4
- General ............................................................................................................................................ 4
- Performance Measurement .............................................................................................................. 4
- MIPS Improvement Activities .......................................................................................................... 6
- MIPS Advancing Care Information .................................................................................................. 7
- APMs .............................................................................................................................................. 8
- QCDRs ........................................................................................................................................... 8

**References** .................................................................................................................................. 13
MACRA Deep Dive

General

Comment – information blocking: Many commenters stated that EHR vendors are the primary cause of existing barriers to interoperability through routine information blocking. Commenters allege that EHR vendors are unwilling to share data in certain circumstances or charge cost-prohibitive fees.4

CMS response: Information blocking is beyond the scope of MACRA

NQRN promotes increased data liquidity between EHRs and other clinical information systems such as registries and data warehouses.

Comment – registry inventory: A commenter recommended that there be a resource or listing of all available public health and clinical registries that MIPS eligible clinicians could engage with to meet the measures of the public health and clinical data registry reporting objective.5

CMS: CMS is planning to develop a centralized public health registry repository to assist MIPS eligible clinicians in finding public health registries available and clinically relevant to their practice.

NQRN continues to maintain its national clinical registry inventory, available at thepcpi.org.

Comment - definitions: Definition of a MIPS eligible clinician. For 2017 and 2018 MIPS eligible clinicians are: physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetist, and groups that include such professionals.6

With some of these types of professionals being newly eligible to participate in MIPS, MACRA presents expanded opportunities for Qualified Clinical Data Registries (QCDRs) to recruit these professionals as participants.

Performance Measurement

CMS – quality measure requirements for MIPS: CMS finalized the following considerations for quality measures submitted for possible inclusion in MIPS:7

- Measures not duplicative of an existing or proposed measure
- Measures beyond the concept phase and for which testing has begun
- Measures that include a data submission method beyond claims-based
- Measures that are outcome-based
- Measures that address patient safety and adverse events
- Measures that identify appropriate use of diagnosis and therapeutics
- Measures that address care coordination
- Measures that address patient and caregiver experience
- Measures that address efficiency, cost and utilization of health care resources
- Measures that address a performance gap
**Comment – non-patient facing clinicians:** Types of measures and/or improvement activities CMS should use to assess non-patient facing MIPS eligible clinicians. Commenters were split, with some advocating for exemptions. Those not in favor of exemptions generally suggested a focus on process measures and that CMS work with specialty societies to develop new, more clinically relevant measures for non-patient facing MIPS eligible clinicians.8

**Comment – 2017 transition period:** Performance period for 2017. Commenters advocated for it to be delayed or treated as a transition year.

CMS response: MIPS eligible clinicians will only need to report for a minimum of a continuous 90-day period within CY 2017, for the majority of the submission mechanisms. This 90-day period can occur anytime within CY 2017, so long as the 90-day period begins on or after January 1, 2017 and ends on or before December 31, 2017.9

**Comment – multi-specialty reporting challenges:** A commenter expressed concern that multi-specialty groups reporting through a QCDR would face challenges if multiple specialties wanted to report non-MIPS measures.

**CMS:** QCDRs are able to report both non-MIPS and MIPS measures. QCDRs are provided a great deal of flexibility and should be able to report for multiple specialties.10

**Comment – measure accuracy:** A commenter suggested that CMS adopt standards and mapping tools to ensure that electronic clinical quality measure (eCQM) calculations are accurate. Another commenter recommended that CMS adopt standards to ensure different EHRs are accurately and uniformly capturing eCQMs.

**CMS:** CMS agrees that adopting standards to accurately and uniformly capture eCQMs is essential. CMS currently uses the Health Level Seven International (HL7) Health Quality Measures Format (HQMF) standard for electronically documenting eCQM content, as well as the Quality Data Model (QDM) for measure logic. CMS will continue to ensure industry standards are used and refined in order to best capture eCQM data.11

**CMS – outcome measures:** Outcome measures are more valuable than clinical process measures. CMS plans to increase the requirements for reporting outcome measures over the next several years through future rulemaking, as more outcome measures become available. CMS also believes that appropriate use, patient experience, safety and care coordination measures are more relevant than process measures for improving patient care.12

**CMS:** For 2017, MIPS eligible clinicians or groups need to report at least six measures including at least one outcome measure. If an applicable (relevant to a particular MIPS eligible clinician’s services or care rendered) outcome measure is not available, then another high-priority measure may be substituted from: appropriate use, patient safety, efficiency, patient experience or care coordination. CMS did not require any cross-cutting measures in 2017.13

**Comment – intermediate outcome measures:** Are intermediate outcome measures outcome measures?
**CMS**: Yes

**Comment – non-MIPS measures**: Can six non-MIPS measures be selected to meet the reporting criteria?  
**CMS**: Yes, as long as one of the six is an outcome or if no outcome measure is available, another high-priority measure. A benefit of participating in QCDRs is the ability to use non-MIPS measures, offering a wider selection of measures to QCDR participants.

**Comment – patient-reported outcome measures**: A commenter recommended that patient-reported outcomes measures (PROMs) be given great weight.  
**CMS**: CMS agrees, but understands that PROMs generally require a cost to clinicians to carry out. In future years CMS will continue to seek methods of expanding reporting of PROMs without unduly penalizing practices that cannot afford the measurement costs.

Because registries capture data on real-world populations over varying periods of time, they are well-suited to the collection of outcomes data, often directly from patients who submit them to registries via registry patient portals or apps.

**Comment – multiple reporting methods**: Some commenters recommended that CMS reduce complexity by reducing the number of available reporting methods as dependence on claims data is reduced.  
**CMS**: CMS believes that broader adoption of registries will allow it to reduce the number of reporting methods, thus reducing complexity and clinician burden.

**CMS – completeness criteria**: Proposed a 90% completeness criterion for QCDRs and other submission mechanisms – 90% of the MIPS eligible clinician or group’s patients that meet a measure’s denominator criteria, regardless of payer, for the performance period.  
**Comment**: A majority of commenters recommended that CMS reduce the quality reporting thresholds to 50%.  
**CMS**: CMS finalized a 50% data completeness threshold for 2017, 60% for 2018. CMS expects to increase these thresholds over time.

**Comment – cost measurement**: A commenter recommended that CMS use a total cost of care measure developed using a methodology that captures data from all payer claims databases.  
**CMS**: CMS is unaware of a national data source that would allow them to accurately capture cost data for payers. CMS is limited to using Medicare cost data for the total per capita cost measure.

**MIPS Improvement Activities**

**CMS – number of activities**: For the improvement activities MIPS category, for 2017 it was finalized that four medium-weighted activities, two high-weighted activities, or a combination of medium and high-weighted activities are required.
Comment – EHR data and improvement activities: Some commenters noted that some improvement activities are not practical to carry out using EHR data alone.\textsuperscript{22} MIPS presents opportunities for QCDR stewards to submit improvement activities, participation in which can be accomplished via QCDR participation.

CMS – call for improvement activities: CMS plans to develop a call for activities process for future years of MIPS, using a process paralleling the annual call for measures. Prospective activities that are submitted through a QCDR [say in a performance period 1] could also be included as part of a beta-test process that may help determine whether that activity should be included in the improvement activities inventory. MIPS eligible clinicians that use QCDRs to capture data associated with an [improvement] activity may be requested to voluntarily submit that same data in performance period 2 to begin identifying a baseline for improvement for subsequent year analysis. CMS believes that for future years, QCDRs would be allowed to define specific improvement activities for specialty and non-patient facing MIPS eligible clinicians and groups through the already-established QCDR approval process for measures and activities.\textsuperscript{23}

CMS – finalized improvement activity list: Finalized list of MIPS improvement activities for 2017 include the use of a QCDR to generate regular performance feedback that summarizes local practice patterns and treatment outcomes, including for vulnerable populations.\textsuperscript{24}

MIPS Advancing Care Information

Comment – registry reporting: Commenters recommended that more bonus credit should be awarded to MIPS eligible clinicians for reporting to additional registries beyond immunization registries.

CMS: In the MIPS advancing care information scoring category, specialized registry reporting [including participation in a QCDR] makes MIPS eligible clinicians eligible for a performance score bonus. In addition, CMS finalized a 5% bonus for reporting to one or more public health or clinical data registries [including QCDRs] beyond the immunization registry reporting measure.\textsuperscript{25}

Comment - interoperability: A commenter suggested that the Health Information Exchange objective does not adequately reflect EHR interoperability. They believe the metric is too focused on the quantity of information moved and not the relevance [semantics] of these exchanges. They urged CMS to refocus the advancing care information MIPS performance category on interoperability by developing specialty-specific interoperability use cases rather than measuring the quantity of data.\textsuperscript{26}

CMS: CMS is very interested in adopting measures that reflect interoperability. CMS urges interested parties to participate in their solicitation call for new measures.\textsuperscript{26}

Comment – interoperability: Several commenters requested that CMS create incentives to make certified health IT more flexible because many registries rely on both automated and manual data entries. Commenters were concerned that most EHRs do not support all the necessary data elements for
advanced quality measures or analytics and require hybrid approaches to data collection, but that other electronic submissions [such as registries] have that data. The commenters believed that CMS should reward eligible clinicians for utilizing registries [including QCDRs] and using leveraging electronic capture among other methods. One commenter wanted to incorporate the use of an EHR with a registry system to minimize double reporting and documentation.27

**CMS:** CMS would expect the elements of a hybrid measure that use essential [common across specialties] patient demographic and clinical data normally managed in certified heath IT e.g., ONC Common Clinical Data Set elements, could be made available to registries [including QCDRs] using electronic means such as transmission in any HL7 Clinical Document Architecture (CDA) format supported in certified health IT, or with an appropriately secure API.27

CMS encourages all registries to pursue standards-based, fully electronic methods for accurately extracting and importing data from other electronic sources, in addition to data supported by certified health IT, as appropriate to their measures. CMS recognizes that for some types of measures, some additional data still require registries to continue alternate, including manual, data entry. In future years, CMS anticipates evolving data standards and data aggregation and management services infrastructure, including robust registries capable of seamlessly aggregating and analyzing data across multiple electronic types and sources, will eventually eliminate the burden of manual processes including chart abstraction.27

**APMs**

**CMS – MIPS APMs:** Finalized that for MIPS eligible clinicians participating in MIPS APMs through a registry, would receive performance feedback in the MIPS quality category through that registry. For feedback on other MIPS performance categories, such as cost, improvement activities or advancing care information, the HHS secretary shall encourage provision of feedback through QCDRs.28

CMS believes that at present [2017 performance year], QCDRs will only be able to provide information on the quality performance category for MIPS in regard to performance feedback. CMS plans to coordinate with third party intermediaries such as health IT vendors and QCDRs as MIPS evolves to enable additional feedback to be sent on the cost, advancing care information and improvement activities performance categories.28

In future QPP program years, performance feedback will continue to be available through a CMS-designated system, which they intend to be a web-based application providing feedback through a dashboard interface. This interface will be available via the QPP website.29

**QCDRs**

**Comment – QCDR benefits:** One commenter requested that CMS explain the benefit of reporting via QCDR and why this method is emphasized.30

**CMS:** QCDRs have more flexibility to collect data from different data sources and to rapidly develop innovative measures that can be incorporated into MIPS. CMS believes that QCDRs provide an
opportunity for innovative measurement that is both relevant to MIPS eligible clinicians and beneficial to Medicare beneficiaries.  

NQRN supports the increased use of QCDRs for performance measurement and improvement.

CMS – QCDR benefits: CMS supports data acquisition for multiple MIPS categories being accomplished through a single submission mechanism. CMS is awarding MIPS quality bonus points for measures gathered and reported through the QCDR along with other mechanisms. CMS encourages the use of QCDRs to report new and innovative quality measures. In addition, several improvement activities emphasize QCDR participation. Finally, CMS allows QCDRs to report data on all MIPS categories that require data submission. CMS hopes that submitting all MIPS data through QCDRs will reduce reporting burden and positively affect their final score.

Comment – open source QCDR: A commenter suggested that CMS consider the development of an open source QCDR that would allow small organizations the opportunity to take advantage of the benefits of QCDRs for measure development, thereby shortening the process for inclusion in MIPS. CMS does not intend to expand QCDR types at this time, but it will take this suggestion into consideration for future rulemaking.

Open-source is a concept for the licensing and use of software in which the original source code is made freely available and may be redistributed and modified. In theory, any organization could create an open-source registry platform and self-nominate to CMS to become a QCDR, just as they would with a software platform that is closed-source - proprietary.

Comment – third-party entities: Several commenters agreed with CMS’ proposal to allow third party entities such as QCDRs to submit data for the MIPS categories of quality, advancing care information and improvement activities. The commenters believed the use of a single third-party data submission method reduces the administrative burden on MIPS-eligible clinicians, facilitates consolidation, and standardization of data from disparate EHRs and other systems, and enables the third parties to provide timely, actionable feedback to MIPS eligible clinicians on opportunities for performance improvement. CMS finalized its proposal that QCDRs have the flexibility to submit data on behalf of the MIPS performance categories – quality, improvement activities, and advancing care information. CMS intends to release additional guidance to third party intermediaries regarding the submission standards that QCDRs would need to comply with for data submissions across the performance categories. CMS will publish this information at qpp.cms.gov prior to the beginning of the performance period.

CMS – QCDR definition: Finalized for the QPP the definition of a QCDR: “A CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.” CMS states as examples of the types of entities that may qualify as QCDRs include, but are not limited to: regional collaboratives, specialty societies, using a commercially available software platform, as appropriate.
**CMS – QCDR time in existence:** Finalized that for an entity to become qualified as a QCDR for a given performance period, the entity must be in existence as of January 1 of the performance period for which the entity seeks to become a QCDR. 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.37

**CMS – self-nomination period:** For 2017 the QCDR self-nomination period was Nov. 15, 2016 – Jan. 15, 2017. For future program years, starting with 2018, the self-nomination period must occur from Sept. 1 of the prior year until Nov. 1 of the prior year.38

**CMS – QCDR requirements:** Summary table of QCDR requirements39

**Required for QCDR self-nomination**
- Organization name
- MIPS categories the QCDR plans to report
- Performance period
- Vendor type e.g., QCDR
- Methods by which data will be obtained for each performance category planned to report: claims, web-based tool, practice management system, certified EHR technology, other, or a combination. If a combination, state which methods.
- Method to verify TIN/NPIs
- Method to accurately calculate performance rates for quality measures
- Method to accurately calculate performance data for improvement activities and advancing care information
- Process for a randomized audit of a subset of data prior to submission to CMS
- Process for data validation for MIPS eligible clinicians and groups within a data validation plan
- Results of the data validation plan by May 31 of the year following the performance period
- For risk-adjusted, non-MIPS measures, details on the risk adjustment methodology

**QCDR required functions**
- If the data are derived from certified EHR technology, indicate data source for measures under the quality performance category
- Provide complete quality measure specifications including data elements for non-MIPS quality measures intended for reporting from certified EHR technology
- Provide a plan to risk-adjust (if appropriate for the measure) the non-MIPS quality measures data and must submit the risk-adjusted results to CMS. The risk adjustment methodology must be integrated with the complete quality measure specifications. The risk adjustment methodology must be posted on the QCDR’s web site.
- Submit quality, advancing care information, or improvement activities data and results to CMS in the applicable MIPS performance categories for which the QCDR is providing data
Mechanisms in place for the transparency of data elements and specifications, risk models and measures (listed on the QCDR’s web site)

Submit to CMS data on measures, activities and objectives for all patients, not just Medicare patients

Provide timely feedback to participating MIPS eligible clinicians or groups, at least four times a year, on all MIPS performance categories that the QCDR is reporting to CMS.

Possess benchmarking capability 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. Provide to CMS or post on the QCDR website prior to the start of the current performance period available prior year performance data. Provide if available the entire distribution of the measure’s performance broken down by deciles.

Comply with CMS requests to review data submitted

Mandatory participation in ongoing support conference calls hosted by CMS

Agree that data inaccuracies affecting in excess of three percent of the total number of MIPS eligible clinicians submitted by the QCDR may result in notations of low data quality and would place the QCDR on probation if they decide to self-nominate for the next program year. Data errors affecting in excess of five percent of the MIPS eligible clinicians may lead to the disqualification of the QCDR from participating in the following year’s program

Be able to submit results for at least six quality measures including one outcome measure, or 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). If no outcome measure is available, the QCDR must provide a justification for not including one.

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.

Enter into and maintain with MIPS eligible clinicians and appropriate business associate agreement

Obtain and keep on file signed documentation that each holder of an NPI has authorized the QCDR to submit data to CMS for the purpose of CMS participation.

Not be owned or managed by an individual locally-owned single specialty group

Be able to separate out and report on all payers

Provide the measure numbers for the MIPS measures reported

Provide the measure title for the MIPS quality measures and improvement activities reported

Report number of eligible instances (reporting denominator)

Report number of instances a quality service is performed (performance numerator)

Report the number of performance exclusions

Comply with a CMS-specified secure method for data submission

Sign a document verifying the QCDR’s name, contact info, cost for clinicians or groups to use the QCDR, services provided, measures and specialty-specific measure sets the QCDR intends to report

Provide attestation statements that all of the data and results are accurate and complete
• Collect a MIPS eligible clinician’s email address and have documentation from the clinician authorizing the release of his or her email address
• Be able to calculate and submit measure-level reporting rates, as well as, when requested, by TIN/NPI or TIN
• Be able to calculate and submit, by TIN/NPI or TIN, a performance rate for each measure on which the TIN/NPI or TIN reports or, upon request the Medicare beneficiary data elements needed to calculate the performance rates
• Provide the performance period start and end dates the QCDR will cover
• Report the number of reported instances where performance was not met
• Provide information on sampling methodology for data validation purposes
• Submit all measures including specifications for the non-MIPS measures to CMS on a designated webpage. 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.

Comment – reporting standards: CMS should work with registries and other stakeholders to identify emerging standards that support a more scalable and flexible data reporting format.40

CMS: CMS will continue to work with QCDRs and other stakeholders to identify and improve its data transmission formats and methods.40

CMS – measure requirements: For each measure, activity or objective the QCDR intends to submit to CMS, it must provide the following information:
• For the 2017 performance year, descriptions and narrative specifications for each measure activity or objective by Jan. 15 of the performance period. In future years beginning with 2018, provide these specs no later than Nov. 1 prior to the applicable performance period.
• For non-MIPS quality measures, the specifications must include: name or title of measures, NQF number if NQF endorsed, denominator, numerator descriptions, denominator exceptions, exclusions, risk adjustment variables and risk adjustment algorithms, when applicable. Narrative specs must be similar to those CMS provides in its measures list
• Non-MIPS 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 are also unlikely to be approved for inclusion in the QCDR.
• For MIPS measures, the QCDR only needs to submit the MIPS measure numbers and the specialty-specific measure sets, if applicable
• The QCDR must publicly post the measure specifications, no later than 15 days following CMS approval of these specs, for each non-MIPS measure it intends to submit for MIPS. The QCDR may use any public format it prefers.41

CMS - non-MIPS measures: Finalized the following types of measures as non-MIPS quality measures:
• A measure not in the annual list of MIPS quality measures for the applicable performance period
• A measure that may be in the annual list, but has substantive differences in the manner it is submitted by the QCDR
• CAHPS for MIPS survey

CMS - non-MIPS measure format: A QCDR that is submitting non-MIPS measures is not required to use HQMF or QRDA, and may choose to use an API or other relevant standards supported by its participants’ health IT to achieve standards-based access to quality measurement data.

CMS – QCDR in collaboration with another entity: An entity that may not meet the criteria of a QCDR solely on its own but could do so in conjunction with another entity would be eligible for qualification through collaboration with another entity.

CMS - APMs: Beginning in 2019, if an eligible clinician participates in an Advanced APM, that eligible clinician may become a Qualified Participant (QP). QPs are excluded from MIPS. For 2021 and later, eligible clinicians may become QPs through a combination of participation in Advanced APMs and Other Payer Advanced APMs.

CMS - APMs: APM Entities are defined as entities that participate in an APM or payment arrangement with CMS or another payer, respectively, through a direct agreement with CMS or the other payer, or through federal or state law or regulation.

CMS - APMs: Quality measures on which the Advanced APM bases payment must include at least one of the following types of measures provided that they have an evidence-based focus, are reliable, and are valid:
• Any MIPS measure
• Quality measures endorsed by a consensus-based entity
• Quality measures developed under section 1848(s) of the Act
• Quality measures submitted in response to the MIPS Call for Quality Measures
• Any other quality measures that CMS determines to have an evidence-based focus and be reliable and valid e.g., NQF-endorsed measures or non-MIPS QCDR measures.

References

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5. MACRA Final Rule, p.77236
6. MACRA Final Rule, p.77036
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