



October 5, 2020

SUBMITTED ELECTRONICALLY VIA www.regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Physician Clinical Registry Coalition's Comments on the Proposed CY 2021 Revisions to Payment Policies Under the Medicare Physician Fee Schedule and Updates to the Quality Payment Program (CMS-1734-P)

Dear Administrator Verma:

The undersigned members of the Physician Clinical Registry Coalition (the "Coalition") appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS's") proposed rule on updates to the Medicare Physician Fee Schedule and Quality Payment Program for calendar year ("CY") 2021 (the "Proposed Rule" or "NPRM") relating to Qualified Clinical Data Registries ("QCDRs") and Qualified Registries ("QRs").¹ The Coalition is a group of medical society-sponsored clinical data registries that collect and analyze clinical outcomes data to identify best practices and improve patient care. We are committed to advocating for policies that encourage and enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of clinical outcomes. Most of the members of the Coalition have been approved as QCDRs or QRs for 2021.

¹ Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy, 85 Fed. Reg. 50,074 (Aug. 17, 2020) [hereinafter "CY 2021 MPFS"].

We confine our comments to CMS's proposals regarding data validation and QCDR measure testing. We believe that these proposals in the NPRM would significantly and unreasonably burden QCDRs, QRs, and participants. **We fear that CMS is attempting to shift costs and burden of administering the Merit-based Incentive Payment System ("MIPS") program onto specialty societies that create measures and operate QCDRs, activities in which specialty societies have invested heavily.** These investments to support physician participation in MIPS continue to increase, without recognition of the costs of participating in the program.

The Coalition believes that these proposals run counter to the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), which directs the Secretary of the Department of Health and Human Services to encourage the use of QCDRs and certified electronic health record technology for reporting measures under the Quality performance category of MIPS. Therefore, we urge CMS to reconsider these costly and burdensome provisions of the Proposed Rule that are inconsistent with the agency's mandate to develop policies that encourage, not inhibit, the use of QCDRs for MIPS reporting.

1. Data Validation and Targeted Audit Requirements

CMS proposes that beginning with the 2021 performance year, QCDRs and QRs must conduct data validation audits for the payment year before submitting any data for that payment year to CMS for purposes of the MIPS program.² If a data validation audit identifies one or more deficiencies or data errors, the QCDR or QR must conduct a targeted audit into the impact and root cause of each deficiency or data error and correct such deficiencies or data errors prior to the submission of data for that MIPS payment year.³ CMS delineates extensive obligations for data validation and targeted audits in the Proposed Rule.

The Coalition appreciates the importance of reporting true, accurate, and complete data. We are concerned, however, that CMS's proposals regarding data validation and targeted audits are unnecessarily complicated, costly, and burdensome for QCDRs, QRs, and clinicians. These proposals also fail to recognize that QCDRs and QRs currently employ rigorous internal quality data controls and conduct external audits to ensure the accuracy of data. We elaborate on our concerns below.

a. Data Validation Audits for Each Performance Category

Under the Proposed Rule, QCDRs and QRs must conduct data validation for each performance category for which they will submit data.⁴ The Coalition expressed concerns regarding pre-submission audits of the Improvement Activities ("IA") and Promoting Interoperability ("PI") performance categories in the attached comment letter dated September 27, 2019, in response to the proposed rule updating the Quality Payment Program for CY 2020, as well as the attached

² *Id.* at 50,403-04.

³ *Id.*

⁴ *Id.*

letter to CMS dated October 24, 2019. We reiterate and incorporate those concerns and recommendations by reference here.

We continue to believe that mandating data validation for each performance category prior to submitting any data to CMS would be exceedingly difficult. Although QCDRs and QRs encourage all clinicians to enter data often and in a timely manner, not all clinicians have incorporated this activity into their daily/weekly operations. In fact, a large percent of clinicians who are manually entering performance data do not complete this task until late in the performance year. However, the proposal requiring QCDRs and QRs to audit all three performance categories would require QCDRs and QRs to initiate audit activities earlier in the year to ensure timely completion prior to CMS submission. The timing of data submission by participants to QCDRs and QRs is, therefore, incompatible with CMS's proposed data validation requirements.

Moreover, the data submitted for the PI performance category is essentially an attestation. Physicians copy and paste the numerators and denominators for the measures from a report provided by their electronic health records ("EHR"). Although QCDRs and QRs can conduct a randomized audit requesting to examine the report from the EHR that lists the PI measure data, any errors discovered will be errors on the part of the *practice or physician*, not the QCDR or QR. Accordingly, we urge CMS to clarify that it is the participants' responsibility to correct data errors prior to submitting the data to the QCDR or QR. Further, we are concerned that EHR vendor companies are charging practices to run these reports when a third party entity (such as a QCDR or QR) requests them.

It would also be unreasonable to require QCDRs and QRs to audit IAs. CMS has not provided QCDRs or QRs with appropriate guidance to complete such audits and has previously stated that the agency is responsible for validating data for IA.⁵ As the Coalition has previously indicated, the validation of more than 100 different IAs for 50% of a group's total National Provider Identifiers ("NPIs"), including whether the documentation provided by clinicians or their groups meet the spirit of the IA, would be unachievable.

We request that CMS withdraw its proposal for QCDRs and QRs to validate and audit the PI and IA performance categories. If CMS still plans to move forward with the proposal, we urge the agency to provide further guidance, engage with our registries in feedback sessions, and delay the implementation of these requirements by at least one year.

⁵ CMS, *2019 Merit-based Incentive Payment Program (MIPS) Improvement Activities Performance Category Fact Sheet*, <https://qpp.cms.gov/mips/improvement-activities>.

b. Data Validation for Each Submitter Type

CMS is proposing to require QCDRs and QRs to conduct data validation on data for each submitter type for which they will submit data (*i.e.*, MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants).⁶ This proposal would disproportionately burden participants reporting as MIPS eligible clinicians. The majority of participants in our registries prefer to report as groups, as opposed to reporting as MIPS eligible clinicians. Given that the sample size of individual participants reporting as MIPS eligible clinicians is considerably smaller than other submitter types who report as groups, the randomized auditing requirements from CMS would likely result in participants reporting as individuals experiencing more frequent audits than other submitter types. CMS has failed to provide an adequate reason for this proposal that would justify its disparate, burdensome impact. The Coalition urges CMS to not adopt this proposal.

c. Use of Clinical Documentation to Validate Data

CMS proposes to require QCDRs and QRs to use clinical documentation to validate that the action or outcome measured actually occurred or was performed.⁷ This proposal inappropriately limits the type of documentation that may be used to validate the occurrence of a particular clinical activity or the achievement of a clinical outcome. CMS's proposal fails to recognize that documentation of clinical activities or outcomes may exist in records that are not necessarily tied directly to the patient record. For instance, MIPS 404 requires that an anesthesiologist or his or her proxy must advise patients to not smoke on the day of surgery. The recording of that action may be noted in clinical or medical notes, spreadsheets, apps, or other documents that are not directly tied to the patient record. Other MIPS and QCDR measures also rely on non-clinical data to complete the measure. Similarly, we are concerned with CMS' proposal that a QCDR must use clinical documentation to conduct validation for the IA performance category. For example, CMS outlined within its 2020 MIPS Data Validation – Improvement Activities document “suggested documentation” for IA_EPA_1 is a review of “patient record from EHR,” “patient encounter/medical record/claim,” or “same or next day patient encounter/medical record/claim” “with date and time stamp.” Requiring eligible clinicians and their groups to generate and submit clinical documentation such as this to a registry for their IA audit validation – in *addition* to the clinical documentation being submitted for quality measure validation is unnecessarily burdensome for clinicians and QCDRs.

In addition, we are concerned that mandating information directly from clinical records could cause practitioners and QCDRs/QRs to violate the “minimum necessary” rules under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) if practitioners provide more protected health information (“PHI”) than the QCDR or QR needs. The HIPAA Rules permit covered entities to share PHI with business associates for permitted uses and disclosures if they

⁶ CY 2021 MPFS at 50,403-04.

⁷ *Id.*

enter into business associate agreements that meet regulatory requirements for protecting PHI.⁸ Covered entities may only disclose to business associates the “minimum necessary” information for the business associate to perform its services or functions.⁹ Currently, most QCDRs and QRs do not receive PHI from their participants; rather, the participants submit PHI to vendors engaged by the QCDR or QR, and the vendors submit de-identified data to the QCDR or QR for purposes of MIPS reporting. Many medical societies do not have the resources to collect this type of data and do not want to hold the PHI because of the legal risk of a data breach. Moreover, while requiring redaction of identifiable elements before submission may mitigate these privacy concerns, it would present a significant burden on MIPS eligible clinicians and groups, as this would be a time consuming and manual process for most.

d. Sampling Methodology

Under the Proposed Rule, QCDRs and QRs must conduct each data validation audit using a sample size of at least three percent of the Taxpayer Identification Numbers (“TINs”)/NPIs for which the QCDR and QRs will submit data to CMS, subject to certain exceptions.¹⁰ In general, QCDRs and QRs would also be required to conduct each data validation audit using a sample that includes at least twenty-five percent of the patients of each TIN/NPI in the sample.¹¹ This proposal is burdensome on individual practices, QCDRs, and QRs with limited resources. Thus, we urge CMS to reconsider this proposal.

2. QCDR Measure Testing Requirements

In the CY 2020 Medicare Physician Fee Schedule final rule, CMS finalized a requirement that all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, beginning with the CY 2023 payment year.¹² Due to the COVID-19 public health emergency, however, CMS delayed the QCDR measure testing requirement until the 2022 performance period.¹³

In the NPRM, CMS proposes that all QCDR measures must be face valid prior to being self-nominated for the 2022 performance period.¹⁴ The agency also proposes that QCDR measures approved for the 2022 performance year with face validity must be fully tested prior to being

⁸ 45 C.F.R. § 164.502(e), 164.504(e).

⁹ 45 C.F.R. § 164.502(b).

¹⁰ CY 2021 MPFS at 50,403-04.

¹¹ *Id.*

¹² Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations, 84 Fed. Reg. 40,482, 40,816 (Aug. 14, 2019).

¹³ CY 2021 MPFS, 85 Fed. Reg. at 50,326-27.

¹⁴ *Id.* at 50,327.

self-nominated for any subsequent performance periods in order to be considered for inclusion in the MIPS program.¹⁵ To be approved for the 2023 performance year and future years, CMS proposes that a *new* QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved.¹⁶ Additionally, under the Proposed Rule, an existing QCDR measure must be fully tested at the clinician level in order for the measure to be considered for inclusion in a MIPS Value Pathway for the 2022 performance year and future years.¹⁷

The Coalition appreciates CMS meeting with us early this year to discuss important issues affecting registries, including the measure testing requirement. We also applaud the speed and flexibility of CMS in reacting to the COVID-19 pandemic, particularly the agency's decision to delay the implementation of the QCDR measure testing policy by one year. We continue to believe, however, that additional safeguards are necessary to reduce burden on QCDRs and prevent QCDRs from ceasing measure development or leaving the program.

The Coalition has raised its concerns about CMS's QCDR measure testing policy on several occasions, including in our attached September 27, 2019 comment letter in response to the CY 2020 Medicare Physician Fee Schedule proposed rule, as well as in our attached letter dated December 11, 2019. On January 15, 2020, the Coalition, along with the Council of Medical Specialty Societies ("CMSS"), submitted the attached proposal on QCDR measure testing options. We reiterate and incorporate those concerns and recommendations by reference here.

If CMS insists on requiring testing beyond face validity, we urge the agency to allow new QCDR measures to be face valid for the first two MIPS payment years for which they are approved and fully tested for all subsequent MIPS payment years. We request further guidance and/or data from CMS to help measure stewards validate their measures. In light of our experience that it is difficult to motivate practices to engage in measure testing or to report new measures, we request that CMS provide an incentive (in the form of bonus points or quality improvement credit) for practices to choose to submit data on new QCDR measures.

We also urge CMS to exempt measures targeted for harmonization by CMS from satisfying the measure testing requirement *prior* to self-nomination. Lastly, we believe that QCDR statisticians familiar with sample sizes and populations should decide the level of testing (clinical, facility, or group) required.

* * * * *

The Coalition appreciates CMS's attention to these important issues. We are concerned that many of the aforementioned proposals impose unduly burdensome requirements on QCDRs and QRs that conflict with and impede the critical role that registries play in improving patient outcomes and quality of care. We urge the agency to adopt the Coalition's suggestions to avoid

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.* at 50,284, 50,328.

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increasing burdens on our participants, and to incentivize the use of QCDRs and other clinical outcomes data registries. The goal is to allow the use of registries to grow and ultimately result in even greater improvements in the quality of patient care.

Thank you for the opportunity to submit these comments. If you have any questions, please contact Rob Portman at Powers Pyles Sutter & Verville, PC (Rob.Portman@PowersLaw.com or 202-872-6756).

Respectfully submitted,

American Academy of Dermatology Association
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Otolaryngology – Head & Neck Surgery
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons/Congress of Neurological Surgeons American
American College of Emergency Physicians
American College of Gastroenterology
American College of Radiology
American College of Rheumatology
American Gastroenterological Association
American Society for Gastrointestinal Endoscopy
American Society of Anesthesiologists/Anesthesia Quality Institute
American Society of Nuclear Cardiology
American Society of Plastic Surgeons
American Urological Association
Association for Clinical Oncology
College of American Pathologists
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons



September 27, 2019

SUBMITTED ELECTRONICALLY VIA www.regulations.gov

Ms. Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Baltimore, MD 21244- 8016

RE: Physician Clinical Registry Coalition’s Comments on the Proposed CY 2020 Revisions to Payment Policies Under the Medicare Physician Fee Schedule and Updates to the Quality Payment Program (CMS-1715-P)

Dear Administrator Verma:

The undersigned members of the Physician Clinical Registry Coalition (the “Coalition”) appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services’ (“CMS’s”) proposed rule on updates to the Medicare Physician Fee Schedule and Quality Payment Program for calendar year (“CY”) 2020 (the “Proposed Rule” or “NPRM”) relating to Qualified Clinical Data Registries (“QCDRs”).¹ The Coalition is a group of medical society-sponsored clinical data registries that collect and analyze clinical outcomes data to identify best practices and improve patient care. We are committed to advocating for policies that encourage and enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of clinical outcomes. Most of the members of the Coalition have been approved as QCDRs or are working towards achieving QCDR status.

The Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”) requires the Secretary of the Department of Health and Human Services to encourage the use of QCDRs and certified electronic health record (“EHR”) technology (“CEHRT”) for reporting measures under the Quality performance category of the Merit-based Incentive Payment System (“MIPS”). While the Coalition appreciates CMS’s proposal to adopt a multi-year approval cycle for QCDRs,

¹ Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations, 84 Fed. Reg. 40,482 (Aug. 14, 2019).

many of CMS's other proposals in the NPRM would place significant and unreasonable burdens on QCDRs and run counter to Congress' intention to encourage the use of QCDRs.

CMS has proposed a considerable number of recommendations and modifications related to QCDR requirements. We fear that CMS is attempting to shift costs and burden of administering the MIPS program onto specialty societies that create measures and operate QCDRs. Specialty societies have invested heavily in QCDRs and in measure development. These investments to support physicians in MIPS continue to increase, without recognition of the costs of participating in the program. CMS has failed to acknowledge the significant costs associated with many of the proposed requirements set forth in this Proposed Rule. We urge CMS to reconsider these costly and burdensome provisions of the Proposed Rules that are inconsistent with the agency's mandate to develop policies that encourage, not inhibit, the use of QCDRs for MIPS reporting.

The following comments focus on CMS's proposals that will have the most significant effects on QCDRs.

1. CMS Should Adopt a Multi-Year Approval Cycle for QCDR Measures

Currently, CMS approves QCDR measures on a year-to-year basis. Beginning with the 2021 performance period, CMS is proposing to allow QCDR measures to be approved for two years, at CMS discretion and subject to annual review.² Under this proposal, CMS would be permitted to revoke the approval of the second year if the QCDR measure is determined to be topped out; duplicative of a more robust measure; reflective of an outdated clinical guideline; or in need of QCDR measure harmonization. In addition, CMS may revoke the measure's second-year approval if the QCDR proposing the QCDR measure is no longer in good standing. Such revocation would occur during annual review after the first year.

The Coalition appreciates and strongly supports CMS's proposal to adopt a multi-year approval cycle for QCDRs. This proposal appropriately rewards QCDRs that have remained in good standing in the program and alleviates burden associated with the annual self-nomination process. It would allow group practices and QCDRs the necessary time to put in the substantial work required to develop and implement measures, especially with the increasing complexity of outcomes-related measures and the movement toward automated data integration for reporting. However, we believe that the two-year QCDR measure approval should not be subject to CMS discretion. CMS should be required to approve a QCDR measure for two years if the measure satisfies the QCDR measure requirements (with the exception of the requirement regarding the number of clinicians reporting the measure). Therefore, we urge CMS to adopt a non-discretionary multi-year approval cycle.

² *Id.* at 40,818.

2. CMS Should Publish a Separate Request for Information Followed by a Notice of Proposed Rulemaking to Seek Feedback on Incorporating QCDR Measures into MVPs

CMS is seeking public comments on whether QCDR measures should be integrated into MVPs along with MIPS measures and how CMS can continue to encourage clinicians to use QCDRs under MVPs. The Coalition is concerned that the MVP proposal is unclear and underdeveloped and that CMS has provided insufficient time for stakeholders to comment. We are worried about the impact the proposal would have on QCDRs.

The Coalition supports the integration of QCDR measures into MVPs (if CMS goes forward with implementation of MVPs) and believes that many of these measures could potentially provide credit across multiple performance categories. However, the Proposed Rule lacks sufficient detail to allow stakeholders to provide meaningful comments on how QCDR measures would be used in MVPs. Accordingly, the Coalition urges CMS to publish a separate request for information (“RFI”) followed by a notice of proposed rulemaking (“NPRM”) adequately describing how CMS will fulfill its statutory mandate to encourage the use of QCDRs under its MVP proposal. This should include the proposed integration of QCDR measures into MVPs, so that the public can provide a thoughtful response. Therefore, the Coalition urges CMS to delay adoption of any proposal to implement MVPs pending issuance of an RFI followed by an NPRM dedicated to this issue.

3. CMS Should Support Measure Development by Respecting and Protecting the Ownership Rights of QCDR Measure Developers

CMS currently allows QCDRs to seek permission from another QCDR to report on an existing measure that is owned by the other QCDR. If a QCDR would like to use an existing QCDR measure that is owned by another QCDR, it must obtain permission from the QCDR measure owner that it can use the measure for the performance period and include proof of such permission in its self-nomination application.³

Beginning with the 2020 performance period, CMS proposes that in considering whether to approve a measure, it may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the owner of the QCDR measure for purposes of MIPS. Under this proposal, CMS has the discretion to not approve a QCDR measure if it concludes that such measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs.⁴

The Coalition strongly opposes this proposal because it undermines QCDR measure ownership and development. As noted in the Coalition’s comments on the CY 2019 Quality Payment

³ Medicare Program; CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstances Policy for the Transition Year, 82 Fed. Reg. 53,568, 53,813-14 (Nov. 16, 2017).

⁴ 84 Fed. Reg. at 40,815.

Program Proposed Rule,⁵ QCDR measures clearly constitute works of authorship that are subject to ownership (through copyright protection) by the QCDRs that develop them. CMS recognized this fact in the CY 2018 Quality Payment Program Final Rule when it adopted the current policy of requiring QCDRs that wish to use the QCDR measures of another QCDR to obtain permission from the QCDR owner before using them in the MIPS program.⁶ In 2018, CMS proposed to significantly alter this policy by requiring QCDRs to license their QCDR measures to CMS without charge and allowing the agency to make them freely available to other QCDRs. After receiving substantial negative feedback about the adverse effects of the proposal, CMS decided not to finalize this mandatory licensing policy.⁷

The ability of QCDRs to license measures (and charge reasonable licensee fees or royalties) allows QCDRs to ensure the appropriate use of their measures, incentivizes organizations to invest in developing new and improved measures and is crucial to ensuring that users respect the intellectual property rights of measure developers. CMS's proposal to consider the availability of measures to other (non-owner) QCDRs as a condition of measure approval threatens to effectively nullify the right of QCDRs to ensure the appropriate use of their measures and to collect a reasonable royalty from other qualified QCDRs that wish to use them.

As with the mandatory licensing proposal, we believe that this proposal is an arbitrary and capricious reversal of the current policy, which protects the intellectual property rights of measure owners, and is in violation of the Administrative Procedure Act. CMS has failed to provide evidence that QCDRs are withholding access to their measures to qualified QCDRs—i.e., those who have clinical expertise and experience in measure development. The agency also provides no guidance as to how it will determine whether a QCDR measure is sufficiently unavailable as to warrant withholding approval of a QCDR measure. It is unclear what objective standard the agency would apply or if due process (i.e., notice and opportunity to respond) would be afforded to the QCDR measure owner, which may have legitimate reasons for denying a licensee's request (e.g., inappropriate use of the measure).

The agency makes no attempt to consider the negative effects of reversing its existing policy. For instance, withholding measure approval based on unsubstantiated concerns about lack of availability to other QCDRs would deprive eligible clinicians of an otherwise valid and useful measure to report on. In addition, putting undue pressure on QCDR measure owners to license their measures to QCDRs that do not have the experience or expertise to properly implement a measure will lead to the misclassification of care. In our collective experience, measuring the

⁵ Coalition, Comment Letter on CY 2019 Physician Fee Schedule and Quality Payment Program Proposed Rule (Sept. 10, 2018), https://www.registrycoalition.net/wp-content/uploads/2018/09/PCRC_Comments_on_CY_2019_PFS_Proposed_Rule_D0797467.pdf.

⁶ 82 Fed. Reg. at 53,813-14.

⁷ Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program-Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program-Accountable Care Organizations-Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, 83 Fed. Reg. 59,452, 59,906 (Nov. 13, 2018).

same quality measure, with the same measure specification across registries does not ensure accurate benchmarking due to inconsistencies in program implementation and data interpretation, including the lack of standardized data definitions, lack of standardized risk adjustment/data analytics, inconsistency of data ascertainment methods, and lack of common normalization methods.⁸ Ultimately, effectively requiring licensing of QCDR measures to other QCDRs will discourage the development of QCDR measures because the measure developers will have no means to ensure the appropriate use of their measures or to recoup their investments through reasonable royalty fees. This will result in a lack of data integrity across registry cohorts against which the original QCDR measure owner's participants will be benchmarked.

Based on the agency's failure to (a) provide any evidence to support its decision to adopt a policy change that violates the intellectual property rights of QCDR measure owners, (b) consider the negative effects of this policy on the development of QCDR measures, and (c) consider reasonable alternatives, the proposed policy is "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law."⁹

Accordingly, we urge CMS to not adopt its proposal to withhold measure approval based on the extent to which a QCDR makes its measures available to other QCDRs. At a minimum, it should elaborate on what criteria it would use to determine whether a measure is truly unavailable for reporting through other QCDRs and provide an opportunity for QCDR measure owners to respond to allegations of unavailability before this is allowed to be a consideration in the measure approval process. In any case, we stand ready to continue to work with CMS to ensure that QCDRs can enforce their intellectual property rights in the measures they develop, while also ensuring that the measures are readily available to other QCDRs with clinical expertise and experience in quality measure development.

4. CMS Should Support Measure Development by Explicitly Recognizing and Protecting the Ownership Rights of MIPS Measure Developers

Although CMS requires QCDRs to license QCDR measures from the QCDR measure owner, CMS has not published regulatory language, discussion, or guidance on the licensing of MIPS measures from their measure owners. In order to address concerns that certain MIPS measure stewards have been limiting or prohibiting the use of their MIPS measures by third party intermediaries, CMS proposes to adopt an additional removal criterion for when CMS determines that a MIPS quality measure is not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians.¹⁰

⁸ Ju MH et al., *A Comparison of 2 Surgical Site Infection Monitoring Systems*, 150(1) JAMA SURG. 51-57 (2015), <https://www.ncbi.nlm.nih.gov/pubmed/25426765>.

⁹ 5 U.S.C. § 706(2)(A); *see Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency action is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."). An argument can also be made that CMS's proposal would also constitute an unconstitutional taking of private property without justification or reasonable compensation. *Ruckelshaus v. Monsanto*, 467 U.S. 986, 1011 (1984).

¹⁰ 84 Fed. Reg. at 40,751-52.

As with QCDR measures, the Coalition strongly opposes this proposal because it undermines MIPS measure ownership and development. For the same reasons mentioned above, CMS should explicitly recognize and respect the intellectual property rights of MIPS measure developers in their MIPS measures. Medical societies that develop MIPS measures can and do assert copyright ownership of such measures and should be able to control their use by third parties. The copyright notice for MIPS measures typically states that the measures can be reproduced and distributed for noncommercial purposes, but commercial uses require a license agreement. Commercial uses include the direct sale, license, or distribution of the measures for financial gain, or incorporation of the measures into a product or service that is sold, licensed, or distributed for profit. Medical societies may also elect to charge a licensing fee for the use of MIPS measures.

Coalition members have learned that EHR vendors and other commercial entities are incorporating MIPS measures developed by medical societies into their products and charging their physician-customers to use such measures without entering into licensing agreements to the measure owner. In some cases, the commercial entity is making slight revisions to the measure and treating it as if it were a separate measure from the measure from which it was derived.

The assertion of copyright ownership in MIPS measures is not intended to limit physicians' ability to report on the measures, but rather to protect the integrity of the measures, ensure uniform application for reimbursement purposes and benchmarking, and incentivize organizations to invest in developing new and improved measures by limiting inappropriate use and preventing commercial entities from profiting off of the societies' intellectual property. When commercial entities, such as EHR vendors, take advantage of these measures with no accountability, the validity of the entire program suffers. The improper implementation of measures threatens the success of the Quality Payment Program because it decreases data integrity leading to misclassification of care and incorrectly penalizes good providers while rewarding poor providers. If payments to physicians are not based on actual performance on quality measures, improvements in quality of care will not be achieved and the clinicians that have the best quality of care performance may not be compensated appropriately. In addition, if commercial parties can routinely use these measures and profit off of the society's time and expense, medical societies may no longer be able to dedicate resources to developing MIPS measures. Without the contribution of medical societies, the MIPS measures available to eligible clinicians may be poorly refined and inaccurately capture quality performance.

We are concerned that the proposed removal criterion improperly interferes with MIPS measure developers' ability to monitor and control who is an appropriate licensee and user. Moreover, this proposal lacks adequate justification. CMS has failed to provide concrete evidence that MIPS eligible clinicians are being deprived access to approved MIPS quality measures. It also provides no guidance as to how CMS will determine when a MIPS quality measure is "not available."

For all of these reasons, the Coalition recommends that CMS not finalize this "unavailability" criterion as currently proposed. Instead, we urge CMS to explicitly affirm that MIPS measure developers/owners, including medical societies and clinical data registries, can enforce their

ownership rights in their measures, and that third parties wishing to use such measures must enter into licensing agreements with measure owners before they can properly use MIPS measures.

5. CMS Should Require Harmonization Only When Doing So Is Clinically Appropriate

In circumstances where similar, multiple QCDR measures exist, CMS is proposing that it may provisionally approve the QCDR measure for one year with the condition that the QCDRs must address certain areas of duplication with other approved QCDR measures for subsequent years.¹¹ QCDRs could accomplish this by either significantly differentiating the measure from other comparable QCDR measures or harmonizing the measures. If QCDR measure harmonization does not occur, the Proposed Rule would permit CMS to reject the duplicative QCDR measure. This proposal would take effect beginning with the 2020 performance period.

The Coalition supports CMS's proposal to allow QCDR measures that are identified as potentially duplicative to be provisionally approved. However, we strongly urge CMS to implement adequate safeguards to ensure that measure harmonization occurs only when it is clinically appropriate to do so.

CMS proposes to identify duplicative QCDR measures during the previous year's QCDR measure review period. However, CMS fails to provide any details regarding the criteria used to identify duplicative measures. We strongly urge CMS to publish clear guidance on when measures should be harmonized in order to ensure that contractor decisions are as uniform as possible. It is imperative that CMS contractors consult with clinicians and measurement staff in the specialty societies regarding clinical aspects of measurement. If CMS identifies a measure that needs to be harmonized, CMS should provide the clinical rationale for harmonization. In addition, CMS should implement a formal process for appealing decisions regarding measure harmonization. An appeal process would give QCDRs an opportunity to provide CMS with additional information, including if there is a clinical rationale for why measures should not be harmonized or if a measure is an appropriate derivative work of another existing measure. If the measure owner can provide a documented clinical rationale for keeping the measures separate, then CMS should not require measure harmonization.

Although we understand that CMS's goal for this policy is to avoid redundant measures, we believe that CMS should tread cautiously in determining which measures are subject to harmonization. We encourage CMS to consider the level of rigor in evidence or testing process between QCDRs prior to requesting harmonization. In identifying related and competing measures, CMS should base its determination on a comparison of the technical specifications, rather than measure titles. Furthermore, we believe that there are particular instances where harmonization is inappropriate. For instance, measure harmonization is not appropriate where one QCDR is effectively trying to use another QCDR's measure without license or compensation. We also believe that CMS should only reject an existing measure with baseline

¹¹ *Id.* at 40,817-18.

performance data in favor of a new measure when the new measure is able to accrue a similar level of such data.

We are also concerned that the problems of inaccurate use of measures by QCDRs that do not have appropriate experience or expertise in the field of medicine covered by the measure would be exacerbated by CMS's proposed harmonization policy. There is no accountability for how such QCDRs would report on the same measures and no standardization for how they would use data. Even if a QCDR meets CMS's revised definition of a qualified QCDR by having clinical expertise and experience in measure development, that does not guarantee the QCDR will have relevant expertise or experience in the specialty or treatment area covered by a particular measure. Registries with less expertise on how to accurately implement measures may use different standards or employ inconsistent methods for obtaining, risk adjusting, and aggregating data, which creates variation in how providers are measured and how their care is classified, as discussed above. Given the inconsistencies in implementation and methods, harmonizing measures across registries does not ensure accurate benchmarking. Therefore, the Coalition recommends that CMS implement appropriate safeguards to ensure that measure harmonization occurs only when doing so is clinically appropriate.

6. CMS Should Not Require QCDR Measures to Be Fully Developed and Tested Prior to Self-Nomination

Beginning with the 2021 performance period, CMS is proposing to require that *all* QCDR measures submitted at the time of self-nomination be fully developed and tested with complete testing results at the clinician level. Although CMS notes that the testing process for measures is dependent on the type of measure, it specifically refers to the National Quality Forum's ("NQF's") guidance on measure testing criteria and standards.¹²

The Coalition strongly opposes this overly burdensome, "one-size fits all" proposal, as it would stifle measure development and possibly lead to increases in licensing fees or registry participation fees for clinicians. This proposal fails to recognize the many deliberate and defensible steps used in developing QCDR measures. Quality measures submitted by QCDRs are created by subject matter experts, undergo significant expert vetting, and are supported by literature, guidelines, and preliminary data, providing rigorous face validity for each measure. Currently QCDRs typically review performance data before and after implementing a measure in the registry (although measure testing after implementation is not necessary in every instance). However, most QCDRs do not complete measure testing according to the standards outlined in the Proposed Rule. The proposed measure testing requirements lack justification and would place undue burden on physicians and their practices that would necessarily need to be engaged in the testing. Full measure testing as proposed by CMS prior to self-nomination would require QCDRs to reach out to practices and other participating providers to ask for volunteers for measure testing and chart reviews to test the validity of every measure on which the QCDR plans to report. Further, it would require QCDRs to invest significantly more resources in terms of time and money on the testing process, and such expenses would need to be recouped.

¹² *Id.* at 40,816-17.

Submitting a measure for endorsement by NQF or some similar entity would require even more time and resources and would likely require some costs to be passed on to practices. Given the heightened level of measure review, QCDRs may encounter barriers to recruiting practices to volunteer for measure testing. The additional time and costs associated with NQF-type endorsement will deter the development of QCDR measures. Most QCDRs are administered by nonprofit medical societies that do not have the resources available to fully test all of their QCDR measures according to the testing standards proposed.

Mandating measure testing may actually cause some QCDRs to cease measure development altogether. Some QCDR measure developers may be forced to increase measure licensing fees to cover the increased cost of measure testing or to increase fees for clinicians participating in the registries. We ultimately believe that this proposal is contrary to MACRA's requirement to encourage the use of QCDRs for reporting measures, especially given that MIPS measure developers are not subject to this proposed testing requirement.

For these reasons, we urge CMS to reconsider and withdraw this proposal. There are other ways CMS could verify measure rigor, including by using the QCDR's robust data sets outside of the full measure testing outlined in the Proposed Rule. We would greatly appreciate an opportunity to work with CMS to establish alternative ways of determining the validity of new measures. By withdrawing this proposal and conferring with stakeholders regarding testing methodologies, QCDRs would be afforded time to adequately prepare for any new testing requirement prior to self-nomination.

7. CMS Should Not Require QCDRs to Collect Certain Data on QCDR Measures Prior to Self-Nomination

Beginning with the 2021 performance period, CMS proposes that QCDRs must collect data on a QCDR measure, appropriate to the type of measure, prior to submitting the QCDR measure for CMS consideration during the self-nomination period. CMS is proposing to require that the "data collected must demonstrate whether the QCDR measure is valid and reflects an important clinical concept(s) that clinicians wish to be measured on."¹³

As a general matter, we recognize the importance of collecting data on QCDR measures and the value in collecting data as early as possible. This proposal, however, would establish an unrealistic and unduly burdensome deadline for the collection of data on new measures. To comply with this new requirement, QCDRs would need time to adjust their operational workflows, including the quality measure development cycles. Some QCDRs convene technical expert workgroups to meet in the summer to refine existing and develop new measures for the following year, and this timeframe would not allow for the required data collection in the Proposed Rule. We hope to work with CMS on a timeline that is feasible and leads to properly functioning QCDRs that can meet the goals of the MIPS program.

¹³ *Id.* at 40,817.

8. CMS Should Provide Clarification Regarding Linking QCDR Measures to a Cost Measure, Improvement Activities and/or an MIPS Value Pathway (“MVP”)

CMS proposes that, beginning with the 2021 performance period, QCDRs must “link their QCDR measures to the following at the time of self-nomination: (i) Cost measure, (ii) improvement activity, (iii) an MVP.”¹⁴ It is unclear, however, whether CMS would require QCDRs to link the QCDR measure to one or all three of the aforementioned, enumerated items. Throughout the preamble of the Proposed Rule, CMS interchangeably uses the terms “and” and “or” when describing this proposal, and we seek clarification regarding whether QCDRs must link their measures to a cost measure, improvement activity, or a CMS-developed MVP.

As a threshold matter, we appreciate CMS’s recognition that not all measures may have a direct link to a cost measure or improvement activity and support the agency’s proposed exception for QCDR measures that lack a clear connection to a cost measure, improvement activity, or an MVP. Beyond that, the Coalition members have a variety of views on this proposal. We refer CMS to the comment letters of individual Coalition members for their different perspectives on this issue.

9. CMS Should Issue a Separate RFI Followed by an NPRM on its Proposal to Require All QCDRs to Provide Educational Services in Quality Improvement and Leading Quality Improvement Initiatives

CMS is proposing to require QCDRs, beginning with the 2023 MIPS payment year, to foster services to clinicians and groups to improve the quality of care furnished to patients by “providing educational services in quality improvement and leading quality improvement initiatives.”¹⁵ CMS provides specific examples of broad quality improvement services and individual clinical process-specific quality improvement services. The agency clarifies that these QCDR quality improvement services are distinct from activities that are reported on under the improvement activities performance category.¹⁶

We agree, in principle, that QCDRs can play an important role in providing educational services to promote quality improvement. However, implementing new educational services will likely require most QCDRs to expend considerable resources. The Coalition needs substantially more information and time to evaluate the feasibility and value of CMS’s proposal. We, therefore, urge CMS to not impose this requirement on all QCDRs at this time. Instead, we ask that CMS publish a separate RFI followed by an NPRM that describes this proposal in more detail so that the public can provide a more thoughtful response.

¹⁴ *Id.* at 40,926.

¹⁵ *Id.* at 40,813.

¹⁶ *Id.*

10. CMS Should Not Require QCDRs to Audit All Three MIPS Performance Categories (Quality, Improvement Activities, and Promoting Interoperability)

Currently, CMS permits QCDRs to submit data for any of the following MIPS performance categories: Quality, Promoting Interoperability, and improvement activities. CMS proposes, beginning with the 2021 performance period, that QCDRs must be able to submit data for all three MIPS performance categories.

Although members of the Coalition have differing perspectives on whether QCDRs should be required to submit data for all three performance categories, we unanimously oppose CMS's proposal to the extent it can be interpreted to require QCDRs to *audit* all three performance categories, as such a requirement would be exceedingly difficult. CMS is seemingly requiring this in the 2020 self-nomination process, which is not reasonable. Although QCDRs encourage all clinicians to enter quality performance data often and in a timely manner to ensure that they can identify quality improvement opportunities as soon as possible, not all clinicians have incorporated this activity into their daily/weekly operations. In fact, a large percent of clinicians who are manually entering quality performance data do not complete this task until late in the fourth quarter of the year. However, a proposal requiring QCDRs to audit all three performance categories would require QCDRs to initiate audit activities early in the fourth quarter of the year to ensure timely completion prior to CMS submission.

With regard to Promoting Interoperability, the data submitted for this MIPS performance category is essentially an attestation. Physicians copy and paste the numerators and denominators for the measures from a report provided by their EHR. Although QCDRs can conduct a randomized audit requesting to examine the report from the EHR that lists the Promoting Interoperability measure data, any errors discovered will be errors on the part of the practice or physician, not the QCDR. Further, we are concerned that EHR vendor companies are charging practices to run these reports when a third party entity (such as a QCDR) requests them. The Office of the National Coordinator for Health IT Interoperability and Data Blocking final rules have yet to be published, so there are no codified policies governing this type of data blocking. If CMS requires a detailed audit on attestation categories, further guidance is needed.

It would also be unreasonable to require QCDRs to audit improvement activities. As an initial matter, in the 2019 MIPS Improvement Activities Performance Fact Sheet, CMS indicated that it “will validate data on an ongoing basis.”¹⁷ Requiring QCDRs to validate improvement activities imposes undue burden on QCDRs to perform an activity that CMS has openly stated it will perform. For QCDRs to implement an improvement activity audit for performance year 2019 and 2020, they would need to contact clinicians/practices, describe what documentation is required, and review and confirm that documentation is appropriate. Moreover, CMS has failed to fully define what constitutes “improvement activities,” which creates operational challenges in auditing such activities. It is also unclear what, if any, documentation would be required to demonstrate that such audit activity occurred.

¹⁷ CMS, *2019 Merit-based Incentive Payment Program (MIPS) Improvement Activities Performance Category Fact Sheet*, 8, <https://www.asge.org/docs/default-source/practice-support/qualifies-as-mips-improvement-activity.pdf> (last visited Sept. 11, 2019).

Therefore, we urge CMS to refrain from requiring QCDRs to audit all three MIPS performance categories.

11. CMS Should Provide an Exception to the Performance Feedback Requirement When the QCDR Does Not Receive Data Until the End of the Performance Period

CMS currently requires QCDRs to submit timely performance feedback at least four times a year on the MIPS performance categories that the QCDR reports to CMS. CMS is proposing that, beginning with the 2023 MIPS payment year, QCDRs must provide performance feedback at least four times a year to their clinicians and groups, and provide specific feedback to their clinicians and groups comparing them to other clinicians who have submitted data on a given measure within the QCDR. In the Proposed Rule, CMS proposes that an exception “to this requirement *may* occur if the QCDR does not receive the data from their clinician until the end of the performance period.”¹⁸ In fact, CMS has received feedback from QCDR stakeholders that they are unable to provide meaningful feedback to their clinicians four times a year because some clinicians wait until the end of the performance period to submit data to the QCDR.¹⁹ In addition, some hospital-based physicians are unable to access hospital data in a timely manner or at all.

The Coalition agrees that in many instances, clinicians do not submit data to QCDRs until the end of the performance period. As currently drafted, the Proposed Rule permits, but does not require, an exception when the QCDR does not receive data until the end of the performance period. The Coalition urges CMS to explicitly adopt an exception to the performance feedback requirement when the QCDR is not in receipt of data until the end of the performance period. In addition, we encourage CMS to incentivize hospitals to make available data to hospital-based physicians for purposes of MIPS reporting.

12. CMS Should Not Adopt a Higher Data Completeness Criteria/Threshold

In the Proposed Rule, CMS seeks to increase the data completeness criteria to 70 percent for the 2022 MIPS payment year. The agency also proposes to adopt a higher data completeness threshold for the 2020 MIPS performance period, such that MIPS eligible clinicians and groups submitting quality measure data on QCDR measures, electronic clinical quality measures (“eCQMS”), and MIPS CQMs must submit data on at least a 70 percent of the MIPS-eligible clinician’s or group’s patients that meet the measure’s denominator criteria, regardless of payer for the 2020 MIPS performance period.²⁰

We are concerned that this proposal will place a heavy burden on eligible professionals in small and rural practices without EHRs. The additional time it would take to hand enter the increased volume of data would likely eliminate these eligible professionals and practices from participation in the MIPS program because they do not have access to any other reporting

¹⁸ *Id.* at 40,814.

¹⁹ *Id.*

²⁰ *Id.* at 40,747-48.

mechanism. The increase seems counter to CMS's overall strategy to reduce burden while improving quality. The inability to participate in MIPS could cause some eligible professionals to choose not to participate in the Medicare program. Accordingly, we would urge CMS to either refrain from making this change or create an exception for eligible practitioners in small or rural practices.

We should also note that although the data completeness threshold has continued to increase, the Promoting Interoperability performance category has failed to advance alongside it. The Promoting Interoperability performance category does not require the advanced health information technology capacity that should accompany an increased threshold for data completeness. The Promoting Interoperability program in its current state does not support the data model needed for a true value-based program.

13. CMS Should Finalize Its Proposal to Reweight Performance Categories for a MIPS Eligible Clinician Who Has Compromised Performance Category Data Due to Circumstances Outside of the Control of the Clinician or Its Agents

CMS currently assigns different weights to the performance categories and redistributes weight from one performance category to another under certain circumstances where it determines that reweighting is appropriate. Under the current regulatory regime, these circumstances do not include incidences where a MIPS eligible clinician or the clinician's agent submits data that are inaccurate, unusable, or otherwise compromised.

Beginning with the 2018 MIPS performance period and 2020 MIPS payment year, CMS is proposing to reweight the performance categories for a MIPS eligible clinician who has performance category data that are inaccurate, unusable, or otherwise compromised due to circumstances outside of the control of the clinician or its agents, including third-party intermediaries, as long as CMS learns of the relevant information prior to the beginning of the associated MIPS payment year.²¹

The Coalition supports CMS's proposal to reweight scores in the above circumstances, especially if it includes situations where data is compromised due to third-party vendor performance issues. Clinicians, practices, and their third-party intermediaries (including QCDRs) should not be held accountable for submission issues outside of their control.

* * * * *

The Coalition appreciates CMS's attention to these important issues. We are concerned that many of the aforementioned proposals are contrary to MACRA's requirement to encourage the use of QCDRs for reporting MIPS measures. In fact, given the limited resources available to nonprofit specialty societies and the increasing burden CMS is imposing on QCDRs, some Coalition members are no longer seeking certification as a QCDR for their registries, which is

²¹ *Id.* at 40,797.

Ms. Seema Verma, MPH

September 27, 2019

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discouraging given the success these registries have had in promoting quality improvement and facilitating MIPS reporting for their member physicians.

We urge the agency to adopt the Coalition's suggestions to facilitate and promote the use of QCDRs and other clinical outcomes data registries. The goal is to allow the use of registries to grow and ultimately result in even greater improvements in the quality of patient care. We encourage CMS to adopt policies across the board to further incentivize the development of high quality measures and avoid imposing unduly burdensome requirements on QCDRs that conflict with and impede the critical role that registries play in improving patient outcomes and quality of care.

Thank you for the opportunity to submit these comments. If you have any questions, please contact Rob Portman at Powers Pyles Sutter & Verville, PC (Rob.Portman@PowersLaw.com or 202-872-6756).

Respectfully submitted,

American Academy of Dermatology
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American College of Emergency Physicians
American College of Gastroenterology
American College of Radiology
American College of Rheumatology
American Society for Gastrointestinal Endoscopy
American Society for Radiation Oncology
American Society of Clinical Oncology
American Society of Nuclear Cardiology
American Society of Plastic Surgeons
American Urological Association
College of American Pathologists
Congress of Neurological Surgeons
North American Spine Society
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons



October 24, 2019

Via Electronic Mail

Dr. Daniel Green, MD
Ms. Sophia Sugumar
Quality Measurement and Value-Based Incentives Group
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Department of Health and Human Services
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Daniel.Green@cms.hhs.gov
Sophia.Sugumar@cms.hhs.gov

RE: QCDR Pre-Submission Audits of MIPS Improvement Activities and Promoting Interoperability Categories

Dear Dr. Green and Ms. Sugumar:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition) write to express our concerns regarding the Centers for Medicare and Medicaid Services' (CMS's) requirement for pre-submission audits by Qualified Clinical Data Registries (QCDRs) and Qualified Registries (QRs) of the Improvement Activities (IA) and Promoting Interoperability (PI) categories of the Merit-based Incentive Payment System (MIPS). The Coalition is a group of medical society-sponsored clinical data registries that collect and analyze clinical outcomes data to identify best practices and improve patient care. We are committed to advocating for policies that encourage and enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of clinical outcomes. Most of the members of the Coalition have been approved as QCDRs or are working towards achieving QCDR status.

The Coalition commented on this provision in the 2020 Quality Payment Program (QPP) Proposed Rule. Significantly more concerning is that on recent CMS QCDR vendor support calls, CMS expressed the intent, purportedly under the authority of the 2017 Final Rule, that all randomized audits and subsequent detailed audits must be completed for ALL MIPS performance categories supported by a QCDR, not just Quality. In addition, CMS said that all such audits must occur prior to submission of data to CMS. CMS also stated that while it has not previously enforced this requirement for Performance Year (PY) 2017 and PY2018 Data Validation Reports, adherence to both of these criteria would be required for PY2019 and all future years.

It appears that based on feedback during those vendor support calls, CMS retracted this edict in the minutes of the call, published in September. Because societies expect the minutes to reflect what was stated in the call, it was unclear to most societies that CMS had retracted the mandate for PY2019. Because this new edict was stated emphatically on a vendor call, and societies were not separately notified of the retraction (except for the buried statement in the minutes of the call), **we urge CMS to issue a separate notice of its retraction of the broader PY2019 audit requirements and to be more transparent in the future about announcing substantive program changes.**

While the Coalition appreciates that CMS has retracted the requirement for registries to also audit the IA and PI categories of MIPS this year, the overarching concerns about registry responsibilities for auditing MIPS program data remains. We elaborate on those concerns below.

Improvement Activities (IA) Performance Category Audit

CMS has provided very limited guidance as to what constitutes appropriate documentation for each Improvement Activity and has previously stated that CMS will be responsible for validating data for Improvement Activities.¹ We believe the arbitrary requirement that QCDRs validate the Improvement Activities shifts an undue burden to QCDRs to perform an activity that CMS should be conducting. If CMS is now committed to a model where QCDRs will be responsible for the Improvement Activities audit, we request that this requirement be retracted (or at least postponed until PY2021) for the following reasons:

1. CMS has not provided QCDRs with appropriate guidance to complete such an audit. We respectfully request CMS clearly define what CMS considers to be primary source documentation for each individual Improvement Activity. This will (a) ensure all eligible clinicians understand what will be required of them during an Improvement Activities audit, and (b) provide clear direction to QCDRs as to what documentation CMS will find appropriate.
2. QCDRs would only be able to implement an Improvement Activities audit for PY2020 with a totally manual process. Contacting clinicians/practices, describing what documentation is needed and reviewing and confirming whether documentation is appropriate, would place an undue burden on QCDRs.

¹ Centers for Medicare and Medicaid Services, *2019 Merit-based Incentive Payment Program (MIPS) Improvement Activities Performance Category Fact Sheet*. Retrieved from <https://qpp.cms.gov/mips/improvement-activities>.

Given that CMS has not made primary source documentation available and has not given QCDRs sufficient time to automate the collection of Improvement Activities documentation, we strongly urge CMS to rescind this new and unexpected requirement.

At a minimum, CMS should delay implementation until at least PY 2021. A delay in implementation would allow CMS to develop and disseminate appropriate guidance to QCDRs by the PY2021 Self Nomination deadline to ensure all QCDRs clearly understand the agency's expectations and know what they are committing to prior to submission of the 2021 QCDR Self Nominations. This delay might also allow QCDRs to automate the collection of the Improvement Activities documentation, reducing the ultimate burden on the clinicians/practices when performing an audit.

Performing Interoperability (PI) Performance Category Audit

The data submitted for the PI category is essentially an attestation. Physicians copy and paste the numerators and denominators for the measures from a report provided by their Electronic Health Records (EHRs). While QCDRs can perform a randomized audit asking to see the report from the EHR that lists the PI measure data to ensure the data was transposed properly, any errors discovered will be errors on the part of the practice or physician, not the QCDR. Further there is a worry that EHR vendor companies are charging practices to run these reports when a third-party entity (such as a QCDR) requests them. The Office of National Coordinator's (ONC's) Interoperability and Data Blocking Final Rules have yet to be published, so federal policies have not yet been codified in rulemaking that QCDRs can point to when an instance of data blocking of this type occurs. Overall though, there is little QCDRs can do to perform a detailed audit on attestation categories. We urge CMS to withdraw this requirement, but if CMS plans to move forward, further guidance and additional implementation time needs to be provided.

Common Concerns about Audit Requirements

In addition to the category specific concerns outlined above, the Coalition has concerns that would apply to audits for both the IA and PI categories. Specifically, QCDRs/QRs have no official role, delegated authority, or guidance from CMS as a CMS auditor. As such, if a practice disagrees with the decision of a QCDR audit, there is no clear path as to how a QCDR could respond and be supported in their decision by CMS. There could also be financial and legal consequences in a situation where a practice passes the QCDR audit but subsequently fails a CMS audit. This exposes the QCDR to financial and legal action from practices that perceive an error on the QCDR's part. In order to protect QCDRs from additional financial and legal burdens, CMS should allow IA and PI submissions that QCDRs receive be sent to CMS' QPP helpdesk so that the helpdesk can provide guidance to QCDRs on whether each submission can be accepted/approved. This QPP review could then serve as a final determination on any future audit.

Dr. Daniel Green, MD
Ms. Sophia Sugumar
October 24, 2019
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For these reasons, the Coalition strongly urges CMS to withdraw, or at least significantly postpone, the requirement that QCDRs perform mandatory randomized audits for the MIPS Improvement Activities and Promoting Interoperability categories prior to CMS data submission. Not only does CMS' arbitrary mandate impose additional burdens on QCDRs, it puts them in a position of having to decide whether practices have successfully met criteria and documentation that are not sufficiently defined by CMS.

Thank you for the opportunity to submit these comments. If you have any questions, please contact Rob Portman at Powers Pyles Sutter & Verville, PC (Rob.Portman@PowersLaw.com or 202-872-6756).

Respectfully submitted,

American Academy of Dermatology/Association
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Orthopaedic Surgeons
American Academy of Otolaryngology – Head & Neck Surgery
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American College of Emergency Physicians
American College of Gastroenterology
American College of Radiology
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Society for Gastrointestinal Endoscopy
American Society of Anesthesiologists/American Quality Institute
American Society of Clinical Oncology
American Society of Nuclear Cardiology
American Society of Plastic Surgeons
American Urological Association
College of American Pathologists
Congress of Neurological Surgeons
North American Spine Society
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons

Cc: Kate Goodrich, MD, MHS, Director/Chief Medical Officer, Center for Clinical Standards & Quality, CMS (Kate.Goodrich@cms.hhs.gov)



PHYSICIAN CLINICAL REGISTRY COALITION

December 11, 2019

Via Electronic Mail

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Daniel.Green@cms.hhs.gov
Sophia.Sugumar@cms.hhs.gov

RE: QCDR Measure Testing Requirement

Dear Dr. Green and Ms. Sugumar:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition)¹ write to express our concerns regarding the Centers for Medicare and Medicaid Services' (CMS's) requirement that Qualified Clinical Data Registries (QCDRs) must fully test their QCDR measures prior to including them in their self-nomination applications. This letter provides additional background on this issue in preparation for our upcoming call with CMS staff.

We greatly appreciate CMS's willingness to meet with us to discuss important issues impacting registries, including the new measure testing requirement. As you know, the Coalition opposed this measure testing requirement in the 2020 Quality Payment Program (QPP) proposed rule (2020 QPP Proposed Rule).² Nonetheless, CMS finalized its proposal that beginning with the 2021 performance period, all QCDR measures must

¹ As you know, the Coalition is a group of medical society-sponsored clinical data registries that collect and analyze clinical outcomes data to identify best practices and improve patient care. We are committed to advocating for policies that encourage and enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of clinical outcomes. Most of the members of the Coalition have been approved as QCDRs or are working towards achieving QCDR status.

² Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations, 84 Fed. Reg. 40,482 (Aug. 14, 2019).

be fully developed with completed testing results at the clinician level prior to submitting the QCDR measure at the time of self-nomination.³ Under the final rule (2020 QPP Final Rule), all QCDR measures, regardless of whether they have been approved for previous performance periods or are new QCDR measures, will be expected to meet this new QCDR measure testing requirement to be approved for the 2021 performance period and beyond.⁴ The agency acknowledged that small specialties may lack the resources to comply with this testing requirement, but stated that the benefits of completed measure testing far outweigh the increased time and cost burdens associated with this requirement.⁵ CMS also stated that it believes it would be inappropriate to have untested measures within the Merit-based Incentive Payment System (MIPS) program because clinician's performance on measures directly affects their payments and it may lead to issues with the measure mid-performance period.⁶

As noted in our comments on the 2020 QPP Proposed Rule, the Coalition strongly opposes this requirement because it is not attainable for most, if not all, QCDRs and will, therefore, either cause QCDRs to submit far fewer measures or drop out of the MIPS program altogether. The cost of measure testing is significant. Coalition members have received estimates from vendors that perform measure testing that the cost of testing *each* QCDR measure can range between \$30,000 and \$100,000. For QCDRs that steward numerous measures, the cost of fully testing all of their measures could be in the millions of dollars. This is an expense that nonprofit medical societies cannot bear.

Moreover, certain measure testing vendors have indicated to Coalition members that it would be impossible to complete the testing process by the September 1, 2020 self-nomination deadline for the 2021 performance period. While there has been some discussion about QCDRs leveraging their databases to reduce the cost of testing, this may not be an option for new or substantially modified measures, and there is simply not enough time to explore and develop these other options and complete testing before the September 1st deadline.

We understand CMS's desire that all QCDR measures be appropriate, reliable, and valid. But, as noted in our 2020 QPP Proposed Rule comments, quality measures submitted by QCDRs are created by subject matter experts, undergo significant expert vetting, and are supported by literature, guidelines, and preliminary data, providing rigorous face validity

³ Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule, 84 Fed. Reg. 62,568, 63,067 (Nov. 15, 2019).

⁴ *Id.*

⁵ *Id.* at 63,066.

⁶ *Id.*

for each measure. Currently, QCDRs typically review performance data before and after implementing a measure in the registry. Also, as required by the 2020 QPP Final Rule, QCDRs now must provide performance data that can help demonstrate that QCDR measures are feasible and reliable. All of these combined factors, along with the recently implemented requirement to demonstrate measure development expertise, should give CMS confidence that QCDR measures submitted by medical societies will be appropriate. It is unlikely that the expense of conducting testing will result in many changes to measures, and certainly will not make enough of a difference to justify the significant expense.

Lastly, many of CMS's justifications for the forced testing requirement suggest that the agency thinks that all MIPS measures are tested prior to implementation. There is no such requirement in the QPP rules, and we know for a fact that numerous MIPS measures are not tested at all, let alone before being approved for use in the program.

In short, the Coalition continues to believe that CMS's new measure testing requirement is unreasonable, particularly given the short and infeasible timeline. The new requirement will impose unreasonable cost and other burdens on QCDRs, and such costs will impede measure development, and cause many QCDRs to cease measure development altogether or leave the program. It will significantly impact physicians participating in MIPS by drastically reducing the number of specialty QCDR measures in the program. This requirement fails to recognize the significant investments that QCDRs have already made in measure development and implementation, including the many steps used in developing QCDR measures to ensure their reliability and validity. More generally, the Coalition believes that CMS should adopt a more strategic approach to MIPS and QCDR measure selection and testing to ensure that measures are appropriate, reliable, and valid. The Coalition welcomes the opportunity to assist CMS in establishing such an approach.⁷

For these reasons, we continue to believe that this rule is contrary to the Medicare Access and CHIP Reauthorization Act of 2015's (MACRA's) requirement to encourage the use of QCDRs for reporting measures, especially given that MIPS measure developers are not subject to this testing requirement.

As an alternative to requiring full measure testing by September 1, 2020, CMS should accept the submission of performance data for each QCDR measure instead of requiring QCDR measure testing in accordance with the CMS Measures Management System Blueprint. This would be an appropriate alternative because performance data provides important insight into the usability, feasibility, and performance of the measure. In

⁷ For instance, CMS and the clinical community should set specific quality goals for an episode of care and implement measures that can track to an impact on patient expectations and outcomes. Currently, the entire CMS measure enterprise is mostly ad hoc and largely still based on billable services. The strategic and operational limitations within the measure framework need to be better defined, and a better solution is needed for measuring quality as part of a payment program consistent with various care models.

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addition to the performance data, QCDRs could provide comments to CMS regarding the face validity of measures and any technical issues with vendors in terms of implementing and mapping the measures.

Alternatively, CMS could “grandfather” in existing QCDR measures. For new or substantially modified measures, CMS could provide provisional approval for the measure’s first year in use by QCDRs under the MIPS program, with the requirement that testing data be submitted the following year. This more reasonable timeline would provide QCDRs time to engage a reputable testing vendor and conduct robust measure testing. In addition, this timeline more closely aligns with QCDRs’ measure development cycles, which would prevent unexpected measure disruptions for clinicians and practices when modifications to a measure are necessary.

The Coalition also supports an exemption for any measure for which CMS requests harmonization or modification prior to use. Testing the modification prior to implementation would not be feasible given the current timeline.

If the agency is not willing to reconsider the measure testing requirement or our proposed alternatives, we would respectfully and urgently request a one-year delay in the implementation of this new policy. As noted above, it is simply not feasible for QCDRs to initiate and complete the testing process before the September 1, 2020 deadline. A delay would at least permit QCDRs to investigate the different options and methodologies for testing their measures, prioritize the measures they are able to test, and try to gather the resources necessary to cover the significant cost of testing their measures. The sooner a delay can be implemented the better, as QCDRs must take steps now if they are going to meet the September 1st deadline for at least a few of their measures.

We look forward to discussing this issue in our upcoming in-person meeting. If you have any questions before then, please contact Rob Portman at Powers Pyles Sutter & Verville, PC (Rob.Portman@PowersLaw.com or 202-872-6756).

Respectfully submitted,

American Academy of Dermatology
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Orthopaedic Surgeons
American Academy of Otolaryngology – Head & Neck Surgery
American Academy of Physical Medicine & Rehabilitation
American Association of Neurological Surgeons
American College of Emergency Physicians
American College of Gastroenterology
American College of Radiology

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American College of Rheumatology
American College of Surgeons
American Society for Gastrointestinal Endoscopy
American Society for Radiation Oncology
American Society of Anesthesiologists/Anesthesia Quality Institute
American Society of Clinical Oncology
American Society of Nuclear Cardiology
American Society of Plastic Surgeons
American Urological Association
College of American Pathologists
Congress of Neurological Surgeons
North American Spine Society
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons

cc: Kate Goodrich, MD, MHS, Director/Chief Medical Officer, Center for Clinical Standards & Quality, CMS (Kate.Goodrich@cms.hhs.gov)
Michelle Schreiber, MD, Director, Quality Measurement and Value-Based Incentives Group, CMS (Michelle.Schreiber@cms.hhs.gov)

QCDR Measure Testing Discussion Draft

Key issues:

- CMS requests that all QCDR measures (both previously approved/new) must be fully tested at the clinician level to be approved for the 2021 performance period and beyond
- Self-nomination deadline 9/1/2020 is not adequate for measure testing (confirmed by senior methodologist at NQF)
- QCDRs need to understand available testing options that would meet the expectations of the CMS Blueprint to plan for timely testing within the given measure steward/non-profit entity's budget year. The QCDRs and specialty societies that established them view themselves as partners with CMS in the success of the program, different from the for-profit vendors that support other reporting submission mechanisms.
- QCDRs need more options that are feasible, timely, and less costly
- Important data accessibility issues limit testing by QCDRs (e.g., IRBs (QI v research designation), inability to host protected PHI data)

CMS Rule and Comments

CMS Rule

As stated in the CY 2020 PFS proposed rule (84 FR 40816 through 40817), we proposed that all QCDR measures submitted at the time of self-nomination must be fully developed with completed testing results at the clinician level, as defined by the CMS Blueprint for the CMS Measures Management System (available at <https://www.cms.gov/Medicare/QualityInitiatives-Patient-AssessmentInstruments/MMS/Downloads/Blueprint.pdf>), and as used in the testing of MIPS quality measures prior to the submission of those measures to the Call for Measures.

As a reminder, we do not currently require QCDR measures to be NQF endorsed in order to be approved for use in the program. We believe in utilizing the existing NQF testing standard without variation, to avoid inconsistencies that may result from substandard results. We understand that measure testing requires an additional level of effort, cost, and time, but believe that measure testing ensures that measures are reliable, valid, and feasible. By completing this testing, QCDRs will avoid instances of discovering mid-year that their measure is not feasible or collectible, and will avoid adding to clinician reporting burden.

Comments:

- *There is no testing standard "without variation" as stated in the rule. NQF testing standards offer a wide variety of testing approaches*
 - From NQF Scientific Advisory Panel: Key points for evaluating Scientific Acceptability
 - NQF is not prescriptive about how empirical testing is done; similarly, NQF has not set minimum thresholds for reliability and validity results
- *NQF testing standards currently allows for **face validity** for new measures and for existing measures, with justification (see Current Testing Requirements)*
 - From Scientific Advisory Panel: Key points for evaluating Scientific Acceptability

- For new measures, we allow face validity (subjective determination by experts that the measure appears to reflect quality of care, done through a systematic and transparent process, that explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality, with degree of consensus and any areas of disagreement provided/discussed). For maintenance measures, empirical testing is expected; however, face validity may be accepted if you accept the justification provided by the developer for why empirical testing was not conducted.
- CMS states that “by completing this testing, QCDRs will avoid instances of discovering mid-year that their measure is not feasible or collectible, and will avoid adding to clinician reporting burden”
 - *This comment refers to feasibility testing; not formal reliability/validity testing*
 - *If measure can be reported, it is inherently feasible*

Proposed Testing Options for CMS Discussion

1) Existing QCDR Measures

- a. Submission of face validity for existing measures with agreed upon documentation and descriptive statistics (as noted in NQF guidance)
- b. Grace period for reliability testing: Provide one-year delay to submit reliability testing (data element OR measure score)
 - Potential exception: Existing measures with benchmarking (52/712 measures for 2020) where measure score reliability testing could be readily submitted (only requires numerator, denominator, and exclusions)
- c. Testing exception needed for measures targeted for harmonization by CMS
- d. After submission of initial testing results, no expectation for repeat testing unless the measure has been substantially changed. CMS’s support for measure stability would ensure that registries can assess trends in performance over time.

2) New QCDR Measures

- a. Submission of face validity for new measures with agreed upon documentation and descriptive statistics (as noted in NQF guidance)
- b. Grace period for reliability testing: Provide two-year delay to submit reliability testing (data element OR measure score). The two-year period aligns with CMS rule that measures that without data submission will be removed from QCDR program.
- c. Consider incentive (QI credit/bonus points) for practices that choose to submit data on new measures (since they will not likely achieve maximal score on new measures)
- d. Testing exception needed for measures targeted for harmonization by CMS