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PHYSICIAN CLINICAL REGISTRY COALITION

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Via Electronic Mail

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Room S3-02-01
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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.

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

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

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