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PHYSICIAN CLINICAL REGISTRY COALITION

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VIA ELECTRONIC MAIL

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8013
Room S3-07-17
Pierre.Yong@cms.hhs.gov

Re: Concerns Regarding QCDR Measure Review and Self-Nomination Process

Dear Dr. Yong:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition)[1] are writing to express our concerns about the difficulties we have experienced with the Qualified Clinical Data Registry (QCDR) measure review and self-nomination process under the Merit-based Incentive Payment System (MIPS), which was established by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). While we appreciate the efforts that your office has made to increase the flexibility and responsiveness of the QCDR program, there are several areas that still require improvement.

We recognize that the CY 2018 Updates to the Quality Payment Program (QPP) proposed rule (CY 2018 proposed rule) addresses some aspects of the data submission process by third-party intermediaries.[2] We plan to comment on the proposed rule through the official rulemaking process, but believe the issues we describe in this letter warrant a separate letter and immediate attention and discussion. We offer these comments as part of our continuing dialogue with your office about these important matters.

We previously sent a letter to you dated October 29, 2016 in which we discussed concerns about emails from the Centers for Medicare & Medicaid Services (CMS) Physician Quality Measures

[1] The Coalition is a group of more than 20 medical societies and other physician-led organizations that sponsor clinical data registries that collect identifiable patient information for quality improvement and patient safety purposes to help participating providers monitor clinical outcomes among their patients. We are committed to advocating for policies that enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of these outcomes. Over half the members of the Coalition have been approved as qualified clinical data registries and most of the others are working toward that goal.

[2] *See* 82 Fed. Reg. 30,010 (June 30, 2017).

Management (PQMM) Team to QCDRs regarding consolidation of proposed non-Physician Quality Reporting System (PQRS) quality measures with a variety of other measures.[3] In our previous letter, we noted how the QPP team sent these emails to QCDRs without any notice or warning and did not consult with QCDRs before recommending changes to measures.[4] During the 2017 QCDR self-nomination and measure review process, Coalition members have experienced a similar unstructured and disorganized process that has created confusion and frustration. While the QCDR entity approval process took a couple of months, the QCDR measures review process was condensed into timeframe of only a few weeks. This rushed review period caused some of the confusion and disorganization outlined in this letter, as the measures review is the more time-consuming part of the QCDR reporting process and should be allotted a longer review period than the QCDR entity approval process. We detail our concerns below and would like to work with CMS to develop a more organized, transparent and consistent process in the future.

Concerns Regarding the QCDR Measure Review Process

Many Coalition members experienced an opaque, disorganized, and contradictory process during the 2017 QCDR measure review period. Members experienced frustrations with CMS during every aspect of the process, including inconsistent feedback and decisions on submitted measures, impractical timelines, a lack of rationale for rejected measures, and a lack of responsiveness to correct errors in measures. Overall, we request that CMS develop a standardized process for review of QCDR measures with structured timeframes for an initial review period, an appeals process, and a final review. We also request that CMS assign a coordinator for each QCDR and create an official database containing decisions on measures to ensure there are no conflicting messages.

- Inconsistent Feedback and Decisions. Coalition members have too often received conflicting responses and decisions from QPP contractors and staff during QCDR measure review process. For instance, one of our members reports that during fall 2016, a CMS contractor asked for significant changes to its proposed QCDR measures. The contractor did not engage in any discussion with the QCDR regarding the clinical importance of the measures or why the changes were needed, but simply demanded the changes. After the Coalition member scheduled a call with the CMS contractor to explain the clinical justification for the measures, CMS approved the measures without changes. However, a few months later, a different CMS contractor notified the Coalition member that 5 measures were not approved, 2 of which were previously-approved by the first contractor. The 3 additional rejected measures were a shock to the Coalition member as CMS had not previously commented on the measures. After appealing to CMS and the contractor, CMS agreed to approve the 2 measures that were previously approved in fall 2016 and 1 of the 3 additional pending measures. CMS asked for additional information on the 2 remaining measures, and ultimately approved all but one measure. In addition, multiple Coalition members report that their proposed measures are

[3] Letter from the Physician Clinical Registry Coalition to Pierre Yong re QCDR Quality Measures, October 29, 2016.
[4] *Id*. at 4.

still under review or their appeals of rejected measures are still pending. Several other Coalition members experienced similar problems with conflicting messages and decisions from QPP contractors, staff, and the JIRA system during this year's QCDR measure-approval process.

- Impractical Timelines. CMS has frequently set unreasonable deadlines for Coalition members to make changes to measures or replace certain measures. For example, CMS asked one member to combine two measures within a single day. CMS asked another Coalition member for additional information on 5 measures with a one-day deadline, even though the member already asked CMS for feedback on these measures in the months prior. CMS gave another member only a few hours to provide evidence supporting performance gaps for rejected measures.

- Lack of Rationale for Rejected Measures. Coalition members report that CMS has rejected measures without providing any rationale. A few commenters on the "JIRA" review site appeared to not understand the clinical rationale behind some of the measures, but never asked for clarification. For example, one of the rejected measures involved peripherally inserted central catheter (PICC) placement in patients with Stage IV or V renal disease. CMS did not give a reason for rejecting this measure, but the rejection makes no sense because it is obvious to an interventional radiologist that placement of such catheters into peripheral veins should be avoided in patients who require a fistula or graft for optimizing safety. Another member reports that 3 approved measures were missing from the public posting for the QCDR. Upon inquiring about the status of the measures, CMS said they were either rejected or still under review. Shortly afterwards, CMS told the QCDR that the measures were denied for being "low bar" without any additional details or warning.

- Lack of Responsiveness/Communication. One Coalition member reports that it gave CMS edits to the final QCDR posting to ensure the correct measures were listed. When the postings were published, the member noticed that CMS ignored several of the corrections made to the posting. For example, CMS listed measures that the QCDR is not offering and did not list some approved measures that it was offering. In addition, Coalition members report receiving contradictory emails about whether CMS approved or denied measures. For instance, a member reports receiving several emails for a single measure stating that the measure was rejected, and then approved, and then rejected again within the same hour. CMS also ignored a Coalition member's requests for changes to incorrect subspecialty measure sets and classification of measures as "process" or "outcome" measures.

Other QCDR Measure Approval Issues

During the 2017 QCDR measure review process, Coalition members also expressed concerns regarding the effect of topped-out measures, inappropriate measure consolidations, approval time for new MIPS measures, provisional measure approval, and limitations due to the 30 non-MIPS measures cap.

- Effect of Topped Out Measures. If CMS determines that many of a subspecialty's MIPS measures are "topped out"—*i.e.*, having reached 90% in average performance rate or greater, it may not be possible for a subspecialty to maintain a QCDR due to the lack of measures. In the CY 2018 proposed rule, CMS proposes the removal of a topped-out MIPS quality measure after a measure has been identified as topped out for 3 consecutive years and its removal is proposed during the 4th year through the comment and rulemaking process.[5] For QCDR measures, CMS proposes removal after a measure has been identified as topped out for 3 consecutive years, but without going through the comment and rulemaking process.[6] CMS' 3-year vetting of measures could reduce the ability of subspecialties to develop and strengthen new measures. Congress created the QCDR mechanism to fill critical gaps in the traditional quality measure sets and to ensure that clinicians have access to measures that are more meaningful and relevant to their specialty. The combination of topped-out measures and slow approval of QCDR measures creates an effect that is counter to the statutory purpose of QCDRs of being innovative and targeted to the needs of different specialties.

- Inappropriate Measure Consolidations. Additionally, CMS has rejected, otherwise opposed, or required consolidation of measures that appear too similar to existing QPP measures. However, the measures that have similar descriptions are often quite different, based on the nature of the condition and/or the area of the body affected. For instance, CMS has asked the American Association of Neurological Surgeons to replace its Unplanned Reoperation Following Spine Procedure within the 30-Day Post-Operative Period measure with the generic PQRS #355: Unplanned Reoperation within the 30-Day Postoperative Period. This means that a surgeon repairing a hernia will be held to the same performance standard as a surgeon performing a multi-level spinal fusion on a patient with osteoporosis who has a higher risk of needing additional surgery due to non-union of weakened bones. Moreover, the QCDR program allows QCDRs to modify and update existing QPP measures on an annual basis in an effort to improve and offer better alternatives to existing QPP measures. In many cases, it would be preferable for CMS to allow a QCDR to modify its measure than to force it to consolidate the measure with the measure of another QCDR.

  As noted in our previous letter, harmonizing QCDR measures does not ensure accurate benchmarking. In theory, harmonizing measures for use in the public domain facilitates cross-cutting comparisons. However, harmonizing quality measures across registries alone 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. This was demonstrated when the American College of Surgeons (ACS) harmonized the surgical site infection (SSI) National Surgical Quality Improvement Program (NSQIP) measure

[5] 82 Fed. Reg. 30,010, 30,046 (June 30, 2017).
[6] *Id*.

with the CDC National Healthcare Safety Network (NHSN) SSI measure. After harmonization, results showed that NSQIP participants had higher SSI rates compared to the CDC NHSN registry participants. Through further study, ACS found that this discrepancy was not because NSQIP participants had poorer surgical outcomes; instead, the discrepancy was due to the lack of rigor used to track patients and collect data for use in the NHSN registry when compared to NSQIP. ACS also found that standardized risk adjustment methodologies are critical when comparing clinical outcomes across different registries/cohorts. For example, in the ACS Surgeon Specific Registry, unadjusted SSI PQRS measure rates were compared to the risk-adjusted SSI PQRS rates and found that approximately 50% of cases were misclassified when risk adjustment was not performed.

- Approval Time for New MIPS Measures. Newly- proposed MIPS measures take approximately 2 years (i.e. the performance year after the next) to be incorporated into the MIPS program. For certain medical specialties that have a wide range of sub-specialization, this 2-year time frame coupled with the 30 reportable non-MIPS measure cap may be extremely limiting and stifle innovation. Vetted new MIPS measures add significant value to QCDRs and a 2-year delay is unnecessary. Therefore, we request that CMS consider a fast track for certain high-priority MIPS measures to be incorporated into QCDRs, based on CMS's discretion.

- Provisional Measure Approval. Some Coalition members report only provisional approval of their QCDR measures. According to these members, CMS requires QCDRs to provide data from the provisional measures during the 2017 performance year on the 2018 self-nomination form. However, the timing between the approval of the measures and the 2018 self-nomination process is too short to adequately capture data. One Coalition member reports that its measures were approved by CMS at the end of May and that it will take a few weeks for the measures to be incorporated into the QCDR. As the 2018 self-nomination application opens in September, the Coalition member will have only collected approximately three months of data from the measures before being required to report the data to CMS. If the measures are being reported through a web portal, data sometimes is not collected by the QCDR until after the conclusion of the calendar year. If CMS must collect data on provisionally-approved measures, we request that QCDRs be permitted to collect such data for at least one full year. Therefore, data on the provisional measures from the 2017 performance year should be submitted on the 2019 self-nomination application.

  In addition, another Coalition member reports that CMS expects the member's provisionally-approved measures to be included on the Measures Under Consideration (MUC) list so they can be used for the 2019 performance year. We disagree with requiring QCDRs to submit provisionally-approved measures for MIPS inclusion. Some Coalition members wish to keep certain measures as QCDR measures, not MIPS measures, due to concerns about how they might be implemented by other entities and to protect their intellectual property rights in such measures.

- Expansion of the non-MIPS Measure Cap. The 30 non-MIPS measure cap can restrict the ability of QCDRs to report on meaningful subspecialty-focused measures. This is particularly limiting for subspecialties that share a QCDR, as each subspecialty is effectively limited to 15 non-MIPS measures instead of 30. We request that CMS increase the measure cap to 30 non-MIPS measures per subspecialty for all QCDRs.

Concerns about the Self-Nomination Application and Timeframe

Several Coalition members also experienced frustrations with the initial QCDR self-nomination process due to incomplete information requests on the application. First, the QCDR application currently does not ask about the ownership and licensing of non-MIPS measures. To ensure the smooth sharing of non-MIPS measures, CMS needs to properly record ownership of all approved measures to protect the intellectual property rights of the owner of the measure. The licensing of measures incentivizes organizations to invest in developing new and improved measures and it is crucial for CMS to create a process to ensure other users respect the intellectual property rights of the measure developers.

We acknowledge that the CY 2018 proposed rule makes some progress on ownership and licensing issues by proposing that QCDR vendors must seek permission from another QCDR to use an existing measure that is owned by the other QCDR for the performance period.[7] The proposed rule also requires that such permission be granted at the time of self-nomination so the QCDR using the measure can include proof of permission in its application for CMS review and approval of the measure's use during the performance period.[8] While this is a significant step in the right direction for protecting QCDR measure ownership, we believe further improvement could be made to properly record and track ownership rights. For instance, CMS should clarify what form of proof must be submitted to show permission to use another QCDR's measure. It should also make the ownership information it collects generally available to QCDRs to facilitate sharing of non-MIPS measures between these entities.

Other members report that CMS requested the details of a plan for risk adjustment several months after completing the self-nomination application. In fact, CMS asked one member why a description or attachment of the plan was not included with the application. We are surprised to learn CMS expected this information, as the self-nomination application does not ask for the details of a risk adjustment plan. Rather, the application simply asks the applicant to answer "yes" or "no" as to whether they have such a plan. We suggest that the QCDR self-nomination application include all of the information needed to determine QCDR status to avoid delays and frustration.

We recognize and appreciate that the CY 2018 proposed rule details a simplified self-nomination process where existing QCDRs in good standing can continue participating in MIPS by attesting that there are no changes from the previous year's MIPS performance period, or can go through an expedited review by only making changes where necessary.[9] However, we still urge CMS to

[7] *Id*. at 30,160.
[8] *Id*.
[9] *Id*. at 30,159.

increase the length of QCDR approval from one to two years. Even with a simplified self-nomination process, it is still administratively burdensome to report changes on an annual basis. Many registries may not seek QCDR status because of the escalating administrative burden required to participate on a long-term basis. This result could stifle quality measure innovation, which was the premise for creating QCDRs in the first place.

As noted above, we applaud your flexibility and willingness to discuss the Coalition's past concerns. In that same vein, we would appreciate the opportunity to meet with you and other appropriate CMS representatives to discuss our concerns in person. Please contact Rob Portman at 202-872-6756 or rob.portman@powerslaw.com to let us know if you are able to meet with representatives of the Coalition and, if so, what time would be best for you.

Respectfully submitted,

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION
AMERICAN ACADEMY OF NEUROLOGY
AMERICAN ACADEMY OF OPHTHALMOLOGY
AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY
AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION
AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS/NEUROPOINT ALLIANCE
AMERICAN COLLEGE OF EMERGENCY PHYSICIANS
AMERICAN COLLEGE OF GASTROENTEROLOGY/GIQUIC
AMERICAN COLLEGE OF RHEUMATOLOGY
AMERICAN COLLEGE OF SURGEONS
AMERICAN GASTROENTEROLOGICAL ASSOCIATION
AMERICAN JOINT REPLACEMENT REGISTRY
AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY/ GIQUIC
ANESTHESIA QUALITY INSTITUTE/AMERICAN SOCIETY OF ANESTHESIOLOGISTS
AMERICAN SOCIETY FOR RADIATION ONCOLOGY
AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY
AMERICAN SOCIETY OF PLASTIC SURGEONS
AMERICAN UROLOGICAL ASSOCIATION
NORTH AMERICAN SPINE SOCIETY
SOCIETY OF INTERVENTIONAL RADIOLOGY
SOCIETY OF NEUROINTERVENTIONAL SURGERY
THE SOCIETY OF THORACIC SURGEONS