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PHYSICIAN CLINICAL REGISTRY COALITION

December 6, 2018

VIA ELECTRONIC MAIL

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RE: Concerns Regarding Qualified Clinical Data Registries and MIPS

Dear Dr. Green and Ms. Sugumar:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition) are writing to express our concerns and offer our suggestions regarding several issues that we have experienced as Qualified Clinical Data Registries (QCDRs) participating in 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.[1] Most of the members of the Coalition have been approved as QCDRs or are working towards achieving QCDR status. We previously sent a letter to your office, dated July 11, 2017, in which we discussed concerns regarding the QCDR measure review and self-nomination process and offered to work with the Centers for Medicare and Medicaid Services (CMS) to develop a more organized, transparent, and consistent process in the future. A copy of that letter is attached. We offer these comments as part of our continuing dialogue with your office about the QCDR program and QCDR participation in MIPS.

TIN/NPI Verification

CMS currently requires that QCDRs participating in MIPS verify eligible clinicians' taxpayer identification numbers (TINs) and national provider identifiers (NPIs). Coalition members

[1] For more information about the Coalition, see www.registrycoalition.net.

report that CMS has indicated that QCDRs may be at risk of being placed on probation if there is a mismatch between clinicians' TINs and NPIs. While it is relatively easy for QCDRs to confirm an eligible clinician's NPI, as this information is publicly available, confirming the accuracy of TINs is significantly more difficult. There is no way for a QCDR to verify an eligible clinician's TIN unless the QCDR has access to confidential information. QCDRs must rely on clinicians to accurately provide and confirm their TINs prior to data submission. As a result, the burden should be on the clinician to accurately provide this information. QCDRs should not be penalized for errors made by clinicians in entering and confirming the accuracy of their TINs. The Coalition recommends that CMS accept attestations from clinicians that their NPI and TIN are correct as verification of NPI and TIN by QCDRs, and not penalize QCDRs for mismatches between a clinician's NPI and TIN due to the clinician providing an incorrect TIN.

MIPS Eligibility Verification

CMS requires that QCDRs verify MIPS eligibility status for all clinicians reporting through the QCDR for MIPS. Currently, the only way to verify eligibility is by looking up each individual clinician's NPI on CMS's participation lookup tool. In other words, QCDRs must look up each registry participant one-by-one, as there is no other way to verify this information. This is incredibly burdensome for QCDRs, especially because many QCDRs operate with limited staff and have high numbers of participating clinicians. Further, the Coalition questions the value of this burdensome eligibility check, as CMS permits and encourages all clinicians to voluntarily report even if they are not eligible for MIPS. We ask CMS to remove this requirement unless CMS is able to create a tool for QCDRs to check eligibility status in bulk.

Data Completeness Verification

CMS currently requires that QCDRs use the total eligible patient population, exclusions, and exceptions for each quality measure reported by participating providers to calculate the data completeness rate and verify that their participating providers meet the data completeness threshold for each quality measure.[2] For electronic health record (EHR) integrated practices, this may not impose a significant burden on QCDRs, as QCDRs are able to access all patients in the EHR system, although there may be instances where this is still challenging because a physician works at multiple locations with different, unconnected EHR systems. This is a significant challenge, however, for QCDRs that have a web portal option for non-EHR integrated practices, because the practices manually input patients and QCDRs have no way of knowing what the total eligible patient population is for each measure. CMS has stated that QCDRs must collect supporting documentation from all participating practices to confirm that providers meet the data completeness threshold for each quality measure, including documentation to verify the total number of eligible patients for each quality measure. For 2018, this requirement was not made clear until just recently and will impose a significant burden on QCDRs, as well as participating

[2] Under 42 C.F.R. § 414.1340(a)(2), for MIPS payment years 2020 and 2021, MIPS eligible clinicians and groups submitting quality measure data using a QCDR must submit data on at least 60% of their patients that meet the measure's denominator criteria, regardless of payer, in order to meet the data completeness criteria for the quality performance category.

providers. Clinicians are already overwhelmed with MIPS compliance, and this requirement would require clinicians to mine their billing records for additional information to submit to the QCDR. CMS has stated that burden reduction is a top priority, and removing this requirement would help to alleviate burden on both clinicians and QCDRs. In addition, as stated above with regard to TIN/NPI verification, QCDRs should not be held accountable for an aspect of data submission for which the clinician should be responsible. The Coalition recommends that CMS remove the requirement that QCDRs include data completeness calculations for all quality measure submissions. Instead, CMS should allow QCDRs to accept attestations from clinicians that data they have submitted meets the data completeness threshold for quality and they have reported on 60% of eligible patients for each quality measure.

ICD-10 Code Update

On October 1, 2018, CMS released a fact sheet identifying quality measures that have been significantly impacted by ICD-10 code updates and stating that, for these measures, the performance score for the quality measure will be based only on the first nine months of the twelve-month performance period for those identified measures.[3] The following four measures were identified by CMS as having been "significantly impacted" by the ICD-10 code updates:

- Melanoma: Continuity of Care – Recall System
- Melanoma: Coordination of Care
- Melanoma: Overutilization of Imaging Studies in Melanoma
- Basal Cell Carcinoma (BC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician

The limiting of performance data for these measures to the first nine months of the twelve-month performance period has not only caused operational challenges for QCDRs, but will result in scoring and penalty impact for eligible clinicians and negatively impair their ability to report these measures. This update will affect eligible clinicians' score significantly because these measures are among the most utilized measures in dermatology. In addition, for all specialties that report these measures, it will be difficult for clinicians to meet the case minimum, as well as the required data completeness rate, if the performance period is reduced to just the first three quarters, rather than a full calendar year. The Coalition also asks that CMS clarify whether CMS will evaluate whether a clinician has satisfied data completeness over a nine-month period, instead of a twelve-month period (i.e., will CMS include the patients seen over the last quarter of the year when evaluating a clinician's patient population for the purposes of data completeness?).

CMS's announcement came at an extremely inopportune time, as the majority of QCDR participants had been preparing all year to report measures for MIPS. Many eligible clinicians rely on data submitted for the last quarter of the year to avoid penalties, particularly those who are at paper-based practices. Without adequate time to submit data, these clinicians have been

[3] *See* CMS, Quality Payment Program, 2018 MIPS Quality Measures Impacted by ICD-10 Updates Effective October 1, 2018, https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Measures-Impacted-by-ICD-10.pdf.

forced to change their plans and processes by having to choose alternative, less relevant, measures or attest to improvement activities. As mentioned above, with the performance period for these measures limited to the first nine months of 2018, participating practices and clinicians may not be able to achieve the required data completeness rate or the case minimum, or earn the maximum points for MIPS.

Following the release of CMS's fact sheet, QCDRs have worked diligently to announce these changes to their membership through numerous channels, including webpage updates, e-mail blasts, conference calls, and other communications. QCDR measure stewards anticipate ongoing education through the end of the submission period will be necessary to ensure eligible clinicians are sufficiently informed to make selections for 2018 MIPS reporting. In addition, numerous technical modifications were made to QCDR platforms, dashboards, and online tools to implement data entry restrictions and other changes related to this new requirement. The resources and staff time required to date, as well as those needed through the end of March 2019, are difficult to quantify, but the burden has been substantial and experienced by numerous specialty societies. CMS places the responsibility for educating eligible clinicians on QCDRs, and QCDRs must modify their operations to meet CMS's requirements; however, QCDRs and eligible clinicians were not allotted any time to prepare for this new requirement considering the announcement of this change was made after the October 1st implementation date.

The Coalition strongly recommends that CMS reconsider the scoring and penalty impact on measures significantly impacted by the ICD-10 updates mid-performance period and allow QCDRs and eligible clinicians the time to review and submit comments on these prior to the reporting year. In addition, the Coalition recommends that CMS hold harmless practices that submit these measures by accepting the data as complete, even if case minimums and/or data completeness rates are not met.

Measures Reported Electronically and Manually

In the CY 2019 Physician Fee Schedule Final Rule, CMS stated that it expects "that a QCDR measure for which data is abstracted through EHRs or manually (that is, paper records) would have to be approved as two separate measures."[4] This has historically not been the case for Coalition members with measures that are available to both manual registry participants (non-EHR) and electronic registry participants (EHR-abstracted). If a QCDR is required to separately submit each measure for approval as two different measures, the QCDR's measure allowance would essentially be cut in half. This requirement also seems to be contrary to CMS's goal of reducing duplicative measures. Instead, QCDR measures with different collection types should have distinct benchmarks for electronic and manual reporting. By refusing to create separate benchmarks, CMS disadvantages and discourages electronic reporting of QCDR measures.

[4] CY 2019 PFS Final Rule, 83 Fed. Reg. 59,452, 59,842 (Nov. 23, 2018).

QCDR Measure Approval Process: Timeline for Required Changes and Measure Harmonization

When approving QCDR measures, CMS and its contractors currently employ four different feedback options: Approval, Provisional Approval, Rejection, and Required Changes. The Coalition appreciates that CMS and its contractors have improved their response time for approval of QCDR measures, but we are concerned that CMS often requires changes to QCDR measures at the last minute. Such changes have included greatly expanding the measure denominator, requiring the merging of two separate measures, and submitting an updated specification within a week of CMS's and its contractors' decisions.

Requiring significant measure specification changes on such short notice is contrary to the spirit of QCDR measure development framed by the CMS Measure Blueprint and the standards for measure development established by the National Quality Forum. Quality measures submitted by QCDRs are developed by subject matter experts, undergo significant expert vetting, and are supported by literature, guidelines, and preliminary data. By requiring a measure change at the last possible moment, in a manner that would determine the approval fate of the QCDR measure, CMS fails to take into consideration the many deliberate and defensible steps used in developing the measure. Expanding denominators or merging different measures by such sweeping means will undermine established quality benchmarks and previous measure testing. The Coalition is concerned that making such significant decisions in a hasty manner increases the risk of unintended consequences associated with implementation of the measures and limits opportunity for necessary expert review and input.

CMS also currently has no formal process for harmonizing measures, particularly at the end of the self-nomination period. Coalition members who are QCDR measure stewards have reported being contacted by other QCDRs at the last minute regarding measure harmonization. These other QCDRs state that CMS has directed them to harmonize their measures with the established measures owned by Coalition members, despite the Coalition members receiving no such notification from CMS. These Coalition members have also received no assurances from CMS that CMS will not reject the Coalition members' QCDR measures due to the other QCDR's failure to harmonize its measures with those of the Coalition members.

The Coalition requests that CMS allow QCDR measures that are identified for required changes to be provisionally approved. The Coalition believes that CMS could, in addition to provisionally approving the original measures, request that the measure steward consider the proposed CMS measure changes during an annual review cycle. The Coalition also strongly urges CMS to implement formal processes and set reasonable timelines for harmonizing measures to avoid the situation where a QCDR contacts a QCDR measure owner at the last minute regarding measure harmonization.

QCDR Measure Licensing Timeline and Supporting Documentation

CMS currently allows QCDRs to seek permission from another QCDR to use an existing measure that is owned by the other QCDR. Coalition members that own QCDR measures report being contacted at the last minute by other QCDRs wishing to use their measures. This requires the measure owners to expend a significant amount of time to confirm that the other QCDR's data collection and measure logic are consistent with the QCDR measure owner's, in order to ensure that any variance in average performance is not due to inconsistent data collection or measure logic calculation. Such inconsistencies would be unfair to both the QCDR measure owner's and the other QCDR's participants. The Coalition hopes to work with CMS to develop appropriate timelines for QCDRs seeking permission from QCDR measure owners to use these measures.

The Coalition is also interested in what steps CMS takes to confirm that permission has been granted to use another QCDR's measures. Some Coalition members report that they provide documentation to QCDRs that license their measures and also inform CMS that permission for another QCDR to use their measures has been granted via the QCDR measure owner's self-nomination in the JIRA tracking system. The Coalition is concerned, however, that there may be instances where another QCDR claims to have permission to use a measure, but that QCDR has not actually sought or been granted such permission. The Coalition asks that CMS issue guidance regarding supporting documentation that must be reported when QCDRs use another QCDR's measures. As stated in the Coalition's comments on the CY 2019 Physician Fee Schedule Proposed Rule, the Coalitions hopes to work with CMS to create safeguards to protect the proper implementation of measures and ensure that QCDRs can enforce their intellectual property rights, while also ensuring that the measures are readily available to other QCDRs with clinical expertise and experience in quality measure development.

QCDR Measure Removal and Self-Nomination Period Timeline

Currently, MIPS measures are not finalized prior to the QCDR self-nomination period. As a result, QCDRs must make decisions based on the current year's measures with incomplete information. This current timeline leads to inefficient use of both QCDRs' and CMS's time and resources. For example, CMS may decide to remove MIPS measures that had been included in a QCDR's application, resulting in the application containing outdated information. If CMS continues to follow its current rulemaking timeline, this problem will persist under CMS's recent changes to the self-nomination period, as MIPS measures will continue to not be finalized prior to the QCDR self-nomination period.[5] We hope to work with CMS to address these timing issues for next year's self-nomination period.

[5] CY 2019 PFS Final Rule, 83 Fed. Reg. at 59,898.

January 1st "Up and Running" Date

On June 18, 2018, QCDRs received an e-mail from CMS stating that all QCDRs must be "up and running (able to support data collection and submission) on January 1, 2018 for the 2018 performance period." As a threshold matter, we ask that CMS clarify what is meant by "up and running," "operational," and "operational plan." These terms must be more clearly defined so that QCDRs can carry out their work with a little more certainty. For example, a Coalition member notes that when its registry team met with Dr. Green, Dr. Green agreed that registries should have the ability to log cases by the first of the year. However, if by "up and running," CMS means more than logging cases as of January 1st, then this new requirement is likely not feasible. Requiring QCDRs to be "up and running" on January 1st is both unreasonable and could result in poorly functioning QCDRs.

QCDR specifications are not always approved until late in the calendar year prior to the performance period. It typically takes significantly longer than one month to build and test a data dictionary and web tool based on QCDR specifications. As a result, if the current timeline for specification approval remains the same, QCDRs will simply be unable to build and test the proper systems by the January 1st deadline. In addition, Quality Payment Program (QPP) specifications are not available until the QPP rule is finalized. There have been years when the rule has not been finalized until December 27th of the year prior to the performance period. While most specifications do not change, even minor revisions take significantly longer than three days to enter and to test. As a result, the requirement that QCDRs must be operational as of January 1st is entirely inconsistent with CMS's own timeline for rulemaking.

Many QPP resources are not available on January 1st. The CMS portal for eligible clinicians is also not available on January 1st. If CMS expects QCDRs to be operational on January 1st, CMS must also have all of the necessary tools available under the same timeline. Finally, implementation of measures has a variable timeline from registry-to-registry due to significant differences in IT infrastructure and resources. Registries with much larger IT staffs, particularly non-physician led registries, may have an easier and faster time establishing fully-operational measures.

In its e-mail, CMS did not clarify whether timely operation of QCDRs is an ongoing, overarching issue or whether this e-mail was directed to specific QCDRs. We hope to work with CMS on a timeline that is feasible and ensures properly functioning QCDRs that meet the goals of the MIPS program.

QCDR Measure Benchmarking Proposal

In the CY 2019 Physician Fee Schedule Proposed Rule, CMS sought comment on an approach to develop QCDR measure benchmarks based off historical measure data.[6] In the CY 2019 Physician Fee Schedule Final Rule, CMS indicated that it may adopt a benchmarking plan in

[6] CY 2019 PFS Proposed Rule, 83 Fed. Reg. 35,704, 35,955 (July 27, 2018).

future rulemaking.[7] One of the advantages of QCDRs is their ability to provide measures other than the MIPS measures, but this value is greatly diminished by only allowing providers to receive three achievement points for a significant amount of QCDR measures applicable to their practice. As CMS alluded to in the CY 2019 Physician Fee Schedule Proposed Rule, as a result of only receiving three measure achievement points for QCDR measures without established benchmarks, providers may decline to report QCDR measures without established benchmarks or attempt to use primary care measures that are not relevant to their practice, unless CMS provides a firm plan to implement benchmarks for QCDR measures.

The Coalition is eager to work with CMS on an approach to develop QCDR measure benchmarks and hopes to meet with CMS on these issues as soon as possible. The Coalition is particularly interested in working with CMS on proposals that would allow QCDRs to calculate benchmarks internally, which would address CMS's concerns about the ability of QCDRs to submit historical data to CMS. The Coalition also notes that some measures are significantly changed from year to year, at CMS's request, resulting in the potential need to benchmark measures on an annual basis. QCDR measure benchmarking is incredibly complex and is an urgent issue for many Coalition members. The Coalition looks forward to engaging with CMS on this issue as soon as possible.

Measure QPP226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

The Coalition has significant concerns about the benchmark for Measure QPP226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention. This measure was changed this year to have three strata. CMS plans to use the second stratum for scoring, despite the measure owner originally indicating that the third stratum would be used for scoring. The second stratum is significantly different from what was used to develop the benchmark for this measure. As a result, most providers are likely to struggle to earn more than three points on this measure, if they use the measure at all. The Coalition urges CMS to consider this a non-benchmarked measure and determine a performance period benchmark for stratum two with data from 2018.

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Thank you for your attention to these important issues. The Coalition would welcome the opportunity to meet with CMS to discuss these concerns. If you have any questions, please contact Rob Portman at Powers Pyles Sutter & Verville PC (rob.portman@powerslaw.com or 202-872-6756).

[7] CY 2019 PFS Final Rule, 83 Fed. Reg. at 59,915.

Respectfully submitted,

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION
AMERICAN ACADEMY OF NEUROLOGY
AMERICAN ACADEMY OF OPHTHALMOLOGY
AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ACADEMY OF OTOLARYNGOGLOGY – HEAD AND 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 FOR RADIATION ONCOLOGY
AMERICAN SOCIETY OF ANESTHESIOLOGISTS
AMERICAN SOCIETY OF CLINICAL ONCOLOGY
AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY
AMERICAN SOCIETY OF PLASTIC SURGEONS
AMERICAN UROLOGICAL ASSOCIATION
COLLEGE OF AMERICAN PATHOLOGISTS
NORTH AMERICAN SPINE SOCIETY
SOCIETY OF INTERVENTIONAL RADIOLOGY
SOCIETY OF NEUROINTERVENTIONAL SURGERY
THE SOCIETY OF THORACIC SURGEONS

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PHYSICIAN CLINICAL REGISTRY COALITION

July 11, 2017

VIA ELECTRONIC MAIL

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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