



October 29, 2016

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Department of Health and Human Services
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Room S3-07-17
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Re: QCDR Quality Measures

Dear Dr. Yong:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition)¹ are writing to express our concerns about recent email communications from the Centers for Medicare & Medicaid Services (CMS) Physician Quality Measures Management (PQMM) Team to entities that operate Qualified Clinical Data Registries (QCDRs) under the existing Physician Quality Reporting System (PQRS), which is soon to be transitioned into the Merit-based Incentive Payment System (MIPS) pursuant to the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The emails “request” that the QCDRs consolidate one or more of their proposed non-PQRS quality measures with (a) existing, traditional PQRS quality measures, (b) other non-PQRS measures proposed by other QCDRs, or (c) non-PQRS measures proposed by the QCDR to which the email is addressed. The emails state that the purpose of the request is to streamline the entire set of non-PQRS QCDR measures to reduce redundancy and thereby ensure the QCDR measures are “rigorous and defensible” and “will allow for performance measurement across a broader cross-section of Eligible Clinicians allowing for a more robust comparison of clinician performance.” While the emails are crafted as requests, they appear to imply that if the QCDR does not comply, CMS will pick the QCDR measures that may be used by clinicians in given specialties and eliminate the ones CMS finds to be redundant or otherwise deficient.

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 (QCDRs) and most of the others are working toward that goal.

The Coalition believes these communications are inconsistent with congressional intent to give QCDRs substantial flexibility and autonomy in developing non-PQRS measures. Haphazard consolidation of non-PQRS QCDR measures is also bad policy in that it will undermine the purpose of creating the QCDR option for quality reporting. Lastly, CMS's process in issuing these email demand letters has not provided adequate notice or opportunity to be heard and at least initially imposed unreasonable deadlines for responsive action. We understand that CMS has since suggested there is more flexibility on the timing for QCDR's to respond to CMS's consolidation requests, but it is now unclear what the deadline is for such responses. For these reasons, the Coalition strongly objects to CMS taking any steps to unilaterally modify, consolidate, or eliminate non-PQRS QCDR measures without substantial input from the affected QCDRs, the issuance of detailed criteria by which QCDR measures will be evaluated, and a much more open and transparent process for the submission, evaluation, and acceptance of QCDR measures. We appreciate that CMS held a call on October 18, 2016 for QCDRs to discuss this issue, but we also request a meeting to present our concerns in-person as soon as possible.

The Letters are Inconsistent with Congressional Intent of the QCDR Mechanism

The Coalition supports efforts to streamline federal quality reporting requirements, but believes these efforts should focus on reducing administrative complexity and reporting burden rather than limiting the availability of more diverse, relevant, and nuanced measures. Eliminating QCDR measures in favor of what CMS characterizes as "similar" existing PQRS measures contradicts the Congressional intent of the QCDR reporting mechanism and reverses years of progress that has been made since the QCDR mechanism was first authorized to promote the development of more specialty-focused and more clinically-thoughtful measures. Congress created the QCDR mechanism to fill critical gaps in the traditional PQRS measure set and to ensure that clinicians have access to measures that are more meaningful and relevant to the specific nature of their care. For this reason, MACRA specifically exempted QCDR measures from the requirements that apply to the MIPS quality measures. By asking QCDRs to consolidate their non-PQRS measures with PQRS measures, CMS is re-creating the same one-size-fits-all approach that has longed plagued physician-level quality measurement and that the QCDR mechanism was intended to resolve.

In addition, MACRA requires that CMS encourage the use of QCDRs, and the ability for QCDRs to offer a number of relevant and high quality measures is an incentive for physicians to use QCDRs. Requiring QCDRs to consolidate their proposed non-PQRS measures or work with other entities that represent different specialties or have different missions is also counter to the intent of MACRA.

Arbitrary Consolidation of QCDR Measures Is Bad Health Policy

Substituting QCDR measures for "similar" existing PQRS or proposed non-PQRS measures reflects a lack of appreciation for the nuanced nature of the practice of medicine. We are concerned that CMS is attempting to sacrifice greater clinical accuracy and relevancy for

simplicity. Shifting to broadly-defined measures that capture a greater cross-section of clinicians will not help to achieve a “robust and valid comparison of clinician performance.”

When CMS sets performance benchmarks for PQRS quality measures, it evaluates the performance of any and all clinicians reporting on the measure. It does not apply a specialty adjustment, as it does for cost measures, to ensure more apples-to-apples comparisons of providers. As a result, the complexity of the patient or the procedure is largely ignored. Replacing current QCDR measures with existing PQRS measures or arbitrarily consolidating QCDR non-PQRS measures with other similar QCDR measures based on similar titles will result in CMS lumping together cases that bear little resemblance to each other and have different outcome and risk profiles.

For example, 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 removing 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. As this example shows, although some QCDR measures that CMS wants to eliminate might be similar in “title” to existing PQRS measures, there are nuances in the specifications that make them very different. In some instances, these differences could have negative implications for scoring quality and for scoring resource use.

Likewise, CMS has asked the American Academy of Ophthalmology to consolidate four of its QCDR measures into two. In both instances, the two paired measures are outcome measures and should remain separate. In both instances, one of the paired measures is focused on a patient-centered function important to quality of life and activities of daily living (*i.e.*, visual acuity) and the other is focused on a clinical observable outcome, the absence of inflammation indicating a desired clinical outcome. Combining these would not accomplish the objectives to screen and treat disease or to combine complications, because both measures in the pairing are separate outcome measures.

Some PQRS measures have restrictive conditions, such as only applying if physicians use electronic health records. In some cases, QCDRs have adopted non-PQRS measures that do not include such conditions, thus allowing a greater number of physicians to use the measure.

CMS is also requiring some QCDRs to consolidate their non-PQRS measures with other QCDRs with seemingly similar non-PQRS measures. The problem with this approach is that CMS is not necessarily grouping QCDRs of like specialty or focus, so there are important reasons why different organizations would have similar, but separate measures. In some cases, CMS is demanding that nonprofit organizations work with for-profit entities that may have a proprietary interest in their measures and a completely different purpose in developing such measures.

Significantly, harmonizing QCDR 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. For example, when ACS harmonized the Surgical Site Infection (SSI) American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) measure with the CDC National Healthcare Safety Network (NHSN) SSI measure, results showed that NSQIP participants had higher SSI rates compared to the CDC NHSN registry. After 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 in the NHSN registry when compared to NSQIP.²

It is also very difficult to risk adjust across different registries/cohorts without the standardization of both risk variable definitions and risk adjustment methodologies.. Standardized risk adjustment is critical when comparing clinical outcomes. For example, ACS compared the unadjusted SSI PQRS measure rates to the risk-adjusted SSI PQRS rates and found that approximately 50% of cases were misclassified when risk adjustment was not performed.

We encourage CMS to adopt policies that support greater (not less) diversity in the set of measures available to clinicians in order to accomplish our shared goal of improved quality and patient outcomes.

Concerns about CMS' Consolidation Process and Timeline

The emails from CMS were issued in early October without any notice or warning to the medical societies or clinical data registries that sponsor QCDRs. CMS did not consult with these organizations before sending emails "recommending" that QCDRs make changes to their measures. To our knowledge, CMS did not seek input from clinical experts to understand the rationale and intent of QCDR measures, including why there is a need for multiple QCDR measures or why specific QCDR measures are different from PQRS measures or other QCDR measures.

It is also unclear what, if any, data CMS is using to support its requested changes. CMS should review and evaluate performance data for at least a one-year period and consider input from clinical experts prior to requiring changes to the QCDR measures proposed by specialty societies and other groups with demonstrated clinical and medical expertise. Without such data, CMS cannot accurately gauge the impact of requiring the consolidation of QCDR measures with seemingly similar PQRS measures.

In order to make significant changes to measures, including merging multiple measures into a composite measure, QCDRs need sufficient time to review and compare the measures and

² Ju, M.H., Ko, C.Y., Hall, B.L., Bosk, C.L., Bilimoria, K.Y., Wick, E.C. A comparison of 2 surgical site infection monitoring systems. JAMA Surg. 2015;150:51. Available at <http://jamanetwork.com/journals/jamasurgery/article-abstract/1934729>

performance data, consult clinical experts, and make appropriate changes. The timeframe CMS has provided is insufficient to perform these tasks. We appreciate the recent email from CMS and call with the QPP Team offering flexibility in the timeline in which QCDRs have to comply, but remain uncertain about what changes are required, when they must be made, and what changes CMS will make if the deadlines are not met. Additionally, in some cases, CMS is asking QCDRs to combine measures that are in their first year of use. Without a full year of data, it is difficult to understand how CMS can believe there is a need for consolidation.

CMS should not take steps to eliminate QCDR measures until QCDRs are provided clear guidance on the criteria against which CMS is evaluating QCDR measures. Although the Coalition very much appreciates the flexibility that CMS has provided QCDRs to date in terms of measure development, this sudden decision to eliminate and consolidate measures is arbitrary and unfair given the lack of formal standards with which QCDRs have been expected to comply. CMS's email notices requiring consolidation are particularly disturbing given that on a vendor call earlier this year CMS told QCDRs that they would be given meaningful feedback regarding their measures. CMS also promised to develop an evaluation process for all measures in October of 2016. In addition, CMS told the QCDRs they would have until the QCDR application and submission deadline in January of 2017 to update and submit their measure information.

CMS should not take steps to eliminate QCDR measures before the first year of MIPS has even begun, as it is important to maintain sufficient choice in measures for providers. The proposed quality reporting criteria under MIPS requires reporting on outcome measures. By definition, eliminating a significant number of QCDR outcome measures would make it challenging for some physicians to succeed and to earn bonus points necessary to maximize their quality scores. Furthermore, consolidation of certain measures will leave some specialties with only a few outcomes measures to report on, which is inconsistent with the MIPS requirement that QCDRs report on at least six measures.

In the initial emails, CMS offered QCDRs less than 30 days to make these changes, with no guarantee that taking these actions will even result in the preservation of the affected measures. In addition, CMS' strategy for communicating these decisions has been disjointed and confusing. For example, it has sent individual QCDRs as many as 8-10 separate emails, rather than a single communication listing all suggested changes. CMS has provided QCDRs with an appeals process that may or may not allow for an adequate opportunity for QCDRs to make their case before being faced with 2017 deadlines. The fact that CMS had not yet finalized the MIPS regulations for 2017 when it sent its initial emails has added to the confusion since, until the final rules were issued, QCDRs could not have known how these changes would affect their members' ability to comply with MIPS.

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As noted above, 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@ppsv.com to let us know if you are willing to meet with representatives of the Coalition.

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 JOINT REPLACEMENT REGISTRY
AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY/GIQUIC
AMERICAN SOCIETY FOR RADIATION ONCOLOGY
AMERICAN SOCIETY OF CLINICAL 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