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PHYSICIAN CLINICAL REGISTRY COALITION

October 24, 2019

Via Electronic Mail

Dr. Daniel Green, MD
Ms. Sophia Sugumar
Quality Measurement and Value-Based Incentives Group
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Room S3-02-01
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RE: QCDR Pre-Submission Audits of MIPS Improvement Activities and Promoting Interoperability Categories

Dear Dr. Green and Ms. Sugumar:

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

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

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

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

Improvement Activities (IA) Performance Category Audit

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

1. CMS has not provided QCDRs with appropriate guidance to complete such an audit. We respectfully request CMS clearly define what CMS considers to be primary source documentation for each individual Improvement Activity. This will (a) ensure all eligible clinicians understand what will be required of them during an Improvement Activities audit, and (b) provide clear direction to QCDRs as to what documentation CMS will find appropriate.

2. QCDRs would only be able to implement an Improvement Activities audit for PY2020 with a totally manual process. Contacting clinicians/practices, describing what documentation is needed and reviewing and confirming whether documentation is appropriate, would place an undue burden on QCDRs.

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

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

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

Performing Interoperability (PI) Performance Category Audit

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

Common Concerns about Audit Requirements

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

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

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

Respectfully submitted,

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

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