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PHYSICIAN CLINICAL REGISTRY COALITION

November 10, 2020

**VIA ELECTRONIC MAIL**

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**RE: Data Validation for Merit-based Incentive Payment System Performance Year 2020**

Dear Dr. Green and Ms. Sugumar:

The Physician Clinical Registry Coalition (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. Most of the members of the Coalition have been approved as Qualified Clinical Data Registries (QCDRs) or are working towards achieving such status. The undersigned members of the Coalition respectfully request that the Centers for Medicare and Medicaid Services (CMS) and its contractors honor the 2020 Merit-based Incentive Payment System (MIPS) performance year data validation plans that the Qualified Registries (QRs) and QCDRs submitted in September of 2019 as part of the annual self-nomination process and that CMS approved late last year. We are concerned that CMS and its contractors require additional validation and auditing criteria beyond those set forth in the final rule updating the Quality Payment Program for 2020 (2020 Final Rule).[1] We do not believe it is appropriate or legal for CMS to arbitrarily and retroactively apply unpublished data validation and auditing criteria to the 2020 performance year.

[1] 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, (Nov. 15, 2019) [herein after "2020 Final Rule"].

**We request that CMS provide written confirmation that QR and QCDR-submitted and CMS-approved data validation plans for performance year 2020 remain in effect and that no additional criteria, apart from the CMS-approved plans, will be imposed on QRs or QCDRs for the 2020 performance year.**

Our concerns stem from the October 13, 2020 CMS vendor call for QRs and QCDRs. During that call, CMS staff and contractors discussed the following auditing criteria that QRs and QCDRs must perform for 2020 data validation, neither of which are required by the 2020 Final Rule, any published CMS guidance currently in effect, or the 2020 data validation plans submitted by the majority of registries:

1. **Groups or individuals selected for a randomized audit must be audited across all three performance categories.** Last year, CMS finalized a policy that beginning with the 2021 performance year, QRs and QCDRs must be able to submit data for all of the MIPS performance categories (quality, improvement activities, and promoting interoperability).[2] CMS also noted last year that QRs and QCDRs "must audit a subset of data prior to submission for all performance categories that the QCDR or qualified registry is submitting data on, that is, quality, improvement activities, and promoting interoperability."[3] The proposed rule updating the Quality Payment Program for 2021 (2021 Proposed Rule) also proposes that QRs and QCDRs must conduct data validation for each performance category for which they will submit data.[4]

   Neither the 2020 Final Rule nor the 2021 Proposed Rule states that each performance category's data validation must be performed for the same individual or group. Even if these rules could be interpreted to impose additional data validation requirements, these requirements would only apply to the 2021 performance year. By imposing additional data validation requirements for the 2020 performance year, CMS is effectively engaging in retroactive rulemaking, which is prohibited by the Social Security Act and the Administrative Procedure Act. Section 1871 of the Social Security Act permits CMS to engage in retroactive rulemaking only if the Secretary determines that such retroactive application is necessary to comply with statutory requirements or that failure to apply the policy retroactively would be contrary to the public interest.[5] CMS has failed to satisfy either of these conditions and, therefore, is statutorily prohibited from retroactively applying additional data validation requirements to the 2020 performance year. Moreover, CMS is statutorily barred from implementing new data validation requirements for the 2020 performance year without prior written notice and a

[2] 42 C.F.R. § 414.1400(a)(2).
[3] 2020 Final Rule, 84 Fed. Reg. at 63,052.
[4] Medicare Program; CY 2021 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; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy, 85 Fed. Reg. 50,074, 50,403 (Aug. 17, 2020).
[5] 42 U.S.C. 1395hh(e)(1)(A).

meaningful opportunity to comment on such requirements. The Administrative Procedure Act states that an agency may adopt a rule only after the agency publishes the proposed rule in the Federal Register, considers comments from the public, and then finalizes the rule.[6] CMS may not establish new policy by telephone.

Requiring an audit of all performance categories for the 2020 reporting year would delay the completion of an audit until a group or individual has data available in all categories. Such delays increase the burden for registries to complete audits in a timely manner and for participants to make necessary corrections before data is submitted to CMS by March 31 of the following year. Provided that the minimum sample sizes have been audited for each performance category in accordance with a CMS-approved data validation plan, it should not be relevant whether the same group or clinician is selected for an audit in one or more categories. Moreover, requiring audits for all performance categories across the same practices would impose burden on practices that chose to report all three performance categories via QCDRs or QRs, while excepting from audits those who chose not to report a performance category via a QCDR or QR or who report some performance categories via other mechanisms. We do not believe CMS desires to delay the completion of randomized audits, submission of performance data to CMS, or increase administrative burdens on registries and participants without due cause.

2. **QRs and QCDRs must obtain proof that 50 percent of a group's National Provider Identifiers (NPIs) participated in an improvement activity**. CMS' published guidance states that a group can attest to an activity when at least 50 percent of the clinicians in the group perform the same activity during any continuous 90-day period. "Attest" is defined as "providing information by manually entering a numerator and denominator, or marking an action or activity as performed."[7] It was stated on the vendor call that a QR or QCDR would need to prove that more than 50 percent of clinicians within the group performed the improvement activity in order to certify that the data is true, valid and accurate prior to submission. It was not clear whether QRs and QCDRs may rely on the group's attestation as such proof despite CMS' published guidance.

   Requiring more substantial documentation (e.g., payrolls and other legal forms that would clearly substantiate a group's NPIs and their employment dates against each improvement activity) this late in the 2020 performance period would unduly burden groups and registries. Moreover, we do not believe CMS intends to require QRs and QCDRs to collect more substantial proof than CMS collects through its portal. The focus of an audit conducted by QCDRs and QRs should be limited to completeness and accuracy of measures and activities and not crossover to assessment of fraud which seems to be indicated by checking employment dates for NPIs within a Tax Identification Number.

Our registry participants have been collecting and reporting data for the first 10 months of 2020 based upon the 2020 Final Rule and other official, published CMS guidance that align with that

[6] 5 U.S.C. § 553(b)-(c).
[7] CMS, *Improvement Activities Requirements*, Quality Payment Program https://qpp.cms.gov/mips/improvement-activities (last visited Oct. 26, 2020).

rule. Any change to our 2020 data validation and auditing procedures this late in the 2020 CMS reporting year will diminish trust in CMS and in the Quality Payment Program and significantly burden participating groups and individuals, many of which are experiencing unprecedented challenges due to the global pandemic and recent natural disasters.

Our registry members have contracted with our participants and their vendors that are subject to our CMS-approved data validation plans for 2020. Effectuating changes to documentation and auditing requirements this late in the 2020 reporting year risks breaching these contracts and straining our business relationships.

The Coalition does not request special exceptions to the 2020 performance period regulatory requirements for data validation and auditing. **CMS approved each of our data validation plans for the 2020 MIPS performance period. We wish to carry out those plans as approved and receive confirmation from CMS that additional criteria outside of such plans are not required.**

Thank you for your attention to these important issues. 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 Otolaryngology – Head and Neck Surgery
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons/Congress of Neurological Surgeons
American Board of Family Medicine
American College of Emergency Physicians
American College of Radiology
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Society of Anesthesiologists/Anesthesia Quality Institute
American Society of Nuclear Cardiology
American Society of Plastic Surgeons
American Urological Association
Association for Clinical Oncology
College of American Pathologists
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons

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