P•C•R•C

PHYSICIAN CLINICAL REGISTRY COALITION

September 6, 2022

Submitted Electronically via www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1770-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Physician Clinical Registry Coalition's Comments on the Proposed 2023 Updates to the Quality Payment Program (CMS-1770-P)

Dear Administrator Brooks-LaSure:

The undersigned members of the Physician Clinical Registry Coalition (the "Coalition") appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS's") proposed rule on updates to the Quality Payment Program ("QPP") for calendar year 2023 (the "Proposed Rule") relating to Qualified Clinical Data Registries ("QCDRs") and Qualified Registries ("QRs").[1] 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.

The Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") requires the Secretary of the Department of Health and Human Services to encourage the use of QCDRs and certified electronic health record ("EHR") technology for reporting measures under the quality performance category of the Merit-based Incentive Payment System ("MIPS") program.[2] The Coalition urges CMS to adopt proposals that support MACRA's directive by encouraging QCDR

[1] Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts, 87 Fed. Reg. 45,860 (July 29, 2022).
[2] MACRA, Pub. L. No. 114-10, § 101(c), 129 Stat. 87 (2015).

participation in the MIPS program and encouraging the development of strong QCDR measures and a framework that supports accurate quality data measurement. Conversely, the Coalition requests that CMS refrain from finalizing proposals that would impose burdensome requirements on registries that conflict with and impede the critical role that registries play in improving patient outcomes and quality of care.

The Coalition's comments are confined to those proposals that will have the most significant effects on registries.

QCDR Measure Testing Requirements

CMS is proposing to delay the requirement for a QCDR measure to be fully developed and tested. To be approved for the 2024 performance year, CMS proposes that a new QCDR measure must be face valid. However, beginning with the 2024 performance year, a QCDR measure approved for a previous performance year must be fully developed and tested, with complete testing results at the clinician level, prior to self-nomination.

The Coalition appreciates CMS's decision to delay the implementation of the QCDR measure testing policy for measures in the traditional MIPS program. The QCDR measure testing policy imposes costly testing requirements for QCDR measures, while not holding MIPS quality measures to the same testing standards. For instance, CMS proposes to adopt the Screening for Social Drivers of Health measure, despite it not having undergone testing at the physician level, in order to fill an important measure gap. This demonstrates that CMS has the flexibility to relax measure testing requirements in order to meet certain measure priorities. We appreciate the importance of measure testing and are not requesting that CMS waive measure testing requirements in their entirety; however, we are requesting that CMS adopt a more flexible approach when considering new QCDR measures for approval and the important gaps in specialty measures that they may fill.

We continue to believe that because the COVID-19 extreme and uncontrollable circumstances exception policy decreased the number of clinicians and groups reporting to MIPS via QCDRs, CMS should revise its measure testing policy to:

- Require face validity for the first two MIPS payment years for which the measures are approved.
- Support the decision of QCDR statisticians familiar with sample sizes and populations relative to the level of testing (clinician, facility, or group) required.
- Offer additional incentives for practices to choose to submit data on new QCDR measures.
- Provide further guidance and/or data from CMS to help measure stewards validate their measures.
- Exempt measures targeted for harmonization by CMS from satisfying the measure testing requirement *prior* to self-nomination.

Lastly, CMS should similarly delay the requirement that QCDR measures must be fully tested prior to their inclusion in a MIPS Value Pathway ("MVP"). This would simplify the program's

rules by maintaining consistency between traditional MIPS and MVPs. It would also provide an opportunity for more specialty-specific measures to be included in MVPs, which is critical as we move towards subgroup reporting.

QCDR Measure Specifications

We appreciate the agency's clarification that QCDRs are required to publicly post the CMS-approved measure specifications for the QCDR measure no later than 15 calendar days following CMS posting of all approved specifications for the QCDR measure.

Data Completeness

We appreciate the proposal to continue the data completeness criteria at 70 percent for the 2023 performance period. However, the Coalition opposes the proposed increase to 75 percent for the 2024 and 2025 performance periods. Percentage requirements of higher than 70 percent do not account for physicians who provide care beyond a single site and wrongly assume that data is fluid between sites. Some specialties provide services across multiple sites using the same National Provider Identifier ("NPI")/Taxpayer Identification Number ("TIN"); however, not all sites (including across sites of service) may: (1) participate in MIPS; or (2) use the same registry or EHR that the physician uses for MIPS reporting. Until physicians and other eligible clinicians can work within an environment where data and care are integrated seamlessly across settings and providers, it is premature to continue to increase the MIPS data completeness requirement.

Previously Finalized Specialty Measure Sets Proposed for Combination

The Coalition has significant concerns with the proposal to create combined specialty sets of "Psychiatry" to the title of "Mental/Behavior Health" and merging "Optometry" to "Ophthalmology." This type of combination of specialties could lead to providers who lack the knowledge, licensure, or experience necessary to safely treat patients to the currently expected level of care. We have concerns that, by grouping together fairly divergent levels of caregivers into two larger amalgamations, the distinctions between the specialties will not be addressed clearly, such as differences in patient populations. This kind of change may have serious long-term implications in terms of the scope of practice which providers in these specialties may attempt to be reimbursed for in the future.

We are also concerned about the claims made about having received the "interested parties' feedback." To our knowledge, the measure steward for at least one of these specialties was not aware of this consideration prior to its announcement in the Proposed Rule. The lack of input from the measure steward in advance of such significant changes sets a disturbing precedent and will inevitably lead to future measure harmonizations that may be inappropriate or that cannot be smoothly implemented.

MIPS Value Pathways

The Coalition believes that CMS's efforts to design, evaluate, and implement the MVP program must comply with the language and spirit of MACRA. To ensure that MVPs will provide meaningful information to clinicians and their patients, MVPs must be developed with measures that form a clinically aligned, cohesive reporting mechanism and should ensure that the cost measures incorporated into an MVP have clinical association with the quality measures in the same MVP. It is important that CMS not take a one-size-fits-all approach to the MVP program but, instead, recognize that a tailored approach is necessary for all clinicians, including primary care.

I. *Sunset of the Traditional MIPS Program*

In the Proposed Rule, CMS notes that it has not yet determined the timing for the sunset of the traditional MIPS program. The Coalition reiterates its strong belief that it is premature to consider retiring traditional MIPS. CMS should maintain the current process of MIPS reporting for all eligible clinicians and groups and continue to recognize MVP participation as voluntary.

The development and implementation of MVPs, as well as the campaign to educate clinicians regarding the new program, will take time. Clinicians have expressed concerns that measures included in proposed MVPs are not meaningful to providers and that MVP reporting will necessitate IT support that is costly. Some specialty societies already predict that it will be several years before they can develop an appropriate candidate MVP. Some barriers to MVP development include lack of applicable MIPS measures that apply to the specialty, lack of benchmarks for existing QCDR measures, measure testing requirements that will limit the number of QCDR measures eligible for inclusion in MVPs, and lack of relevant cost measures. At this point in the MVP implementation process, it is simply too early to contemplate a timeline for sunsetting traditional MIPS.

II. *MVP Development Process*

CMS proposes to modify the MVP development process such that the agency would evaluate a submitted candidate MVP through the MVP development process, and if CMS determines that the candidate is "ready" for feedback, the agency would post a draft version of the submitted candidate on the QPP website and request feedback for a 30-day period. Under the Proposed Rule, if the agency concludes that the candidate MVP should be amended, CMS would not notify the party that originally submitted the candidate MVP for consideration in advance of the rulemaking process.

It is crucial that the agency commit to working collaboratively with specialty societies and measure stewards to develop MVPs that are clinically relevant and meaningful to specialties, subspecialties, and patients. We urge CMS to view specialty societies and measure stewards as valuable partners during the MVP development process. The development and implementation of MVPs place a tremendous strain on the financial and administrative resources of specialty

societies and their clinical data registries. To ensure that resources are appropriately invested, the Coalition urges CMS to provide greater transparency in the MVP approval process.

Such transparency includes clearly communicating the agency's priorities with respect to the scope and intent of MVPs, providing additional guidance regarding the criteria that governs when a candidate MVP is "ready" for feedback, providing access to more QPP and claims data that would help drive the development of specialty-specific cost measures, and notifying the party that originally submitted the candidate MVP if the agency determines that changes should be made to the candidate MVP. In addition, if CMS receives two MVP candidates that concern the same specialty, CMS should inform both MVP developers of this information to give the developers of the MVP candidates time to coordinate their efforts.

Further, we believe that a 30-day comment period may not offer sufficient time to provide meaningful comments on the candidate MVP. We encourage CMS to expand the comment period to 60 days, which parallels the timeframe for notice-and-comment rulemaking. We understand that the agency reviews MVPs on a rolling basis; however, we believe that this comment period should take place as early in the year as possible.

III. *Request for Information on Third Party Intermediary Support of MVPs*

CMS previously finalized a requirement that, beginning with the 2023 performance period, QCDRs and QRs must support MVPs that are "applicable to the MVP participant on whose behalf they submit MIPS data." We urge the agency to publish guidance on how to determine whether an MVP is "applicable to the MVP participant on whose behalf they submit MIPS data."

Additionally, in the 2022 Medicare Physician Fee Schedule final rule, CMS indicated that it expects QCDRs and QRs that support MVPs to support all measures and activities across the quality, promoting interoperability, and improvement activities performance categories that are included in the MVP. The Coalition believes that third party intermediaries should have the flexibility to choose which measures they will support within an MVP. Supporting an entire MVP is very different from supporting the inclusion of specific QCDR measures in an MVP and could carry much more burden for the registry. A QCDR or QR should not be forced to support all measures within MVP when it did not assist with or does not agree with the MVP measures.

In addition, there may be operational barriers to reporting all measures within an MVP, particularly with respect to MVPs that span multiple specialties or settings. A QCDR or QR may not have access to all the necessary data (e.g., inpatient v. outpatient data). For example, a medical oncology registry would face operational challenges if it were required to support an MVP containing the Q462: *Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy* measure. Medical oncologists use iKnowMed (an EHR web-based platform), whereas radiation oncologists use a different EHR vendor—MOSAIQ Medical Oncology. Requiring a medical oncology registry to support the Q462 measure would place an undue burden on a medical oncology registry to collect both radiation oncology data and medical oncology data.

The Coalition recently sought clarification from CMS regarding whether a QCDR supporting an MVP would be required to support another QCDR's measure in the MVP. We were informed that QCDRs are encouraged to support all QCDR measures in the MVP but are not required to support QCDR measures owned by another QCDR if they have not obtained permission to use such measure. In other words, QCDRs do not need to support *all* QCDR measures in an MVP if they do not steward or co-own the QCDR measure. If a QCDR intends on supporting *all* QCDR measures, it must first obtain permission to use any QCDR measure owned by another QCDR. Further, a QCDR is not required to grant permission to other QCDRs. In addition, because only QCDRs may report QCDR measures, QRs cannot support QCDR measures in an MVP. We ask CMS to explicitly confirm these policies in the 2023 Medicare Physician Fee Schedule final rule.

Regardless of whether the agency moves forward with requiring QCDRs to support all measures and activities across the quality, promoting interoperability, and improvement activities performance categories that are included in an MVP, CMS should notify QCDR measure stewards whether and how much data has been submitted on their measure. In addition, if CMS moves forward with its policy to require third party intermediaries to support all measures within the MVP, CMS should delay this requirement by one calendar year after the MVP has been finalized.

* * * * *

The Coalition appreciates the opportunity to submit these comments and CMS's attention to these important issues. If you have any questions, please contact Rob Portman or Leela Baggett at Powers Pyles Sutter & Verville, PC (Rob.Portman@PowersLaw.com or Leela.Baggett@PowersLaw.com).

Respectfully submitted,

American Academy of Dermatology Association
American Academy of Neurology
American Academy of Ophthalmology
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 Gastroenterological Association
American Society for Gastrointestinal Endoscopy
American Society of Anesthesiologists
American Society of Clinical Oncology
American Society of Plastic Surgeons
American Urological Association
Center for Professionalism and Value in Health Care
College of American Pathologists
Congress of Neurological Surgeons
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons