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PHYSICIAN CLINICAL REGISTRY COALITION

September 11, 2023

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–1784–P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Physician Clinical Registry Coalition's Comments on the Proposed 2024 Updates to the Quality Payment Program (CMS-1784-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 2024 (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.

Clinical data registries are major sources of real-world evidence, including patient-reported outcomes data. The comprehensive and valuable measures developed by clinical data registries are meaningful and relevant to participating providers and their patient populations. Clinical data registries provide a valuable data collection infrastructure to accomplish numerous objectives, including:

[1] Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program, 88 Fed. Reg. 52,262 (Aug. 7, 2023).

- Improving quality of healthcare by providing timely and actionable feedback to practitioners on their performance and identifying best clinical practices;
- Monitoring the prevalence and trends of specific conditions and diseases;
- Monitoring the effectiveness, cost-effectiveness, and comparative effectiveness of specific devices or treatments;
- Identifying opportunities to research patient outcomes and performing other research; and
- Identify deficiencies or disparities in care that require corrective action.

We continue to have serious concerns regarding the agency's complex and cumbersome MIPS policies that have created obstacles for clinical data registries to successfully accomplish these goals. As a result, some QCDRs have dropped out of the traditional Merit-based Incentive Payment System ("MIPS") program, which adversely impacts practitioners. Therefore, 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.

Notably, 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 for reporting measures under the quality performance category of the MIPS program.[2] The Coalition urges CMS to adopt proposals that support MACRA's directive by encouraging QCDR participation in the MIPS program and encouraging the development of strong QCDR measures and a framework that supports accurate quality data measurement.

Although the Proposed Rule addresses many policies governing the MIPS program, the Coalition's comments are confined to those proposals that will have the most significant effects on registries.

MIPS Value Pathways ("MVPs")

The MVP program provides an opportunity to increase scoring simplicity and predictability, appropriately evaluate and reward performance improvement, collaborate with specialty societies to identify and address priority areas, ensure that quality measurement is clinically relevant to physicians, and focus on patient-centered care. In developing the MVP program, we encourage the agency to adopt MVP policies that will remedy the substantial administrative burdens of the current, traditional MIPS program. The Coalition believes that CMS's efforts to design, evaluate, and implement the MVP program must comply with the language and spirit of MACRA that encourages the use of QCDRs for reporting measures under the quality performance category of the MIPS program.

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

[2] MACRA, Pub. L. No. 114-10, § 101(c), 129 Stat. 87 (2015).

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. Additionally, we encourage the agency to adopt MVP policies that will remedy the substantial administrative burdens of the current, traditional MIPS program. Notably, the current number of measures in the traditional MIPS program is not the source of significant administrative burden on practitioners. Therefore, we oppose limiting physicians' choice of quality measures in an MVP.

I. *Maintain the Traditional MIPS Program*

Although the Proposed Rule does not propose to establish the timing for ending the traditional MIPS program, the Coalition would like to reiterate 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 costly IT support. Some specialty societies 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. *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." 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 applauds the agency's recognition that many third party intermediaries may not support measures for clinicians in all specialty areas that might report an 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.

We appreciate the agency's clarification that QCDR measures are only required to be reported by the QCDR measure owner. 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. We applaud CMS for explicitly confirming QCDRs are not required to support QCDR measures owned by another QCDR if they have not obtained permission to use such measure. Similarly, because only QCDRs may report QCDR measures, QRs cannot support QCDR measures in an MVP.

In addition, CMS proposes that if an MVP includes several specialties, then a QCDR or a QR must only support the measures that are pertinent to the specialty of their MIPS eligible clinicians. We appreciate the agency's recognition that there may be operational barriers to reporting all measures within an MVP that span multiple specialties. A QCDR or QR may not have access to all the necessary data (e.g., inpatient v. outpatient data). We urge the agency to provide sufficient flexibility to registries when determining the precise scope of a specialty.

The Coalition asks CMS to share submitted data on a QCDR measure with the steward of that measure. At the request of CMS, our member QCDRs have licensed their measures to a number of other QCDRs. However, these QCDRs are oftentimes unaware of whether the licensee actually reports the measure and if the measure is being consistently implemented and reported across all licensees. By CMS sharing submitted data with a QCDR steward in the summer following the reporting year, the steward will have a better opportunity to assess the feasibility and implementation of its measures. It also allows QCDR stewards to understand whether the licensee has fulfilled its contractual obligations with the measure steward.

Lastly, CMS should delay the MVP support requirement by one calendar year after the MVP has been finalized. This will permit QCDR's and QR's sufficient time to adapt to the new program.

Health Information Technology ("IT") Vendors

We applaud the agency for proposing to eliminate the health IT vendor as a third party intermediary category, beginning with the 2025 performance period. CMS previously established data validation audit and targeted audit requirements that apply specifically to QCDRs and QRs; however, such requirements were not imposed on health IT vendors. This inequity has led to health IT vendors submitting inaccurate and unusable data. We appreciate the agency's recognition that the lack of data validation requirements for these third-party intermediaries has undermined the integrity of the MIPS program. This proposal will help ensure the accuracy of MIPS data and fair and equitable assessment of eligible clinicians.

We also agree that the proposed elimination of the health IT vendor category would create a clearer distinction between those vendors that are submitting data for the purposes of MIPS and those that work with clinicians through the sale and support of health IT that permits the clinician or group to submit the data. Further, we encourage CMS to establish data validation standards for direct reporting. This would curtail the ability of health IT vendors to facilitate the submission of data of questionable integrity purposes of direct reporting.

Data Completeness

CMS previously finalized a policy increasing the data completeness threshold to 75 percent for the 2024 and 2025 performance periods. The agency is proposing to maintain the data completeness criteria threshold at 75 percent for the 2025 and 2026 performance periods. For the 2027 performance period, CMS proposes to increase the data completeness criteria threshold by 5 percent from 75 percent to 80 percent.

The Coalition opposes the proposed data completeness thresholds for the 2027 performance period. The proposed increase is inconsistent with the agency's goals of reducing provider burden in the MIPS program. CMS admits that the increased data completeness criteria threshold will pose a "substantial burden to MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities" that manually extract and report quality data. Further, 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 electronic health record vendor that the physician uses for MIPS reporting. In addition, practices report that they often encounter barriers such as the lack of agreed upon semantic and syntactic standards, data privacy concerns, and patient misidentification. 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.

Performance Threshold

We strongly oppose the agency's proposal to increase the performance threshold to 82 points for the 2024 performance period, based on a three-year average of performance data from 2017 to 2019. The proposed establishment of a higher, more rigorous performance threshold will increase administrative burden on physicians and place a financial strain on smaller practices. The agency estimates that more than one-half of MIPS eligible clinicians will be subject to a negative payment adjustment penalty due to the proposed increase of the performance threshold. The payment cuts associated with the proposed performance threshold will compound the financial distress currently facing physicians who are dealing with high inflation and workforce shortages, as well as substantial proposed cuts in overall Medicare physician reimbursement. These burdens are magnified for small and rural physician practices.

The proposed reliance on performance data from 2017 to 2019—a period up to seven years old—fails to reflect the contemporary MIPS program. Data for the 2017, 2018, and 2019 performance periods reflect different performance category weights; quality measures that have since been removed; and certain bonus points that have since been phased out. For instance, the Cost performance category was weighted at 15 percent in 2019, but it is now weighted at 30 percent. Additionally, inventories of measures and activities for the Promoting Interoperability and Improvement Activities performance categories have evolved. Further, the first year of MIPS reporting under the QPP was 2017, which included a "Pick Your Pace" approach.

We encourage the agency to create opportunities for performance improvement without increasing burden on providers. Accordingly, we urge CMS, at a minimum, to maintain a performance threshold of 75 points for the 2024 performance year. As many eligible clinicians are now returning to reporting, the agency should prioritize continuity in the MIPS program, including the MIPS performance threshold.

Quality Measures and Associated Benchmarks

The Coalition urges CMS to prioritize continuity in the availability of meaningful quality measures and consistent quality measure benchmarks. The comprehensive and valuable measures developed by clinical data registries are meaningful and relevant to participating providers and their patient populations. Medical societies expend considerable resources and time in developing clinically relevant quality measure that will improve quality of care. We are concerned that the agency continues to reject measures developed by clinical data registries that have undergone considerable testing.

In fact, many MIPS eligible clinicians who relied on the MIPS Extreme and Uncontrollable Circumstances Exception for the past several years may be surprised by the lack of quality measures that were previously utilized in prior years. The lack of meaningful quality measures adversely impacts clinicians, resulting in potential negative payment adjustments and workflow adjustments to satisfy less familiar quality measures. Therefore, the Coalition respectfully requests that the agency prioritize the maintenance and development of quality measures, including a 2-year approval cycle of quality measures, developed by clinical data registries.

Targeted Reviews

Under the Proposed Rule, requests for targeted review must be submitted during the targeted review request submission period, which begins on the day CMS makes available the MIPS final score, and ends 30 days after publication of the MIPS payment adjustment factors for the MIPS payment year. If CMS requests additional information from the MIPS eligible clinician, subgroup, virtual group, or group that is the subject of a request for a targeted review, the information must be provided and received by CMS within 15 days of CMS' request.

The Coalition urges CMS to provide a 60- or 90-day target review period after the publication of the MIPS payment adjustment factors for the MIPS payment year. This would provide clinicians sufficient time to fully evaluate their final MIPS scores. We also request that CMS provide additional time for MIPS eligible clinicians, subgroups, virtual groups, and groups to respond to the agency's request for additional information. A 15-day timeframe to respond to CMS's request for additional information is simply too short.

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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 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 Psychiatric Association
American Society for Gastrointestinal Endoscopy
American Society of Anesthesiologists
American Society of Plastic Surgeons
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