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PHYSICIAN CLINICAL REGISTRY COALITION

September 9, 2024

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-1807-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Physician Clinical Registry Coalition's Comments on the Proposed 2025 Updates to the Quality Payment Program (CMS-1807-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 2025 (the "Proposed Rule") that impact Qualified Clinical Data Registries ("QCDRs"), Qualified Registries ("QRs"), and their participants.[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 organized data collection and analysis systems operated by or affiliated with a national medical society, hospital association, or other health care association. These registries collect and analyze data on specified outcomes submitted by physicians, hospitals, and other types of health care providers related to a wide variety of medical procedures, diagnostic tests, and/or clinical conditions. They perform data aggregation and related benchmarking analyses that support one or more predetermined scientific, clinical, or policy purposes, including, but not limited to, describing the natural history of disease, determining the effectiveness (including the comparative effectiveness) of therapeutic

[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).

modalities, and measuring quality of care. 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. These measures provide important information that is not available from claims data. Accordingly, registry data can and should be the foundation of any innovative quality-based payment program.

Overall, we continue to have serious concerns regarding the agency's complex and cumbersome Merit-based Incentive Payment System ("MIPS") policies that have created obstacles for clinical data registries to successfully accomplish their goals in supporting physicians in delivering high-quality, safe, and patient-centered care. As CMS considers adopting policies for 2025 and beyond, we urge the agency to encourage QCDR participation in the MIPS program and encourage the development of strong QCDR measures and a framework that supports accurate quality data measurement.[2] To that end, the Coalition offers the following comments and recommendations.

MIPS Value Pathways ("MVPs")

I. *Maintain the Traditional MIPS Program*

Although the Proposed Rule does not propose to establish the timing for ending the traditional MIPS program, the agency is seeking feedback on clinicians' readiness to sunset the traditional MIPS program by the 2029 performance period. 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.

Medical societies have expressed serious concerns regarding the development of MVPs applicable to their specialties. Specifically, medical societies are concerned that measures included in proposed MVPs are not meaningful to providers and that MVP reporting will necessitate costly IT support. 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. Therefore, we believe it would be inappropriate to sunset the traditional MIPS program by the 2029 performance period. The agency needs additional time to work collaboratively with stakeholders to develop a proper MVP framework that results in more clinically relevant and meaningful performance data for specialties and subspecialties, as well as patients. We also urge the agency, in developing the MVP program, to address the current shortcomings of the MIPS program.

[2] Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, § 101(c), 129 Stat. 87 (2015).

II. *MVP Development – Quality Measures*

We have serious concerns that CMS is developing the MVP framework contrary to the language and spirit of Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"). As you are aware, MACRA requires the Secretary of Health and Human Services to encourage the use of QCDRs for reporting measures under the quality performance category of the MIPS program.[3] Although the agency notes that one barrier to MVP development is the apparent lack of MIPS quality measures, CMS appears to be limiting the number of QCDR measures in MVPs by excluding QCDR measures or asking QCDR measures to be harmonized with existing measures. During the MVP development process, CMS has declined, on numerous occasions, to adopt QCDR measures recommended by medical societies. In doing so, the agency failed to provide a sufficient rationale for refusing to include measures that were deemed by providers to be clinically meaningful. This directly contravenes MACRA and significantly disadvantages providers who are already facing a scarcity of relevant MIPS measures—particularly harming small and rural practices.

For instance, the American Society of Clinical Oncology ("ASCO") and Practice Insights by McKesson in collaboration with The US Oncology Network – QCDR sent comments to the CMS PIMMS MVP Support Team in April of 2024, advocating for the addition of two QCDR measures (PIMSH15 and PIMSH16) to the Advancing Cancer Care MVP for performance year 2025. Because both measures are worth 10 points, they are more valuable to reporting oncologists than others in the current Advancing Cancer Care MVP. Based on the data transmitted to CMS by the Practice Insights' registry for 2023, it was known that both measures would receive performance year benchmark illustrating wide variability. CMS published the performance period benchmarks for both measures in July of 2023. Although CMS acknowledge receipt of their recommendation, the agency did not include these measures in the proposed Advancing Cancer Care MVP, and the agency did not provide any rationale for the exclusion.

The lack of transparency is troubling for both medical societies and the clinicians they represent. The agency's selection of measures appears arbitrary and has created immense confusion among the medical field. The dearth of guidance and transparency has a disparate impact on certain specialties. CMS criteria for MVP development state that MVP candidate submissions must have "a clear intent and goal." We agree that establishing clear intentions and goals for MVP candidates upfront is vital to ensure the MVP will enhance patient quality of care in practice. However, several medical societies have raised concerns that proposed MVPs do not have a clear intent or intended outcome. For instance, the proposed MVP titled "Gastroenterology Care" has five specialty-specific quality measures assessing colorectal cancer prevention, two quality measures assessing Hepatitis C, one quality measure assessing Inflammatory Bowel Disease ("IBD"), and one episode-based cost measure focused on screening/surveillance colonoscopy. This measure set lacks the ability to measure and evaluate the full spectrum of care under the purview of gastroenterologists, particularly those gastroenterologists who subspecialize.

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[3] *Id.*

The proposed Surgical Care MVP arbitrarily throws together a disparate mix of measures relevant to numerous distinct surgical specialties that have no clinical connection (i.e., spine surgery, breast surgery, CABG surgery, and general surgery). In another example, the proposed Dermatological Care MVP relies on an excessively broad measure set that lacks alignment and is incapable of offering meaningful feedback to enhance patient care since it encompasses both inflammatory and neoplastic disease processes. The Dermatological Care MVP fails to distinguish between very separate disease processes (e.g. psoriasis vs. melanoma), which are treated by different subspecialists. This will inevitably lead to unfair comparisons among dermatologists with varying sub-specializations and patient populations.

In addition, medical societies have expressed concerns that specialty care is being assessed through the lens of quality measures and improvement activities that are actually intended for use by primary care providers. For instance, QID 113 Colorectal Cancer Screening is not intended for gastroenterologists; instead, it is intended to assess primary care physicians ordering colorectal cancer screening. Because CMS's approach to benchmarking does not differentiate quality based on specialty, inclusion of a measure geared toward primary care physicians versus being broadly applicable in a specialty-specific MVP increases the likelihood that performance differences across specialties will be masked and further undermines the utility of the measure by establishing benchmarks that do not provide a fair and reasonable comparison between providers based on specialty.

Another cause of confusion concerns CMS's decision to not include measures from the specialty measure set in MVPs. CMS has already determined that quality measures in the specialty measure sets are relevant to a specialty's practice and expertise. Therefore, medical societies are grappling to understand why those measures are not included in the corresponding MVP. Continuity between specialty measure sets and MVPs is important to provide a smooth transition between the traditional MIPS program and the MVP program.

Medical societies have invested considerable funding into the development QCDR measures and the move towards MVPs is devaluing their investment in clinically relevant performance measures. As CMS "explor[es] options of how MVPs can be further developed to facilitate greater reporting rates for clinicians with fewer measures available for their specialty," we urge the agency to include clinically appropriate QCDR measures in MVPs. 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.

III. *MVP Development – Cost Measures*

The lack of relevant cost measures for certain specialties also complicates the utilization of MVPs. For instance, medical societies have expressed concerns regarding the inclusion of the Total Per Capita Cost ("TPCC") Measure. This measure's flawed methodology and lack of transparency, particularly in how it measures care utilization, can unfairly penalize physicians for appropriate care provision, such as providing preventative services. CMS should heed the concerns expressed by medical specialty societies and recognize the unintended consequences

that such measures can create. CMS should seek the knowledge of medical specialty societies, which have been extensively involved in developing specialty-specific episode-based cost measures, to address these unintended consequences.

CMS currently employs a single contractor, Acumen, LLC, to develop new episode-based cost measures. Although this process is comprehensive, it is lengthy, relies strictly on claims data, and does not simultaneously account for quality, which results in a flawed assessment of overall healthcare value. We encourage CMS to develop more innovative, out-of-the-box solutions related to cost measurement.

One solution may include the integration of clinical registry data with claims data to most accurately evaluate value and the use of appropriate measures to assess cost. However, current regulatory barriers prevent such integration. The Virtual Research Data Center ("VRDC") does not provide clinician-led clinical data registries with the type of timely, broad, and continuous access to claims data necessary for registries to effectively link their outcomes data with claims data. The VRDC is limited to narrowly defined research questions and is slow, costly, and cumbersome. Moreover, CMS's decision to treat QCDRs as quasi-qualified entities for purposes of obtaining access to claims data does not provide QCDRs (or other clinician led clinical data registries) with the long-term, continuous, and timely access to claims data. The scope of the data provided under the Qualified Entity Program does not satisfy registry needs. In addition, the Qualified Entity Program requirements on eligibility, operations, and governance are extremely lengthy and burdensome.

Therefore, we urge CMS to implement regulatory changes to provide clinical data registries with better access to claims data so that they can help develop a broader inventory of specialty-specific cost measures.

IV. *Mandatory Subgroup Reporting Requirement*

Beginning in the CY 2023 performance period, clinicians can choose to form a subgroup, comprised of clinicians with similar scopes of care, to report an MVP through. CMS has previously finalized that such subgroups will become mandatory for multispecialty groups choosing to report MVPs beginning in the 2026 performance period, and that multispecialty groups will no longer be able to submit data at the group level. Instead, these multispecialty groups will be required to form subgroups and clinicians who do not fit within a particular subgroup would have to report individually. Under established rulemaking, whether a practice counts as a multispecialty or single specialty practice is based on Medicare Part B claims data and PECOS data, with a multispecialty group defined as a group that consists of two or more specialty types.

In this Proposed Rule, CMS requested comment on what limits should be established on the composition of clinician subgroups, and how to provide flexibility for practices that meet the definition of a multispecialty practice but where it would be onerous for the practice to report data through separate submissions.

If MVP reporting is not required at this time, we believe it is inappropriate to require subgroup reporting by the 2026 performance period. This unnecessarily adds complexity to the MVP program, particularly considering the lack of guidance regarding the definition of a multispecialty practice. Imposing mandatory reporting during the transition process from MIPS to MVPs increases the administrative burden of practices by potentially requiring a multi-specialty group practice to report on multiple MVPs. This also may create an additional administrative burden on registries. Before finalizing any proposal regarding mandatory subgroups, CMS should gather appropriate data to evaluate the formation and reporting/performance patterns of subgroups.

Topped Out Measures

Currently, measures identified as topped out for 2 or more consecutive years will be subject to a scoring cap of 7 out of 10 achievement points. In the Proposed Rule, CMS noted concern about specialty measure sets, where many of the measures in a particular specialty measure set are topped out and subject to this cap. Hence, CMS is proposing that beginning in the 2025 performance period, CMS will remove the 7-point cap for selected topped out measures as determined by CMS. CMS' proposed methodology for identifying specific measures that would fall under this policy relies on an analysis of MIPS specialty measure sets to evaluate which are "at-risk" due to scoring limitations. CMS would also take into consideration whether or not a measure within the specialty measure set is considered cross cutting, whether it is broadly applicable (i.e., included in three or more specialty sets), and whether there are more than ten measures, by collection type, available in the specialty set.

We recommend that CMS conduct a more granular analysis and consider the number and percentage of specialty-specific measures in the specialty measure set that are topped out. Under the proposed methodology, specialties with sets that are large or include numerous broad, non-specialty specific measures will always be at a disadvantage and their specialty-specific measures will never qualify for the removal of the 7-point cap. For example, the Rheumatology specialty set currently includes 17 measures, the majority of which are broad or cross-cutting. However, 100% of the four measures in the set that are focused specifically on treating patients with rheumatic diseases are topped out, thus limiting the ability of rheumatology clinicians to report on measures that are relevant to their specialty and perform well in the program.

Importantly, several QCDR measures are currently subject to the 7-point cap. However, CMS' proposed methodology for identifying "at-risk" measure sets relies exclusively on analyses of MIPS specialty sets, which do not include QCDRs. Thus, there would be no mechanism to exempt any QCDR measures from the 7-point cap. We respectfully remind CMS that Congress created the QCDR mechanism to fill critical gaps in the traditional quality measure sets and to ensure that clinicians have access to measures that are more meaningful and relevant to their specialty. CMS's current policy concerning topped out measures creates an effect that is counter to the statutory purpose of QCDRs being innovative and targeted to the needs of different specialties. Therefore, we urge CMS to also remove the 7-point cap for QCDR measures.

We also ask the agency to remove the 7-point cap for a specified timeframe to ensure stability for clinicians. Additionally, to the extent that the measure subject to this 7-point cap exception appears in multiple specialty sets, the Coalition urges CMS to remove the 7-point cap for that measure across *all* specialty sets.

Moreover, we wish to take this opportunity to reiterate our concern regarding CMS's policy allowing the agency to remove a QCDR measure from the program as soon as it is identified as topped out rather than subjecting it to the 4-year removal timeline that applies to non-QCDR topped out measures. This policy fails to reward physicians' sustained excellence in providing care. Once a topped out measure is removed from the program, it is challenging to monitor for new performance gaps over time. In addition, topped out measures are only topped out for clinicians who report them. Topped out measures may represent an opportunity for improvement among the vast majority of clinicians who do not report them.

Data Completeness

CMS previously finalized a policy increasing the data completeness threshold to 75 percent for the 2024 and 2025 performance periods. The agency also maintained the data completeness criteria threshold at 75 percent for the 2026 performance period. CMS is now proposing to maintain the data completeness criteria threshold of at least 75 percent through the 2028 performance year.

The Coalition applauds the agency for refraining from increasing the data completeness threshold through the 2028 performance year. We continue to believe that any proposed increase is inconsistent with the agency's goals of reducing provider burden in the MIPS program. Higher data completeness thresholds have a disparate impact on participants that manually extract and report quality data. Further, higher percentage requirements 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 appreciate the agency's decision not to increase the performance threshold for the 2025 performance period. The establishment of a higher, more rigorous performance threshold would increase administrative burden on physicians and place a financial strain on smaller practices. The payment cuts associated with a higher performance threshold would 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 would be magnified for small and rural physician practices. Accordingly, we urge CMS to maintain a performance threshold of 75 points for the 2025 performance year and subsequent years.

Performance Category Reweighting

CMS proposes to add a new circumstance in which the agency may reweigh certain performance categories. Beginning with the 2024 performance period, CMS may reweigh quality, improvement activities, or promoting interoperability performance categories when a clinician was unable to submit data for these categories because the data submission was delegated to a third-party intermediary which did not submit the data. The Coalition supports the agency's proposed reweighting policy to ensure that clinicians are not unfairly penalized due to third party intermediary actions outside of the clinician's control (e.g., where a third-party intermediary goes out of business).

In addition, we wish to take this opportunity to raise an issue concerning the operations of clinical data registries. In order for clinical data registries to accomplish their missions, they must be able to collect data from electronic health record ("EHR") vendors. Unfortunately, clinical data registries continue to encounter roadblocks in gathering critical data elements from these sources, creating a major challenge to interoperability between EHRs, providers, and clinical data registries. Until true interoperability is realized, clinical data registries will fall short of their tremendous potential to improve and progress the quality-based payment paradigm.

Despite the adoption of recent regulations targeting information blocking, EHR vendors, in particular, continue to hinder data transfer to clinical data registries in myriad ways. For example, EHR vendors refuse to enter into negotiations for the transfer of patient information to registries, and therefore are prohibiting registries from any degree of access to such information. EHR vendors also require providers to pay unjustified, large fees to send their data from the EHR to the registry or their software vendor. Further compounding these challenges is a systemic failure to establish a common platform for all proprietary systems to exchange data and information from multiple sources in a language the entire healthcare system can use. If registries simply import unstructured EHR data, lacking precise and standardized definitions, the integrity and unique value of registry data will be compromised. This results in stalled innovation and interoperability.

Data Submission for the Performance Categories

Currently, the agency will consider any submission received during the designated MIPS submission period as a data submission and assign a score for the submission. CMS is proposing that a submission for the quality performance category must include numerator and denominator information for at least one quality measure to be considered a data submission and scored. In other words, data submission with only a date and practice ID would not be considered a data submission and would be assigned a "null" score.

Further, under the Proposed Rule, beginning with the 2024 performance period (data submission period in calendar year 2025), CMS is proposing that a data submission for the PI performance category must include all of the following elements to be considered a qualifying data submission and scored:

- Performance data, including any claim of an applicable exclusion, for the measures in each objective;
- Required attestation statements;
- CMS CEHRT ID from the Certified Health IT Product List; and
- The start date and end date for the applicable performance period.

In other words, a submission with only a date and practice ID would not be considered a data submission and would be assigned a "null" score. Also, it would not override reweighting of the PI category.

Lastly, when CMS receives multiple data submissions with conflicting data for the PI category, the agency will assign PI score of zero. However, under the Proposed Rule, beginning with the 2024 performance period (data submission period in calendar year 2025), CMS will instead calculate a score for each data submission and use the highest score received as the PI score.

The Coalition supports these proposals to amend what qualifies as a data submission. We appreciate the agency's efforts to ameliorate the negative impacts of data submission errors on clinicians.

Ambulatory Specialty Care

CMS is exploring developing a mandatory payment model for specialists in ambulatory settings that would leverage the MVP framework. Under this model, participants would not receive a MIPS payment adjustment. Instead, the participant would receive a payment adjustment based on (1) a set of clinically relevant MVP measures that they are required to report and (2) comparing the participant's final score against a limited pool of clinicians (other model participants of their same specialty type and clinical profile, who are also required to report on those same clinically relevant MVP measures).

We believe that it is premature to move forward with a new mandatory payment model until CMS has had an opportunity to refine the MVP program and analyze all appropriate QPP frameworks. In the interim, the Coalition strongly urges CMS to collaborate with applicable specialty societies to think through other ways to develop more appropriate, specialty-focused payment models. The Coalition also strongly believes that future payment models that focus on specialty care should include clinically meaningful QCDR measures and leverage clinical data registries to improve quality of healthcare. Clinical data registries provide timely and actionable feedback to practitioners on their performance. This quality improvement effort is typically

achieved by developing benchmarks on performance/treatment outcomes from data submitted by all registry participants and sharing those benchmarks with each registry participant. Registry data helps identify best clinical practices, determine the relative value of physician services, and identify deficiencies or disparities in care that require corrective action. Clinical data registries are major sources of real-world evidence, including patient-reported outcomes data.

Response to Request for Information on Guiding Principles for Patient Reported Outcome Measures in Federal Models and Quality Reporting and Payment Programs

The Coalition appreciates CMS' development of a list of guiding principes for the Patient Reported Outcome Measures ("PROMs") and Patient Reported Outcome Performance Measures ("PRO-PMs"), including data infrastructure, measure testing, feasible clinical implementation, accessible, patient engagement, and equity. While this list is a good start, many Coalition member providers serve patients with complex needs that are not captured by these principles alone. We believe that an additional principle or principles specific to specialty care should be developed to capture the experience of patients with condition-specific comorbidities and/or complex care needs.

CMS also requested comment on how the agency can "accelerate the development of PRO-PMs and advance them more rapidly into use." To encourage the development and adoption of PRO-PMs, the Coalition recommends that CMS provide process-level incentives for eligible clinicians that reward clinicians for collecting PRO-PMs before it implements outcomes-based incentives in the program. A gradual, incentive-based approach rather than a mandated implementation approach will encourage clinician participation and buy-in. A gradual implementation approach will also allow CMS to address implementation problems as they arise, ensuring that the program will run smoothly as it expands.

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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 Leela Baggett at Powers Pyles Sutter & Verville, PC (Leela.Baggett@PowersLaw.com).

Respectfully submitted,

American Academy of Dermatology Association
American Academy of Ophthalmology
American Academy of Otolaryngology – Head & Neck Surgery
American Academy of Physical Medicine & Rehabilitation
American Association of Neurological Surgeons
American College of Gastroenterology
American College of Radiology
American College of Rheumatology
American Society for Gastrointestinal Endoscopy
American Society of Plastic Surgeons
American Urological Association

Association for Clinical Oncology
College of American Pathologists
Congress of Neurological Surgeons
Outpatient Endovascular and Interventional Society National Registry
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons