

September 12, 2025

## Submitted Electronically via www.regulations.gov

The Honorable Mehmet Oz Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1832-P Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

RE: <u>Physician Clinical Registry Coalition's Comments on the Proposed 2026 Updates to the Quality Payment Program (CMS-1832-P)</u>

Dear Administrator Oz:

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 2026 (the "Proposed Rule").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 and promote the health and well-being of Americans through the analysis and reporting of clinical indications, treatments, and outcomes.

Clinician-led clinical data registries are uniquely positioned to advance the healthcare system's transformation toward value-based care. Their infrastructure enables timely and actionable feedback to providers, as well as sophisticated data aggregation and benchmarking analyses in support of a wide range of scientific, clinical, and policy objectives. By using registry data to benchmark provider performance against peers, registries can help identify variation in care delivery, which can highlight opportunities for improvement or reveal best practices to emulate. These registries generate real-world evidence critical to evaluating the cost-effectiveness of treatments and informing whether services are reasonable and necessary.

<sup>&</sup>lt;sup>1</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32,352 (July 16, 2025).

Additionally, clinician-led clinical data registries perform data aggregation, curation, benchmarking, and analytic services on behalf of covered entities (e.g., physician practices). They also perform secondary research on de-identified data and "limited data sets" that provide real-world evidence. The Health Insurance Portability and Accountability Act ("HIPAA") rules effectively ensure that protected health information that registries collect is properly safeguarded. Clinical data registries take data security very seriously and diligently comply with the HIPAA Privacy and Security Rules.

Clinician-led clinical data registries report medical and clinical data to the CMS on behalf of their participating health care providers for purposes of the Merit-Based Incentive Payment System ("MIPS") and for more general patient and disease tracking. In fact, CMS relies on qualified clinical data registries ("QCDRs") and other registries as a way to extend federal resources and enhance the efficiency and impact of the MIPS program. For instance, QCDRs and registries take over a major chunk of the data collection and quality reporting work, which would otherwise require substantial CMS resources. Further, QCDRs often develop custom quality measures that are more relevant and clinically meaningful for specialists than CMSdeveloped measures. QCDR quality measures are developed by subject matter experts, thoroughly reviewed by professionals, and backed by literature, clinical guidelines, and initial data. Congress recognized the value of QCDR measures when it enacted the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"). Under MACRA, the Secretary of Health and Human Services is directed to encourage the use of QCDRs for reporting quality measures within the MIPS.<sup>2</sup> Further, Congress explicitly recognized the role of QCDRs in "linking [claims] data with clinical outcomes data and performing risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety."<sup>3</sup>

As CMS considers policies for performance year 2026 and beyond, we urge the agency to recognize the value of clinician-led clinical data registries and implement polices that promote the growth of clinical data registries and enhance their role in advancing care quality and research. To that end, the Coalition offers the following comments and recommendations regarding key MIPS and MIPS Value Pathway ("MVP") proposals that impact registries and/or the participants they serve.

### **Third Party Intermediary Support of MVPs**

**RECOMMENDATION:** Finalize proposal to provide QCDRs and qualified registries a one-year period to prepare for the support of newly finalized MIPS Value Pathways ("MVPs").

Currently, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data. If an MVP is intended for reporting by multiple specialties, a QCDR or a qualified registry is required to report those measures pertinent

<sup>&</sup>lt;sup>2</sup> MACRA, Pub. L. No. 114-10, § 101(c), 129 Stat. 87 (2015).

<sup>&</sup>lt;sup>3</sup> *Id.* § 105(b)(1)(A), 129 Stat. 136 (2015).

to the specialty of its MIPS eligible clinicians. If an MVP includes a QCDR measure, it is not required to be reported by a QCDR other than the measure owner.

CMS is proposing that, beginning with the 2026 performance period, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data no later than one year after finalization of the MVP. We strongly support this proposal. We appreciate that CMS has acknowledged the operational and technical challenges QCDRs and qualified registries face in preparing to support MVP reporting during the brief period between issuance of the final rule—typically in November—and the start of the performance year in January. Allowing QCDRs and qualified registries a full year to prepare will facilitate successful implementation.

# **RECOMMENDATION:** Clarify whether QCDRs and qualified registries are required to support MVP measures that are not specific to any one specialty.

As stated above, when an MVP is intended for reporting by multiple specialties, CMS requires that a QCDR or qualified registry "report those measures pertinent to the specialty of its MIPS eligible clinicians." However, the existing regulation does not explicitly address whether QCDRs and qualified registries must report measures that are not tied to any single specialty. For instance, the Pulmonology Care MVP includes the measure "Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan," which applies broadly across specialties.

Coalition members have sought clarification regarding the scope of this reporting requirement but have received conflicting information from CMS and its contractor. In some instances, members have been told that QCDRs and qualified registries must support all measures within an MVP, regardless of whether they are specialty-specific. Other members have been told that they must support all measures except those owned by other registries. On another occasion, the Coalition has been advised that "[i]f the general measure is not relevant to the scope of practice of the clinicians the QCDR supports, it is not required to support that measure." This inconsistency has created significant uncertainty for registries seeking to comply with CMS requirements.

In light of these conflicting interpretations, the Coalition respectfully requests that CMS clarify whether QCDRs and qualified registries are required to support MVP measures that are general in nature and not specific to any one specialty. The Coalition's position is that QCDRs and qualified registries should not be required to report such "generic" measures if they are not pertinent to the specialty of their MIPS eligible clinicians. Imposing a one-size-fits-all mandate that obligates registries to support every measure in an MVP would create unnecessary administrative burdens without providing meaningful benefit to clinicians. Instead, QCDRs and

<sup>&</sup>lt;sup>4</sup> 42 C.F.R. § 414.1400(b)(1)(ii)(A).

<sup>&</sup>lt;sup>5</sup> Email from MIPS QCDR/Registry Support Team, Ticket No. CS2515773 (July 24, 2025).

qualified registries should retain the flexibility to determine whether supporting a broadly applicable measure within an MVP would add value to their participating clinicians.

# **Maintain the Traditional MIPS Program**

**RECOMMENDATION:** The Coalition strongly urges CMS to refrain from sunsetting the traditional MIPS reporting pathway. CMS should maintain the current MIPS reporting structure and continue to treat participation in MVPs as strictly voluntary.

Medical societies have consistently raised significant concerns regarding the development and implementation of MVPs relevant to their specialties. Several barriers continue to hinder meaningful MVP participation, including:

- Many MVPs include a narrow set of measures that do not reflect the clinical activities or priorities of various specialties and subspecialties,
- Specialty societies report insufficient collaboration and transparency in the MVP development process,
- There is a lack of benchmarks for existing QCDR measures,
- Measure testing requirements limit the ability to include new QCDR measures in MVPs, and
- Many specialties lack applicable cost measures.

Given these ongoing challenges, it is premature to establish a timeline for sunsetting the traditional MIPS program. 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.

#### Breadth of Quality Measures Within the Traditional MIPS Program and MVPs

**RECOMMENDATION:** CMS should refrain from limiting the number of quality measures available in the traditional MIPS program and MVPs in order to preserve reporting flexibility and ensure accurate quality assessment.

Over the past several years, CMS has steadily reduced the number of quality measures available for reporting under MIPS. While measure refinement and removal of duplicative or low-value measures can improve the program, an overly restrictive approach risks undermining the program's core objective: accurately assessing and improving quality of care. Clinicians, and particularly specialists, require access to a sufficient pool of clinically relevant quality measures to capture the nuances of the care they provide. Too often, broad or generic measures are not applicable to specialty practice, leaving clinicians with limited or irrelevant options.

While CMS's goal in reducing measures is to minimize burden on clinicians, when CMS eliminates or harmonizes measures that are meaningful and clinically appropriate, it inadvertently narrows reporting pathways and increases administrative burden. Clinicians may be forced to attempt reporting on measures that do not reflect their scope of practice, which leads

to inaccurate assessment and creates frustration rather than fostering quality improvement. Moreover, the absence of applicable measures makes it difficult to evaluate performance fairly or to provide providers with an accurate picture of care quality.

Therefore, the Coalition strongly urges CMS to maintain a sufficient breadth of clinically relevant quality measures—including QCDR measures—within both traditional MIPS and MVPs.

**RECCOMMENDATION:** CMS should establish polices to expedite the development and approval of quality measures. The agency should also better align the QCDR self-nomination process with the annual QPP rulemaking cycle.

Concerns with the lack of quality measures are amplified by the fact that it takes years to develop and gain approval for new measures. For example, the American Gastroenterological Association began working with CMS on the Sustained Virological Response ("SVR") measure for patients with hepatitis C in the summer of 2022. This measure has just now been included in this Proposed Rule and will not have benchmarking data until 2028. Measures take considerable time and resources to develop and implement. We urge the agency to establish polices to expedite the development and approval of quality measures, including QCDR measures. Additionally, we urge CMS to better align the QCDR self-nomination process with the annual QPP rulemaking cycle.

### **MVP Development – Quality Measures**

**RECOMMENDATION:** CMS should establish a transparent and collaborative MVP development process.

The lack of communication and transparency in the MVP development process remains a significant concern 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, compromising confidence in the program. Several medical societies have raised concerns that proposed MVPs lack a clearly defined purpose or intended outcome, making it difficult for stakeholders to understand how these frameworks are expected to drive quality improvement.

As discussed below, CMS has repeatedly excluded clinically meaningful measures from MVPs without providing any rationale to the specialty societies that recommended their inclusion. By improving transparency and communication, CMS can develop clinically meaningful frameworks and promote wider adoption.

RECOMMENDATION: CMS must design, evaluate, and implement the MVP program in accordance with the language and spirit of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") that encourages the use of QCDRs for reporting measures under the quality performance category of the MIPS program.

We have serious concerns that CMS is developing the MVP framework contrary to the language and spirit of 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.<sup>6</sup> Notwithstanding this congressional directive, 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.

QCDRs have in-depth clinical knowledge and expertise that enable them to understand, and create QCDR measures that capture, the nuanced differences in providing medical care. QCDR measures can uniquely collect and track data across settings and disease states, and can inform quality improvement, clinical guidelines, and research. We are concerned that CMS attempts to harmonize QCDR measures overlook these nuances, and therefore disproportionately exclude QCDR measures that offer meaningful quality measurement for clinicians. 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.

Additionally, CMS should prioritize measures developed by clinician-led clinical data registries over vendor-led registries. Vendor-led registries do not have clinical expertise or in-depth understanding about quality measurement. Instead, they are created only for commercial purposes. For-profit companies, such as EHR vendors, do not appear to have any population health impact, as measured by published articles in the scientific peer-reviewed literature and practice guidelines for clinicians. Without the leadership and contribution of medical societies, the measures available to eligible clinicians may be poorly defined and inaccurately capture quality performance.

# **RECOMMENDATION:** CMS should ensure greater continuity between specialty measure sets and MVPs.

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. A source of confusion among specialty societies stems from CMS's decision to exclude certain measures from specialty measure sets when developing MVPs. These specialty measure sets were established by CMS specifically to reflect the types of care provided by clinicians within a given specialty. As such, they are presumed to be clinically relevant, meaningful, and appropriate for evaluating performance within those disciplines. Accordingly, it is unclear why CMS would not include measures from the specialty measure sets in the corresponding MVPs. If a long-standing measure is included in a specialty measure set, it is

<sup>&</sup>lt;sup>6</sup> MACRA, Pub. L. No. 114-10, § 105(b)(1)(A), 129 Stat. 136 (2015).

unclear why would it be deemed unsuitable in the context of MVPs. Therefore, we urge CMS to maintain alignment between specialty measure sets and MVPs to facilitate continuity between traditional MIPS and MVPs.

### **MVP Development – Cost Measures**

**RECOMMENDATION:** Integrate clinical registry data with claims data to most accurately evaluate value and the use of appropriate measures to assess cost.

As stated above, the continued lack of relevant cost measures for certain specialties complicates the utilization of MVPs. To address this issue, 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 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 specialtyspecific cost measures.

Legislation has already been introduced to advance this goal. This year, Representatives John Joyce and Kim Schrier reintroduced the bipartisan Access to Claims Data Act (H.R. 4331), which would establish a process to provide clinician-led clinical data registries with timely, comprehensive, and continuous access to federal claims data. This legislation builds upon Section 105(b) of MACRA, which instructs the Secretary of Health and Human Services to provide QCDRs access to Medicare claims data for the purpose of linking it with clinical outcomes and conducting scientifically valid, risk-adjusted analyses to support quality improvement and patient safety.<sup>7</sup> The Access to Claims Data Act would require the Secretary of Health and Human Services to establish a process to expand access to claims data under certain Federal health plans in order to facilitate research and quality improvement. We strongly support this legislation and urge Congress to swiftly advance this important bill.

#### **Performance Threshold**

**RECOMMENDATION:** CMS should maintain the 75-point threshold for the 2026 performance year.

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<sup>&</sup>lt;sup>7</sup> *Id*.

CMS has proposed to continue the current MIPS performance threshold of 75 points through the 2028 performance period. We appreciate the agency's decision not to raise the threshold for the 2026 performance year, as this demonstrates an awareness of the ongoing challenges faced by clinicians, particularly those in small, rural, or resource-limited practices. Increasing the threshold at this time could result in undue financial penalties for practices. Maintaining the 75-point threshold would continue to incentivize high-quality care while acknowledging the practical constraints that clinicians experience in meeting program requirements. Accordingly, we strongly support CMS's proposal.

## **Informational-Only Feedback Period**

**RECOMMENDATION:** CMS should finalize its proposal to offer informational-only scoring for two years for new cost measures.

Beginning in the 2026 performance period, CMS is proposing to offer informational-only scoring for two years for new cost measures. This proposal would provide clinicians with the opportunity to become familiar with new cost measures and understand their impact prior to the measure impacting their MIPS score. We urge the agency to finalize this proposal. Further, we request that CMS apply this informational-only scoring policy not only to new measures, but also existing measures that undergo a re-evaluation or other substantive changes. Updating measures can be as impactful as creating new ones. In addition, we encourage CMS to explore the possibility of retroactively applying this proposal.

### Total Per Capita Cost ("TPCC") Measure Change

**RECOMMENDATION:** CMS should finalize its proposal to update candidate event and attribution rules for the TPCC measure beginning in the 2026 performance period.

The TPCC measure is a population-based cost measure that evaluates a patient's overall cost of care. The measure is intended to be applicable to primary care providers. CMS is proposing to exclude events initiated by an advanced care practitioner if all other non-advanced care practitioners in their group are excluded based on specialty exclusion criteria, and to require second candidate events to be an evaluation and management ("E/M") or other primary care service.

We appreciate CMS' responsiveness to concerns raised by specialty societies regarding the TPCC measure's attribution methodology. The current methodology has led to the inappropriate attribution of data to clinicians who should be excluded from the measure, often resulting in inaccurate cost scores and unwarranted penalties. The proposed changes represent a positive step toward improving attribution accuracy and ensuring that the TPCC measure is applied only to appropriate clinicians. We support this proposal and encourage CMS to explore the possibility of retroactively applying this proposal.

## **New Measure Suppression Policy**

#### **RECOMMENDATION:** CMS should finalize its measure suppression policy.

Beginning in the 2026 performance period, CMS is proposing a new measure suppression policy that would provide the agency with the flexibility to suppress and not score a measure in an applicable performance period for MIPS eligible clinicians, hospitals, and critical access hospitals in certain circumstances. We commend CMS for proposing this new flexibility. It is crucial to recognize, and have mechanisms to address, the external factors that can negatively impact a MIPS-eligible clinician's ability to report certain measures. This proposal will help ensure that assessment of performance under the MIPS program is fair, accurate, and meaningful to both clinicians and patients. We encourage CMS to explore how this suppression policy could be translated to other measures and MIPS categories where measurement accuracy may be compromised by changing conditions.

# Request For Information: Transition Toward Digital Quality Measurement

CMS is soliciting feedback on ways to continue to advance digital quality measurement and the use of the Health Level 7 Fast Healthcare Interoperability Resources ("FHIR") standard. CMS stated its goal to fully transition to digital quality measurement ("dQM") in quality reporting and value-based purchasing programs.

When contemplating this transition, we urge CMS to avoid actions that would devalue registries and the critical support registries provide to practices to understand, implement, and improve performance on quality measures. Specifically, we are concerned that FHIR-based reporting favors EHR vendors over registries. Clinician-led clinical data registries play a vital role in improving the quality, relevance, and effectiveness of healthcare delivery. Clinician-led registries are purpose-built to capture nuanced, specialty-specific information that is often missed or misrepresented in other datasets. Any efforts to standardize the exchange of data should not unintentionally favor EHR vendors over registries. EHRs are not designed to support longitudinal quality measurement, benchmarking, or population-level improvement, nor can they offer the same specialty-focused expertise. EHR systems are primarily built to serve billing, documentation, and internal clinical workflow needs. Clinician-led clinical data registries also are designed by clinical experts within a specific medical specialty, ensuring that the data are clinically accurate, relevant, and meaningful to specific patient populations. In contrast, EHRs are administrative tools not developed by clinical specialists and may lack the clinical nuance required for specialty-specific insights. Simply put, registries are far better suited for evaluating care coordination, disease progression, and outcomes over time.

Further, some practices, especially small and rural practices, continue to rely on manual data entry because they are unable to retrieve their data due to restrictions imposed by their EHR vendor or affiliated hospital system. In these cases, the barrier to achieving digital measurement is not due to unwillingness or incapacity on the part of the provider or registry—but rather due to limitations in data access due to third-party health IT systems such as EHR vendors. Development of these resources is often very costly and requires technical support. As CMS

develops and refines its digital measurement strategy, we urge the agency to acknowledge these real-world constraints and avoid placing undue burden on providers who are eager to participate but are blocked by EHRs.

### **Request For Information: Data Quality**

CMS is requesting feedback regarding how clinicians exchange health information and what steps can be taken to improve the quality and usability of health information. As a preliminary matter, clinician-led clinical data registries should be integral to CMS's efforts to improve the quality of health information. CMS should champion and expand the use of clinician-led clinical data registries as essential tools in improving care quality and facilitating research.

Under the 21st Century Cures Act, clinician-led clinical data registries must meet high standards that demonstrate their rigor and reliability. Clinician-led clinical data registries must be clinician-led or controlled, operate as tax-exempt entities, and be devoted to the care of a population defined by a specific disease, condition, exposure, or therapy. Additionally, clinician-led clinical data registries must conduct core activities such as collecting detailed, standardized data on an ongoing basis, providing feedback to participants, meeting standards for data quality, and providing ongoing training and support for participants. To ensure accuracy and integrity, clinician-led clinical data registries also are required to systematically collect data, use standardized data elements, verify data completeness and validity, and ensure regular data audits.

Given these requirements, clinician-led clinical data registries are well-positioned to aid in accomplishing CMS's goals. Registries take on much of the work of interpreting and submitting quality measures, and they offer tailored dashboards and benchmark comparisons that would be burdensome or impossible for individual providers to create themselves. QCDRs create quality improvement opportunity for practices by giving them actionable quality scores throughout the year, not just annual reporting options. For instance, a radiology practice can rely on a registry to track multiple performance measures and benchmark against peers—far easier and more clinically useful than navigating generalized EHR reports. In addition to feedback and insights, QCDRs develop and offer measures that are deeply relevant to providers and reflect clinical priorities. QCDR quality measures are developed by subject matter experts, thoroughly reviewed by professionals, and backed by literature, clinical guidelines, and initial data.

However, registries continue to face operational challenges due to information blocking and overregulation. Current exceptions to information blocking prohibitions are being misused to impede data sharing with registries. Specifically, the "fees exception" is increasingly being invoked by EHR vendors and large health systems to block access to data requested by clinicianled clinical data registries. Registries continue to encounter barriers in accessing essential data from EHR vendors and hospital systems. EHR vendors frequently decline to engage in goodfaith negotiations to enable the transfer of clinical data to registries, effectively denying registries

<sup>8 42</sup> U.S.C. § 300jj-14(b)(1).

<sup>&</sup>lt;sup>9</sup> *Id.* § 300jj-14(b)(2)-(5).

<sup>&</sup>lt;sup>10</sup> *Id.* § 300jj-14(b)(4).

any access to such data. Others impose prohibitively high and often unjustified fees for data transfers, placing significant financial burdens on providers and undermining the registries' ability to function. For registries to fulfill their mission, they must be able to collect accurate and timely data from both providers and EHR systems. The current restrictions on data flow stifle progress in quality measurement, evidence-based care, and innovation. Tackling information blocking practices head-on is essential to realizing a truly interoperable healthcare system.

Additionally, overly burdensome regulatory obligations diminish registries' capacity to serve both providers and CMS:

- First, data validation audit requirements are unnecessarily complicated, costly, and burdensome for registries and clinicians. QCDRs and qualified registries are required to conduct these annual validation audits, 11 but the audits are duplicative of independent audits CMS conducts on clinicians. 12 Annual validation audits also fail to recognize the rigorous internal quality data controls and external audits registries employ.
- Second, measure testing requirements are costly, unnecessarily excessive, and duplicative. 13
- Third, CMS's over-use of measure harmonization results in unnecessarily complex measures that increase burden on clinicians and confusion in the program. Through the measure harmonization process, CMS may provisionally approve the individual QCDR measures for one year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years.<sup>14</sup> If such areas of duplication are not addressed, CMS may reject the QCDR measure.<sup>15</sup> CMS has failed to implement adequate safeguards to ensure that measure harmonization occurs only when it is clinically appropriate to do so.
- Finally, flawed topped out measures and benchmark policies hinder registries' capacity to serve both providers and CMS. Current CMS policy "tops out" a measure with a performance rate of 95 percent or higher. This regulation fails to recognize that measures are expensive to develop, test, and submit to CMS and to reward physicians' sustained excellence in providing care. Congress created the QCDR mechanism to fill critical gaps in the traditional quality measure sets, and the "topped out" measure policy as applied to QCDRs is counter to this statutory purpose. Additionally, CMS has a policy of generally assigning clinicians zero points for reporting on a measure that lacks a benchmark, which provides little incentive for clinicians to report on these measures. 17

<sup>&</sup>lt;sup>11</sup> 42 C.F.R. § 414.1400(b)(3)(v).

<sup>&</sup>lt;sup>12</sup> Id. § 414.1390.

<sup>&</sup>lt;sup>13</sup> *Id.* § 414.1400(b)(4)(iii)(A)(3).

<sup>&</sup>lt;sup>14</sup> *Id.* § 414.1400(b)(4)(iii)(A)(5).

<sup>15</sup> Id.

<sup>&</sup>lt;sup>16</sup> *Id.* §§ 414.1305, 414.1400(b)(4)(iv)(D).

<sup>&</sup>lt;sup>17</sup> *Id.* § 414.1380(b)(1)(i)(A)(1).

To encourage measure development and clinician use of meaningful specialty measures, we request that CMS work with stakeholders to develop a more appropriate scoring policy.

CMS should reform the MIPS program by simplifying and streamlining these requirements for both providers and registries. Easing regulatory burdens on clinical data registries is not about relaxing oversight—it strategically empowers registries to better serve providers. When registries can focus on their core functions, CMS and providers benefit.

## **Request for Information: Core Elements MVP**

CMS is considering a policy that would categorize certain quality measures within each MVP as "core elements," requiring all MVP participants to report on measures within this designated subset. Although we appreciate CMS's intent to promote consistency and comparability across participants, we have significant concerns about this approach and we urge CMS not to move forward with this concept. Conceptually, MVPs already serve as a collection of core measures, although, as noted above, there is a lack of relevant and clinically meaningful quality measures within many MVPs, particularly for numerous specialties and subspecialties. Moreover, it is likely that "core elements" would be cross-cutting measures. Yet these may not focus on aspects of care of most interest to patients to inform choice of specialty providers and may have the unintended consequence of increasing reporting burden without improving patient outcomes for care that is most relevant to their practice. Instead of further complicating the program and potentially increasing burden by requiring clinicians to shift focus from other more relevant measurement and improvement activities, CMS should focus its efforts on ensuring that each MVP offers a sufficient number of meaningful measures—including QCDR measures—that appropriately reflect the care delivered by the specialty or subspecialty.

#### Request for Information: Procedural Codes for MVP Assignment

CMS is seeking feedback on a policy that would use procedural billing codes to assign clinicians to an MVP. The Coalition strongly opposes this concept, as it is premature and may inappropriately assign clinicians to MVPs. Under the current set of MVPs, many clinicians could be assigned to frameworks that do not accurately reflect their practice, while others may find no MVP available that is relevant to them at all. This risks misalignment between the clinician's scope of care and the measures used to assess performance. A clinician who occasionally furnishes a service outside of their routine scope of practice could inadvertently be placed into an MVP that does not capture their day-to-day care. Such misassignments would lead to flawed measurement, increase administrative burden, and diminish clinician confidence in the program. The most appropriate and effective approach is to allow clinicians to self-select the MVP that best reflects their practice. Clinicians are better positioned to identity the most appropriate MVP based on their own scope of care, the patients they serve, and the measures that are most relevant to assessing the quality of that care. In the event that the agency moves forward with this concept, which again, we strongly oppose, it is absolutely critical that CMS work with specialty societies to identify codes and thresholds that would trigger assignment to an MVP.

Lastly, CMS requested feedback on how to "encourage specialty reporting of relevant MVPs based on the scope of care provided." We believe that funding should be provided to incentivize the development of QCDR measures that can be incorporated into MVPs, ensuring that each specialty has access to clinically relevant and meaningful measures. In addition, CMS should establish incentives for physicians to utilize registry-based measures. Registries are uniquely positioned to capture the complexity and nuances of specialty care, and their use can significantly enhance the accuracy and applicability of quality reporting. By investing in both measure development and physician adoption of registry measures, CMS can help ensure that MVPs reflect real-world clinical practice, reduce reliance on generic or misaligned measures, and ultimately promote more accurate and fair quality assessment.

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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 (<u>Leela.Baggett@PowersLaw.com</u>).

#### Respectfully submitted,

American Academy of Ophthalmology
American Academy of Otolaryngology—Head and Neck Surgery
American Association of Neurological Surgeons
American Board of Family Medicine
American College of Gastroenterology
American College of Rheumatology
American Psychiatric Association
American Society for Gastrointestinal Endoscopy
American Urological Association
College of American Pathologists
Congress of Neurological Surgeons
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons