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PHYSICIAN CLINICAL REGISTRY COALITION

May 12, 2025

Submitted Electronically (mehmet.oz@cms.hhs.gov)

The Honorable Mehmet Oz
Administrator
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Physician Clinical Registry Coalition's Comments on Deregulation Initiative

Dear Administrator Oz:

The undersigned members of the Physician Clinical Registry Coalition (the "Coalition") write to provide comments on the implementation of the *Executive Order on Unleashing Prosperity Through Deregulation* and the *Executive Order on Ensuring Lawful Governance and Implementing the President's "Department Of Government Efficiency" Deregulatory Initiative* ("Executive Orders").[1] As you know, under the first Executive Order, for each new regulation issued, at least ten prior regulations must be identified for elimination to alleviate unnecessary regulatory burdens. Under the second Executive Order, each agency must initiate a process to review all regulations to identify unlawful regulations and regulations that undermine the national interest.

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. As the agency begins its process to review regulations for potential repeal, the Coalition respectfully urges the Centers for Medicare and Medicaid Services ("CMS") to consider rescinding Merit-based Incentive Payment System ("MIPS") policies that impose significant financial and administrative burden on clinician-led clinical data registries. This includes policies concerning data validation, measure testing, harmonization, scoring, and the MIPS Value Pathways. To improve access to data, we also request that CMS waive the data

[1] Unleashing Prosperity Through Deregulation, The White House (Jan. 31, 2025), https://www.whitehouse.gov/presidential-actions/2025/01/unleashing-prosperity-through-deregulation/; Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative, The White House (Feb. 19, 2025), https://www.whitehouse.gov/presidential-actions/2025/02/ensuring-lawful-governance-and-implementing-the-presidents-department-of-government-efficiency-regulatory-initiative/.

request fees associated with the Virtual Research Data Center ("VRDC"). The current fee structure is a barrier to most registries requesting data from the VRDC.

Clinician-Led Clinical Data Registries

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 modalities, and measuring quality of care. Medical societies have invested millions of dollars in a system of quality performance evaluation through Qualified Clinical Data Registries ("QCDRs") and other clinician-led clinical data registries. 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 improve quality of healthcare by providing 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.

The federal government, health care products manufacturers, accreditors, and state and local governments have increasingly come to rely on clinical data registries for a wide variety of purposes. Clinical data registries report medical and clinical data to the CMS on behalf of their participating health care providers for purposes of the MIPS and for more general patient and disease tracking. In fact, CMS relies on 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 CMS-developed measures. Congress recognized the importance of QCDRs when it passed the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"). 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. MACRA, Pub. L. No. 114-10, § 101(c), 129 Stat. 87 (2015).

Elimination of Burdensome MIPS Policies

Over recent years, however, CMS has established policies that contravene the language and intent of MACRA, including policies that disincentivize the development of meaningful specialty measures and impose financial and administrative burdens on registry operations. The Coalition has serious concerns regarding the agency's complex and cumbersome MIPS policies that have created obstacles for clinician-led clinical data registries to successfully accomplish their goals in supporting physicians in delivering high-quality, safe, and patient-centered care. To ease regulatory burdens, we urge CMS to consider eliminating the following MIPS policies:

1. **Data Validation Requirements**

QCDRs and qualified registries ("QRs") must conduct annual data validation audits. 42 C.F.R. § 414.1400(b)(3)(v). If a data validation audit identifies one or more deficiencies or data errors, the QCDR or QR must conduct a targeted audit into the impact and root cause of each deficiency or data error and correct such deficiencies or data errors prior to the submission of data for that MIPS payment year. *Id*. § 414.1400(b)(3)(vi)(A). The Coalition appreciates the importance of reporting true, accurate, and complete data; however, we are concerned that the data validation and targeted audit requirements contravene MACRA's directive to encourage the use of QCDRs for reporting measures. CMS's policies regarding data validation and targeted audits are unnecessarily complicated, costly, and burdensome for QCDRs, QRs, and clinicians. These policies also fail to recognize that QCDRs and QRs employ rigorous internal quality data controls and conduct external audits to ensure the accuracy of data.

To reiterate, Coalition supports the idea of reporting true, accurate, and complete data. However, CMS's implementation of this goal disproportionally burdens QCDRs and QRs compared to other reporting mechanisms (e.g., direct reporting). Moreover, the audits that QCDRs and QRs are required to conduct are duplicative of independent audits that CMS conducts on clinicians. CMS should not shift the burden of auditing onto registries.

Therefore, we request that CMS rescind 42 C.F.R. § 414.1400(b)(3)(v) and (vi) and consider data validation options that are less burdensome on QCDRs, QRs, and clinicians.

2. **Measure Testing**

CMS may approve a QCDR measure only if the QCDR measure meets face validity. *Id*. § 414.1400(b)(4)(iii)(A)(3). "Face validity" is the "extent to which a measure appears to reflect what it is supposed to measure 'at face value.' It is a subjective assessment by experts about whether the measure reflects its intended assessment." *Measures Testing*, CMS Measures Management System (Mar. 2025), https://mmshub.cms.gov/measure-lifecycle/measure-testing/evaluation-criteria/scientific-acceptability/validity. However, 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. 42 C.F.R. § 414.1400(b)(4)(iii)(A)(3).

We understand and agree with CMS's desire that all QCDR measures be appropriate, reliable, and valid. The key to "appropriate measures" is the development of measures by medical specialty societies. Medical specialty societies play a major role in supporting the quality performance category by developing, testing, and maintaining a majority of the current MIPS quality measure inventory. Quality measures submitted by QCDRs are created by subject matter experts, undergo significant expert vetting, and are supported by literature, guidelines, and preliminary data, thus providing implicit face validity for each measure.

However, CMS's specific testing requirements are unnecessarily excessive for QCDRs and/or measures, and contrary to the MACRA's requirement to encourage the use of QCDRs for reporting measures. The cost of full measure testing is significant (approximately $500,000 per measure and sometimes more) and is an expense that nonprofit medical societies, particularly small specialties, cannot bear. The unfunded mandate to test measures imposes unreasonable cost and other burdens on QCDRs, and such costs are already causing many QCDRs to reduce or cease measure development or to leave the program. **The Coalition believes that 42 C.F.R. § 414.1400(b)(4)(iii)(A)(3) should be rescinded and a more strategic and flexible approach to measure testing is warranted. CMS should engage with registries to develop more appropriate measure testing requirements.**

3. Harmonization

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. *Id*. § 414.1400(b)(4)(iii)(A)(5). If such areas of duplication are not addressed, CMS may reject the QCDR measure. *Id*.

CMS has failed to implement adequate safeguards to ensure that measure harmonization occurs only when it is clinically appropriate to do so. This has resulted in specialty societies being forced to "harmonize" their QCDR measure with other distinct and non-risk stratified measures, ultimately at the disadvantage of specialists who are left with fewer meaningful measures to report. In addition, asking measure developers to combine measures may result in unnecessarily complex measures that increase burden on clinicians and confusion in the program. **Therefore, we request that CMS rescind the measure harmonization requirement at 42 C.F.R. § 414.1400(b)(4)(iii)(A)(5).**

4. Flawed Scoring Policies: Topped Out Measures and Benchmarks

CMS should eliminate its flawed MIPS scoring policies and work with registries to craft a more appropriate solution to scoring measures. For instance, considerations for whether to remove a QCDR measure from the program include whether the QCDR measure is topped out—a measure with a median performance rate of 95% or higher. *Id*. §§ 414.1305, 414.1400(b)(4)(iv)(D). This

regulation fails to recognize that measures are expensive to develop, test, and submit to CMS. 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 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. In addition, CMS's policy fails to reward physicians' sustained excellence in providing care. **Therefore, we urge CMS to rescind 42 C.F.R. §§ 414.1305, 414.1400(b)(4)(iv)(D).**

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. *Id.* § 414.1380(b)(1)(i)(A)(1). To encourage measure development and clinician use of meaningful specialty measures, we request that CMS rescind this policy at 42 C.F.R. § 414.1380(b)(1)(i)(A)(1) and work with stakeholders to develop a more appropriate scoring policy.

5. Mandating MIPS Value Pathways ("MVPs")

CMS has expressed a desire to replace the traditional MIPS program with its new MVPs framework by the 2029 performance period. Traditional MIPS is a deeply flawed program that requires significant reform. Unfortunately, the implementation of MVPs only exacerbates these problems. The MVP framework fails to resolve foundational issues in the MIPS program, including problematic MIPS scoring rules and other policies that often disincentivize the development and use of more clinically focused measures and participation pathways that better align with clinical practice. In addition, medical societies have expressed serious concerns regarding the development of MVPs applicable to their specialties. Specifically, medical societies are concerned that measures included in 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. We have serious concerns that CMS is developing the MVP framework contrary to the language and spirit of MACRA. 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.

CMS should continue to recognize MVP participation as voluntary and work with stakeholders to craft a solution that better responds to concerns regarding the traditional MIPS program.

6. Mandatory Subgroup Reporting Requirement

Beginning in the 2023 performance period, clinicians can choose to form a subgroup, comprised of clinicians with similar scopes of care, to report an MVP. *Id*. § 414.1400(b)(1)(iii). 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. *Id.* § 414.1305. The Coalition believes that defining the specifics of mandatory subgroups for multispecialty practices is premature. Requiring mandatory subgroup reporting would be logistically challenging for many practices. Doing so during the transition process from MIPS to MVPs increases the administrative burden of practices attempting to switch to MVP reporting. **Therefore, we request that CMS rescind the requirement that multispecialty groups must report via subgroups at 42 C.F.R. § 414.1305.**

Virtual Research Data Center

The VRDC is a virtual research environment under which registries can—in theory—access Medicare claims data for research purposes. Registries' use of the VRDC process is often limited because the process is slow, cumbersome, and expensive. The VRDC process provides for the release of a defined set of data only for discrete research projects, and data requests can take months and sometimes years to process with no guarantee of approval. The costs associated with requesting data is so great that it acts as a barrier to most registries requesting data from the VRDC. **To improve access to claims data, we request that CMS remove the assessment of VRDC fees and work with stakeholders to allow for access to data in a manner that is more cost-effective.**

Addressing these challenges is critical to ensuring that clinician-led registries can continue to play an essential role in improving clinical outcomes and advancing quality care. Therefore, we respectfully urge you to consider repealing these overbearing and burdensome MIPS policies and VRDC fees.

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The Coalition appreciates your consideration of our concerns and recommendations regarding the implementation of the Executive Orders. 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 and Neck Surgery
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American College of Radiology
American College of Rheumatology
American Society of Plastic Surgeons
Association for Clinical Oncology
Congress of Neurological Surgeons
Outpatient Endovascular and Interventional Society
Society of Interventional Radiology
Society of Neurointerventional Surgery
The Society of Thoracic Surgeons