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PHYSICIAN CLINICAL REGISTRY COALITION

July 9, 2025

Hearing of the United States House Committee on Ways and Means
Subcommittee on Health
on
"Health at Your Fingertips: Harnessing the Power of Digital Health Data"

Statement for the Record by the Physician Clinical Registry Coalition

Chairman Buchanan, Ranking Member Doggett, and Members of the Subcommittee:

The undersigned members of the Physician Clinical Registry Coalition (the "Coalition"), appreciate the opportunity to submit this statement for the record with respect to the hearing entitled, "Health at Your Fingertips: Harnessing the Power of Digital Health Data," held by the Committee on June 25, 2025. 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.

Clinician-led clinical data registries use digital health data to enhance quality reporting, promote value-based care, and augment valuable research efforts. As Congress evaluates pathways to utilize and improve digital health data, we respectfully call on the Subcommittee on Health and the full Ways and Means Committee to direct the Department of Health and Human Services ("HHS") to (1) integrate clinician-led clinical data registries into value-based care models, (2) remove regulatory barriers that hinder the operation and effectiveness of registries, (3) improve access to claims data, and (4) strengthen enforcement against information blocking. Our recommendations aim to preserve and expand the role of registries in value-based care, improving provider experience and ensuring that quality programs remain meaningful and actionable for clinicians.

Harnessing Clinician-Led Clinical Data Registries to Strengthen Value-Based Care

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.[1] 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

[1] 42 U.S.C. § 300jj-14(b)(1).

data quality, and providing ongoing training and support for participants.[2] 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.[3]

Given these requirements, 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. These registries also contribute vital data to public health efforts. Many registries collect patient-reported outcomes measures, which provide additional insights for clinicians and health officials.

Moreover, the measures developed by Qualified Clinical Data Registries ("QCDRs") are deeply relevant to providers and reflect clinical priorities. These measures are often more clinically relevant than other traditional CMS data sources. 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 Merit-Based Incentive Payment System ("MIPS").[4] 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."[5]

In addition, registries are a source of real-world evidence to support clinical research and innovation and inform the development of clinical practice guidelines. Registries and their robust data sets enable quicker and less expensive randomized clinical trials, longitudinal studies, and other observational studies. In contrast, electronic health records ("EHRs") are not designed to support longitudinal quality measurement, benchmarking, or population-level improvement, nor can they the 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 is 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. Although EHRs are a necessary component of modern clinical practice, they are not a substitute for the robust, purpose-driven infrastructure that registries provide. Therefore, clinician-led clinical data

[2] *Id*. § 300jj-14(b)(2)-(5).
[3] *Id*. § 300jj-14(b)(4).
[4] MACRA, Pub. L. No. 114-10, § 101(c), 129 Stat. 92 (2015).
[5] *Id*. § 105(b)(1)(A), 129 Stat. 136 (2015).

registries should be prioritized for quality measurement and value-based care initiatives, as they offer the clinical insight, analytical rigor, and longitudinal perspective that EHRs alone cannot deliver.

Eliminating Regulatory Barriers that Hinder the Operation and Effectiveness of Registries

When registries are weighed down by overly burdensome regulatory obligations, including requirements that contravene the language and intent of MACRA, their capacity to serve both providers and CMS diminishes. CMS derives substantial value from the critical services provided by registries through the extension of federal resources and enhancement of the efficiency and overall impact of the MIPS program. Registries assume significant responsibilities in data collection and quality reporting—functions that would otherwise demand considerable investment from CMS. 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. Moreover, QCDRs develop specialized, clinically meaningful quality measures that are better tailored to the needs of specific specialties than other measures. QCDRs often standardize or normalize data before calculating quality measures, offering practices and providers with more reliable data for reporting and quality improvement efforts. QCDRs also 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 contrast, providers often cannot extract usable data from their EHRs without significant customization, IT support, or fees.

Over recent years, CMS has established policies that disincentivize the development of meaningful specialty measures and impose financial and administrative burdens on registry operations. Removing these burdens would allow registries to operate more efficiently. To that end, we recommend that Congress direct HHS to reconsider the following policies:

- **Data Validation Requirements**: QCDRs and qualified registries ("QRs") must conduct annual data validation audits.[6] 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.[7] 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. 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

[6] *Id.* § 414.1400(b)(3)(v).
[7] *Id.* § 414.1400(b)(3)(vi)(A).

auditing onto registries. Therefore, Congress should direct HHS to 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.

- **Measure Testing**: CMS may approve a QCDR measure only if the QCDR measure meets face validity.[8] "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."[9] 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.[10] We understand and agree with CMS's desire that all QCDR measures be appropriate, feasible, 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. Moreover, approval is not guaranteed for the following year, making it an annual uncertainty. 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.

- **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.[11] If such areas of duplication are not addressed, CMS may reject the QCDR measure.[12] 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).

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[8] Id. § 414.1400(b)(4)(iii)(A)(3).
[9] *Measures Testing, CMS Measures Management System* (Mar. 2025), https://mmshub.cms.gov/measure-lifecycle/measure-testing/evaluation-criteria/scientific-acceptability/validity.
[10] 42 C.F.R. § 414.1400(b)(4)(iii)(A)(3).
[11] *Id*. § 414.1400(b)(4)(iii)(A)(5).
[12] *Id*.

- **Flawed Scoring Policies: Topped Out Measures and Benchmarks**: Congress should direct HHS to 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.[13] 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, 42 C.F.R. §§ 414.1305, 414.1400(b)(4)(iv)(D) should be rescinded. 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.[14] To encourage measure development and clinician use of meaningful specialty measures, CMS should work with stakeholders to develop a more appropriate scoring policy.

  Further, even when quality measures have established benchmarks, these benchmarks often fall short as reliable indicators of performance across the healthcare system due to the flawed structure of this program that forces practices to focus on a narrow set of conditions and procedures not necessarily representative of the scope of their work. The aforementioned scoring policies incentivize clinicians to report on measures they will perform well on, even if they are not truly relevant to their patients, simply to comply with the program and avoid a penalty. As a result, the benchmarks are inherently biased—skewed upward and unrepresentative of the broader clinical landscape. Consequently, a clinician's quality score is often less a reflection of actual care quality and more a function of measure availability, EHR system capabilities, and access to a knowledgeable registry.

  We strongly recommend against mandating that clinicians report on a standard set of measures given the diversity of patient populations seen by clinicians across specialties and even within the same specialty. One of the main purposes of the QCDR pathway is to move away from a one-size-fits-all approach to quality measurement and towards a program that recognizes varied clinical relevance, practice patterns, and patient populations across and within disciplines. It is critical that CMS preserve this flexibility to ensure MIPS performance assessments are fair, accurate, and meaningful to both clinicians and patients.

- **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

[13] *Id*. §§ 414.1305, 414.1400(b)(4)(iv)(D).
[14] *Id*. § 414.1380(b)(1)(i)(A)(1).

> 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.

Congress should reform the MIPS program by simplifying and streamlining 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, everyone benefits.

Improving Access to Claims Data

Section 105(b) of MACRA directs CMS to provide Medicare claims data to QCDRs "for purposes of linking such data with clinical outcomes data and performing risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety." Despite this mandate, the agency has not provided the timely, broad, and continuous access to Medicare claims data contemplated by Section 105(b) and necessary for QCDRs to effectively link their outcomes data with Medicare claims data. This failure to comply with the clear statutory mandate in MACRA limits QCDRs' ability to perform longitudinal and other data analyses for quality improvement, patient safety, cost-effectiveness, and research purposes.

Currently, QCDRs have two options for accessing Medicare claims data—the Qualified Entity ("QE") Program and the Virtual Research Data Center ("VRDC"). The VRDC is a virtual research environment under which QCDRs can—in theory—access Medicare claims data. However, the VRDC program only allows the use of claims data for very specific research purposes. The VRDC application and data request process also is slow, cumbersome, and expensive.

The QE Program enables organizations approved as "qualified entities" to receive Medicare claims data for use in evaluating provider performance for quality improvement purposes. CMS offers QCDRs the option of becoming "quasi-qualified entities" under this program. However, quasi-qualified entity status only provides QCDRs access to provider-wide and state-specific data. QCDRs generally need data on a provider-specialty specific and nationwide basis. Thus, qualified entity status would provide QCDRs with both more and less data than they need to link Medicare Claims data with provider-level clinical outcomes data. In addition, the application

process and associated fees imposed by this program is too costly and cumbersome to provide registries with timely and meaningful access to claims data. Neither the VRDC process nor QE Program provide QCDRs with the type of access to Medicare claims data that satisfies the requirements of Section 105(b).

Therefore, we urge Congress to direct CMS to establish a dedicated program or revisit its existing programs to truly satisfy the requirements of Section 105(b). CMS should accommodate a range of data query options, including provider-specific, state-level, and national datasets. In order to link claims data with patient-level clinical outcomes, registries must be permitted to use either direct patient identifiers or validated probabilistic matching methodologies. Moreover, the cost structure for data access should be reasonable, and the application process should be streamlined. Once appropriate data use agreements are in place, registries should be granted automatic eligibility to request and query datasets that enable timely linkage between clinical outcomes and claims data. CMS could further enhance usability by developing a secure dashboard or portal system that allows authorized registries to access and analyze Medicare claims data—mirroring the access registries already provide to their participating clinicians. Such a system would meaningfully support quality measurement, care coordination, and innovation in value-based care.

Strengthening Enforcement Against Information Blocking

It is critical to foster an ecosystem where data flows securely, efficiently, and meaningfully—from EHRs/hospital systems to registries and back to providers. In response to concerns that EHR vendors, along with large hospitals and health systems, were knowingly impeding the exchange of electronic health information ("EHI")—by charging excessive fees, imposing onerous contract terms, or simply refusing to respond to requests—Congress enacted the 21st Century Cures Act. This legislation and its implementing regulations prohibit health care providers, as well as health information technology developers, exchanges, or networks (including EHR vendors), from engaging in "information blocking," defined as any practice that is likely to interfere with, prevent, or materially discourage access to, exchange of, or use of EHI. A practice is not considered information blocking if it meets one or more of the exceptions outlined by the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology ("ASTP/ONC").

Despite this directive in the 21st Century Cures Act, our registries continue to be harmed by information blocking practices which inhibit the free-flow of digital health data. We urge Congress to direct ASTP/ONC to reexamine the current exceptions, particularly the "fees exception." This exception is increasingly being invoked by EHR vendors and large health systems to block access to data requested by clinician-led clinical data registries. EHR vendors frequently decline to engage in good-faith negotiations to enable the transfer of clinical data to registries, effectively denying registries 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 example, we are aware of at least one EHR vendor charging over $20,000 to solo practitioners for data access.

Another example involves a cloud-based EHR system that explicitly informed a registry that it "doesn't integrate with any systems to extract data for MIPS reporting." This blanket refusal to enable data access for a federally supported quality reporting program poses a serious problem. It not only impedes provider participation in MIPS, but also obstructs the registry's role in aggregating, analyzing, and reporting data critical to improving patient outcomes. Even if a specific refusal technically does not satisfy the current definition of information blocking, a categorical denial of integration with any system—without justification or a path forward—violates the spirit of the law by materially discouraging the use and exchange of EHI.

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. Therefore, ASTP/ONC should reevaluate the effectiveness of the existing information blocking rules and narrow exceptions that are being misused to impede data sharing with registries. ASTP/ONC could consider limiting an actor's ability to charge fees to the recovery of costs reasonably incurred to provide access, exchange, or use of EHI, based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests. Additionally, in the interest of transparency, actors should be required to disclose the methodology behind their fees.

In parallel, the Office of Inspector General ("OIG") and CMS should utilize their existing authority to enforce existing regulations against EHR vendors and hospital systems that continue to obstruct data exchange to clinical data registries. The OIG should closely examine these kinds of systemic refusals/fees as potential forms of information blocking and take timely enforcement action where appropriate. Additionally, the OIG should respond to complaints of information blocking within a reasonable timeframe.

If ASTP/ONC are unable to curtail these harmful practices, Congress should direct CMS to establish a hardship exemption under the MIPS program. Information blocking practices may adversely affect performance scores under the MIPS program. When EHR vendors categorically deny access to data or impose prohibitively high fees, providers are placed in an untenable position. As with current exceptions, the inability to report would stem from circumstances beyond the provider's control. Clinicians should not be penalized for the bad-faith actions of EHR vendors that obstruct access to essential data.

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The Coalition appreciates your consideration of our concerns and recommendations.

Respectfully submitted,

American Academy of Ophthalmology
American Academy of Otolaryngology–Head and Neck Surgery
American Association of Neurological Surgeons
American College of Rheumatology
American Society of Plastic Surgeons
American Urological Association
Congress of Neurological Surgeons
Outpatient Endovascular and Interventional Society
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Association for Clinical Oncology
The Society of Thoracic Surgeons