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PHYSICIAN CLINICAL REGISTRY COALITION

June 16, 2025

Submitted Electronically

The Honorable Mehmet Oz
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: Request for Information; Health Technology Ecosystem; CMS-0042-NC
7500 Security Boulevard
Baltimore, MD 21244

RE: Physician Clinical Registry Coalition's Comments in Response to the Request for Information on Health Technology Ecosystem (CMS-0042-NC)

Dear Administrator Oz:

The undersigned members of the Physician Clinical Registry Coalition (the "Coalition") appreciate the opportunity to provide comments in response to the Request for Information ("RFI") concerning health technology, clinical quality data, and interoperability. 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 play an indispensable role in enhancing quality reporting, promoting value-based care, and augmenting valuable research efforts. As the Centers for Medicare and Medicaid Services ("CMS") and the Assistant Secretary for Technology Policy ("ASTP")/Office of the National Coordinator for Health Information Technology ("ONC") evaluate pathways to utilize and improve health technology infrastructure, we respectfully urge the agencies to focus on promoting the continued endorsement and support of clinician-led clinical data registries; removing regulatory barriers that hinder the operation and effectiveness of registries; refining quality measurement policies to preserve clinical relevance; improving data access; and strengthening 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. For more information regarding the value of registries and the members of the Coalition, please refer to the enclosed white paper.

1. **TD-12: Should CMS endorse non-CMS data sources and networks, and if so, what criteria or metrics should CMS consider?**

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.[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 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,

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[1] 42 U.S.C. § 300jj-14(b)(1).
[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).

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

2. **PR-12: Should ASTP/ONC consider removing or revising any of the information blocking exceptions or conditions within the exceptions (45 CFR part 171, subparts B through D) to further the access, exchange, and use of electronic health information (EHI) and to promote market competition?**

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 prohibits 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.[6] A practice is not considered information blocking if it meets one or more of the exceptions outlined by ASTP/ONC.[7]

While we applaud ONC's commitment to promoting the secure and efficient flow of health information, we urge 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. Registries continue to face substantial barriers in accessing essential data from EHR vendors and hospital systems. 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 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.

[6] 42 U.S.C. § 300jj–52; 45 C.F.R. §§ 171.102, 171.103.
[7] 45 C.F.R. § 171.103(a)(1).

Therefore, we urge ONC to reevaluate the effectiveness of its existing information blocking rules and narrow exceptions that are being misused to impede data sharing with registries. 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 addition, when evaluating the value of the existing information blocking rules, ONC should also consider how to improve physician access to data. The ASTP/ONC collaboration with the American Board of Family Medicine ("ABFM")[8] found that only 8% of family physicians reported that information obtained from organizations that use different EHR developers' products than their own was very easy to use.[9] In contrast, 38% reported that information obtained from organizations that use the same EHR developer's product was very easy to use.[10] At the point of care, family physicians reported that the electronic transfer of medication data from outside organizations, the ability to find it, and the ability to use it to reconcile differences was only possible 13% of the time.[11] This is not safe for patients and creates tremendous burden for clinicians.

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.

3. **TD-18: Could you, as a technology vendor, provide examples for the types of practices you have experienced that may constitute information blocking. Please include both situations of non-responsiveness as well as situations that may cause a failure or unusable response?**

As noted above, registries continue to encounter significant barriers in obtaining essential electronic health data from EHR vendors—barriers that directly undermine their ability to support quality improvement and reporting. A striking example involves Practice Fusion, a cloud-based EHR system, which 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. As discussed above, some EHR vendors charge exorbitant fees to access data, which may be infeasible for solo practitioners, small practices, rural practices, and other provider types that lack significant financial resources

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[8] Jordan Everson, Bob Phillips, & Nathaniel Hendrix, *New Data Available on How Physicians Experience Interoperability*, HealthIT Answers (Aug. 19, 2024), https://www.healthitanswers.net/new-data-available-on-how-physicians-experience-interoperability.

[9] Nathaniel Hendrix et. al., *Impact of Response Bias in Three Surveys on Primary Care Providers' Experiences with Electronic Health Records*, 31 J. Am. Med. Informatics Assoc. 1754 (2024).

[10] *Id.*

[11] Am. Bd. Fam. Med., Inc., Presentation at the 2024 ASTP Annual Meeting on Family Medicine Physicians' Interoperability Experience (Dec. 5, 2024), https://www.healthit.gov/sites/default/files/2025-01/Tracking-Impact-Family-Medicine-Physicians-Experience_508.pdf.

to afford these fees. For example, we are aware of at least one EHR vendor charging over $20,000 to solo practitioners for data access. These types of behaviors run counter to the core intent of the information blocking prohibition under the 21st Century Cures Act, which was designed to ensure that health information flows across the healthcare ecosystem. 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 same applies to charging unreasonable fees for data. 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. In the Practice Fusion example above, the registry's complaint still remains unanswered months after the submission of a complaint.

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. If ASTP/ONC are unable to curtail these harmful practices, CMS should address this by establishing a hardship exemption under the MIPS program. 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.

4. **PR-8: What are ways CMS or partners can help with simplifying clinical quality data responsibilities of providers?**

CMS should reduce provider burden while leveraging the strengths of clinician-led clinical data registries. As discussed above, CMS should foster an ecosystem where data flows securely, efficiently, and meaningfully—from EHRs to registries and back to providers. The elimination of information blocking by EHRs and large health systems will ultimately benefit providers. In addition, reducing regulatory burdens imposed on registries will support providers' quality reporting responsibilities. 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 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.

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. Moreover, QCDRs develop specialized, clinically meaningful quality measures that are better tailored to the needs of specific specialties than other measures.

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 the following policy changes:

- **Data Validation Requirements**: QCDRs and qualified registries ("QRs") must conduct annual data validation audits.[12] 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.[13] 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 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.

- **Measure Testing**: CMS may approve a QCDR measure only if the QCDR measure meets face validity.[14] "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."[15] 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.[16] 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

[12] *Id*. § 414.1400(b)(3)(v).
[13] *Id*. § 414.1400(b)(3)(vi)(A).
[14] Id. § 414.1400(b)(4)(iii)(A)(3).
[15] *Measures Testing, CMS Measures Management System* (Mar. 2025), https://mmshub.cms.gov/measure-lifecycle/measure-testing/evaluation-criteria/scientific-acceptability/validity.
[16] 42 C.F.R. § 414.1400(b)(4)(iii)(A)(3).

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.[17] If such areas of duplication are not addressed, CMS may reject the QCDR measure.[18] 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).

- **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.[19] 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.[20] 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.

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[17] *Id*. § 414.1400(b)(4)(iii)(A)(5).
[18] *Id*.
[19] *Id*. §§ 414.1305, 414.1400(b)(4)(iv)(D).
[20] *Id*. § 414.1380(b)(1)(i)(A)(1).

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.

As CMS considers solutions to this problem, including adjustments to current scoring policies, 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 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.

CMS 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, CMS and providers benefit.

5. **PR-8: In what ways can the interoperability and quality reporting responsibilities of providers be consolidated so investments can be dually purposed?**

Consolidation must be carefully balanced with the need to preserve specialty-specific clinical relevance. To the extent CMS is considering to further consolidate measures within the MIPS program, we urge the agency to proceed with caution as consolidation must not come at the expense of meaningful quality measurement or specialty-specific relevance. As noted above, CMS's current approach to harmonization lacks adequate safeguards to ensure that alignment of measures occurs only when clinically appropriate. This has led to situations where QCDRs are compelled to "harmonize" their measures with unrelated measures. Forced harmonization diminishes the clinical integrity of quality reporting and leaves specialists with fewer, less meaningful options for performance evaluation.

Moreover, we are concerned by CMS's increasing tendency to exclude clinically meaningful QCDR measures from MVPs, even in cases where the applicable specialty society has strongly advocated for their inclusion. This results in limited measure choice, weakens the overall validity of MVPs, and risks shifting the focus of quality programs away from genuine clinical improvement. The current MVP framework, as implemented, does little to incentivize the development or adoption of more robust, evidence-based quality measures. If CMS intends to strengthen the MVP program and maintain clinician engagement, it must prioritize the inclusion of meaningful, validated QCDR measures and preserve the flexibility providers need to report on what matters most to their patients and practices. Overall, consolidation should not be prioritized over clinical relevance and patient care.

Further, as the agency undertakes consolidation efforts, we urge CMS to properly utilize registries. For instance, the Coalition encourages CMS to provide full credit under the MIPS Promoting Interoperability category to eligible clinicians and groups using an EHR to participate in a QCDR. Allowing providers to receive credit under the Promoting Interoperability Program for interoperability activities would reduce health care provider burden while giving providers the flexibility to pursue innovative applications of health IT.

6. **PC-8: What data is valuable, but hard for patients and caregivers, or app developers and other technical vendors, to access for appropriate and valuable use (for example, claims data, clinical data, encounter notes, operative reports, appointment schedules, prices)?**

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."[21] 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

[21] 42 U.S.C. § 1395kk-2(b)(1)(A).

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 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.[22] 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 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.

7. **PR-8: Are there requirements CMS should consider for data registries that would support access to real-time quality data for healthcare providers to inform clinical care in addition to simplifying reporting processes?**

Clinician-led clinical data registries are equipped to bridge the gap between clinical care and administrative reporting by capturing timely, granular, and actionable data. Unlike traditional reporting mechanisms, registries often offer customized dashboards and advanced analytics tools that are tailored to the specific needs of providers and care teams. By striving to deliver near

[22] *See* Final Rule, "Medicare Program: Expanding Uses of Medicare Data by Qualified Entities," 81 Fed. Reg. 44,456 (July 7, 2016).

real-time access to data, registries support quality improvement efforts, enhance patient outcomes, and facilitate research and innovation.

However, registries may encounter operational limitations that prevent "instantaneous" data delivery. These challenges often stem from variability in how frequently EHR systems transmit data to registries, as well as technical constraints among vendors that may delay same-day data processing. CMS itself has experienced similar limitations in providing real-time data under MIPS, particularly in the cost performance category, where timely feedback has proven difficult to operationalize. Given these realities, it would be unreasonable and inconsistent for CMS to impose more stringent expectations on registries than those currently met by the agency's own programs. We urge CMS to clearly define what it means by "real-time" in the context of access to quality data, and to adopt a practical, achievable standard that reflects the current state of health IT infrastructure.

8. **PR-8: Are there requirements CMS should consider for data registries to support digital quality measurement in a more efficient manner?**

CMS has expressed its intent to transition all quality measures to digital quality measures ("dQMs"). Registries are implementing dQMs. Currently, CMS defines dQMs as quality measures, organized as self-contained measure specifications and code packages, that use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems. While we support the agency's vision of a more efficient, data-driven quality measurement framework, 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. 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.

Specifically, 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. 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 EHR and hospital systems.

9. **VB-3: What are essential health IT capabilities for value-based care arrangements? What other health IT capabilities have proven valuable to succeeding in value-based care arrangements?"**

We strongly encourage CMS to integrate clinician-led clinical data registries into value-based care models. For the reasons addressed above, clinical data registries are vital to value-based care because they provide the infrastructure and clinical relevance needed to assess and improve quality of care. In fact, CMS has integrated clinical data registries into existing value-based care

arrangements. For example, under the BPCI-A, CMS adopted a set of "alternate" episode-specific measures, which were developed by specialty societies and could be submitted through clinical data registries. These measures are more relevant to each episode than the generic measures originally adopted for the program, rely on more informative clinical data versus claims data, provide participants with greater choice and flexibility, reduce administrative burden, and result in more actionable and meaningful feedback. Accordingly, we ask CMS to continue to allow for these types of opportunities to integrate registries into value-based care models.

In addition, registries also hold promise in more accurately assessing cost in value-based care. Currently, value-based care is held back by cost measure development that relies strictly on claims data and does not simultaneously account for quality. Integrating registry data with claims data would lead to a more accurate and fuller assessment of healthcare value. To optimize this integration, we urge the agency to provide clinician-led clinical data registries with more meaningful access to claims data, as described above.

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The Coalition appreciates your consideration of our concerns and recommendations. 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 Association of Neurological Surgeons
American College of Radiology
American Psychiatric Association
American Society of Plastic Surgeons
American Urological Association
Association for Clinical Oncology
Center for Professionalism and Value in Health Care
College of American Pathologists
Congress of Neurological Surgeons
Outpatient Endovascular and Interventional Society
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons