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PHYSICIAN CLINICAL REGISTRY COALITION

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VIA ELECTRONIC MAIL (MACRA.RFI@MAIL.HOUSE.GOV)

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The Honorable Kim Schrier, M.D.
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The Honorable Michael C. Burgess, M.D.
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The Honorable Earl Blumenauer
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The Honorable Brad R. Wenstrup, D.P.M.
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The Honorable Bradley Schneider
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The Honorable Mariannette Miller-Meeks
United States House of Representatives
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Washington, DC 20515

Re: Physician Clinical Registry Coalition Comments on Medicare Access and CHIP Reauthorization Act of 2015

Dear Representatives Bera, Bucshon, Schrier, Burgess, Blumenauer, Wenstrup, Schneider, and Miller-Meeks:

The undersigned members of the Physician Clinical Registry Coalition ("Coalition") appreciate the opportunity to provide comments regarding the Centers for Medicare and Medicaid Services' ("CMS") implementation of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") as it relates to Qualified Clinical Data Registries ("QCDRs") and clinician-led clinical data registries. 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.

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. Registries play an essential role in promoting quality of care. Clinical data registries are major sources of real-world evidence, including patient-reported outcomes data. QCDRs and clinician-led clinical data registries provide timely and actionable feedback to providers on their performance, speeding and enhancing quality improvement opportunities. 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 to identify best practices.

Medical societies have invested millions of dollars in a system of quality performance evaluation through QCDRs because QCDRs are effective in improving quality in specialty areas. The measures developed by QCDRs and clinician-led clinical data registries are comprehensive, meaningful, and relevant to participating providers and their patient populations. They also provide important information that is not available from claims data alone.

As you are aware, MACRA requires the Secretary of Health and Human Services ("Secretary") to encourage the use of QCDRs and certified electronic health record technology for reporting measures under the quality performance category of the Merit-Based Incentive Payment System ("MIPS") program.[1] In addition, section 105(b) of MACRA directs the Secretary 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."[2]

Given these statutory mandates, it is important that CMS adopt policies that provide clinical data registries with meaningful access to Medicare claims data, encourage QCDR participation in the MIPS program, and promote the development of strong QCDR measures and a framework that support accurate quality data measurement. Over recent years, however, CMS has established policies that contravene the language and intent of MACRA, including policies that deter registry access to Medicare claims data and disincentivize development of meaningful specialty measures. These increasingly burdensome and often extraneous requirements have resulted in a significant decline in the number of QCDRs participating in MIPS.

Therefore, we respectfully urge Congress to critically review CMS policies and reforms discussed below; and consider standalone credit for participation in a QCDR. Although most of these reforms can be accomplished through regulation, we believe that legislative intervention is necessary to ensure that CMS is properly implementing the plain language and intent of MACRA.

In addition, we greatly appreciate the inclusion of language in the bipartisan legislation—H.R. 5394, the Meaningful Access to Federal Health Plan Claims Data Act—introduced by Dr.

[1] MACRA, Pub. L. No. 114-10, § 101(c), 129 Stat. 87 (2015).
[2] *Id*. § 105(b)(1)(A).

Bucshon and Dr. Schrier. As discussed below, this legislation would help address CMS's failure to provide QCDR's and clinician-led clinical data registries with meaningful access to Medicare claims data for research and quality improvement purposes.

Measure Testing

To be approved for the 2023 performance year/2025 MIPS payment year, all QCDR measures must meet "face validity" for the initial MIPS payment year for which the measure is approved.[3] For subsequent years after being initially approved, all QCDR measures must be fully developed and tested, with complete testing results *at the clinician level*, prior to submitting the QCDR measure at the time of self-nomination.[4] To be included in a MIPS Value Pathway ("MVP") for the 2024 MIPS payment year and future years, a QCDR measure must be fully tested.[5]

We understand and agree with CMS's desire that all QCDR measures be appropriate, reliable, and valid. However, these specific testing requirements are unnecessarily excessive for some 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 and is an expense that nonprofit medical societies, particularly small specialties, cannot bear. These requirements impose 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. These requirements are further complicated by the COVID-19 extreme and uncontrollable circumstances exception policy, which decreased the number of clinicians and groups reporting to MIPS via QCDRs.

To encourage the use of QCDRs, the policy should:

- Require face validity for the first two MIPS payment years for which the measures are approved.
- Support the decision of QCDR statisticians familiar with sample sizes and populations relative to the level of testing (clinician, facility, or group) required.
- Provide funding to assist measure stewards in testing their measures, such as offering financial incentives or improvement activity credit for practices to choose to submit data on new QCDR measures.
- Exempt measures targeted by CMS for harmonization with other QCDR measures from satisfying the measure testing requirement prior to self-nomination.

CMS should delay the requirement that QCDR measures must be fully tested prior to their inclusion in an MVP. This would simplify the program's rules by maintaining consistency between traditional MIPS and MVPs.

[3] 42 C.F.R. § 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.'
[4] *Id*.
[5] *Id*. § 414.1400(b)(4)(iii)(A)(3)(i).

Data Validation Requirements

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. Beginning with the 2021 performance year, QCDRs and qualified registries must conduct annual data validation audits for the payment year before submitting any data for that payment year to CMS for purposes of the MIPS program.[6] If a data validation audit identifies one or more deficiencies or data errors, the QCDR or qualified registry 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]

CMS's policies regarding data validation and targeted audits—particularly now that they apply to not only the quality category, but also the Promoting Interoperability ("PI") and Improvement Activities ("IA") performance categories—are unnecessarily complicated, costly, and burdensome for QCDRs, qualified registries, and clinicians. These policies also fail to recognize that QCDRs and qualified registries employ rigorous internal quality data controls and conduct external audits to ensure the accuracy of data. CMS's policies impose considerable burden on clinicians given that the agency has not provided adequate guidance on validating PI and IAs, that not all IAs are reported electronically, and that PI is largely out of the control of registries.

Therefore, we request that Congress direct CMS, not QCDRs, to conduct data validation audits of participating providers. It is inappropriate for the agency to shift its program integrity responsibility to QCDRs. At the very least, Congress should require CMS to work with QCDRs to establish more reasonable data validation requirements that align with MACRA's directive to encourage the use of QCDRs.

Harmonization

Congress should direct CMS to implement appropriate safeguards to ensure that measure harmonization occurs only when doing so is clinically appropriate. Beginning with the 2022 MIPS payment year, in circumstances where multiple, similar QCDR measures exist, CMS may provisionally approve the QCDR measure for one year with the condition that the QCDR must address certain areas of duplication with other approved QCDR measures or MIPS quality measures for subsequent years.[8] If QCDRs cannot collaborate to harmonize their measures, CMS may reject the duplicative QCDR measure.[9]

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,

[6] *Id*. § 414.1400(b)(3)(v).
[7] *Id*. § 414.1400(b)(3)(vi).
[8] *Id*. § 414.1400(b)(4)(iii)(5).
[9] *Id*.

ultimately at the disadvantage of specialists who are left with fewer meaningful measures to report.

In addition, CMS has not implemented a formal process for appealing decisions regarding measure harmonization. An appeal process would give QCDRs an opportunity to provide CMS with additional information, including if there is a clinical rationale for why measures should not be harmonized or if a measure is an appropriate derivative work of another existing measure. If the measure owner can provide a documented clinical rationale for keeping the measures separate, then CMS should not require measure harmonization. Therefore, Congress should direct CMS to ensure that measure harmonization occurs only when doing so is clinically appropriate.

Topped Out Measures

The Coalition has concerns regarding the effect of topped out measures—a measure with a median performance rate of 95% or higher.[10] Beginning with the 2020 performance period, considerations for whether to remove a QCDR measure from the program include whether the QCDR measure is topped out.[11] In addition, beginning with the 2023 MIPS payment year, QCDR measures may be approved for two years, at CMS discretion, by attaining approval status by meeting QCDR measure considerations and requirements.[12] CMS, however, may revoke a QCDR measure's second year approval upon annual review if the QCDR measure is found to be topped out.[13]

The public health emergency, and the corresponding extreme and uncontrollable circumstances exception policy, dramatically reduced the number of providers reporting within the program in the 2020 and 2021 performance years. For instance, the GIQuIC QCDR experienced a 44% drop in QCDR reporters for the 2020 performance year compared to the 2019 performance year and then a drop of 48% in QCDR reporters for the 2021 performance year compared to the 2020 performance year. CMS should allow QCDR measures to remain in the MIPS program for at least two full performance years in which there is no disruption in public quality reporting. This is necessary to meaningfully assess the performance of the measures and their continuation in the program.

If CMS determines that many of a subspecialty's MIPS measures are topped out, it may not be possible for a subspecialty to maintain a QCDR due to the lack of measures. Moreover, 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.

[10] *Id.* § 414.1305.
[11] *Id.* § 414.1400(b)(4)(iv)(D).
[12] *Id.* § 414.1400(b)(4)(iii)(C).
[13] *Id.*

Once a topped out measure is removed from the program, it is challenging to monitor for new performance gaps over time. Measures play a key role in identifying disparities in care, particularly with respect to race, gender, ethnicity, and age. Removing "topped out" measures may hinder efforts to monitor and rectify health equity and disparities. Rather than removing topped-out measures, or even imposing scoring caps on such measures, CMS should consider a more appropriate transition period to extend the utility of "topped-out" measures.

MVP Program

CMS has expressed a desire to replace the traditional MIPS program with its new MVP framework at the end of a transition period. The Coalition strongly believes that CMS should maintain the current process of MIPS reporting for all eligible clinicians and groups and continue to recognize MVP participation as voluntary. Instead of CMS requiring MVP participation, Congress should increase funding and payment for those participants opting to report MVPs. Assigning bonus points for MVP participation would encourages more participants to transition from traditional MIPS reporting to MVP reporting.

CMS's efforts to design, evaluate, and implement the MVP framework must comply with the language and spirit of MACRA. The agency should work collaboratively with stakeholders to develop an MVP framework that results in more clinically relevant and meaningful performance data for specialties and subspecialties, as well as patients. This includes finding solutions to aspects of MIPS that are fundamentally flawed, which are described in this letter and unfortunately are not addressed by the current MVP framework. To ensure that resources are appropriately invested, CMS also should provide greater transparency during the MVP development and approval process. For instance, if CMS receives two MVP candidates that concern the same specialty, CMS should inform both MVP developers of this information prior to the commencement of the notice-and-comment rulemaking process to give the developers of the MVP candidates time to coordinate their efforts.

CMS could encourage participation in value-based models through MVPs. We believe specialties should not be siloed within the MVP framework. CMS should develop multispecialty MVPs to ensure that the full perioperative team has a common interest to perform well as a group. Developing MVPs specifically designed to capture the individual members of a multispecialty case would help clear up existing ambiguities in attribution and strengthen the relationship between specialties in delivering patient-centered care. Individual specialists would still report their specialty-specific measure to their specialty-specific registries in the process. But in working through these attribution issues, multispecialty MVPs may also help CMS identify additional delivery of care models and future Alternative Payment Models.

Cost Measures

The lack of relevant cost measures for certain specialties is an ongoing challenge for traditional MIPS, which the new MVP framework fails to address. CMS currently employs a single contractor, Acumen, LLC, to develop new episode-based cost measures. Although this process

is comprehensive, it is lengthy, relies strictly on claims data, and does not simultaneously account for quality, which results in a flawed assessment of overall healthcare value. The Coalition urges Congress to put pressure on CMS to accommodate more innovative, out-of-the-box solutions related to cost measurement, such as the integration of clinical registry data with claims data to most accurately evaluate value and the use of appropriateness measures to assess cost. As noted above, CMS should provide QCDRs with better access to claims data so that they can help develop a broader inventory of specialty-specific cost measures. If changes that make cost measures more relevant and fair cannot be implemented, Congress must release/reduce the emphasis on this flawed approach.

The budget neutrality requirement of the MIPS program already poses a significant challenge for many clinicians, particularly those in smaller independent practices. Being assessed for value on measures using a narrow set of retrospective claims data adds to the pressures MIPS exerts on physicians and unlike quality measures, registries are largely unable to assist clinicians in interpreting and improving performance.

Additional Funding to Registries

Over the years, CMS has imposed a significant number of QCDR requirements to shift the cost and burden of administering the MIPS program onto specialty societies and other entities that operate QCDRs and develop QCDR measures. In addition, registries have been adversely affected by the COVID-19 pandemic, resulting in a significant decline in provider participation. Congress should authorize and appropriate federal funding and/or grants to clinical data registries to maintain operations and offset these burdens.

CMS Cooperative Agreements with QCDRs

Congress should encourage the use of cooperative agreements between CMS and QCDRs for the development, improvement, and expansion of quality measures for MIPS. CMS currently relies heavily on contractors to develop specialty-specific MIPS quality measures without specialty organizations' active input. For measures that have been developed by specialty organizations, CMS has required changes that are not clinically appropriate for the specialty. It would make more sense, where appropriate, for CMS to use those same resources to instead collaborate directly with specialty society QCDRs that already have the clinical expertise and infrastructure in place to assist with new measure development.

Access to Medicare Claims Data

We respectfully urge the House of Representatives to swiftly pass bipartisan legislation—H.R. 5394, the Meaningful Access to Federal Health Plan Claims Data Act—introduced by Dr. Bucshon and Dr. Schrier. This legislation would provide clinician-led clinical data registries with an essential tool to play a pivotal role in creating a safer, more efficient, and patient-centered health care delivery system.

Contrary to Section 105(b) of MACRA, CMS has not provided clinician-led clinical data registries with a meaningful way to gain continuous access to Medicare claims data. CMS initially refused to implement Section 105(b), stating that QCDRs could access Medicare claims data through the Research Data Assistance Center ("ResDAC") process.[14] After the Coalition and other stakeholders expressed concerns regarding the ResDAC process, CMS provided QCDRs with an alternative mechanism for accessing Medicare claims data, by permitting QCDRs to serve as quasi-qualified entities under the Qualified Entity Program.[15] Neither option, however, provides QCDRs with the type of 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

The ResDAC process does not provide sufficient access to Medicare claims data for quality improvement purposes. The ResDAC process is also slow, costly, and cumbersome. Moreover, CMS' decision to treat QCDRs as quasi-qualified entities for purposes of obtaining access to Medicare claims data does not provide QCDRs (or other clinician-led clinical data registries) with the long-term, continuous, and timely access to Medicare claims data required under Section 105(b). Quasi-qualified entities cannot use Medicare data for research purposes without submitting a separate research protocol to ResDAC for review and approval. QCDRs and other clinician-led clinical data registries generally need data on a provider-specialty specific and nationwide basis; however, quasi-qualified entity status only provides registries access to provider-wide and state-specific data. In addition, the Qualified Entity Program requirements on eligibility, operations, and governance are extremely lengthy and burdensome. Quasi-qualified entity status only lasts for three years and continued participation in the program requires re-application. Therefore, it does not allow for the continuous access needed for monitoring quality improvement over time. CMS' failure to properly implement Section 105(b) hinders clinician-led clinical data registries' ability to perform longitudinal and other data analyses for quality improvement, patient safety, cost-effectiveness, and research purposes.

The Meaningful Access to Federal Health Plan Claims Data Act would allow QCDRs and clinician-led clinical data registries to gain more meaningful access to Medicare, Medicaid, and State Children's Health Insurance Program for quality improvement, patient safety, and research purposes. It also would permit more comprehensive use of the data—including research, quality of care measurement, and reporting—while at the same time ensuring that the data is protected and used appropriately through data use agreements. Tying Medicare claims data to clinical outcome information would enable clinician-led clinical data registries to better track patient outcomes over time, expand their ability to assess the safety and effectiveness of medical treatments, and provide them with the information necessary to assess the cost-effectiveness of alternative therapies. Therefore, we respectfully urge the House of Representatives to pass this bipartisan legislation.

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[14] *See* Medicare Program: Expanding Uses of Medicare Data by Qualified Entities, 81 Fed. Reg. 5,397, 5,408 (Feb. 2, 2016) (proposed rule).
[15] Medicare Program: Expanding Uses of Medicare Data by Qualified Entities, 81 Fed. Reg. 44,456 (July 7, 2016).

The Coalition appreciates your consideration of our request. If you have any questions, please contact Rob Portman or Leela Baggett at Powers Pyles Sutter & Verville, PC (Rob.Portman@PowersLaw.com or Leela.Baggett@PowersLaw.com).

Respectfully submitted,

American Academy of Dermatology Association
American Academy of Neurology
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 Emergency Physicians
American College of Gastroenterology
American College of Rheumatology
American Gastroenterological Association
American Society for Gastrointestinal Endoscopy
American Society of Anesthesiologists/Anesthesia Quality Institute
American Urological Association
Association for Clinical Oncology
Center for Professionalism and Value in Health Care
College of American Pathologists
Congress of Neurological Surgeons
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons