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PHYSICIAN CLINICAL REGISTRY COALITION

August 2, 2024

VIA ELECTRONIC MAIL

The Honorable Larry Bucshon, MD
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

Re: Physician Clinical Registry Coalition's Response to the Cures Request for Information

Dear Representatives Bucshon and DeGette:

The undersigned members of the Physician Clinical Registry Coalition ("Coalition") write to offer our recommendations for legislative reform as part of your 21st Century Cures initiative. 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.

The Coalition commends your commitment to modernize the health care delivery system and better utilize real-world data and real-world evidence across federal agencies. Clinician-led clinical data registries collect and analyze data on specified outcomes submitted by physicians, hospitals, and other types of clinicians related to a wide variety of medical procedures, diagnostic tests, and/or clinical conditions. These registries play an essential role in promoting quality of care. Clinician-led clinical data registries are major sources of real-world evidence, including patient-reported outcomes data. They provide timely and actionable feedback to clinicians 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, identifying clinicians and patients for participating in controlled clinical trials, describing the natural history of disease, building predictive models for earlier diagnosis, determining the effectiveness (including the comparative effectiveness) of therapeutic modalities, post market surveillance of pharmaceuticals, and measuring quality of care to identify best practices.

Medical societies have invested millions of dollars in a system of quality performance evaluation through Qualified Clinical Data Registries ("QCDRs") and other clinician-led clinical data registries. The measures developed by these 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. Congress recognized the importance of QCDRs when it passed the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"). MACRA requires the Secretary of Health and Human Services ("Secretary") to encourage the use of QCDRs for reporting measures under the quality performance category of the Merit-Based Incentive Payment System ("MIPS") program.[1]

Over recent years, however, the Centers for Medicare and Medicaid Services ("CMS") has established policies that contravene the language and intent of MACRA, including policies that deter registry access to Medicare claims data, disincentivize the development of meaningful specialty measures, and impose financial and administrative burdens on registry operations. Therefore, we respectfully urge Congress to critically review CMS policies and consider the following legislative reforms that would build upon provisions of the 21st Century Cures Act that underscore how clinician-led clinical data registries are uniquely positioned to drive quality improvement initiatives.[2]

Access to Claims Data

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."[3] Unfortunately, significant regulatory barriers have prevented meaningful registry access to federal health plan claims data. Currently, CMS offers a way of accessing its program data through the Virtual Research Data Center ("VRDC"), a virtual research environment under which QCDRs can—in theory—access Medicare claims data. The VRDC, however, is limited to narrowly defined research questions and is slow, costly, and cumbersome. The current process does not provide clinician-led clinical data registries with the type of timely, broad, and continuous access to claims data contemplated by Section 105(b) and necessary for registries to effectively link their outcomes data with claims data.

Moreover, CMS's decision to treat QCDRs as quasi-qualified entities for purposes of obtaining access to claims data does not provide QCDRs (or other clinician led clinical data registries) with the long-term, continuous, and timely access to claims data. The scope of the data provided under the Qualified Entity Program does not satisfy registry needs. 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.

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[1] MACRA, Pub. L. No. 114-10, § 101(c), 129 Stat. 87 (2015).

[2] The 21st Century Cures Act defines the term "clinician-led clinical data registry" as a clinical data repository that is established or operated by a clinician-led or controlled, tax-exempt professional society or other similar organization; designed to collect detailed, standardized data on an ongoing basis for medical procedures, services, or therapies for particular diseases, conditions, or exposures; provides feedback to participating data sources; provides ongoing participant training and support; and meets certain quality standards. 21st Century Cures Act, Pub. L. No. 114-255, § 4005, 130 Stat. 1033, 1180-81 (2016).

[3] MACRA § 105(b).

These barriers impede progress toward health care delivery modernization. Tying 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. **To perform longitudinal and other data analyses for quality improvement, patient safety, cost-effectiveness, and research purposes, clinician-led clinical data registries require regular, continuous, and sometimes long-term access to large data sets to better track clinical outcomes over time**.

Legislation is needed to solve this long running problem and allow for clinician-led clinical data registries to link their provider-level clinical outcomes data with Medicare, Medicaid, and State Children's Health Insurance Program claims data. This would allow us to unlock powerful insights into long-term patient outcomes and device performance. We respectfully urge you to include in a Cures package language guaranteeing clinician-led clinical data registries access to claims data for quality improvement, patient safety, and research purposes, all of which are necessary to build (or explore) evidence-based models of value-based care to benefit patients.

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. QCDRs and qualified registries must conduct annual data validation audits.[4] 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.[5]

CMS's policies regarding data validation and targeted audits 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.

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.

[4] 42 C.F.R. § 414.1400(b)(3)(v).
[5] *Id*. § 414.1400(b)(3)(vi)(A).

Measure Testing

CMS may approve a QCDR measure only if the QCDR measure meets face validity.[6] 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.[7]

We understand and agree with CMS's desire that all QCDR measures be appropriate, reliable, and valid. The key to "appropriate measures" is the development of measures by medical specialty societies. Medical specialty societies play a major role in supporting the quality performance category by developing, testing, and maintaining over 60 percent of the current MIPS quality measure inventory. 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 (in some cases as much as $100,000 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. To help alleviate these costs, we request that Congress direct CMS to offer grants to medical specialty societies to aid in measure development.[8]

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.
- Exempt measures targeted by CMS for harmonization with other QCDR measures from satisfying the measure testing requirement prior to self-nomination.
- Incentivize physicians to test new or significantly revised QCDR measures by awarding pay-for-reporting credit for three years.
- Reward clinicians for reporting new measures by awarding such clinicians improvement activity credit.

Harmonization

Congress should direct CMS to implement appropriate safeguards to ensure that measure harmonization occurs only when doing so is clinically appropriate. CMS may provisionally approve the individual QCDR measures for one year with the condition that QCDRs address

[6] *Id*. § 414.1400(b)(4)(iii)(A)(3).
[7] *Id*.
[8] Similar grant funding was previously made available to entities via the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). *See* Quality Payment Program, Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Funding Opportunity: Measure Development for the Quality Payment Program.

certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years.[9] If such areas of duplication are not addressed, CMS may reject the QCDR measure.[10]

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.

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. For example, when measures are harmonized, the denominator combines disease categories that have different risk profiles of successfully complying with the numerator criteria. This can unjustly disadvantage some clinicians relative to others who report the 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, which by definition should fall to the medical specialty society as the entity with the relevant clinical expertise.

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.[11] 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.[12]

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.

[9] *Id*. § 414.1400(b)(4)(iii)(A)(5).
[10] *Id*.
[11] *Id*. § 414.1305.
[12] *Id*. § 414.1400(b)(4)(iv)(D).

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.

Topped out measures are only topped out for clinicians who report them. Topped out measures may represent an opportunity for improvement among the vast majority of clinicians who do not report them. To address this opportunity, CMS could allow MIPS participants to report measures with a performance rate of over 95% for two or three years, celebrating their success for that period, but then requiring them to move on to other measures with potential for improvement.

Promoting Interoperability

Congress should recognize the value of clinician-led clinical data registries by authorizing clinicians to satisfy the Promoting Interoperability requirements via participation in a clinical data registry.

MIPS Value Pathways Program

CMS has expressed a desire to replace the traditional MIPS program with its new MIPS Value Pathways ("MVPs") framework. 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. It is premature to consider retiring the traditional MIPS program. Medical societies have expressed serious concerns regarding the development of MVPs applicable to their specialties. We also 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. This directly contravenes MACRA and significantly disadvantages providers who are already facing a scarcity of relevant MIPS measures—particularly harming small and rural practices. As stated above, medical societies have invested considerable funding into the development QCDR measures and the move towards MVPs is devaluing their investment in clinically relevant performance measures.

The agency needs additional time to work collaboratively with stakeholders to develop a proper MVP framework that results in more clinically relevant and meaningful performance data for specialties and subspecialties, as well as patients. This includes ensuring clinically appropriate QCDR measures are included in MVPs. It also 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.

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 fairer 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 unfunded QCDR requirements that shift the cost and burden of administering the MIPS program onto specialty societies and other entities that operate QCDRs and develop QCDR measures. Congress should authorize and appropriate federal funding and/or grants to QCDRs to maintain operations and offset these burdens.

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The Coalition appreciates your leadership in modernizing the provision of health care, and we stand ready to work with you during this process. 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 & Neck Surgery
American Academy of Physical Medicine & Rehabilitation
American Association of Neurological Surgeons
American College of Emergency Physicians
American College of Gastroenterology

American College of Radiology
American Psychiatric Association
American Society for Gastrointestinal Endoscopy
Association for Clinical Oncology
Congress of Neurological Surgeons
Outpatient Endovascular and Interventional Society National Registry
PRIME Registry (the Center for Professionalism and Value in Healthcare)
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons