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PHYSICIAN CLINICAL REGISTRY COALITION

White Paper on Clinical Data Registries: Challenges and Policy Solutions

The Physician Clinical Registry Coalition ("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. Most of the members of the Coalition meet the definition of clinician-led clinical data registry under the 21st Century Cures Act. This white paper highlights key challenges that clinical data registries face and potential policy solutions that would alleviate such burdens.

Background on Clinical Data Registries

Clinical data registries are organized data collection and analysis systems operated by or affiliated with a national medical society, hospital association, or other health care association. These registries collect and analyze data on specified outcomes submitted by physicians, hospitals, and other types of health care providers related to a wide variety of medical procedures, diagnostic tests, and/or clinical conditions. They perform data aggregation and related benchmarking analyses that support one or more predetermined scientific, clinical, or policy purposes, including, but not limited to, describing the natural history of disease, determining the effectiveness (including the comparative effectiveness) of therapeutic modalities, and measuring quality of care. Clinical data registries are major sources of real-world evidence, including patient-reported outcomes data. The comprehensive and valuable measures developed by clinical data registries are meaningful and relevant to participating providers and their patient populations. These measures provide important information that is not available from claims data.

The appropriate collection and use of protected health information ("PHI") is the foundation of registry work. Most clinical data registries serve as business associates of the hospitals, physicians, and other covered entity sites from which they receive PHI and other data. These clinical data registries perform data aggregation, curation, benchmarking, and analytic services on behalf of these covered entities. They also perform secondary research on de-identified data and "limited data sets" that provide real-world evidence. The Health Insurance Portability and Accountability Act ("HIPAA") rules effectively ensure that PHI that registries collect is properly safeguarded. Clinical data registries take data security very seriously and diligently comply with the HIPAA Privacy and Security Rules.

The federal government, health care products manufacturers, accreditors, and state and local governments have increasingly come to rely on clinical data registries for a wide variety of purposes. For instance, clinical data registries report medical and clinical data to the Centers for Medicare and Medicaid Services ("CMS") on behalf of their participating health care providers for purposes of the Merit-based Incentive Payment System ("MIPS") and for more general patient and disease tracking.

Major Challenges that Clinical Data Registries Face and Potential Policy Solutions that Would Alleviate Such Burdens

At a time when the need for clinical data registries is growing, so too are the regulatory barriers and burdens, as well as other challenges.

Accessing Data from Electronic Health Record ("EHR") Vendors and Providers

In order for clinical data registries to accomplish their missions, they must be able to collect data from providers and EHR vendors. Unfortunately, clinical data registries continue to encounter roadblocks in gathering critical data elements from these sources, creating a major challenge to interoperability between EHRs, providers, and clinical data registries. Until true interoperability is realized, clinical data registries will fall short of their tremendous potential to improve and progress the quality-based payment paradigm.

EHR vendors, in particular, hinder data transfer to clinical data registries in myriad ways. For example, EHR vendors refuse to enter into negotiations for the transfer of patient information to registries, and therefore are prohibiting registries from any degree of access to such information. EHR vendors also require providers to pay unjustified, large fees to send their data from the EHR to the registry or their software vendor. Further compounding these challenges is a systemic failure to establish a common platform for all proprietary systems to exchange data and information from multiple sources in a language the entire healthcare system can use. If registries simply import unstructured EHR data, lacking precise and standardized definitions, the integrity and unique value of registry data will be compromised. This results in stalled innovation and interoperability.

Certain providers also contribute to the data-blocking clinical data registries face. Efforts should be made to develop standards for EHRs and providers that can support the needs of specialty registries. The Department of Health and Human Services should work with existing registries and medical specialties to establish standards for the extraction of data for registries to promote interoperability, prohibit information-blocking, and ensure clinical data registries' have the ability to access and use essential data.

Meaningful Access to Federal Health Plan Claims Data

Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") directs the Secretary to provide Medicare claims data to Qualified Clinical Data Registries ("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."[1] CMS has not provided 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. Current programs—the Qualified Entity Program and the Virtual Research Data Center ("VRDC")—place restrictions on the use of data: allowing registries to access data for very specific research purposes, or for quality improvement, but not both. In addition, the application processes and associated fees are too costly and cumbersome to provide registries with timely and meaningful access to claims data. CMS' failure to properly implement

[1] MACRA, Pub. L. No. 114-10, § 105(b)(1)(A), 129 Stat. 136 (2015).

Section 105(b) hinders clinical data registries' ability to perform longitudinal and other data analyses for quality improvement, patient safety, cost-effectiveness, and research purposes.

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. CMS should work with clinical data registries to ensure that all registries that meet the 21st Century Cures Act's definition of clinician-led clinical data registries have more meaningful access to Medicare, Medicaid, and State Children's Health Insurance Program 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.[2] To the extent that legislative action is necessary to ensure more timely and continuous access to claims data, the Coalition supports such legislation.

The MIPS Program

MACRA requires the Secretary of Health and Human Services ("Secretary") to encourage the use of QCDRs and certified electronic health record technology ("CEHRT") for reporting measures under the quality performance category of the MIPS program.[3] Over recent years, however, CMS has established policies that impose burdensome requirements on registries that conflict with and impede the critical role that registries play in improving patient outcomes and quality of care.

1) MIPS Value Pathways ("MVPs")

In developing the MVP program, we encourage CMS to adopt MVP policies that will remedy the substantial administrative burdens of the current, traditional MIPS program, some of which are described below. The MVP program provides an opportunity to increase scoring simplicity and predictability, appropriately evaluate and reward performance improvement, collaborate with specialty societies to identify and address priority areas, ensure that quality measurement is clinically relevant to physicians, and focus on patient-centered care. The Coalition believes that CMS's efforts to design, evaluate, and implement the MVP program must comply with the

[2] The 21st Century Cures Act defines a "clinician-led clinical data registry" as:

> "[A] clinical data repository— (1) that is established and operated by a clinician-led or controlled, tax-exempt (pursuant to section 501(c) of the Internal Revenue Code of 1986), professional society or other similar clinician-led or -controlled organization, or such organization's controlled affiliate, devoted to the care of a population defined by a particular disease, condition, exposure or therapy; (2) that is designed to collect detailed, standardized data on an ongoing basis for medical procedures, services, or therapies for particular diseases, conditions, or exposures; (3) that provides feedback to participants who submit reports to the repository; (4) that meets standards for data quality including—(A) systematically collecting clinical and other health care data, using standardized data elements and having procedures in place to verify the completeness and validity of those data; and (B) being subject to regular data checks or audits to verify completeness and validity; and (5) that provides ongoing participant training and support."

21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016).

[3] MACRA§ 101(c).

language and spirit of MACRA that encourages the use of QCDRs for reporting measures under the quality performance category of the MIPS program.

2) Measure Testing

CMS may only approve a new QCDR measure if the measure meets face validity for the initial MIPS payment year.[4] 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.[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, do not allow QCDRs to be nimble in terms of introducing new and innovative measures, and are contrary to the MACRA's requirement to encourage the use of QCDRs for reporting measures. The cost of 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 fail to recognize that 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. Prior to these policies, QCDRs typically reviewed performance data before and after implementing a measure in the registry. This, along with the recently implemented requirement to demonstrate measure development expertise, should give CMS confidence regarding QCDR measures that are submitted by medical societies. The Coalition believes that CMS should adopt a more strategic and flexible approach to MIPS and QCDR measure selection and testing, including allowing alternative testing approaches and additional time to collect data for testing, in order to ensure that measures are appropriate, reliable, and valid.

3) Data Validation Requirements

Beginning with the 2021 performance year, QCDRs and qualified registries must conduct 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]

Although it is important to ensure that reporting is true, accurate, and complete, the current data validation and targeted audit requirements contravene MACRA's directive to encourage the use

[4] 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.' It is a subjective assessment by experts about whether the measure reflects its intended assessment." *CMS Measures Testing,* CMS MEASURES MANAGEMENT SYSTEM (June 2023), https://mmshub.cms.gov/measure-lifecycle/measure-testing/evaluation-criteria/scientific-acceptability/validity.
[5] 42 C.F.R. § 414.1400(b)(4)(iii)(A)(3).
[6] *Id*. § 414.1400(b)(3)(v).
[7] *Id*. § 414.1400(b)(3)(vi)(A)-(B).

of QCDRs for reporting measures. 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.

4) Harmonization

In circumstances where similar, multiple QCDR measures exist, CMS may provisionally approve the QCDR measure for one year with the condition that the QCDRs 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 allegedly 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, ultimately at the disadvantage of specialists who are left with fewer meaningful measures to report. CMS should implement appropriate guardrails to ensure that measure harmonization occurs only when doing so is clinically appropriate.

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.

5) 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] Considerations for whether to remove a QCDR measure from the program include whether the QCDR measure is topped out.[11] In addition, CMS may approve QCDR measures for two years by attaining approval status by satisfying 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]

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

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

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. 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.

Incentivizing Clinical Data and Measure Testing Participation

Clinician reporting contributes to real world data. However, clinicians must invest time and money to use registries and QCDRs, particularly in light of ongoing data access barriers imposed by EHR vendors and providers, as described earlier. Therefore, clinicians are much more likely to pursue these means when there are more significant benefits to making the investment. Currently, the MIPS program provides too little credit for submitting data through a QCDR. In accordance with MACRA's directive to encourage the use of QCDRs for reporting measures, CMS should provide more meaningful credit/incentivization for clinical data and measure testing participation.

Measuring Nuanced Social Determinants of Health or Broader Economic Impacts of Treatments/Devices

Stakeholders across the health care landscape increasingly acknowledge the major impact that social determinants of health ("SDOH") have on care quality, health outcomes, and costs. Clinical data registries can be instrumental in measuring utilization of services and care outcomes across the general population, as well as in populations at risk. Understanding disparities in these measures is instrumental to ensuring that health care is more equitable for all. The American Academy of Ophthalmology's IRIS Registry has several studies in peer-reviewed publications that address these issues of population disparities in blindness and visual impairment due to various causes, and most studies compare outcomes across age, gender, race and ethnicity, and insurance coverage groups.

However, many clinical data registries are still unable to draw meaningful conclusions from SDOH data because both providers and EHR vendors make it difficult for clinical data registries to access such data. To overcome this limitation, some clinical data registries incorporate a proxy for socio-economic status and risk-adjust based on an area-deprivation index score. However, without fully incorporating SDOH data into their metrics, clinical data registries are unable to fully analyze health disparities. CMS should help establish and implement a strategy for how health equity data elements are standardized and collected across the health system.

Conclusion

Clinical data registries provide a valuable data collection and analysis infrastructure and stand well-positioned to serve as the lynchpin of any value-based payment program. However, clinical data registries face numerous burdens which threaten to undermine their tremendous value. Targeted policy changes can alleviate these burdens and ensure registries reach their full

potential of advancing research, monitoring conditions and treatments, and improving quality of care.

Respectfully submitted,

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 Gastroenterology
American College of Radiology
American Society for Gastrointestinal Endoscopy
American Urological Association
Association for Clinical Oncology
Center for Professionalism and Value in Health Care
College of American Pathologists
Outpatient Endovascular and Interventional Society
Society of Interventional Radiology
The Society of Thoracic Surgeons