P•C•R•C
PHYSICIAN CLINICAL REGISTRY COALITION

June 3, 2019

Ms. Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1694-P
P.O. Box 8011
Baltimore, MD 21244-1850

[Submitted online at: https://www.regulations.gov/document?D=CMS-2019-0039-0001]

Re: RIN 0938-AT79 – Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers

Dear Ms. Verma:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition) appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) proposed rule to improve interoperability and access to health care data (the Proposed Rule).[1] 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.[2] The Coalition's comments on the Proposed Rule focus largely on CMS's future rulemaking on interoperability activities as potential alternatives to measures in the Promoting Interoperability Program, as well as CMS's request for information (RFI) on advancing interoperability across the care continuum.

While the Coalition understands that this Proposed Rule focuses largely on patient access to health care data, the Coalition hopes to work with CMS to expand provider access to data in order to promote quality of care and enhance health care decision making. Provider access to

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[1] Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally- Facilitated Exchanges and Health Care Providers, 84 Fed. Reg. 7,610 (Mar. 4, 2019).
[2] For more information about the Coalition, see https://www.registrycoalition.net/.

data is essential to their ability to report complete and accurate information to clinical data registries and thus for registries to fulfill their mission of improving quality of care through the collection, analysis, and benchmarking of data on health care diagnoses, treatments, and outcomes. The Coalition understands that this Proposed Rule is only the first phase of CMS's policymaking on interoperability and access to health care data. The Coalition looks forward to working with CMS on these issues in future rulemaking.

1. Promoting Interoperability Program: Interoperability Activities

In the Proposed Rule, CMS seeks comments to inform future rulemaking on potential updates to the Promoting Interoperability Program to encourage eligible hospitals and critical access hospitals (CAHs) to engage in certain activities focused on interoperability.[3] Specifically, CMS invites comments on ideas for priority health IT or interoperability activities that would serve as alternatives to measures in the Promoting Interoperability Program for hospitals and CAHs.

The Coalition urges CMS to include the use of an electronic health record (EHR) to participate in a clinician-led qualified clinical data registry (QCDR) as an interoperability activity. 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. Given CMS's stated goal of supporting alignment between the Promoting Interoperability Program and the Quality Payment Program (QPP), the Coalition encourages CMS to include electronic reporting through a clinician-led QCDR as an interoperability activity in the Promoting Interoperability Program, as well as provide full credit under the Merit-based Incentive Payment System (MIPS) Promoting Interoperability category to eligible clinicians and groups using an EHR to participate in a clinician-led QCDR, as discussed below.

2. RFI on Advancing Interoperability Across the Care Continuum

CMS's RFI seeks input on potential strategies for advancing interoperability across care settings to inform future rulemaking activity in this area.[4] The Coalition appreciates CMS's attention to the ongoing challenge of advancing and incentivizing interoperability. In light of CMS's concern about the lack of agreed-upon measure concepts to gauge how well providers are routinely and effectively engaging in exchange of information across settings, the Coalition continues to encourage CMS to provide full credit under the MIPS Promoting Interoperability category to eligible clinicians and groups using an EHR to participate in a clinician-led QCDR. This proposal would be particularly helpful due to the potential for increased provider burden in the event that CMS pursues its proposal of expanding the scope of interoperability measurement beyond settings that were eligible for the EHR Incentive Programs. This proposal would also be consistent with Congress's mandate under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. No. 114-10) that the Secretary of the Department of Health and

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[3] Proposed Rule, 84 Fed. Reg. at 7,618. This future rulemaking would build on concepts discussed in the FY 2019 IPPS/LTCH PPS Proposed Rule, 83 Fed. Reg. 20,164, 20,537–38 (May 7, 2018).

[4] Proposed Rule, 84 Fed. Reg. at 7,654.

Human Services encourage the use of QCDRs and certified EHR technology for reporting measures under the Quality performance category of MIPS.[5]

3. Information Blocking by Hospitals and Health Systems

The Coalition appreciates CMS's efforts to address information blocking by hospitals by proposing to require public reporting of the three prevention of information blocking statements to which eligible hospitals and CAHs must attest for purposes of the Promoting Interoperability Program.[6] Many clinicians require access to data from hospital systems for the purpose of reporting on quality measures. As CMS eliminates claims-based measures, clinicians that rely on data from their hospital's EHRs or Laboratory Information Systems (LISs) are disadvantaged because it is difficult or impossible to access the hospital's data. Many clinicians need data from hospitals to support their ongoing participation in MIPS or Alternative Payment Models (APMs). Data from hospitals may include critical information such as laboratory tests and utilization, images, and other diagnostic information, emergency department care, etc. Without these data elements, many measures cannot be fully calculated and scored.

Clinicians working in and supporting hospitals should have access to all of a patient's data from the hospital's EHR and LIS. In many cases, however, this does not occur or is made extremely difficult. As a result, a large number of clinicians using clinical data registries to report quality measures do not receive any data from their hospitals. While hospitals often claim that they cannot share the data for privacy and security purposes, CMS has indicated that there are no regulations that impede hospitals from sharing this information with clinicians. In addition, because each hospital has its own unique legal and administrative framework for potentially accessing data, clinicians and registries currently must invest significant resources in attempting to access data from multiple hospitals. As a result, the lack of data availability from hospitals is a significant resource problem for the system as a whole. In light of this serious issue for hospital-based clinicians, the Coalition encourages both the Office of the National Coordinator for Health Information Technology (ONC) and CMS to continue to address this important issue and improve the flow of information between hospital EHRs, LISs, imaging systems, and registries.

4. Complex Framework of Federal and State Privacy Laws

As CMS notes in the Proposed Rule, covered entities under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and their business associates must comply with a complex framework of laws and regulations that includes the HIPAA regulations and the Federal Trade Commission (FTC) Act, as well as state privacy laws and security standards.[7] The lack of harmonization among these laws, as noted by CMS, can create uncertainty or confusion for HIPAA covered entities and their business associates that want to exchange health information.[8]

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[5] Social Security Act (SSA) § 1848(q)(1)(E); SSA § 1848(q)(5)(B)(ii)(l).

[6] Proposed Rule at 7,647-48.

[7] *Id.* at 7,617, 7,621.

[8] *Id.* at 7,617.

While the Coalition understands that nothing in this Proposed Rule is intended to alter the HIPAA regulations, the Coalition strongly urges CMS and ONC to work with the Office for Civil Rights, the Office of Human Research Protections, and the FTC to eliminate conflicts or duplication between HIPAA, the Common Rule, the FTC's enforcement efforts, and this new regulatory scheme. Given that many privacy and security regulations were not created within the scope of the current digital landscape and may be outdated, there is an urgent need to align the various regulatory frameworks applicable to data privacy and security. The Coalition looks forward to working with each of these agencies and departments on this important issue.

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The Coalition appreciates the opportunity to comment on the Proposed Rule. We urge CMS to adopt the Coalition's suggestions to facilitate and promote the use of QCDRs and other clinical outcomes data registries. The goal is to allow the use of registries to grow and ultimately result in even greater improvements in the quality of patient care. In light of the critical role that registries play in improving patient outcomes and quality of care, we encourage CMS to work closely with ONC to adopt consistent policies across the board to further incentivize interoperability and electronic exchange of data between providers and clinical data registries.

Thank you again for the opportunity to submit these comments. If you have any questions, please contact Rob Portman at Powers Pyles Sutter & Verville PC (rob.portman@powerslaw.com or 202-872-6756).

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/GIQUIC
AMERICAN COLLEGE OF RADIOLOGY
AMERICAN COLLEGE OF RHEUMATOLOGY
AMERICAN COLLEGE OF SURGEONS
AMERICAN GASTROENTEROLOGICAL ASSOCIATION
AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY/GIQUIC
AMERICAN SOCIETY FOR RADIATION ONCOLOGY
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AMERICAN SOCIETY OF CLINICAL ONCOLOGY
AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY
AMERICAN SOCIETY OF PLASTIC SURGEONS
AMERICAN UROLOGICAL ASSOCIATION
COLLEGE OF AMERICAN PATHOLOGISTS

SOCIETY OF INTERVENTIONAL RADIOLOGY
SOCIETY OF NEUROINTERVENTIONAL SURGERY
THE SOCIETY OF THORACIC SURGEONS