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PHYSICIAN CLINICAL REGISTRY COALITION

February 12, 2019

Roger Severino
Director, Office for Civil Rights
Department of Health and Human Services
200 Independence Ave SW, Room 509F
Washington, DC 20201

[Submitted online at: https://www.regulations.gov/document?D=HHS-OCR-2018-0028-0001]

Re: HHS-OCR-0945-AA00 – Request for Information on Modifying HIPAA Rules to Improve Coordinated Care

Dear Mr. Severino:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition) appreciate the opportunity to comment on the Office for Civil Rights (OCR) Request for Information on Modifying HIPAA Rules to Improve Coordinated Care (HIPAA RFI).[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. Clinical data registries uniformly collect protected health information (PHI) from their participating health care providers (Participants) and must adopt policies and procedures to comply with the HIPAA Rules in doing so.

The Coalition greatly appreciates OCR's attention to promoting information sharing. In conjunction with the Office of the National Coordinator for Health Information Technology (ONC) rulemaking to implement the information blocking requirements in the 21st Century Cures Act, the Coalition looks forward to working with OCR to promote information sharing and interoperability and reduce regulatory and administrative burden.

1. Promoting Information Sharing for Treatment and Care Coordination

The Coalition appreciates OCR's efforts, as expressed in the HIPAA RFI, to ensure that any potential new requirements to disclose PHI are consistent with the ONC rulemaking to prohibit ''information blocking,'' as defined by the 21st Century Cures Act.[2] As described below and as

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[1] Request for Information on Modifying HIPAA Rules to Improve Coordinated Care, 83 Fed. Reg. 64,302 (Dec. 14, 2018).
[2] *Id.* at 64,305.

identified in the Coalition's communications with ONC, Coalition members have faced significant challenges in receiving information from electronic health records (EHR) vendors. Coalition members are concerned that EHR vendors may inappropriately deny access to their health care provider outcomes data based on the false premise that such transfer of data somehow violates HIPAA. Accordingly, OCR can support ONC's efforts to prevent information blocking by clarifying that HIPAA compliance is not a justification for withholding data from clinical data registries and other similar parties if such registries are in compliance with all applicable HIPAA Rules.

Registries that collect and aggregate PHI from their Participants primarily for quality improvement purposes are business associates of their Participants and have business associate agreements in effect to allow for this transfer of PHI. These Participants submit data to registries for a wide variety of quality improvement activities, including for reporting under the Merit-based Incentive Payment System (MIPS) Program, as well as secondary research and public health activities. Other registries that collect data from covered entities primarily for research purposes have approvals and waivers from an institutional review board (IRB) for such transfer. The principal impediment to integration of EHR data into registries is that some EHR companies outright refuse to share their data with registries, impose unnecessary and time-consuming technical or contractual requirements on registries, and/or charge their customers or registries excessive fees for this data exchange.

Owners of EHR systems control the flow of data from Participants to registries and the extraction of clinical data from EHRs is the most efficient method of collecting a large portion of the data collected by registries. When physician practices move from locally-hosted EHRs, from which data can be extracted, to cloud-based solutions, to which data must be pushed, registries must increasingly rely upon EHRs to share complete data. Members of the Coalition and their Participants have experienced major challenges in the exchange of information from EHR vendors, including unreasonably high fees, the imposition of one-sided connectivity agreements or business associate agreements, assertions of intellectual property rights to registry data, limited access to data, and a lack of common technical profiles and standards across EHR systems or appropriate documentation to help registries and their Participants bridge technical gaps where they exist. These barriers interfere with and materially discourage access to information, as well as violate the letter and the spirit of the provisions of the 21st Century Cures Act that prohibit information blocking. EHR vendors may also use information blocking to prevent providers from participating in clinical data registries while the EHR vendor simultaneously develops an application or software to compete with the registry. OCR can prevent EHR vendors from using HIPAA compliance as an excuse for refusing to share PHI with clinical data registries by clarifying that such refusal is not justified where the registry can demonstrate that it is taking all necessary and reasonable steps to comply with the applicable HIPAA Rules.

In the HIPAA RFI, OCR also asks whether business associates should be subject to a requirement to disclose PHI when requested by another covered entity for treatment purposes and whether such a requirement should extend to disclosures made for payment and/or health care operations purposes generally, or, alternatively, only for specific payment or health care operations purposes.[3] The Coalition strongly urges OCR not to directly subject business associates to these proposed required disclosures of PHI. Instead, business associates should forward any such requests for disclosure of PHI to the relevant covered entity and only disclose PHI in response to such requests as directed by the covered entity with which the business associate has a contractual relationship.

2. Additional Ways to Remove Regulatory Obstacles and Reduce Regulatory Burdens to Facilitate Care Coordination and Promote Value-Based Health Care Transformation

OCR seeks information about what provisions of the HIPAA Rules may present obstacles to, or place unnecessary burdens on, the ability of covered entities and business associates to conduct care coordination and/or case management, as well as what provisions of the HIPAA Rules may inhibit the transformation of the health care system to a value-based health care system.[4] To that end, the Coalition strongly urges OCR and the Office of Human Research Protections (OHRP) to coordinate to eliminate conflicts or duplication between HIPAA and the Common Rule. It is duplicative and unnecessary to require business associates and covered entities to comply with the Common Rule in cases where HIPAA also applies. Furthermore, registries and other business associates should be exempted from the Common Rule requirements where registries and others are using PHI for health care operations, public health activities, or research in compliance with the HIPAA Rules. While we understand that this is primarily an issue for OHRP, OCR should work with OHRP to create a “HIPAA compliance” exception to the Common Rule.

The analysis produced by clinical data registries helps to improve care coordination and case management, as well as promotes innovation and the transformation of the health care system to a value-based health care system. In order to encourage clinical data registry participation among physicians, the Coalition hopes to work with OCR to address the protection of provider-specific data in clinical data registries from legal discovery. Specifically, the Coalition supports a safe harbor protection of data that identifies individual physicians and other health care providers from discovery in litigation. This protection would encourage accurate and thorough participation in data collection and analysis. While the Coalition understands that OCR may not currently have the statutory authority to implement such a protection, the Coalition hopes to work with OCR and members of Congress on this issue.

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[3] *Id.* at 64,304.
[4] *Id.* at 64,309.

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Thank you 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 ASSOCIATION OF ORTHOPAEDIC SURGEONS
AMERICAN COLLEGE OF EMERGENCY PHYSICIANS
AMERICAN COLLEGE OF GASTROENTEROLOGY
AMERICAN COLLEGE OF RADIOLOGY
AMERICAN COLLEGE OF RHEUMATOLOGY
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AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY
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NORTH AMERICAN SPINE SOCIETY
SOCIETY OF INTERVENTIONAL RADIOLOGY
SOCIETY OF NEUROINTERVENTIONAL SURGERY
THE SOCIETY OF THORACIC SURGEONS