American Society of Anesthesiologists™

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February 12, 2019

Roger Severino
Director, Office for Civil Rights
U.S. Department of Health and Human Services, Office for Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

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

Dear Mr. Severino:

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

The American Society of Anesthesiologists® (ASA), on behalf of our over 53,000 members, appreciates the opportunity to respond to the U.S. Department of Health and Human Services, Office for Civil Rights (OCR) Request for Information (RFI) on possible modifications to Health Insurance Portability and Accountability (HIPAA) rules. In addition, ASA appreciates the opportunity to respond on behalf of its related organization, the Anesthesia Quality Institute (AQI), which maintains clinical data registries that collect and analyze case data (e.g. PHI) primarily for quality improvement purposes in the clinical practice of anesthesiology as a "business associate" of its participants. As a result, ASA has identified several priority questions within the RFI that would impact its member physician anesthesiologists and AQI's registry participants. We address the posted questions in the order OCR provided them.

> **(13)** ***Should individuals have a right to prevent certain disclosures of PHI that otherwise would be required for disclosure? For example, should an individual be able to restrict or ''opt out'' of certain types of required disclosures, such as for health care operations?***

Clinical data registries, such as AQI's National Anesthesia Clinical Outcomes Registry (NACOR), aim to improve health care outcomes, the quality and coordination of care patients receive and the development of clinical best practices. Data is often collected and contributed to clinical data registries as a component of a participant's "health care operations." Receipt of accurate and complete datasets is critical to a clinical data registry's aim of improving the quality of care that patients receive. For example, receipt of accurate and complete anesthesia datasets, including comorbidities of patients undergoing an anesthetic procedure and resulting outcomes, can lead to a reduction in anesthesia adverse events and other incidents through careful and methodical data analysis and research. Moreover, data reported to a clinical data registry can be used to generate peer-to-peer benchmarks, identify outliers, drive local quality improvement and inform research into anesthesia care. These registry activities contribute to

the health care community transitioning further toward delivering value-based care and improving patient outcomes through evidence-based medicine.

Allowing individuals to arbitrarily opt out of disclosures for certain purposes (e.g. data registries) or opt out of sharing certain data elements (e.g. co-morbidities), that would otherwise be permissible to share under HIPAA, has the potential to seriously restrict the ability of providers to meet government reporting obligations (e.g. Merit-based Incentive Payment System) and identify opportunities to improve and reduce the cost of care delivered to such patients through participation in clinical data registries. For instance, through AQI's NACOR, case data is used to help anesthesiologists better understand treatment choices, develop clinical decision support tools and apply the most recent evidence-based medicine to individual patients. Any obstacles, actual or perceived, to collecting a complete dataset may impact the ability for anesthesiologists and other specialists to use the data for clinical, scientific and policy purposes.

Clinical data registries are required under HIPAA to enter into business associate agreements, safeguard such data and utilize it only for permissible purposes. OCR should take into consideration not just the trust a patient has in their physician or the physician's practice to protect their PHI but also the trust that physicians and their practices have when submitting data to a clinical data registry. Patients, physician anesthesiologists and other health care stakeholders recognize the benefits of the permitted disclosure for health care operations, including registries that include "conducting quality assessment and improvement activities, developing clinical guidelines" and "developing protocols."[1] Not only would such requests be burdensome for providers to manage, ASA is concerned that any possible restrictions on access to complete datasets or data components would harm the relationship between the clinical registries and the practices. ASA sees no harm to patients because other regulations are already in place protecting patient rights. If patients increasingly decide to block access to all or to certain PHI elements reported to registries, we fear that practices might opt to forego participation altogether in clinical data registries. ASA strongly discourages any additional burdens placed on practices and physicians to report data to clinical registries. Moreover, such requests would be incredibly burdensome for providers to manage.

> **(17) Should OCR expand the exceptions to the Privacy Rule's minimum necessary standard? For instance, should population-based case management and care coordination activities, claims management, review of health care services for appropriateness of care, utilization reviews, or formulary development be excepted from the minimum necessary requirement? Would these exceptions promote care coordination and/or case management? If so, how?**
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> ***Are there additional exceptions to the minimum necessary standard that OCR should consider?***

[1] The Office of the National Coordinator for Health Information Technology, Permitted Uses and Disclosures: Exchange for Health Care Operations, available at: https://www.hhs.gov/sites/default/files/exchange_health_care_ops.pdf.

ASA believes that OCR should expand the exceptions to the Privacy Rule's minimum necessary standard to include health care operations that enhance care coordination, value-based initiatives and other innovative models focused on delivering patient-centered care. As noted in ASA's comments on RFI Question 13, AQI's NACOR assists practices and clinicians with quality measurement and improvement, which are both necessary foundations of value-based care and innovation. Moreover, AQI's NACOR assists practices by collecting measure data for the purposes of reporting federal quality reporting program data, driving local quality improvement projects that can identify opportunities for alternative payment models that improve patient outcomes.

Including health care operations within the framework defined in the previous paragraph as an exception to the minimum necessary standard would present an opportunity for clinical registries to contribute expertise and research into transforming health care toward a more value-based enterprise without participants having to analyze whether each data submission constitutes the least amount of data necessary to meet the minimum necessary standard. Building upon previous advancements made by the appropriate collection and analysis of data relied heavily on registries and researchers receiving an adequate amount of patient data throughout the continuum of care. OCR should protect against any detrimental impacts upon these important activities and encourage further growth within these areas.

> **(28) How much time do covered entities take to respond to an individual's request for an accounting of disclosures? How many worker-hours are needed to produce the accounting? What is the average number of days between receipt of a request and providing the accounting to the requesting individual? How would these estimated time periods change, if at all, if covered entities were to provide a full accounting of disclosures for TPO purposes? What is the basis for these revised estimates?**

ASA believes that covered entities needing to provide full accounting disclosures for TPO purposes would represent a significant barrier to patient care in both current and evolving practice and payment models. In 2011, OCR published a proposed rule outlining what this process would entail. The "access report" in the proposed rule would require that patients receive a report of all persons who had viewed their electronic health records within the covered entity. While ASA believes that protecting health care information and restricting access to health care information is critically important, ASA members and their health care organizations aim to protect health care information and disclose to the fewest entities and individuals as necessary for optimal patient care. ASA understands how protection of this information is a necessary component to establishing trust between patients and physicians. However, when health care organizations understand and weigh the potential risks and burdens associated with a possible accounting of disclosure for TPO purposes including a full access report, ASA is concerned this could interfere with patient care.

> **(54) In addition to the specific topics identified above, OCR welcomes additional recommendations for how the Department could amend the HIPAA Rules to further reduce burden and promote coordinated care.**

(c) ***OCR also broadly requests information and perspectives from regulated entities and the public about covered entities' and business associates' technical capabilities, individuals' interests, and ways to achieve these goals.***

ASA supports permitting providers to share information about patients subject to 42 CFR Part 2, Confidentiality of Substance Use Disorder Patient Records, for the purposes of health care treatment, payment, and operations (TPO). In addition, ASA believes it is important for the administration to align 42 CFR Part 2 with HIPAA's consent requirements for the purposes of TPO. Such an action would allow for the appropriate sharing of substance use disorder records between health care providers to ensure persons with opioid use disorder and other substance use disorders may receive appropriate care. Aligning these regulatory actions would best prepare physician anesthesiologists, pain medicine physicians and other health care workers for effectively treating patients with substance use disorders.

ASA recognizes the need for OCR and other enforcement bodies to levy appropriate penalties in the event of disclosure, breach notification requirements and discrimination prohibitions to protect people seeking and receiving SUD treatment. ASA recognizes there may be a need to strengthen protections against use of these records outside of TPO, including in civil, criminal and administrative proceedings or investigations. We believe that OCR can balance patient privacy needs with adequate and meaningful treatment options under the prerogatives of the national public health emergency.

Thank you for your consideration of our comments. We would be very glad to follow up with you as necessary on any issues on which you need additional information or would like further discussion. Please contact Matthew Popovich, Ph.D., ASA Director of Quality and Regulatory Affairs or Beth Quill, J.D., ASA Senior Regulatory Affairs Specialist at 202-289-2222. They may also be reached at gra@asahq.org.

Sincerely,

Linda Mason, M.D., FASA
President
American Society of Anesthesiologists