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February 12, 2019

Roger Severino
Director, Office of Civil Rights
Attn: RFI, RIN 0945-AA00
Huber H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

submitted at www.regulations.gov

RE: Request for Information on Modifying HIPAA Rules to Improve Coordinated Care

Dear Mr. Severino:

The Association of American Medical Colleges (the AAMC, or the Association) appreciates the opportunity to respond to the Office of Civil Rights (OCR) Request for Information on Modifying HIPAA Rules to Improve Coordinated Care, 83 *Fed.Reg.* 64302 (December 14, 2018).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 152 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Together, these institutions and individuals are the American academic medicine community.

As an integral part of their commitment to compliance issues, AAMC members have been leaders in ensuring that patient information is protected and that its use is consistent with both federal and state requirements. The AAMC appreciates the OCR is concerned that the HIPAA privacy rules may create obstacles to efficient care coordination and case management and the transformation to value-based care and has issued this RFI to gather information. HIPAA has caused some challenges but, as will be described below, the AAMC believes that the appropriate way to address many of these issues is through additional education and guidance rather than by modifying the current regulations. There are some situations, however, that we believe rulemaking would be beneficial and also highlight those opportunities below.

Promoting Information Sharing for Treatment and Care Coordination

OCR notes that the Privacy Rule establishes an individual's right to access and obtain a copy of his or her protected health information (PHI) and that a covered entity (CE) must provide access within 30 days following receipt of a request, though a 30-day extension is possible. CE also are permitted but not

required to use and disclose PHI for treatment, payment, and healthcare operations (TPO) though there is no time limit on the amount of time in which the CE must respond to TPO requests. OCR also is interested in whether there should be an exception to the minimum necessary standard for disclosures of PHI to non-provider covered entities for care coordination and/or case management as part of TPO.

Questions 2-4

30 days (with an additional 30-day extension) should continue to be the timeframe for responding for an individual's request for access to his or her PHI even if a covered entity currently maintains such information electronically.

AAMC members continue to maintain some records in paper which primarily reside in offsite archives where their retrieval can be a laborious and time-consuming process. It is neither simple nor straightforward to produce electronically maintained records in a form that is readable. For example, imaging data is particularly problematic in this regard and can require significant effort to create a useful version. Therefore, the current 30-day timeframe should be retained.

Members find that a number of these requests are not in keeping with the spirit of the access guidance at <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>. Providing copies of records and ensuring that the copies are accurate are activities that frequently cost more than the allowable charges for release to the patient. In many instances, these requests relate to a potential legal action. HIPAA already contains rules about responding to requests related to legal actions. Allowing the request for records to be directed to a third party inappropriately shifts the costs associated with a legal action to the health care provider. **OCR should clarify in sub-regulatory guidance that a request for access to a patient's PHI can only be directed to the patient or the patient's personal representative.**

Questions 6 and 7

OCR should not revise the current regulations to mandate that disclosures of PHI should be made when the request is from one CE to another CE for treatment purposes.

AAMC members report that they have not experienced issues obtaining records from other covered entities. CEs also need to retain discretion about disclosure in certain unique cases. For example, state laws related to confidentiality of mental health or HIV status may have conflicting requirements that are better served in the current arrangement. There are times when complying with the complexities of both state and federal law is best served by allowing CEs to have the flexibility in determining the optimal way to respond.

Question 13

OCR should not allow individuals to opt-out of the disclosure of certain types of required disclosures.

The disclosures that currently are permitted for TPO allow for accurate, efficient, and holistic treatment and are essential for ensuring patient safety and appropriate business operations activities. Opt-out rights may seriously impact the quality of information provided to another CE for treatment purposes and the nature of medical notes. It is difficult for a CE to be positive that a clinician has not mentioned a medical condition as a confounding factor without going line by line with strike outs in the medical record. Opt-out rights would require major overhauls of all

existing systems, a huge and costly administrative burden. A patient's right to place restrictions on his/her PHI associated with payment already are extremely burdensome for CEs to handle because separate, labor intensive manual processes often must be used in lieu of the standard automated processes and systems. Opt-out rights would add more complications with very little benefit.

Question 17

The AAMC supports an expansion of the minimum necessary standard for reasons enumerated by OCR, such as population-based care management and care coordination, claims management, review of healthcare services for appropriateness of care, utilization reviews and formulary development.

The expansion of the minimum necessary standard would promote greater flow of information between CEs and others and would support efforts to improve community health and otherwise improve the provision of health care.

Question 18

OCR should allow CEs to disclose PHI to social service agencies and community-based support programs where necessary to facilitate treatment and coordination of care with the provision of other services to the individual.

The AAMC supports allowing disclosure of PHI to social services agencies and community-based programs as suggested by OCR. We are hopeful that that this change to the Privacy Rule can be made through subregulatory guidance combined with education and outreach to CEs but if not, rulemaking should be undertaken. The decision about which organizations the covered entity will share this information with should be left to the discretion of the CE based on their patient population and their knowledge of the community resources that are available. It should not be limited to social services agencies that provide health care products or services, as OCR suggests. Additionally, OCR should not impose a requirement that the social service agency or community-based program would have to enter into a business associate, or similar, agreement; such a requirement would drain resources from these organizations which often are small non-profits with extremely limited resources. We believe that professional judgement is a reasonable approach to determining which organizations have legitimate needs for the information and the type of agreement that should be entered into between the CEs and the social service agencies or community-based programs

Promoting Parental and Caregiver Involvement and Addressing the Opioid Crisis and Serious Mental Illness

OCR states that it is considering a separate rulemaking to encourage covered entities to share PHI with family members, caregivers, and others in a position to avert threats of harm to health and safety, when necessary to promote the health and recovery of those struggling with substance use disorder, including opioid use disorder, and/or serious mental illness (SMI). **The AAMC encourages OCR to pursue this rulemaking to consider whether there are additional circumstances, not already addressed in the Privacy Rule, in which CE's should be permitted to share PHI to support individuals suffering from such conditions.**

Questions 22 and 23

Many AAMC members have reported that the lack of alignment between 42 CFR Part 2 and HIPAA is an enormous barrier to effective care coordination and addressing the opioid crisis. It prevents effective care coordination by reducing the benefits associated with electronic medical records, health information exchanges, and other automated exchanges of information. It also creates administrative burdens. Most EMR systems do not have the capacity to fully sequester 42 CFR Part 2 data in the context of a multispecialty facility. The costs associated with instituting this type of data segmentation are huge and create a barrier to effective treatment of patients. The AAMC suggests that the best approach is for HHS to reopen the 42 CFR Part 2 regulations to allow for alignment with HIPAA upon consent of the patient. The optimal case is that this also would provide for harmonization with state law.

The AAMC appreciates OCR's interest in addressing the perceived and actual barriers that the Privacy Rule presents with respect to sharing PHI with family members, caregivers or others who may be able to support individuals with substance abuse disorders or SMI's. The AAMC agrees that this is a significant and important issue warranting thoughtful consideration. It also recognizes that many factors and perspectives must be considered to craft a rule that appropriately balances the privacy interests of affected individuals, the safety of family members or caregivers and the health policy interests in supporting their care and recovery. The OCR's proposed rulemaking would provide an opportunity to receive input from a wide range of interested parties, including affected communities and individuals, to achieve a well-considered and balanced approach

While the existing regulations do provide some flexibility for sharing PHI in crisis situations and OCR has provided helpful guidance specifically addressing how those rules can apply where individuals have a substance abuse disorder or SMI, greater flexibility could help to reduce the uncertainty and hesitation about sharing PHI when it could benefit those individuals. There are, indeed, times when the current rules put health care providers who treat those individuals in the untenable position of choosing between the risk of violating HIPAA or acting in accordance with the professional and ethical imperative to help their patients, including by reaching out to others who could assist in their care and recovery. More flexible rules could alleviate this dilemma.

The existing provisions of the Privacy Rule cited in the RFI and OCR guidance as relevant to addressing situations involving individuals with a substance abuse disorder (SAD) or SMI have constraints that limit their applicability in those situations. For example, 45 CFR §164.510(b)(3) requires that an individual be unable to provide permission for sharing PHI, such as being incapacitated or unconscious. At that point, the individual has already suffered harm, perhaps to a life-threatening degree, such as an opioid overdose or attempted suicide. Permitting sharing of PHI "after the fact" does not help to prevent the harm in the first place. Permitting more proactive sharing of PHI to involve others to support individuals before harm occurs may serve them even better.

In addition, when individuals with a substance abuse disorder or SMI do not have a personal representative to make decisions for them because they have not been determined to be incompetent, their decision-making may be impaired because of their condition. In some cases,

it may be difficult to obtain the individual's permission to share PHI with others who can assist them. They may not be able to recognize the severity or potential danger of their situation or the need for assistance; or may be reluctant to include others in their care out of shame or embarrassment; or may not be responsive to communications from their health care providers. When such individuals are in crisis, restrictions on the sharing of PHI can be barriers to supporting them, as opposed to protecting them.

The other existing Privacy Rule provision OCR cites as relevant to this issue, 45 CFR §164.512(j), which permits sharing PHI to prevent or lessen threats to the health or safety of an individual or of the public, also has limitations that inhibit the sharing of PHI even if it may be in the best interest of an individual suffering from a substance abuse disorder or SMI. It requires a specific threat that is both serious and imminent. Patients who have substance abuse disorder or SMI may only present in crisis when the benefit to share knowledge is too late to meet this strict criterion.

While this provision of the Privacy Rule provides a necessary and important exception to the general requirement that an individual's authorization must be obtained for sharing PHI, it applies in only very limited circumstances. For example, it would not apply to situations where individuals have not yet manifested a serious and imminent threat to their health or safety (or that of others), such as with an overdose, or a car accident due to substance abuse impairment, or attempted suicide, or other physical harm to themselves or others. And even if an individual actually has suffered an overdose or attempted suicide, and notwithstanding the OCR's guidance on this issue, it remains unclear to what extent the "serious and imminent threat" standard could be met once the immediate crisis has passed.

The AAMC recognizes that permitting more flexible sharing of PHI could affect an individual's right to control who receives this information. As the OCR has identified, such a change to the Privacy Rule could have the undesirable consequence of discouraging individuals from seeking necessary health care services, which would defeat the purpose of the change. To address such concerns, any changes to the Privacy Rule to permit greater sharing of PHI to assist those suffering from substance abuse disorder or SMI should be carefully crafted and narrowly tailored and after extensive consultation with stakeholders.

The AAMC encourages OCR to consider revisions that would provide greater flexibility for health care providers who are caring for an individual with a substance abuse disorder or an SMI to share PHI with a family member, caregiver or other person in a position to support the individual's care and recovery if, in the health care provider's professional judgment, it is in the individual's best interest. Sharing of PHI could be allowed when an individual's permission cannot be obtained for reasons such as incapacity, incompetence, or serious and imminent threats of harm to the individual or others. Indications that would support this sharing could include the individual failing to attend care appointments; not responding to attempts to communicate; or struggling to comply with treatment plans or medication management. This greater flexibility could permit health care providers to reach out to those close to the individual to assist with these matters.

Question 25(a)

The AAMC believes that the Privacy Rule should continue to defer to state law with respect to whether a parent or guardian is the personal representative of an unemancipated minor and is therefore able to obtain the minor's PHI. Instances of substance abuse disorders or mental health issues should not change the limitations on parental access to records related to care provided without parental consent as this could hinder care or cause harm to the minor patient. For example, in cases of abuse by a parent, it is critical that the records remain confidential with respect to disclosure to the parent. Deferral to state law would create a baseline that prevents disclosure unless a clinician using professional judgement deems the release to be in the patient's best interest.

Accounting for Disclosures

According to the RFI, OCR believes that the proposed access report requirement would create undue burden for covered entities without providing meaningful information to individuals and intends to withdraw the notice of proposed rulemaking (NPRM). **The AAMC strongly supports the withdrawal of the Accounting for Disclosure NPRM. As we wrote in our 2011 comment letter, our members receive very few requests for such an accounting.** Responding to those requests places a huge burden on health care organizations as it is difficult to obtain all the information and put it into a form that is meaningful to the individual making the request. In most cases, when a request is made it is because of a fear that someone has "snooped" into the record, something that can be handled through an investigation. Most AAMC members routinely monitor medical records for inappropriate access and have in place policies and procedures for dealing with inappropriate access. Furthermore, any access in violation of the Privacy Rule is subject to the breach notification provisions thereby ensuring that patients are informed of the accesses most of interest to them, without the need for a request of an accounting. There also are substantial concerns about the ensuring the safety and privacy of staff when their names are released to a patient.

Notice of Privacy Practices

The Privacy Rule has a number of requirements related to the Notice of Privacy Practices (NPP). For example, when the provider has a direct treatment relationship with an individual there must be a good faith effort to obtain a written acknowledgement of the receipt of the NPP. OCR asks for comment on whether the signature and other requirements should be eliminated to reduce burden and free up resources for other uses.

General Comment

It would reduce some burden on providers if the acknowledgement form were eliminated. One option would be to leave it to each CE's discretion as to whether or not a signature is obtained. What is important is that the NPP is available to patients, such as on the CE's website or in the patient portal.

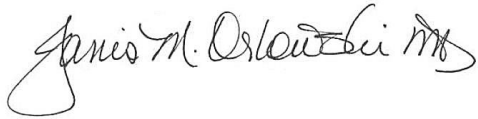
Additional Ways to Remove Regulatory Obstacles and Reduce Regulatory Burdens to Facilitate Care Coordination and Promote Value-Based Health Care Transformation

Guidance from OCR on information sharing in Health Information Exchanges would be a valuable step toward promoting value-based health care.

Roger Severino
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The AAMC appreciates the opportunity to provide comments on modifying HIPAA rules to improve coordinated care. If you have any questions, please contact Ivy Baer, ibaer@aamc.org or 202-828-0499.

Sincerely,

A handwritten signature in black ink that reads "Janis M. Orlowski M.D.". The signature is written in a cursive style with a large initial "J" and "M".

Janis M. Orlowski, M.D., M.A.C.P.
Chief Health Care Officer

cc: Ivy Baer, AAMC