

February 12, 2019

Roger Severino Director Office for Civil Rights U.S. Department of Health and Human Services 200 Independence Avenue, SW Washington, DC 20201

Submitted Electronically

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

Dear Director Severino:

On behalf of the 163,000 members of the American Dental Association (ADA), we are writing in response to the Office for Civil Rights (OCR) Request for Information (RFI) on Modifying HIPAA Rules to Improve Coordinated Care. As an organization dedicated to advancing the oral health of the public, we offer the following thoughts on how changes to the HIPAA Rules could affect dentistry.

Flexibility. The ADA urges OCR to keep in mind when proposing changes to the HIPAA Rules that many covered entities are small and solo dental practices, and that dental practices use a variety of electronic dental records with varying capabilities and functionalities, not all of which may integrate with hospital electronic health record systems.

Opioid Crisis. The ADA urges the promulgation of simplified, standardized and coordinated regulations so covered entities may develop and implement unified requirements for all protected health information (PHI) regardless of source or content. In addition, the ADA urges OCR to help facilitate appropriate communications, such as communications with parents of children affected by the opioid crisis, by providing clear guidance on disclosures to family members, friends and others involved in the individual's care. Finally, the ADA urges OCR to protect from HIPAA enforcement providers who in good faith disclose PHI intended to help patients receive help and support (for example, for a suspected substance use disorder), whether or not the patient is incapacitated.

Accounting of Disclosures. With respect to the HITECH Act direction to modify the Privacy Rule to require that an accounting of disclosures include disclosures made for purposes of treatment, payment and health care operations through an electronic health record during the three years before the request, the ADA urges OCR to limit the requirement to disclosures that were made through an electronic health record that has the present capacity to both record such disclosures for the purpose of responding to a

request for an accounting of disclosures and to generate a compliant accounting of disclosures. The ADA urges OCR to exempt from any such requirement covered providers that do not have an electronic health record, or that have electronic health records that do not have such present capacity.

Notice of Privacy Practices. The ADA urges OCR to eliminate the requirement that covered providers with a direct treatment relationship with an individual to make a good faith effort to obtain a written acknowledgement of receipt of the provider's Notice of Privacy Practices. The ADA believes that this requirement:

- Is potentially confusing to patients, who may misunderstand the form as a waiver or consent.
- Burdens patients and providers with excessive paperwork at a time when patients
 may be requested to complete more important forms such as health history and to
 make choices such as how they wish to receive communications and whom to
 designate as their emergency contact.
- Takes up staff time without a corresponding benefit to patients or to providers, neither of which likely find the signed acknowledgment form useful.

The requirement to request signature on the Notice of Privacy Practice acknowledgment form should be eliminated to help reduce a regulatory burden on providers and to free up time and resources for providers to spend on treatment and care coordination.

The ADA also urges OCR to eliminate the requirement to provide a copy of the Notice of Privacy Practices to individuals who do not request a copy. Instead, the ADA urges OCR to require providers to simply post the Notice of Privacy Practices in a conspicuous location.

Requests for Access.

Timeframe for responding to access request. OCR notes that the Privacy Rule requires covered entities to respond to a patient's request for access to PHI in no more than 30 days, with a possible one-time extension of an additional 30 days, and asks what burdens a shortened timeframe for response to patients' access requests would place on covered entities. The ADA believes that a shorter response time would burden covered entities and urges OCR not to shorten the time frame for responding to an access request. A small or solo health care provider would be particularly burdened by a shorter time frame, which could divert staff time and attention from clinical tasks and patient care without a corresponding benefit to patients or providers. For example, a small dental practice might cross-train staff to perform both clinical and administrative functions, might close so that the dental team can provide charity dental care, or might close for holidays or vacations, increasing the likelihood that staff would be required to prioritize paperwork over patient care to meet access request deadlines.

Clearinghouses. OCR also asks whether health care clearinghouses should be subject to the individual access requirement, which would require clearinghouses to provide individuals with access to their PHI in a designated record set upon request. The ADA believes that this change could increase risk with no corresponding benefit, and urges OCR not to change the HIPAA Rules to subject clearinghouses to the individual access requirements, as this change is unnecessary and could harm patients and burden providers.

The ADA notes that a covered provider and clearinghouse can currently provide in their business associate agreement that an individual may access PHI held by the clearinghouse. Thus no change to the HIPAA Rules is necessary to permit this access where both the provider and the clearinghouse deem such access acceptable and appropriate. It is not clear that clearinghouses could provide better or faster access to PHI than providers, nor that any benefit to subjecting clearinghouses to individual access requirements would outweigh resulting harm to patients and burden to providers.

Clearinghouses generally do not have full, up-to-date patient records, but instead have only the minimum necessary PHI provided for the purpose of the submitting claims, such as the claims themselves and certain situation-specific attachments, and PHI regarding inquiries such as eligibility. Clearinghouses lack a direct relationship with the patient, which could result in increased access errors as well as role confusion. Clearinghouses may face more challenges than providers with patient identification, identity verification, matching errors, confirming personal representative relationships, and so forth, thus increasing the risk of both data breaches and of inappropriate denial of access. In general, making access increasingly porous could increase the risk of inappropriate access; for example, a provider that has a treatment relationship with a patient could be in a better position than a clearinghouse to detect a request for access from a data thief. Indeed, subjecting clearinghouses to individual access requirements could increase the surface area for identity theft attacks and could put patients at increased risk of medical and financial identity theft.

Lack of a direct relationship may also confuse patients, who may not understand or even be aware of the role that clearinghouses play in processing health care claims. Moreover, clearinghouses likely would not be prepared to answer patients' follow up questions about their PHI nor to prepare a summary of the PHI if requested by the individual. Without a direct relationship, patients would have little leverage with a clearinghouse that did not respond to a request for access in a timely and compliant manner. Patients may thus turn to the provider for help, and even if the clearinghouses provided what information they could, patients may still turn to providers for additional information, explanations and summaries. Responding to such requests could be more burdensome for providers than simply providing access under the current HIPAA Rules. Even if the clearinghouse is required to notify the provider every time access is provided to one of the provider's patients, the provider who receives a follow-up request from the patient may still need to communicate with the clearinghouse to determine details such as the parameters of the

request, the content of the PHI that was and was not provided, etc., in order to address the patient's questions and concerns. In connection with such requests for help, providers may receive from patients claims data concerning other providers, which could also be a burden for the provider who may be burdened with managing and protecting such data, which may not be helpful or relevant to the receiving provider. Small covered providers in particular could be burdened by this process, which could take time away from patient care.

Subjecting clearinghouses to individual access requirements would require clearinghouses to develop infrastructure to respond to patient requests for access, even if the likelihood and volume of such requests is low. The financial burden of such infrastructure could be passed along to patients through their plans and providers, thus increasing health care costs with little or no corresponding benefit.

The ADA is concerned that the issue of clearinghouse access may risk taking attention and efforts away from addressing problems with interoperability and electronic health record performance. Improvements in those areas is more likely to benefit patients and providers.

Thank you for the opportunity to comment on the request for information. The ADA looks forward to continuing to work with OCR. Should you have any questions, please do not hesitate to contact Mr. Patrick Cannady at (312) 440-2760 or cannadyp@ada.org or Ms. Jean Narcisi at (312) 440-2750 or narcisij@ada.org.

Sincerely,

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