American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

May 6, 2021

Robinsue Frohboese
Acting Director and Principal Deputy
Office for Civil Rights
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RIN 0945-AA00

RE: Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement

Dear Dr. Frohboese:

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to respond to a proposed rule released by the Office of Civil Rights (OCR) within the U.S. Department of Health and Human Services (HHS) that attempts to modify the Health Insurance Portability and Accountability Act (HIPAA) privacy and security regulations to promote the transition to value-based health care and encourage coordinated care, while at the same time ensuring that the privacy and security of patients' information remains protected.

ACEP believes that all physicians have an ethical and legal duty to guard and respect the confidential nature of the personal information conveyed during the patient-physician encounter. Emergency physicians implicitly committed to preserve confidentiality of patient information, and in turn promote patient autonomy and trust in their emergency physician. We also feel that while confidentiality of patient information is important it is not absolute. Confidential patient information should be disclosed when patients or their legal surrogates agree to disclosure, when mandated or permitted by law, or when there exist overriding and compelling grounds for disclosure, such as the prevention of substantial harm to other people.

It also critical that we have every opportunity to provide timely and high-quality care to our patients, which requires ready access to their medical records. In many cases, we care for patients with acute conditions who we have never seen before. We deal with life and death situations with limited information, and yet must make near-instantaneous critical decisions about how to treat them. We have found that HIPAA is frequently, and inappropriately, cited as a reason to not disclose information to us or to require burdensome paperwork to get vital information about our patients. This is extremely frustrating and has a detrimental impact on patient care.

HIPAA is tremendously complex for practicing physicians, and in many cases, covered entities are afraid to release any information out of fear of breaching data, violating

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HIPAA, and receiving a (sizable) penalty. ACEP urges OCR to provide better educational materials that will help health care providers and other covered entities understand what is, and is not, permissible under federal law. We recognize that HIPAA represents a floor in terms of legal requirements and that states are allowed to impose stricter laws and regulations governing privacy and security. Helping stakeholders appreciate this critical distinction between state and federal law is also essential.

Further, we ask that OCR consider how any changes to HIPAA would intersect with the information blocking regulations promulgated by the Office of the National Coordinator for Health Information Technology (ONC). These changes just went into effect in early April 2021 and it will be critical for OCR to clearly communicate to both clinicians and patients what data sharing and exchange of information is permissible and/or required under both HIPAA and these new data sharing requirements. OCR also may want to consider delaying the effective date of these changes to patient privacy requirements as clinicians begin complying with the ONC regulations.

With these core principles and objectives in mind, we would like to provide responses to a number of the proposals included in the rule.

Definitions

In the proposed rule, OCR proposes certain new definitions for electronic health record and personal health application. While ACEP has no specific recommended changes, we urge OCR to ensure that definitions and regulatory changes are aligned with those used in the information blocking regulations—thereby avoiding potential confusion that would contribute to administrative burden or unintentional violations.

Strengthening the Access Right to Inspect and Obtain Copies of PHI

OCR proposes to add a new right that generally would enable an individual to take notes, videos, and photographs, and use other personal resources to view and capture personal health information (PHI) in a designated record set as part of the right to inspect PHI in person. The Department requests comment on this proposal, including examples of its possible unintended consequences.

ACEP is very concerned with the proposed relaxed restrictions on personal photos and/or videos taken by patients of their PHI. While OCR states that covered entities can work with patients to arrange a mutually convenient time and place for them to inspect their PHI, in emergency situations and in the ED setting overall, this could be quite challenging or even impossible. If the proposal were finalized, patients receiving care in the ED would probably want access to their information in real time during an encounter since they do not have an established relationship with the physician or other health care practitioner (and therefore would feel that it would be difficult to obtain a video or photo of their PHI after they were discharged from the ED). We would like to avoid situations where physicians or other health care practitioners are being video-recorded or photographed without their prior knowledge and express consent. Further, in the ED there could be instances where an individual tries to gain access to another individual's PHI or attempts to record the care of that individual. Lastly, it is important to note that, as part of the 21st Century Cures Act, ED patients now have access timely to test results and clinical documentation via their electronic health record (EHR) patient portal; this data can be more easily reviewed and further shared by patients compared to photos or videos of PHI.

Therefore, ACEP requests that OCR NOT finalize this proposal. However, if the Department does decide to finalize it, it should create an exception for care delivered in the ED. We already have an issue with patients recording interactions in the EDs without approval, and this proposal, if finalized, would exacerbate the problem.

Modifying the Implementation Requirements for Requests for Access and Timely Action in Response to Requests for Access

OCR proposes to modify the Privacy Rule to expressly prohibit a covered entity from imposing unreasonable measures on an individual exercising the right of access that create a barrier to, or unreasonably delay, the individual from obtaining access. OCR is also shortening the timeframe to respond to requests to be as "as soon as practicable," but in no case later than 15 calendar days after receipt of the request, with the possibility of one 15 calendar-day extension.

ACEP understands OCR's rationale for proposing to shorten the timeframe for responding to PHI access requests and does not believe that the new requirement is unreasonable. However, we do request that the Department build some exceptions into this policy to account for national disasters or other emergency situations that may cause unavoidable delays in responding to PHI requests. **Further, we oppose any effort to establish a time limit shorter than 15 calendar days for a covered entity to submit, or respond to, an individual's access request.**

Addressing the Form of Access

OCR seeks comments on whether to require a healthcare practitioner who has EHR technology and can incorporate a secure, standards-based API without extra cost, to implement the API; and whether to require a health care practitioner that could implement such an API at little cost to do so. ACEP is generally concerned about adding any new requirements to physicians and other healthcare practitioners that could eventually lead to higher costs. We believe that it should be the responsibility of the EHR vendor to handle these sort of requirements—which could be done by making API implementation a condition for EHR certification. Further, we would request that OCR consider the downstream implications of such a policy. Even if APIs could be implemented at little or no cost initially, development, updates and maintenance costs by the vendors would over time be passed down to their subscribers. These costs could pose a significant financial burden on healthcare practitioners, especially those in small practices and those who work in rural areas.

OCR proposes to require that, when a covered entity offers a summary in lieu of access, it must inform the individual that the individual retains the right to obtain a copy of the requested PHI (or direct an electronic copy of PHI in an EHR to a third party) if they do not agree to receive the summary. ACEP believes that there should be more exceptions built into this requirement, as in the case of suspected trafficking, abuse, neglect, or when the physician thinks that release of records may result in danger or harm to an individual. At the very least, these situations should trigger the ability to do a review of the request, rather than the automatic release of the PHI.

Addressing the Individual Access Right to Direct Copies of PHI to Third Parties

OCR is proposing to require a covered health care provider to respond to an individual's request to direct an electronic copy of PHI in an EHR to a third party designated by the individual when the request is "clear, conspicuous, and specific" -- which may be orally or in writing (including electronically executed requests).

ACEP has several concerns about this proposal. First, we believe that healthcare practitioners should be protected in cases where an individual makes a clear, conspicuous, and specific request orally, but then later recants the request (or denies making it in the first place). There needs to be, at a minimum, some standard for how these requests are documented. Second, we believe this proposal, if finalized, may increase the potential for healthcare fraud. Since it would be easier to obtain a patient's consent to send PHI directly to a third party, entities could develop scams where they convince patients that they are legitimate entities, and they tell patients to make a "clear, conspicuous, and specific" request to their physicians to send their PHI directly to them. **Thus, overall, although we support the concept of a "clear, conspicuous, and specific" standard, we disagree with OCR's interpretation that this phrase can include oral communications.**

Adjusting Permitted Fees for Access to PHI and ePHI

ACEP does not have any significant concerns with OCR's proposal to allow there to be a fee when an individual requests electronic or non-electronic copies of PHI through a means other than an internet-based method.

OCR is also proposing to expressly prohibit a covered entity from imposing unreasonable identity verification measures on an individual requesting PHI. While ACEP does agree that there should not be unreasonable barriers to obtaining one's own PHI, physicians and other covered entities still should have the right to ask for additional verification. There also needs to be some guidance of what to do when there is concern about someone falsely attempting to gain a record. Further, we believe that OCR should include a safe harbor for physicians and other covered entities who, as long as they follow all the rules and regulations, mistakenly provide information to the wrong person. If OCR is going to change requirements for identity verification measures, it should build in some liability protection for physicians and other covered entities.

Amending the Definition of Health Care Operations to Clarify the Scope of Care Coordination and Case Management

OCR proposes to modify the definition of health care operations to provide clarity to covered health care providers and health plans that "health care operations" includes not only population-based care coordination and case management, but also individual-focused care coordination and case management activities – and thereby facilitate those beneficial activities. OCR seeks comments on this proposal, including information on how, if at all, this clarification would affect covered entities' decision-making regarding uses and disclosures of PHI for health operations, and on any potential unintended adverse consequences. ACEP supports this proposal, as we believe that it would make it easier to text or email patients about follow-up, without specific consent. It would also lead to increased participation in remote patient monitoring and other efforts aimed at improving care coordination.

Creating an Exception to the Minimum Necessary Standard for Disclosures for Individual-level Care Coordination and Case Management

ACEP supports the intent of OCR's proposal to add an express exception to the minimum necessary standard for disclosures to or requests by a health plan or covered health care provider for individual-level care coordination and case management activities that constitute treatment or health care operations. However, we are concerned that providing additional information to health plans could lead to selective, discriminatory reimbursement models and intrusion on physician medical decision-making power. Thus, if OCR were to finalize this proposal, it must institute appropriate security or privacy guardrails to protect patients or physicians from PHI data abuse. For example, if health

plans request PHI for a patient, they must use the information exclusively for care coordination or case management purposes. If OCR does not add these security measures, restrict how health plans can use PHI, and establish a monitoring mechanism to enforce the requirement, it should not make this change to the minimum necessary standard.

Clarifying the Scope of Covered Entities' Abilities to Disclose PHI to Certain Third Parties for Individual-Level Care Coordination and Case Management that Constitutes Treatment or Health Care Operations

ACEP supports OCR's proposal to expressly permit covered entities to disclose PHI to social services agencies, community-based organizations, home and community based service (HCBS) providers, or similar third parties that provide or coordinate health-related services that are needed for care coordination and case management with respect to an individual.

Encouraging Disclosures of PHI when Needed to Help Individuals Experiencing Substance Use Disorder (Including Opioid Use Disorder), Serious Mental Illness, and in Emergency Circumstances

Good Faith Standard

Some covered entities are reluctant to disclose PHI to family members and other caretakers of individuals facing health crises, including individuals experiencing serious mental illness (SMI) and substance use disorder (SUD) (including opioid use disorder), for fear of violating the Privacy Rule. To help address this reluctance, OCR proposes several modifications to the Privacy Rule to encourage covered entities to use and disclose PHI more broadly in scenarios that involve SUD, SMI, and emergency situations, provided that certain conditions are met. Specifically, OCR proposes to amend the five following provisions of the Privacy Rule to replace "the exercise of professional judgment" with a "good faith belief" as the standard to permit uses and disclosures in the best interests of the individual: (1) Parent or guardian not the individual's personal representative, (2) Facility directories, (3) Emergency contacts, (4) Emergencies and incapacity, and (5) Verifying requestor's identity. OCR also proposes a presumption that a covered entity has complied with the good faith requirement, absent evidence that the covered entity acted in bad faith. OCR assumes that health care providers would incorporate relevant concerns about an individual's risk of abuse as a key factor in whether a disclosure of PHI is in an individual's best interest.

ACEP understands the intent behind this change, as it recognizes the difficult decisions emergency physicians face on a day-to-day basis dealing with patients and their families. The good faith belief is a solid legal standard that provides the necessary protection for front-line clinicians. However, we urge OCR to institute guardrails to the policy to ensure that the new standard would still appropriately protect patients and not potentially undermine the fabric of trust between patients and physicians.

Serious and Reasonably Foreseeable Threat

OCR also proposes to replace "serious and imminent threat" with "serious and reasonably foreseeable threat" standard under which uses and disclosures needed to prevent or lessen a threat are permitted. With the proposed modification, a covered entity that reports a threat to health or safety could potentially benefit from two presumptions under the Privacy Rule: (1) a presumption that the serious harm the covered entity identified was reasonably foreseeable, and (2) a presumption that the covered entity believed the use or disclosure was necessary to prevent harm or lessen the threat.

ACEP supports this proposal in the specific context of emergency medicine. Often emergency physicians do not have complete information about a patient but can perceive that the patient could be in danger or a threat to himself/herself or others. This policy provides more flexibility to us as emergency physicians to do what we believe is in the best interests of our patients, their family, and the broader community. However, again, we request that OCR create guardrails to this policy to ensure that patients' privacy is still always protected.

Eliminating Notice of Privacy Practices Requirements Related to Obtaining Written Acknowledgment of Receipt, Establishing an Individual Right to Discuss the NPP with a Designated Person, Modifying the NPP Content Requirements, and Adding an Optional Element

The Privacy Rule currently requires a covered health care provider who has a direct treatment relationship with an individual to make a good faith effort to obtain a written acknowledgment of receipt of the provider's Notice of Privacy Practices (NPP). Based on a large amount of negative feedback from stakeholders about the NPP, OCR proposes to eliminate the requirement. OCR proposes to replace this requirement with an individual right to discuss the NPP with a person designated by the covered entity. In addition, OCR proposes to modify the content requirements of the NPP to help increase patients' understanding of an entity's privacy practices and their rights with respect to their PHI.

ACEP supports these proposals. We agree with those stakeholders who believe that patients are often confused when presented with the NPP, as they mistakenly believe that their signature or written acknowledgment of the NPP is required to receive treatment. Many other patients simply sign the NPP without actually reading it. Therefore, we do not believe the requirement to sign the NPP is useful and thank OCR for proposing to eliminate it. We think that it is important to make it clear to patients and their families that they always have the right to ask any questions about the privacy and security of their information to physicians or other covered entities.

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,

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ACEP President