American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

February 12, 2019

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

RE: Request for Information on Modifying HIPAA Rules to Improve Coordinated Care (RIN 0945-AA00)

Dear Director Severino:

On behalf of nearly 38,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to respond to a Request for Information (RFI) released by the Office of Civil Rights (OCR) within the Department of Health and Human Services (HHS) that seeks comment on ways that the Health Insurance Portability and Accountability Act (HIPAA) privacy and security regulations can be revised to promote the transformation 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 promise to preserve confidentiality of patient information, a promise that in turn promotes patients' autonomy and trust in their emergency physicians. We also feel that confidentiality of patient information is an important but not absolute principle. Confidential patient information may 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.

While privacy and security of information is of paramount importance, it also critical that we have the best possible opportunity to provide timely and high-quality care to our patients. It is often challenging for us to provide comprehensive care to patients who arrive in our emergency departments (EDs) without having access to their medical records. In many cases, we see patients with acute conditions who we have never seen before. We deal with life and death situations and, with limited information, we must make near-instantaneous critical decisions about how to treat our patients. We have found that HIPAA is frequently, and inappropriately, cited as a reason to not disclose information or to require burdensome paperwork to get information about our patients. This practice is extremely frustrating and has a detrimental impact on patient care.

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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 HIPAA, and receiving a 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.

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

Questions and Answers

Question 2: How feasible is it for covered entities to provide PHI when requested by the individual pursuant to the right of access more rapidly than currently required under the rules? (The Privacy Rule requires covered entities to respond to a request in no more than 30 days, with a possible one-time extension of an additional 30 days.). What is the most appropriate general timeframe for responses? Should any specific purposes or types of access requests by patients be required to have shorter response times?

ACEP firmly believes that patients have the right to receive their own Protected Health Information (PHI) in a timely manner. The current timeframe for covered entities to provide PHI to individuals appropriately accounts for the time it takes for them to respond to each individual request. Setting a timeframe of less than 30 days could increase administrative burden and be difficult for providers (especially those is practice in small groups with limited administrative staff) to meet on a consistent basis.

Question 6: Do health care providers currently face barriers or delays when attempting to obtain PHI from covered entities for treatment purposes? For example, do covered entities ever affirmatively refuse or otherwise fail to share PHI for treatment purposes, require the requesting provider to fill out paperwork not required by the HIPAA Rules to complete the disclosure (e.g., a form representing that the requester is a covered health care provider and is treating the individual about whom the request is made, etc.), or unreasonably delay sharing PHI for treatment purposes? Please provide examples of any common scenarios that may illustrate the problem.

As stated earlier, having access to information is critical in the ED. When it comes to treating patients with acute medical needs, minutes and even seconds matter. Unfortunately, the scenario highlighted in this question, which results in a delay in receiving vital information, is a common occurrence. Emergency physicians often see patients who have received care from another ED, hospital, or provider, sometimes the same day. When a patient comes to the ED, emergency physicians can find out where and when the patient was previously seen, but rarely can see any of the information from that encounter. However, when emergency physicians reach out to the other ED, hospital, or provider to ask what happened to avoid duplication of workup and make sure nothing is being missed, they are referred to a medical records office instead of the treating provider and are told that they need to have the patient sign a consent form for release of information and that they cannot be given information over the phone. This kind of behavior clearly does not benefit patients.

Going forward, OCR should consider providing additional guidance and/or incentives to help reduce administrative barriers that prevent covered entities from providing timely PHI to health care providers. When health care providers have the opportunity to talk directly to each other, they almost always share all the relevant information that is necessary to treat individual patients. Breaking down the barriers that inhibit or delay these

types of conversations from taking place could definitely improve clinical workflow and our ability to provide effective patient care, while still preserving patient privacy and data security.

Question 7: Should covered entities be required to disclose PHI when requested by another covered entity for treatment purposes? Should the requirement extend to disclosures made for payment and/or health care operations purposes generally, or, alternatively, only for specific payment or health care operations purposes?

While ACEP cannot comment on all the circumstances where covered entities could be required to disclose PHI to another covered entity, with respect to emergency care, ACEP believes that, in general, the sharing of information in the emergency setting for care coordination or other treatment purposes can truly benefit the patient. Having more information about our patients helps us understand not only the underlying factors that might be contributing to an acute medical condition, but also what may be the best treatment option for that patient.

If OCR were to mandate the disclosure of PHI in the emergency setting, the office should consider specific circumstances where the sharing of data may not be appropriate or possible. Some possible considerations that OCR should factor into such a policy include:

- Patient preference: There are times that a patient may have good reason not to want certain sensitive information shared between providers, even during an emergency. Emergency physicians may, as appropriate, talk to these patients about the benefits of sharing PHI for treatment purposes.

- Security concerns: As stated above, emergency physicians have an ethical and legal responsibility to protect their patients' PHI. If an emergency physician feels that either his or her electronic system or that of the other provider who is exchanging PHI is not secure, he or she may not feel comfortable either transmitting or receiving PHI on a patient.

- State law: As stated earlier, State law may be more restrictive than HIPAA. Therefore, any OCR policy would have to consider state laws that prohibit or further limit the sharing of PHI between providers.

- Natural or man-made disaster: Physicians may not have access to PHI during and following natural or man-made disasters and would thus be unable to send this information, even for treatment purposes. Thus, any policy OCR enforces must account for these types of emergencies.

Another important issue to consider if OCR were to establish a PHI disclosure requirement for emergency care would be the timeframe within which a covered entity would need to provide PHI to the treating emergency provider. Emergency physicians provide care twenty-four hours a day, seven days a week, and 365 days a year in EDs across the country. We understand that it would be unreasonable to expect to receive information on a patient at 1 AM on a Sunday from a non-ED provider. However, at the same time, we must consider the consequences of not giving that treating emergency physician the information he or she needs as soon as possible to provide the best possible care to the patient.

Question 9: Currently, HIPAA covered entities are permitted, but not required, to disclose PHI to a health care provider who is not covered by HIPAA (i.e., a health care provider that does not engage in electronic billing or other covered electronic transactions) for treatment and payment purposes of either the covered entity or the non-covered health care provider.

ACEP believes that there are certain situations where HIPAA covered entities can provide PHI to a health care provider who is not covered by HIPAA. As long as the health care providers transmitting and receiving the PHI have sufficient safeguards in place to protect the PHI and the exchange of information is permitted by federal and state law, sharing data among health care providers for the purposes of improving care coordination should be encouraged.

Question 14: How would a general requirement for covered health care providers (or all covered entities) to share PHI when requested by another covered health care provider (or other covered entity) interact with other laws, such as 42 CFR part 2 or state laws that restrict the sharing of information?

As stated above, emergency physicians have reported situations where they are told that they cannot receive certain PHI from other covered entities in a timely manner due to HIPAA restrictions. Individuals sometimes use HIPAA as an excuse to not share PHI or to impose burdensome requirements (such as long forms) that delay the exchange of information. However, ACEP understands that in many cases, it is not necessarily only the HIPAA Rules that cause provider confusion about what is or is not legally permissible, but also more stringent state laws and 42 CFR Part 2. With respect to 42 CFR Part 2, we note that there is an exception built in for emergency services, which adds another policy that emergency physicians have to consider as they try to piece together and understand all the different data privacy and security laws and regulations. Under the current 42 CFR Part 2 regulations, information can be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency in which the patient's prior informed consent cannot be obtained. Given this exception and the underlying HIPAA Rules that impact how emergency physicians can share PHI, OCR should develop resources to help ensure clarity regarding the limitations and allowances of sharing PHI during emergencies.

Overall, if OCR does decide to impose a general requirement for covered health care providers (or all covered entities) to share PHI, OCR must consider how any changes would align or otherwise interact with state requirements or 42 CFR Part 2. In other words, OCR must develop a comprehensive approach to modifying the HIPAA Rules that takes all these other laws and regulations into account.

Question 16: What considerations should OCR take into account to ensure that a potential Privacy Rule requirement to disclose PHI is consistent with rulemaking by the Office of the National Coordinator for Health Information Technology (ONC) to prohibit "information blocking," as defined by the 21st Century Cures Act?

The lack of interoperability has significantly impacted the ability to share information and ensure that patient's PHI remains secure. ACEP therefore appreciates efforts taken to prevent actions that block the exchange of information and was pleased to see the issue addressed in the 21st Century Cures Act signed into law at the end of 2016. We look forward to reviewing the proposed rule that the Office of the National Coordinator for Health Information Technology (ONC) just released yesterday that implements these important provisions in the Cures Act. We hope that this rule, once finalized, will open up new opportunities for physicians to engage in comprehensive patient information sharing across sites of care while at the same time ensuring that patients' PHI is properly protected. We also recommend that OCR review and consider carefully the ONC's final rule prior to making changes to the HIPAA regulations to ensure the two sets of regulations will not conflict and cause confusion for physicians.

Question 18: Should OCR modify the Privacy Rule to clarify the scope of covered entities' ability to disclose PHI to social services agencies and community-based support programs where necessary to facilitate treatment and coordination of care with the provision of other services to the individual? For example, if a disabled individual needs housing near a specific health care provider to facilitate their

health care needs, to what extent should the Privacy Rule permit a covered entity to disclose PHI to an agency that arranges for such housing? What limitations should apply to such disclosures? For example, should this permission apply only where the social service agency itself provides health care products or services? In order to make such disclosures to social service agencies (or other organizations providing such social services), should covered entities be required to enter into agreements with such entities that contain provisions similar to the provisions in business associate agreements?

ACEP believes that these rules should be modified. We recognize that social factors have a significant impact on our patients' overall health. Chronic medical illness may predispose a patient to have depression or decompensated mental illness. Homelessness impacts the ability of a patient with diabetes to have access to the insulin they may need. Patients with liver disease and encephalopathy may forget their follow up appointments and have poor adherence. Untreated substance use disorder makes it less likely that a patient will follow a complicated medication regimen properly. Many of our patients require social support services, and having the ability to communicate, share data, and coordinate care with these service providers would truly benefit this patient population. It is understandable for covered entities to have some trepidation about disclosing PHI to service agencies such as housing or other social services, when these agencies are not typically or historically considered health care providers. We do note that many of these organizations already take privacy of clients very seriously and have their own procedures and precautions regarding privacy. Therefore, a restriction limiting data sharing to social services that only provide health care may be overly stringent, as many social agencies that provide services that greatly impact health (housing, food access, child care, education) would be excluded.

Overall, ACEP believes that OCR should be making refinements to HIPAA that would help improve patient access to medical care and social resources and that enhance coordination between health care providers and social support agencies. However, any changes to current HIPAA Rules must balance the potential benefit of sharing PHI with the risk that patients will forego care if they believe that their privacy is abrogated. This is especially true for patients with substance abuse disorders. Inappropriate disclosure of substance abuse data may lead to adverse consequences that include loss of housing, loss of child custody, discrimination from medical professionals, loss of benefits, or loss of employment. Caution is therefore warranted prior to weakening privacy safeguards for this population.

Question 19: Should OCR expressly permit disclosures of PHI to multi-disciplinary/multi-agency teams tasked with ensuring that individuals in need in a particular jurisdiction can access the full spectrum of available health and social services? Should the permission be limited in some way to prevent unintended adverse consequences for individuals? For example, should covered entities be prevented from disclosing PHI under this permission to a multi-agency team that includes a law enforcement official, given the potential to place individuals at legal risk? Should a permission apply to multi-disciplinary teams that include law enforcement officials only if such teams are established through a drug court program? Should such a multi-disciplinary team be required to enter into a business associate (or similar) agreement with the covered entity? What safeguards are essential to preserving individuals' privacy in this context?

Disclosures of this kind could help patients access the full spectrum of health and social services. As stated above, OCR should break down barriers that impede care coordination between health care providers and social support agencies.

However, ACEP does have concerns with sharing PHI with law enforcement for carrying out investigatory activities. As emergency physicians, we have witnessed individuals delaying or avoiding care out of fear of being reported to the authorities. We recognize that law enforcement officials perform valuable functions in the ED

and that one of these functions is investigation of criminal acts. As part of these investigations, law enforcement officials may request PHI gathered in the ED. ACEP believes that emergency physicians should only honor these requests under the following circumstances:

- The patient consents to release of the requested personal health information to law enforcement officers;
- Applicable laws or regulations mandate the reporting of the requested personal health information to law enforcement officers; or
- Law enforcement officers produce a subpoena or court order that is HIPAA-compliant or meets statutory or regulatory provisions that require the release of the requested information to them.

Question 22: What changes can be made to the Privacy Rule to help address the opioid epidemic? What risks are associated with these changes? For example, is there concern that encouraging more sharing of PHI in these circumstances may discourage individuals from seeking needed health care services? Also is there concern that encouraging more sharing of PHI may interfere with individuals' ability to direct and manage their own care? How should OCR balance the risk and the benefit?

With respect to the opioid crisis, it is essential to balance the need for PHI access with vital privacy safeguards. Clarity is required so that providers better understand the limitations and allowances for PHI sharing under not only HIPAA, but also under more stringent state laws and 42 CFR Part 2. ACEP believes that OCR should provide guidance about HIPAA privacy requirements and federal confidentiality requirements governing substance use disorder health information in order to better facilitate the electronic exchange of health information for patient care. Emergency physicians see first-hand the toll that the misuse of drugs takes on individuals, families, and communities and it is vitally important that we have access to and share with other appropriate health care providers a patient's entire medical record to provide the optimal care. This information is necessary for safe, effective treatment and care coordination that addresses all of the patient's health needs. Failure to integrate treatments, services, and support information creates unnecessary risk for patients that can lead to contraindicated prescribing and problems related to patient non-compliance. Furthermore, obtaining multiple consents from a patient while providing emergency medical care can be challenging and time-consuming. For these reasons, it is critical that OCR provide more clarity on how providers, including emergency physicians, can use substance use disorder health information for treatment, payment, and health care operations.

ACEP notes that the Medicaid and CHIP Payment and Access Commission (MACPAC) included a similar recommendation in its June 2018 report to Congress. The Report specifically states that "clarifying guidance on existing regulations would be a meaningful step to help providers, payers, and patients understand rights and obligations under the current law as well as existing opportunities for information sharing."[1] The recently enacted Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act also includes provisions requiring provider education on communication with families and the development of best practices related to the use and disclosure of substance use disorder information.

Question 23: How can OCR amend the HIPAA Rules to address serious mental illness? For example, are there changes that would facilitate treatment and care coordination for individuals with SMI, or ensure that family members and other caregivers can be involved in an individual's care? What are the

[1] The MACPAC June 2018 Report to Congress on Medicaid and CHIP is available at: https://www.macpac.gov/wp-content/uploads/2018/06/June-2018-Report-to-Congress-on-Medicaid-and-CHIP.pdf.

perceived barriers to facilitating this treatment and care coordination? Would encouraging more sharing in the context of SMI create concerns similar to any concerns raised in relation to the previous question on the opioid epidemic? If so, how could such concerns be mitigated?

As EDs are being challenged by a lack of access to outpatient and inpatient psychiatric care, actions OCR can take to help emergency physicians facilitate treatment and care coordination for individuals would be extremely beneficial. In the case when an emergency physician believes that a person is a threat to themselves or others, it is imperative that others living within the same household be notified about the risk.

In terms of what amendments OCR can make to address this issue, as noted in the response to question number 22 above, we feel it is important for OCR to clarify current HIPAA Rules or provide additional guidance so that providers, including emergency physicians, truly understand how they can use PHI to better coordinate care for these patients.

Questions 27-42: Accounting of Disclosures

As discussed in the RFI, OCR's 2011 Notice of Proposed Rulemaking (NPRM) includes a proposal to provide individuals with the right to receive an "access report" that would should show who had accessed the information in an individual's electronic designated record set. ACEP believes that the proposed access report requirement would create undue burden for emergency physicians without providing meaningful information to individuals. Therefore, we support OCR's intention (as referenced in the RFI) to withdraw the NPRM and encourage the office to implement accounting rules that minimize administrative burden on all covered entities.

Question 54 (a): 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? What provisions of the HIPAA Rules may inhibit the transformation of the health care system to a value-based health care system?

ACEP supports the Trump Administration's efforts to shift our health care system to one that rewards value over volume. Every day emergency physicians must make critical decisions about whether their patients should be kept for observation, admitted to the hospital, or discharged. Fundamentally, we act as a gateway to the hospital for many patients. Emergency physicians are therefore in a prime position to be meaningful participants in value-based arrangements and alternative payment models (APMs). However, there are not many opportunities to do so. To address this gap in available models, ACEP developed a physician-focused payment model (PFPM) called the Acute Unscheduled Care Model (AUCM). On September 6, 2018, the Physician-Focused Payment Model Technical Advisory Committee (PTAC) recommended the AUCM to the HHS Secretary for full implementation. We look forward to continuing to work with HHS to improve emergency patient care through the implementation of this model.

While the lack of opportunity is probably one of the largest barriers to participating in APMs, another major impediment is the inability for the average physician to know for sure whether some of the care coordination they are providing is permissible. In order for emergency physicians to actively participate in value-based models and coordinate care for patients that come to the ED, we need to be assured that we are in compliance with all federal laws and regulations, especially those related to the privacy and security of data.

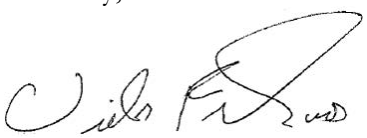
To be successful in an APM or other value-based arrangement, emergency physicians also need to have data on the entire patient population so that we can appropriately target and address the needs of our high-risk patients. We also need a way of tracking our patients across multiple health care settings. Patients routinely come to the ED with acute conditions that require follow-up from non-ED providers either in inpatient or

outpatient settings. In fact, one of the fundamental goals of ACEP's APM, the AUCM, is to foster care coordination between emergency physicians and primary care providers and other specialists who treat patients once they have been discharged from the ED. If emergency physicians are to take on any sort of financial risk for these patients who come to the ED, there must be standardized ways of identifying patients and mechanisms in place for sharing data and coordinating care with the other providers who treat the patient.

In all, ACEP believes that there is a lot of potential for new APMs that allow emergency physicians to coordinate a patient's care with other providers in other healthcare settings. However, clarity is required regarding privacy and security requirements so that they do not impede our ability to follow-up on our patients and coordinate care with other providers significantly limits the likelihood that these APMs will be successful.

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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