February 12, 2019

Alex Azar II
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 600E
200 Independence Avenue SW
Washington, DC 20201

RIN 0945-AA00—Request for Information on Modifying HIPAA Rules to Improve Coordinated Care.

Dear Secretary Azar:

Thank you for the opportunity to comment on the above-captioned request for information. America’s Essential Hospitals appreciates the work of the Department of Health and Human Services (HHS) Office of Civil Rights (OCR) to gather feedback on revisions to the Health Insurance Portability and Accountability Act (HIPAA) privacy and security regulations that might hinder care coordination. We support the agency’s work to improve the delivery of high-quality health care across the health care continuum and reduce regulatory burdens that impede essential hospitals’ ability to fully engage in care coordination.

America’s Essential Hospitals is the leading champion for hospitals and health systems dedicated to providing high-quality care to all. While our members represent just 6 percent of hospitals nationally, they provide 20 percent of all charity care nationwide, or about $3.5 billion, and 14.4 percent of all uncompensated care, or about $5.5 billion.1 The high cost of providing care to low-income and uninsured patients leaves essential hospitals with limited financial resources. Even with their limited means, our 300 member hospitals demonstrate an ongoing commitment to serving vulnerable patients. Essential hospitals provide specialized services that their communities otherwise would lack (e.g., trauma centers, emergency psychiatric facilities, burn care); expand access with extensive networks of on-campus and community-based clinics; furnish culturally and linguistically appropriate care; train health care professionals; supplement social support services; and offer public health programs.

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Essential hospitals regularly meet the complex clinical and social needs of the patients who come through their doors. Our members provide comprehensive ambulatory care through networks of hospital-based clinics that include onsite features—radiology, laboratory, and pharmacy services, for example—not typically offered by freestanding physician offices. Their ambulatory networks also offer behavioral health services, interpreters, and patient advocates who can access support programs for patients with complex needs.

1. **OCR should promote the robust sharing of patient information necessary for effective clinical integration and quality improvement, while maintaining patient privacy protections.**

Under value-based payment models, hospitals no longer are expected simply to treat a diagnosis and episode, but to take responsibility for the overall health and outcomes of their patients. As a result, essential hospitals seek to support patients’ broader health and social needs to improve outcomes and efficiency. Our members have developed innovative care delivery models and participate in a variety of initiatives at the federal, state, and local levels. Like the rest of the hospital industry, essential hospitals are actively engaging in accountable care organizations, patient-centered medical homes, chronic-care management systems, bundled payment models, and other new modes of care delivery. They are well-situated to do so because of the comprehensive, integrated nature of their delivery systems, their strong primary care base, their staffing models, and their historic need to provide high-quality care on a shoestring budget.

We appreciate OCR’s recognition that some individuals—those experiencing homelessness or suffering from chronic conditions, including behavioral health and mental illness—receive care from a variety of sources, including HIPAA-covered entities, social services agencies, and community-based support programs. Our members often serve as anchors within their communities, with deep ties to the residents; this leads to a clear understanding of the nonclinical influences on patients and population health and the need to work with various entities to deliver the most appropriate care. Many essential hospitals screen patients for food insecurity, housing instability, and other social determinants of health and refer these patients to community resources to help meet their social needs. However, challenges exist in developing partnerships, building needed infrastructure, engaging patients, and ensuring necessary information flows freely across the spectrum of health and social services.

Several of our members use sophisticated resource linkage software to screen patients for social needs; link patients to appropriate resources and agencies; track follow-up; and measure impact. It is critical that hospitals create and maintain structures and relationships to aid referrals to appropriate services that meet identified needs. In Massachusetts, one essential hospital created a data-sharing mechanism, whereby the hospital and community organizations alike can update and share information to better

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track follow-up for patient referrals. In many cases, it is making contact with these outside agencies or support programs that is of greatest benefit to patients. In those instances, a patient’s full medical record is not needed. Further, permission obtained in an informal manner from patients would suffice when connecting patients to needed services. We understand the stated concern and reluctance of covered entities to share information with noncovered entities, and we believe OCR should clarify HIPAA’s provisions for such sharing, in particular with social service agencies and community-based support programs. **Further, OCR should examine the relationships that exist between covered entities and social services and community-based programs to determine what, if any, modifications to HIPAA would support these relationships.**

Members of America’s Essential Hospitals understand the importance of non-health care social services in achieving effective care transitions and improved outcomes, including reduced readmissions. Filling a safety-net role in their communities, essential hospitals use their scarce resources efficiently to provide cutting-edge care to all, regardless of income or insurance status. For example, an essential hospital in Missouri developed a care transitions program that reduced hospital admissions, emergency department (ED) visits, and costs. This hospital identified the need for a multidisciplinary team, bringing together licensed clinical social workers, client-community liaisons, and advanced-practice registered nurses, among other staff, to address both the clinical and social issues affecting their patient population.

Additionally, key social needs of patients are not met because of issues within the legal sphere, including housing discrimination and difficulty accessing insurance and other public benefits to which they are legally eligible. Many essential hospitals have implemented medical-legal partnerships—a collaborative arrangement that embeds legal professionals in the health care environment to screen for and consult on legal matters that could mitigate social needs for some patients. For example, an essential hospital in New York has a working partnership with LegalHealth, a division of the New York Legal Assistance Group, to staff attorneys in designated clinics across multiple hospital sites. The attorneys work closely with the care team, especially social workers, and are available for consultation or hand-offs when legal needs arise.

OCR requests feedback on whether it should expressly permit disclosures of personal health information (PHI) to multidisciplinary/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. While we support assembling a team that can address all of a patient’s needs, it is important to avoid any unintended adverse consequences for individuals. For example, the disclosure of PHI to a team that includes law enforcement could place an individual at legal risk. Further, there is a risk that changes to HIPAA might discourage patients from seeking needed health care services if they fear their personal information might be given to those not directly involved in their care. **OCR should promote information sharing, for treatment and care coordination, while maintaining an individual's privacy protections to ensure that patients continue to seek the care they need.**

2. **OCR should ensure comprehensive, coordinated substance use treatment and care through alignment of 42 CFR Part 2 with HIPPA and balance the risk and**
benefit of covered entities sharing information with parents or loved ones related to the treatment of their children.

America’s Essential Hospitals recognizes the complexity and importance of addressing behavioral health issues, particularly as they relate to improving care for our nation’s vulnerable patients. Essential hospitals work to meet the behavioral and mental health needs of their patients by expanding behavioral health services within community health centers, as well as offering “curbside consultations” through which primary care providers can obtain an informal consultation from a psychiatrist. The goal is to train primary care providers to provide moderate psychiatric interventions themselves.

As the health community, along with policymakers, builds out an addiction treatment infrastructure, it is imperative for it to integrate substance use disorder, mental health, and primary care services to produce the best patient outcomes and establish the most effective approach to caring for people with complex health care needs. The modernization of privacy regulations and medical records for people with substance use disorders is a critical component for tackling the opioid crisis and will improve the overall coordination of care in the nation.

a. HHS should work to align 42 CFR Part 2 with HIPAA to ensure harmonization and promote integration and coordination of care.

Efforts to revise privacy regulation to support care coordination will be hampered without harmonizing 42 CFR Part 2 with HIPAA for purposes of treatment, payment, and health care operations. Part 2—federal regulations that govern confidentiality of drug and alcohol treatment and prevention records—sets requirements limiting the use and disclosure of patients’ substance use records from certain substance use programs. Patients are required to give multiple consents, creating a barrier to whole-person, integrated approaches to care. A lack of access to the full scope of medical information for each patient can result in the inability of providers and organizations to deliver safe, high-quality treatment and care coordination. Separation of a patient’s addiction record from the rest of their medical record creates several problems and impedes safe, effective, high-quality substance use treatment and coordinated care.

Modifying Part 2 to ensure that HIPAA-covered entities have access to a patient’s entire medical record will improve patient safety, treatment, and outcomes across the care delivery spectrum. Further, aligning Part 2 with HIPAA will allow appropriate access to patient information essential to providing safe, effective, whole-person care while protecting this information against unlawful disclosure and use. Without harmonizing the varying requirements, it will be challenging, if not impossible, to know whether responding to a specific request is, in fact, allowed by applicable law.

The Substance Abuse and Mental Health Services Administration released a final regulation, as well as informational materials and fact sheets on its website, clarifying how Part 2 relates to the exchange of information between providers. However, these steps do not go far enough to mitigate provider concerns. HHS should work with lawmakers to modify Part 2, allowing for appropriate levels of access for providers to have a complete picture of their patients.
b. OCR should further examine the risks and benefits of parental and caregiver involvement in the treatment of individuals suffering from substance use disorder, including opioid use disorder.

As key stakeholders in combating the opioid crisis, essential hospitals stand ready to implement practices proved effective in reducing opioid dependence and to adopt new care models to respond to this public health emergency. For example, an essential hospital in Oregon worked with several partners—including community organizations and a Medicaid accountable care organization—to conduct a needs assessment and subsequent response to substance use disorder in its area. The hospital and its partners then created a care model for medically complex patients experiencing substance use disorder; the model employs a consultation service, direct access to post-hospital treatment, and a medically supported residential care program. The sharing of information in this context—between HIPAA covered entities—fosters care coordination necessary to support the overall needs of individuals suffering from substance use disorder.

We understand the intent in promoting parental and caregiver involvement in the treatment of their loved ones impacted by the opioid crises. However, changes to HIPAA—specifically, the sharing of PHI in these circumstances—must be considered with attention to both the benefits as well as the risks. There is a very real concern that patients will be discouraged from seeking needed services through the sharing of PHI more broadly, as well as weakening the trust between provider and patient. It is important to balance the benefit of involving caregivers with the risk of interference with individuals’ ability to direct and manage their own care. We encourage further examination of ways to facilitate parental and caregiver involvement in the treatment of a loved one receiving opioid-related treatment, such as education and outreach.

3. OCR should take into consideration pending regulation related to electronic information exchange and interoperability before proposing modifications to HIPAA and seek alignment across the agency.

HHS has conducted important work to promote new technology for providers and encourage increased information exchange across providers. As directed by the 21st Century Cures Act, the Office of the National Coordinator (ONC) in January 2018 released the Trusted Exchange Framework and Common Agreement (TEFCA), which outlines a set of principles for trusted exchange and is intended to enable interoperability. In addition to creating the TEFCA, HHS has yet to complete additional work as directed in the 21st Century Cures Act—including rulemaking on information blocking and application programming interfaces that will affect the way providers exchange patient information across the care continuum.

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Specifically, CMS is drafting a proposed regulation on interoperability and patient access, while ONC is drafting a cross-cutting regulation that will address interoperability and information blocking. This rulemaking would provide much-needed clarification on, and will have implications for, how providers share information with one another and with their patients to improve care coordination.

We support HHS’ efforts to improve interoperability among providers, as well as the use of electronic health records technology to improve the information flow between providers and patients. However, it would be premature for OCR to propose modifications to HIPAA related to the electronic exchange of information when ONC has yet to complete statutorily required work in this area. Without the required rulemaking from ONC and further stakeholder input, modification of HIPAA requirements could result in confusion for providers and patients. **We urge OCR to review proposals from ONC related to interoperability, determine how those proposals might impact HIPAA, and then examine potential modifications to HIPAA that achieve alignment across the agency.**

4. OCR should provide increased public outreach and education on existing provisions of HIPAA and ensure comprehension by providers and patients, in particular, those with limited English proficiency (LEP).

America’s Essential Hospitals and its members continually advance work to improve cultural competency, increase health literacy, and provide communication and language assistance. By involving patients as active participants in their care, hospitals can better help them identify care choices, as well as responses to clinical and social needs that might improve health outcomes.

In many cases, patients are unaware of permitted use and disclosures of PHI for care coordination and/or case management. For example, health care providers who believe that disclosures to certain social service entities are a necessary for, or might assist, the individual’s health or mental health care are permitted to disclose the minimum necessary PHI to such entities without the individual’s authorization. It is important that patients are made aware of, through plain language educational materials, their right to access their medical record and to limit who has access to their PHI. **We encourage OCR to increase its outreach and education around the existing privacy rights of individuals and the specific instances in which providers are authorized to disclose PHI for treatment purposes.**

Further, OCR should develop updated materials for providers that illustrate, in real-world scenarios, when they are permitted to disclose PHI for treatment purposes. In doing so, providers are better able to effectively conduct care coordination activities that promote overall health and well-being. For example, case studies could illustrate the points along the care continuum—from inpatient to post-discharge, community-based care—when PHI might be disclosed, to what extent the minimum necessary standard would apply, and any required authorizations surrounding disclosure.

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Additionally, individuals with LEP require appropriate language assistance or auxiliary aids and services to fully participate in their care plan, including any notice of privacy given to the patient. While people with LEP account for about 8 percent of the U.S. population overall, they represent more than 20 percent of the uninsured population and 12 percent of the Medicaid population.\(^6\) Language barriers jeopardize the health of many LEP individuals by reducing access to care and hindering communication with providers. Members of America’s Essential Hospitals work daily to improve care quality through programs to break down language barriers and engage patients and families to improve the care experience. A patient’s ability to read and understand a notice of privacy practices has an impact on patient safety and the likelihood of a patient seeking care. **We urge OCR to provide outreach in a manner that ensures all patients understand their rights regarding PHI, with particular attention to LEP patients and those having low health literacy levels.**

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America’s Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Senior Director of Policy Erin O’Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO

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