CALIFORNIA HOSPITAL ASSOCIATION
Providing Leadership in Health Policy and Advocacy

April 26, 2021

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

SUBJECT: RIN 0945–AA00; Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement; Notice of Proposed Rulemaking, Federal Register (Vol. 86, No.12), January 21, 2021

Dear Acting Director Frohboese:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) is pleased to submit comments on the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) proposed rule that would modify the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to support and remove barriers to coordinated care and individual engagement.

California's hospitals are committed to ensuring the privacy of patients' health information. CHA strongly supports OCR's goals of strengthening patients' access to their health information, reducing barriers to care coordination, and decreasing administrative burden in privacy regulations. We appreciate OCR's efforts to achieve these goals through the proposed rule and support several proposals that will ease sharing of information for care coordination purposes. However, we are concerned that the proposed rule will introduce additional regulatory complexity at a time when hospitals are beginning to comply with new regulations that prohibit information blocking and anticipating changes to policies for sharing mental health and substance use disorder (SUD) records.

The Office of the National Coordinator for Health Information Technology (ONC) published its final rule, "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program," on May 1, 2020, with an implementation date of April 5, 2021, for the information blocking provisions. California's hospitals already operate in an incredibly complex regulatory environment, navigating both federal and state patient privacy and disclosure laws, including separate requirements for mental health and SUD records. The introduction of information blocking regulations — which represent a sea change in the framework under which health care providers, health insurance plans, and health information technology (HIT) developers and vendors capture and exchange highly sensitive health information — has made compliance with these multiple layers of regulation even more challenging.

In addition, the Coronavirus Aid, Relief, and Economic Security (CARES) Act requires the Substance Abuse and Mental Health Services Administration (SAMHSA) to significantly amend requirements related to the confidentiality of SUD records under 42 of the Code of Federal Regulations (CFR) Part 2 (Part 2). Hospitals look forward to the promulgation of these regulations that are intended to better align SUD disclosures for treatment, payment, and health care operations with the permissions of the HIPAA regulations and urge SAMHSA to move swiftly in issuing a proposed rule. While we welcome these forthcoming changes, we urge HHS to recognize the potential for additional regulatory complexity if not considered as part of a broader privacy regulatory framework.

In its consideration of a final rule on the proposed policies, we urge HHS to take a holistic approach that acknowledges the overlapping regulations of HIPAA, ONC's information blocking regulations, and SAMHSA's Part 2 regulations. We believe that HIPAA should take pre-eminence for health privacy protections, and the other rules should defer to and conform with its privacy obligations. In particular, the information blocking rules should align with the obligations created under HIPAA and should not create duplicative or contradictory requirements. HHS should ensure that patient access regulations both protect and enhance patient privacy while avoiding a complex web of regulatory requirements that divert providers' focus from patients and their community to burdensome regulatory compliance efforts. As a first step, we urge OCR not to implement any proposed changes to HIPAA related to additional rights of access that would be enforced prior to the availability of technologies essential for responding to patient requests, such as those that depend on the widespread adoption of application programming interface (API) capabilities.

In addition to our concerns on the complexity of these overlapping regulatory frameworks, we offer the following comments on the specific provisions of the proposed rule.

Definition of Electronic Health Record

OCR proposes to formalize a definition of electronic health record (EHR) based, in part, on the HITECH Act definition. However, while the proposed definition aligns with the HITECH Act in that it references records of a health care provider that has a direct treatment relationship with patients, it significantly broadens the HITECH Act definition beyond clinical information to include non-clinical records, such as billing records. We believe OCR's proposed definition of EHR is overly broad and inappropriately expands the definition of EHR that Congress provided under the HITECH Act.

Congress clearly intended the definition to include clinical records — not billing records or other information — when it defined the term EHR, using the phrase "information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff." Clinicians do not "create, gather, manage *and* consult" billing records. Billing records generally are contained in systems separate and apart from the EHR, which would require additional effort on the part of health care providers to compile into a single record set. In addition, billing records do not provide information relevant to the delivery of patient care or care coordination. Further, the utilization of different definitions for the same term in the same part of the CFR will cause confusion and increase regulatory complexity and compliance burdens. **We urge OCR to align its definition of EHRs with the HITECH Act by limiting the scope of an electronic record to clinical information of a health care provider that has a direct treatment relationship with patients.**

Strengthening the Access Right to Inspect and Obtain Copies of Protected Health Information

OCR proposes to add a right of access that generally would enable an individual to take notes, videos, and photographs, and use other personal resources to view and capture protected health information (PHI) in a designated record set as part of the right to inspect PHI in person. **CHA supports a policy that would permit a covered entity to allow patient access via a video or photograph of their PHI. However, we urge OCR to include flexibility within the policy to allow a provider to exercise judgment, and where necessary, provide PHI in other formats.** For example, such flexibility could be necessary to protect the health or safety of patients, employees, or others in the event a patient has a communicable disease. CHA also requests that OCR clarify that a covered entity may impose reasonable requirements on individuals while they are viewing their PHI in person, such as not disrupting hospital operations, threatening staff, or otherwise loitering under the guise of reviewing their information.

OCR also proposes to extend the right to inspect to situations in which mutually convenient times and places include points of care where PHI in a designated record set is readily available for inspection by the patient, for example, by viewing X-rays, ultrasounds, or lab results in conjunction with a health care appointment with a treating provider. **CHA is concerned that this proposal is overly broad and requests several clarifications.**

First, we urge OCR to clarify that "health care appointment" means an outpatient appointment and would not apply to inpatients. For example, if a nurse tells an inpatient that she will be back in an hour with the patient's pain medication, this would not constitute an appointment for purposes of an individual's right to view their PHI. Second, we are concerned that this proposal — even if applied only to outpatient settings — could potentially disrupt health care provider workflow and the provision of care. A health care provider would never be able to estimate how long a patient's appointment would take, given that patients would have the right to extend that appointment for as long as they wanted to read their record or take cellphone photos of it. We urge OCR to revise this provision to make it clear that a health care provider may impose reasonable limitations on this right to avoid disrupting care to be provided to other patients and hospital/clinic/office operations. Third, we request OCR revise this provision to clarify that the patient's right to view records at the point of care applies only to those records related to the appointment. For example, if a patient is having a mammogram, the radiology staff should not be required to allow the patient to view their dermatology records, but rather the radiology staff should be permitted to refer the patient to the dermatology clinic.

Addressing Forms of Access

HIPAA requires a covered entity to provide the individual with access to the PHI in the form and format requested, if readily producible in that form and format, or if not, in a readable copy form, or other form and format as agreed to be the covered entity and individual. OCR says that as technology evolves, the "form and format" and the "manner" of producing or transmitting a copy of electronic PHI may become indistinguishable and describes standards-based APIs — such as those that will be required of ONC-certified EHR technology — as an example. As such, OCR suggests that entities that have an API also may be deemed to be able to produce information in the form and format consistent with that API.

CHA is concerned that proposed changes to deem forms and formats required under other regulatory frameworks — such as ONC 21st Century Cures Act regulations — as required under HIPAA puts OCR in the position of enforcing those other laws, in addition to any enforcement appropriately handled by such other governmental authority. Furthermore, we remind OCR that API technology is not fully

mature, nor is it required of certified EHR technology until December 31, 2022. If OCR finalizes API-related requirements, no enforcement should occur until the ONC requirements for APIs are fully implemented and enforced. Any HIPAA enforcement before such time would place hospitals in the untenable position of being required to implement requirements that their health IT systems do not have the capability to support.

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

OCR proposes to create a separate set of provisions that would provide for a right of access to include the right to direct copies of PHI to a third party. Specifically, OCR proposes that requests to direct copies of PHI to a third party would be limited to only electronic copies of PHI in an EHR. **CHA supports OCR's proposal to limit an individual's right to direct copies of PHI to third parties to electronic copies of PHI in an EHR, in accordance with the *Ciox* decision.**

OCR also proposes that a covered health care provider would be required to respond to an individual's request when the request is "clear, conspicuous, and specific," which may be orally or in writing, including electronically executed requests, replacing the current requirement that a request must be in writing and signed by the individual. **CHA urges OCR to reconsider this proposal, and instead consider oral requests as a permissive option for hospitals rather than a requirement. Should OCR finalize an oral request requirement, we request additional guidance on how a provider can verify that an oral request is legitimate and lawful.** For example, covered entities should be provided with guidance on a scenario where an individual calls a hospital health information management department and asks, for example, for a copy of John Smith's record to be sent to Maria Ramos. In a case like this, the guidance should clarify which actions the hospital may take to identify the authority of the caller. We also urge OCR to allow hospitals to establish reasonable limits on the number of requests a patient can make.

In addition, ONC proposes to create a new requirement within the right of access that would require covered health care providers and health plans to submit an access request on behalf of the individual to another health care provider. CHA is concerned that this proposal is overly expansive and burdensome, creating a duplicative layer of information-sharing requirements that would insert hospitals into patient relationships with other providers. A provider should be required to obtain records from another provider only when those records are likely to be useful in caring for the patient, in the provider's judgment. Currently, health information exchanges and health information networks facilitate provider-to-provider exchanges, and the 21st Century Cures Act provides additional opportunities for more streamlined health information exchange. **We urge OCR to allow ONC to continue to lead on health information exchange policies and allow implementation of the 21st Century Cures Act to build technical capabilities and remove barriers to information sharing for patients and health care providers.**

Reducing Identity Verification Burden for Individuals Exercising the Right of Access

In response to individual complaints that covered entities sometimes impose burdensome verification requirements, OCR proposes to expressly prohibit a covered entity from imposing unreasonable identity verification measures on an individual (or their personal representative) exercising a right under HIPAA. In addition, OCR proposes to clarify that unreasonable verification measures are those that require an individual to expend unnecessary effort or expense when a less burdensome verification measure is practicable.

In the proposed rule, OCR says that it assumes a covered entity holding records of an individual in an EHR has necessarily established a treatment relationship with such individual and, therefore, imposing additional verification requirements is unnecessary. However, in a hospital or health system setting — particularly for staff in a health information management department — this is unlikely to be the case. In addition, a patient can appear years after services were rendered, when no provider employees are acquainted with the individual. **We urge OCR to identify examples of permissible identification verification — such as guidance that states a hospital may require as verification the presentation of a driver's license in person (or virtually, such as by Zoom or Skype), or a photocopy by mail — and provide a safe harbor to ensure that complying with such a procedure protects the hospital from an allegation of a breach.** We believe permissible identification standards could be applied to both the individual and their personal representative; however, it is also important that a hospital is able to verify the authority of the personal representative in requesting PHI. We urge OCR to provide examples of permissible authority standards, as well as safe harbors.

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

OCR believes that current regulations define "health care operations" in such a way that unnecessarily limits a health plan's ability to perform individual-level care coordination or case management activities. OCR proposes to amend the definition of "health care operations" to clarify that all care coordination and case management activities of a health plan are health care operations, whether individual level or population based. **CHA supports the proposal because it provides health care providers additional clarity on permitted PHI disclosures to support care coordination activities at the individual level.**

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

HIPAA regulations generally require covered entities to use, disclose, or request only the minimum PHI necessary to meet the purpose of the use, disclosure, or request. CHA has long argued that the minimum necessary standard leads health care providers to fear appropriate sharing of patient information, because health care professionals are concerned that their interpretation of "necessary" might not be correct, and they will be punished for an inadvertent breach. OCR acknowledges the need for flexibility in the application of the standard, in particular to support disclosures that would facilitate better care coordination and patient management for individuals. OCR proposes 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 care coordination and management at the individual level. **CHA supports the proposed exception to the minimum necessary standard and believes it will reduce compliance burden for hospitals sharing PHI for care coordination purposes.**

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

CHA supports OCR's proposal to expressly permit covered entities to disclose PHI to social services agencies, community-based organizations, home, and community-based service providers, and similar third parties that provide or coordinate health-related services needed for care coordination and case management for an individual, either as a treatment activity of a covered health care provider or as a health care operations activity of a covered health care provider or health plan. We believe this change will promote the exchange of necessary information for care coordination and support better care for patients. However, we urge OCR to better define the terms "social services agencies," "community-

based organizations," and "health-related services." This is particularly important as hospitals begin to comply with new information blocking regulations, which limit the ability of a health care provider to use its professional judgment in determining when a disclosure of PHI is appropriate. **To better clarify which disclosures are appropriate, CHA supports a policy that would limit these permissions to services specifically identified in an individual's care plan and/or for which a social need is identified through a screening assessment.**

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

CHA appreciates that OCR has proposed several modifications to the HIPAA regulations intended to increase the disclosure of information related to the care of individuals experiencing SUD, serious mental illness (SMI), or certain other health emergencies where the individual is incapacitated or otherwise unable to express a privacy preference. However, hospitals continue to be challenged by the Part 2 regulations in appropriately sharing information for patients with SMI or SUD, and we urge HHS to move swiftly in promulgating regulations — as required by the CARES Act — to better align the Part 2 requirements with HIPAA.

Specifically, CHA supports OCR's proposal to replace ''the exercise of professional judgment'' standard with a standard permitting certain disclosures — such as those made to family and emergency contacts while a patient is incapacitated — based on a ''good faith belief'' about an individual's best interests. We agree that this proposal will encourage appropriate disclosures by non-physician health care personnel when in the patient's best interest, and as such improve outcomes and access to care. We urge OCR to further clarify examples of permitted and prohibited activities specific to practitioners who treat SUD and SMI patients, including clear guidance on what constitutes definition of "good faith belief" beyond the absence of bad faith. CHA also supports the proposal to replace the "serious and imminent threat" standard with a "serious and reasonably foreseeable" standard. The requirement for harm to be "imminent" at times prevents a provider from making a disclosure that would almost universally be deemed appropriate.

Proposal to Substitute an Individual Right to Discuss Notice of Privacy Practices for the Written Acknowledgement Requirements

CHA supports OCR's proposal to eliminate Notice of Privacy Practices (NPP) written acknowledgement requirements for covered health care providers with a direct treatment relationship to an individual. This includes the elimination of requirements that a provider obtain a written acknowledgment of receipt of the NPP, document good faith efforts to get a written acknowledgement if the covered provider was unable to obtain the written acknowledgment from the individual, and retain copies of such documentation for six years. CHA agrees that these requirements are overly burdensome and have not resulted in increased privacy protection for patients.

Changes to NPP Content

OCR proposes several changes to the NPP to reflect its concerns about patient awareness of HIPAA rights, as well as new rights of access as proposed and an optional element on information related to directing PHI to a third party. While CHA does not have any concerns with the specific content proposals, we note that proposed changes would require significant resources on the part of hospitals to print and post the NPP signage in all of their physical locations. One California hospital system reported that re-printing these posters would cost more than $40,000. We believe that OCR has an

opportunity to further reduce burdens by removing the duplicative requirement that the NPP be posted on notices throughout the facility. Hospitals find that patients rarely review this information on posters, and rather the requirement is better met by providing paper versions of the NPP to each patient and posting the NPP on the hospital's website, as is currently required.

CHA appreciates the opportunity to comment on the proposed rule. If you have any questions, please do not hesitate to contact me at mhoward@calhospital.org or (202) 488-3742, or my colleague Lois Richardson, vice president, legal counsel, at lrichardson@calhospital.org.

Sincerely,
/s/
Megan Howard
Vice President, Federal Policy