MISSOURI HOSPITAL ASSOCIATION

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May 5, 2021

U.S. Department of Health and Human Services
Office for Civil Rights
ATTN: Proposed Modifications to the HIPAA Privacy Rule to Support, and
Remove Barriers to, Coordinated Care and Individual Engagement NPRM
RIN 0945-AA00
Hubert M. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Dear Sir/Madam:

The Missouri Hospital Association on behalf of its 141 member hospitals, offers these comments to the Notice of Proposed Rulemaking published by the Office for Civil Rights proposing to modify the HIPAA Privacy Rule to further care coordination activities and strengthen individuals' right of access to their protected health information. Our members support the agency's efforts to remove barriers that impede the ability of health care providers and social service agencies to coordinate activities to address patients' overall health and well-being and individuals' ability to fully participate in their own care. We also laud efforts to reduce confusion and concerns about information that may be shared with family members or other caregivers to assist loved ones suffering from severe mental illness (SMI) or substance use disorder (SUD).

MHA supports and echoes the comments provided by the American Hospital Association. In particular, MHA believes any changes to the HIPAA Privacy Rule must be carefully considered and thoroughly integrated with the interoperability and information blocking regulations administered by the National Coordinator for Health Information Technology (ONC), as well as the Part 2 regulations administered by the Substance Abuse and Mental Health Services Agency. The failure to ensure these three comprehensive regulatory schemes are complimentary will actually increase the administrative burdens on hospitals and other health care providers and impede the goals of this proposed regulation. In particular, MHA notes the technology requirements required by the Cures Act will not be enforced until the end of 2022. Yet this proposed rule imposes access rights using such technologies. Requiring access to electronic record systems by application programming interfaces creates numerous security risks that must be identified and mitigated to maintain compliance with the HIPAA Security Rule. Due to the vast proliferation of health-related applications, this is no easy task for a hospital, large or small. Therefore, MHA requests that enforcement of access rights be delayed until full consideration can be given to how these changes comport with the requirements imposed by the ONC.

In addition to the issues raised by AHA in its comment letter, MHA asks the OCR to consider the following.

DEFINITION OF ELECTRONIC HEALTH RECORD

Missouri hospitals have become accustomed to basing access decisions on HIPAA's existing definition of a designated record set. The proposed definition of electronic health record vastly expands upon this concept, requiring changes in processes and workflows for granting access to protected health information. MHA believes the incorporation of billing records into the definition of EHR goes too far and will create undue burden on hospitals. The designated record set is the body of data used for clinical decision making that typically is housed in the hospital's electronic record system. Billing data is stored separately. Responding to requests for EHR data as defined in the proposed rule will require hospitals to go through the cumbersome process of gathering data from different sources and databases and combine them in a way to facilitate electronic transfer to the patient. Nor does access to billing information further the goals of this proposed rule — reducing barriers to care coordination activities. MHA urges OCR to limit the scope of this definition to more closely align with the HITECH Act definition and comport with the current definition of a designated record set.

RIGHT TO INSPECT AND COPY

MHA is concerned that the right to inspect records at "mutually convenient times and places," to include points of care, may create unrealistic expectations of access on the part of patients. MHA agrees that patients should be able to view test results in the presence of their health care provider during a regular appointment. However, it does not follow that the time and place where an individual obtains health care treatment will always be a convenient location to view the patient's entire medical record. Spontaneous requests to do so will interrupt workflows and interfere with staff's ability to care for other patients. Imposing reasonable restrictions on the patient's ability to inspect volumes of records should not be considered an unreasonable delay in providing individual access. MHA suggests limiting the number of times a patient may request to inspect the same records and allowing covered entities to impose reasonable policies for providing access to large volumes of records through appropriate channels such as the medical records department.

FORM OF ACCESS

MHA believes the requirement for hospitals to produce ePHI through an application programming interface to an individual's personal health application will create additional burden and potential harm to consumers. Under the proposed rule, the application developer may not manage, share or control the information shared. With the extensive proliferation of these types of applications, it is impossible for a covered entity to determine whether a particular application is an appropriate repository for PHI. Some may be associated with well-known, trusted brands with an established customer base, but others will be unknown and untested. Hospitals will have no way to adequately evaluate the security risk of transferring data to an

unfamiliar application, and it should not be incumbent on the hospital to make that determination. The transfer of data to untested applications represents a significant security risk. If the rule is promulgated as written, covered entities should not be held responsible for misuse or unauthorized disclosures of PHI transferred to a personal health application at a patient's request.

Similarly, OCR oversimplifies the ability of hospitals to produce information in a form and format consistent with an API. Health-related applications are proliferating at a rapid pace, with technologies that are nascent and ever evolving. MHA cautions against incorporating a requirement that assumes a hospital is readily able to produce information in any form or format related to the API.

TIME LIMITS

MHA opposes reducing the time in which a covered entity is required to respond to a request for PHI. The enhanced access rights proposed in this rule likely are to result in increased numbers of requests for production of PHI. At the same time, OCR proposes to reduce the required response time. MHA urges OCR to evaluate the effect of these greater access rights before subjecting health care providers to more restrictive time frames. The proposed rule assumes the presence of technology will allow hospitals to more quickly respond to access requests; however, there are many unknowns in light of the emerging technologies implicated by this rule, and it is not clear they will immediately result in greater ease of production. This especially is true of records directed to third parties, such as attorneys, which are not needed for immediate treatment purposes.

FEES

MHA requests OCR reconsider its stance regarding the strict limitations on fees that may be charged for producing records. MHA believes OCR underestimates the financial and personnel resources necessary for responding to the myriad of requests regularly received by hospitals to produce records to third parties. There are costs associated with transferring data to electronic media that are not captured by the proposed rule, which then shifts those costs to covered entities. As the industry moves to greater interoperability, these disclosures may become more streamlined, but until then, covered entities should be able to recoup the true cost of transferring records to third parties.

ORAL ACCESS REQUESTS

OCR proposes to reduce barriers for individuals, or their representatives, attempting to access their own PHI. MHA supports this effort. Patients who are fully engaged in their health care and health care decision making are likely to have better outcomes and promote the goals of value-based care systems. MHA is concerned that the rule, as written, lessens standards in a way that invites fraud or risks of identity theft. Hospitals must be allowed to develop appropriate identity verification mechanisms to ensure that patient-identifying information is, in fact, being released

in accordance with the patient's stated desires. Creating the impression that a patient need only call to direct the release of records is likely to lead to increased complaints of denied access when hospitals attempt to impose reasonable identity verification methods.

GENERAL ACCESS RIGHTS

As noted above, MHA believes individuals are entitled to open access to their own health information and to direct their PHI be disclosed to others on request. However, MHA is concerned the proposed rule relaxes access standards in ways that could create burdens for hospitals and consequences not fully appreciated by patients. Hospitals will be required to develop new policies, recreate workflows and conduct training for staff. The new standards impose a broader scope of individual autonomy across the enterprise to share PHI with patients, family members, caregivers and third parties. Implementing the rule would move hospitals from centralized processes for the release of information and create decentralized decision points for the workforce to determine whether the release of information is within HIPAA and/or the facility's policies. This creates a greater risk of an erroneous disclosure or breach of PHI.

Additionally, the proposed requirements surrounding disclosures to third parties will be burdensome to hospitals. These requirements require duplication of effort and infrastructure already provided by health information exchanges or health information networks. MHA urges that such data exchanges among providers largely be conducted within existing networks without creating new requirements requiring additional disclosures on the part of individual providers.

CARE COORDINATION AND CASE MANAGEMENT ACTIVITIES

While MHA supports OCR's attempts to make it easier for covered entities to share PHI with other health care providers, social service agencies, family members and informal caregivers to further a holistic approach to care, many of the established guardrails surrounding the disclosure of PHI are removed by this proposed rule. This will require a great deal of labor on the part of covered entities in the form of security assessments, risk mitigation, compliance evaluation, revised workflows and processes, policy development and workforce training. The proposed rule oversimplifies the resources that will be required for hospitals to administer and produce data to patients or their designees.

Additionally, MHA has some concerns about the unintended consequences of sharing PHI with social service agencies that are not health care providers. MHA agrees many of these agencies currently do not receive the information they need to provide ancillary services that improve health outcomes, but there may be information in the patient record that adversely could affect the individual. MHA believes the patient ultimately should determine what information is shared with individuals or entities providing non-health care related assistance to the individual. These entities are not covered entities, so the information does not have HIPAA protections once it is shared. Removing the minimum necessary standard will result in sharing more detailed information, and patients may not appreciate the details that are captured in their medical record. MHA anticipates a rise in the number of patient complaints related to the disclosure of sensitive

information and supports a balance between strict standards that impede access to PHI and inadequate safeguards against releasing sensitive personal data to a noncovered entity.

MHA suggests OCR consider providing definitions of care coordination and case management in the final rule to ensure this exception is not applied so broadly as to create additional burden on covered entities. For example, risk reviews and disability assessments may require a large volume of records but should not be considered care coordination or case management activities.

GOOD FAITH/BEST INTEREST STANDARD

Allowing health care providers to disclose PHI in good faith when the individual believes the disclosure is in the patient's best interest will alleviate provider concerns about releasing information to family members and caregivers involved in a patient's care, especially as it relates to needed interventions related to SMI or SUD. However, MHA believes this change may not be implemented as anticipated by OCR due to continued concerns about HIPAA compliance. A health care provider still will need to make a professional determination as to whether a disclosure is in the patient's best interest, so the change may be a distinction without a practical difference.

Allowing disclosures to prevent a serious and foreseeable risk as opposed to imminent harm is a welcome change and will give health care providers greater latitude to intervene and ensure patients receive assistance from established support networks at critical junctures. With respect to patients suffering from SMI or SUD, this change likely will save lives.

NOTICE OF PRIVACY PRACTICES

MHA supports the proposal to eliminate the written acknowledgement requirement that individuals received a Notice of Privacy Practices, as the process administratively is burdensome and does little to serve the patient — the majority of patients sign without reading the document. Lessening the recordkeeping and resource requirements associated with the NPP will allow hospital staff to focus on activities that provide a direct benefit to the patient.

MHA appreciates the opportunity to comment on this rule. If you have questions or require clarification of our comments, please feel free to contact me at jdrummond@mhanet.com.

Sincerely,

Jane Drummond
General Counsel and Vice President of Legal Affairs

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