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The Honorable Xavier Becerra
Secretary, Department of Health and Human Services
U.S. Department of Health and Human Services
Office of Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

ATTN: Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement (NPRM, RIN 0945-AA00 b)

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The American Psychiatric Association (APA), the national medical specialty society representing more than 37,400 psychiatric physicians, appreciates the opportunity to submit comments on the Department of Health and Human Services' (the Department or HHS) Office of Civil Rights' proposed modifications to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement. We have always advocated for strong privacy protections for patients given the sensitivity of their information and how it may be used. We also recognize the importance of modernizing regulations to allow for more widespread use of effective integrated care models and collaboration between providers, caregivers, and family members to improve health outcomes. Thus, we support many of the flexibilities and clarifications included in the proposed rule to give patients more control over their health information and to help clinicians feel more comfortable sharing information to improve care. **On the other hand, we are concerned about some of the proposed changes. In particular, we believe that clinicians must have the flexibility to use their professional judgment on the best time to share information as to not adversely impact treatment.**

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Below is our specific feedback and recommendations on these proposed changes.

- **III.A.2 Strengthening the Access Right to Inspect and Obtain Copies of PHI (45 CFR 164.524(a)(1))**

Administration
Saul Levin, M.D., M.P.A.
CEO and Medical Director

While we support patients having improved access to their health information, **we are concerned about proposals that require the sharing of protected health information at the point of care.**

The proposal states “When protected health information is readily available at the point of care in conjunction with a health care appointment, a covered health care provider is not permitted to delay the right to inspect.” The proposal also seeks comment on whether to require covered health providers to allow individuals to record PHI, contained in a designated record set, via photographs or recording during such visits. **These provisions of the rule would be burdensome to implement in almost any healthcare setting or specialty, because immediate inspection could require considerable amounts of staff time supervising access, disrupt workflows, and delay essential care to other individuals.** Permitting photography or other recordings could result in privacy loss for other patients being seen in the office or hospital setting. **In addition, we contend that this timeframe is particularly challenging in terms of sharing highly sensitive information with patients, which requires an adequate opportunity for thoughtful conversation and compassionate delivery of information.** In inpatient and emergency psychiatric settings, when individuals are already in a state of high emotional distress, immediate point-of-care access to records may further increase symptoms and distress and disrupt therapeutic relationships, even when a physical harm threshold does not appear to be reached. Increased emotional distress and disruptions in treatment planning may also occur if a patient has immediate access to clinically important information that has been provided in confidence by a patient’s family or caregiver. Although a cornerstone of psychiatric practice is ascertaining the degree to which a patient’s symptoms might result in self-harm or harm to others and identifying factors that may influence such risks, the ability to predict physical harm is not perfect and immediate access could still be associated with some possibility of physical harm without crossing the threshold to deny immediate access. Delaying record access under these circumstances would significantly reduce or eliminate the physical and emotional risks of immediate access at the time of the visit either through in person inspection, patient portal access, or immediate copies by other methods. For these reasons, in terms of physical as well as emotional harms, psychiatrists, as covered entities, should have the flexibility to make a clinical judgment to determine the appropriate time for a patient to be able to access either their partial or complete record.

In addition to supporting improved access to health information for patients, the APA supports the need for true interoperability within the healthcare system so that a patient’s electronic health record can follow them from provider-to-provider. However, providers are currently confused by the definitions and provisions of ONC’s Final Rule on information blocking, and any changes to HIPAA must align with and/or clarify the current HIPAA and ONC definitions and exceptions. **There is still much uncertainty about when a clinician may exercise discretion in temporarily withholding the patient’s data from the patient. This is primarily due to the way the “Preventing Harm” Exception is written, and how it is anticipated to be operationalized, particularly in light of the proposed changes to HIPAA as detailed in this current proposed rule.**

Presently, the original HIPAA Privacy Rule defines *reviewable* grounds for denial (45 CFR 164.524(a)(3)) as when a licensed health care professional has determined in the exercise of professional judgment that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person. But, this ground for denial does not extend to concerns about psychological or emotional harm.

The ONC Final Rule relies upon this definition of harm and also does not expand on it to include psychological or emotional harm (per the ONC, “we believe it would be challenging to define an appropriate and unique standard for purposes of this exception for non-physical harms that all actors defined in § 171.102 could apply consistently and, most importantly, without unduly restricting patients’ rights to access their health information”).

While we appreciate that adopting such a standard would prove challenging, psychiatrists attempting to employ the “Preventing Harm” exception in the ONC rule while reconciling the definition of “harm” with any changes to HIPAA, as outlined in this proposed rule, are likely to encounter many situations where they may begin second-guessing their own professional judgment in order to avoid engaging in activities that may be considered “Information Blocking” by the ONC. To that end, psychiatrists will also face significant moral dilemmas with such an approach. On one hand, they have professional and moral imperatives to reduce psychiatric symptoms and emotional distress, yet they may be compelled under HIPAA and the information blocking rules to release information, even when they feel it is reasonably likely to worsen the patient’s psychological state.

It may perhaps be the case that this rule’s changes to the HIPAA privacy’s harm standard from the original “*serious and imminent threat*” standard to a “*serious and reasonably foreseeable threat*” standard may serve to lower the threshold for when a clinician can exercise their clinical judgment for when to release the patient record, while still seemingly focusing on physical harm; however, still nebulous is how this change in language will affect said threshold at which a psychiatrist must decide how withholding patient data in order to comply with this new standard transacts with the ONC’s “Preventing Harm” Exception. **The APA urges OCR to consider the confusion this may cause at the point-of-care for providers and allow flexibility for clinicians to use judgment for when to share information. HHS also must release clear guidance on how a new HIPAA Privacy Rule and preventing harm standard will intersect with the provisions of the ONC’s Final Rule. For instance, including “emotional or psychological harm” within the HIPAA definition of harm would help to better guide psychiatrists in using the “Preventing Harm” Exception within the ONC Rule, allowing psychiatrists time to contemplate a temporarily delay in releasing the record.**

- **III.E. Disclosing PHI to Social Services Agencies and Community based Organizations to Facilitate Care Coordination and Case Management.**

We support the proposal to clarify covered entities’ abilities to disclose PHI to social services agencies, community-based organizations, Home and Community Based Services (HCBS) providers and other similar third parties that provide health-related services for individual-level care coordination and case management. Individuals with mental health problems need a range of services associated with these programs, including housing, employment, and other community-based services. **However, there should be caution in the amount of information shared to protect patient privacy. For example, if someone is going to live at a community residence that is administering and supervising medications, or helping the patient get their prescriptions from the pharmacy and get to appointments, the needed information is likely to be different than for a supported employment program if the patient's condition is stabilized and they are taking medications independently.** Encouraging greater adoption of electronic health

records and the use of secure information exchange among mental health, substance use, and community providers, would allow better information sharing in these care scenarios.

- **III.F Encouraging Disclosures of PHI when Need to Help Individuals Experiencing Substance Use Disorder (including Opioid Use Disorder), Serious Mental Illness, and in Emergency Circumstances (45 CFR 164.502 and 164.510-514)**

The proposal would amend the Privacy Rule to replace the “serious and imminent threat” standard with a “serious and reasonably foreseeable threat” standard. This is defined to mean “that an ordinary person could conclude that a threat to health or safety exists and that harm to health or safety is reasonably likely to occur if a use or disclosure is not made, based on facts and circumstances known at the time of the disclosure.” It also modifies the standard for certain permitted disclosures from one based on a covered entity’s “professional judgment,” to one based on its “good faith” belief that a disclosure would be in the best interest of the individual.

We support the change to “good faith belief” in place of “professional judgment” and replacing the standard “serious and imminent threat” with “imminent and foreseeable threat” to permit covered entities to share protected health information, when appropriate, with family members, caregivers, and others who are in a position to avert threats of harm and other potential detriments to patients’ health and safety. Family members, friends, and other individuals involved in the patient’s support network can be important sources of collateral information about the reason for an evaluation, the patient’s past history, and current symptoms and behavior.¹ They may also be an important component of a patient’s care team. For example, in Coordinated Specialty Care (CSC), an evidence-based model used to treat people with first episode psychosis, family education and support are key components of the model. Patients who received treatment under CSC achieved significant improvements in education and employment and experienced a decrease in hospitalization rates.² Thus, active and collaborative involvement of family members in treatment can help to identify a patient’s treatment goals with an overall goal of improved patient outcomes.

The proposal notes, some covered health care providers, such as licensed mental and behavioral health professionals, have specialized training, expertise, or experience in assessing an individual’s risk to health or safety (e.g., through a violence or suicide risk assessment) and, therefore, the standard includes an express presumption that such a health care provider has met the reasonably foreseeable standard when it makes a disclosure related to facts and circumstances about which the health care provider (or a

¹ The American Psychiatric Association Practice Guidelines for the Psychiatric Evaluation of Adults, Third Edition. July 2015

² Nossel I, Wall MM, Scodes J, Marino LA, Zilkha S, Bello I, Malinovsky I, Lee R, Radigan M, Smith TE, Sederer L, Gu G, Dixon L. Results of a Coordinated Specialty Care Program for Early Psychosis and Predictors of Outcomes. *Psychiatr Serv.* 2018 Aug 1;69(8):863-870. doi: 10.1176/appi.ps.201700436. Epub 2018 May 15. PMID: 29759055.

member of the team) has specialized training, expertise, or experience. We are concerned, however, that this approach would adversely impact non-mental health clinicians' willingness to report a threat without consultation with a mental health clinician. Already the shortage of mental health clinicians causes challenges to access treatment and this would further exacerbate the challenges. This could create a barrier to helping patients, especially in communities with limited and or no mental health clinicians. **We urge the Department to delete the reference to licensed mental and behavioral health professionals in the definition of "serious and reasonably foreseeable". Moreover, it may still be a challenge for clinicians including mental health professionals to know the threshold for meeting the standards for "foreseeable" threat. Thus, the Department should continue to identify scenarios and examples of when disclosure may be appropriate.**

In addition to the comments above, we offer specific feedback on the following changes related to patients' accessing and sharing their information:

- **I.C. Effective and Compliance Dates**

The APA requests that HHS extend the effective and compliance deadlines for implementing this rule. Healthcare providers, ancillary staff, IT professionals, and others, are still reeling from all of the issues related to the pandemic, which have included multiple IT changes and overwhelmed front-line workers who have been redeployed for critical care needs and to provide the COVID-19 vaccine as rapidly as possible. Moreover, larger organizations are facing challenges of implementing the Information Blocking provisions of the Final Rule, and EHR vendors are still working on the new Interoperability standards within the rule.

Thus, staff still need to be educated about these proposed changes to HIPAA and how they will affect clinical workflows through organizations, large and small. Concerns around these changes will be especially acute if immediate, point-of-care access remains a part of this HIPAA proposed rule. If the changes in HIPAA focused solely on better information sharing with family, as well as the changes to the imminent harm definition, 180 days might be sufficient time for implementation; however, when coupled with the point-of-care access provisions, more time will be needed to make these changes. We recommend at least a year before the law is in effect.

- **III.A.1 Adding Definitions for Electronic Health Record or EHR and Personal Health Application (45 CFR 164.501)**

Definition for Electronic Health Record: In the rule, OCR proposes to categorize health care staff affected by the HIPAA changes to who is covered when accessing, modifying, transmitting, or otherwise using/disclosing PHI between: a) those who have direct treatment relationships with the patient and b) those who have indirect relationships with the patient. The change in definition seems to imply that PHI is only documented to the EHR by those who have a direct treatment relationship (or those staff or workforce members who support the provision of such treatment). APA contends that this might not always be the case, as those with indirect relationships with the patient, such as a party processing requested labs, may upload a final lab report into the EHR. Thus, the provider with a direct relationship

may not necessarily replicate all of these values in the EHR independent of the (indirect) third parties. **APA therefore recommends that the Rule covers entities with both direct and indirect treatment relationships with patients as the best way to ensure the integrity and ultimate privacy of ePHI.**

Definition for Personal Health Application: The APA appreciates the guidance³ offered by OCR for when a personal health application falls under the purview of the original HIPAA Privacy Rule. For example, in the 2016 guidance around the use of apps, most cases in which a consumer is downloading an app to their smart phone and using it to transmit data to their EHR (or download information *from* their EHR), do not fall under HIPAA because there is no business associate agreement involved—i.e., the provider or other covered entity (CE) has not contracted with a vendor for the purposes of managing, sharing, or controlling data with the consumer, and so HIPAA protections do not apply. **However, the current proposed rule, viewed in the light of the ONC’s Final Rule and its focus on the use of open APIs to connect patients and CEs via a variety of health-related apps, will likely necessitate updating the definitions of “managed,” “shared,” and “controlled.”** For additional thoughts and concerns around patients’ accessing their records using APIs and apps, see our comments under the next section III.A.4.

- **III.A.4 Modifying the Implementation Requirements for Requests for Access in Response to Requests for Access: Addressing the Form of Access**

a. “Whether a covered health care provider should be required to inform an individual who requests that PHI be transmitted...not covered by HIPAA Rules.”

The use of personal mobile health-related applications (“apps”) has become nearly ubiquitous, with thousands of apps available for download via various app stores. Further, in light of the ONC’s Final Rule, which requires the use of “open APIs” within the next couple of years, more patients are expected to begin connecting apps to EHRs to either obtain or transmit PHI. While many patients may prove to be savvy users of this technology and mindful stewards of their own sensitive health data, many will undoubtedly still lack the time or expertise to thoroughly evaluate just how, where, when, and why a third-party app—not covered by HIPAA—may send their data (see previous aforementioned concerns around the Personal Health Application definition). Apps may share patient data with third parties for a variety of purposes, from conducting legitimate clinical research, to monetizing user data to the benefit of the app developer. There are also concerns as to how or whether data collected by apps and transmitted to the EHR may be acquired and used by third party payers for determining benefits coverage. **Therefore, APA supports the proposal in this rule to require covered health care providers or health plans to provide educational or advisory language to individuals who choose to share their PHI with other entities through applications that are not regulated by the Privacy Rule. However, the development of such language and educational materials should be undertaken by OCR and provided to covered health care providers/health plans. Clinicians on the front line are already spending much time and resources adapting to the Information Blocking rule, and soon, the HIPAA Rule. Requiring them to create their own educational materials would simply add to this burden.** This will help prevent some

³ Health App Use Scenarios and HIPAA, <https://www.hhs.gov/sites/default/files/ocr-health-app-developer-scenarios-2-2016.pdf>, Retrieved on March 1, 2021

patients from unknowingly or unwillingly providing access to their PHI to exploitative activities by third parties.

- **III.A.5: Modifying the Implementation Requirements for Requests for Access and Timely Action in Response to Requests for Access: Addressing the Individual Access Right to Direct Copies of PHI to Third Parties**

Of additional concern to the APA within the proposal around the patient's right to access their PHI, is *how* the patient may request their PHI. In the past, patients have traditionally done so in writing. The proposed rule, however, considers allowing for patients to request access to their PHI verbally. Allowing such an option would be difficult to fulfill given the challenges with tracking verbal requests and the potential for miscommunication, unclear requests (e.g., when the patient is requesting portions of the record rather than their complete record), and any consequences that result from these administrative errors. This is especially true in practices that may receive multiple requests a day but may not have the administrative or technical support to be able to track them or fulfill them on a timely basis. **We urge you to not include a provision to allow individuals to verbally request PHI.**

- **Confidentiality of Substance Use Disorder Patient Records (42 CFR Part 2)**

Lastly, the implementation of Title 42 of the Code of Federal Regulations (CFR) Part 2 ("Part 2") which regulates the confidentiality of certain substance use disorder records continues to be a barrier to meeting the whole health needs of patients with mental health and substance use disorders (MH/SUDs). Without access to a complete record, providers cannot properly treat the whole person and may, unknowingly, endanger a person's recovery or life. For example, a doctor may not know that he or she is prescribing pain medication to someone with a history of addiction or prescribing a medication that has drug interactions with methadone (with serious potential side effects of the drug interaction such as arrhythmias).

Recent revisions made to the regulations do little to ease the administrative burden and uncertainty that providers encounter when trying to comply with Part 2, making it more difficult for individuals with SUDs to benefit from high-quality, coordinated-care models, which are the future of health care delivery. **Overall, we recommend the release of regulations to implement Section 3221 of the CARES Act, which improved alignment of HIPAA with 42 CFR Part 2.**

Thank you again for your work on this important issue. If you have any questions, please contact Michelle Dirst, APA's Director of Practice Management and Delivery Systems Policy at mdirst@psych.org.

Sincerely,

A handwritten signature in black ink that reads "Saul Levin". The signature is written in a cursive style with a horizontal line under the name.

Saul Levin, M.D., M.P.A., FRCP-E, FRCPsych

CEO and Medical Director

