January 31, 2023

Secretary Xavier Becerra
U.S. Department of Health and Human Services
Office for Civil Rights
Attention: SUD Patient Records
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201


Submitted electronically via http://www.regulations.gov

Dear Secretary Becerra,

UnityPoint Health is pleased to provide comments on this notice of proposed rulemaking (NPRM) related to the Confidentiality of Substance Use Disorder (SUD) Patient Records. UnityPoint Health is one of the nation’s most integrated health care systems. Through more than 32,000 employees and our relationships with more than 480 physician clinics, 40 hospitals in urban and rural communities and 14 home health agencies throughout our 9 regions, UnityPoint Health provides care throughout Iowa, central Illinois, and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics and home health agencies provide a full range of coordinated care to patients and families through more than 8.4 million patient visits.

UnityPoint Health appreciates the efforts of the Department of Health and Human Services (HHS) to modernize and bring into alignment 42 CFR Part 2 protections for the privacy and security of SUD patient records with the privacy, security, breach notifications, and enforcement rules prescribed by the Health Insurance Portability and Accountability Act (HIPAA). The patients requiring SUD treatment may face many challenges, including coordination of care, appropriate involvement of family and other support networks, and often simply making the decision to seek care. UnityPoint Health submits comments to offer a health care system perspective and to particularly focus on reducing barriers to ensure patients receive the best possible care.

**DEFINITIONS (§ 2.11)**

HHS proposes to add and modify several definitions. Within the definition of “record,” HHS is considering whether to create a new definition similar to psychotherapy notes that is specific to the notes of SUD counseling sessions by a Part 2 program professional. As a result, SUD counseling notes could only be
disclosed with a separate written consent that is not combined with a consent to disclose any other type of health information.

Comment: UnityPoint Health recommends flexibility in defining SUD counseling notes to allow for variation in provider practices and patient expectations, as well as ensuring compliance with Information Blocking rules. Currently, UnityPoint Health’s Electronic Medical Record (EMR) allows for certain notes to be hidden, or marked private, by the treating provider or counselor when providing behavioral health or SUD treatment services. This is typically at the provider’s discretion, and in many cases, these notes are made available for the patient to view on their electronic patient portal if they wish to do so. We are concerned that adopting a definition of SUD counseling notes, similar to that of psychotherapy notes, may impact our ability to share these notes with patients. The flow of information between providers and patients is a large part of establishing trust in the utilization of treatment services and could be inadvertently impacted through adoption of this definition.

SECURITY FOR RECORDS AND NOTIFICATION OF BREACHES (§ 2.16)

HHS proposes to change the requirements in § 2.16(a) for paper and electronic records to more closely align with the HIPAA de-identification standard. Comments are sought on whether this approach has unintended consequences and whether de-identification standards should differ.

Comment: UnityPoint Health supports the adoption of the HIPAA de-identification standard but suggests that this be crafted to conform with various state reporting requirements and patient expectations. UnityPoint Health is required by various state regulations to track and report certain statistical information for the patient populations that we serve. Adopting the HIPAA standard should be done in a way to allow for continued compliance with these regulations.

Additionally, UnityPoint Health suggests that care be taken to balance the potential benefits of additional de-identification with the expectations from patients that their information will remain confidential at all times. Patients are at times very hesitant to seek treatment and may do so only with the absolute assurances that their information will remain confidential. Patients may express discomfort with the notion that their information may be subject to disclosure after de-identification. This may present a barrier to starting treatment or providing treating providers/counselors with necessary information to support optimal patient care.

NOTICE TO PATIENTS OF FEDERAL CONFIDENTIALITY REQUIREMENTS (§ 2.22)

HHS proposes to modify both the Patient Notice requirements at § 2.22 and the Notice of Privacy Practices (NPP) requirements at 45 CFR 164.520 to provide notice requirements for all Part 2 records.

Comment: UnityPoint Health supports the requirements that the NPP be understandable by patients but suggests implementation flexibility for covered entities that currently issue an NPP. As a covered entity, UnityPoint Health currently issues and posts the required NPP document in all circumstances where mandated to do so. As an integrated health care system, our NPP and that of other similar covered entities, by necessity, must include information on all permissible uses and disclosures of patient information. We would suggest that covered entities be permitted to utilize existing NPP documentation already produced, as it may be burdensome to adopt additional NPP language to comply with specific SUD
treatment program requirements.

**ACCOUNTING OF DISCLOSURES (§ 2.25)**

HHS proposes to add a new “Accounting of disclosures” section to establish the patient’s right to receive, upon request, an accounting of disclosures of Part 2 records made with written consent for up to three years prior to the date the accounting is requested. As proposed, HHS aligns the accounting of disclosures requirements of HIPAA and Part 2 by incorporating a general requirement for an accounting of disclosures and a limited requirement with respect to Treatment, Payment, and Operations (TPO) disclosures.

**Comment:** UnityPoint Health requests clarity and flexibility with a proposed requirement to account for disclosure of information for TPO. As a large integrated health care system with a multitude of departments, software and consulting vendors, and others who may appropriately receive Personal Health Information (PHI) under required Business Associate Agreements or other arrangements, we are concerned with the ability to accurately track all possible uses/disclosures of information that are expressly permitted. It would present large and burdensome technical and administrative challenges to track and log all uses of information within and outside of our organization, as well as to present this information, if requested, in an understandable and useful format.

**USES AND DISCLOSURES PERMITTED WITH WRITTEN CONSENT (§ 2.33)**

HHS proposed to replace the provisions requiring consent for uses and disclosures for payment and certain health care operations with permission to use and disclose records for TPO with a single consent given once for all such future uses and disclosures, until such time as the patient revokes the consent in writing.

**Comment:** UnityPoint Health supports efforts that improve coordination of care and simplify the flow of information within an integrated health care system and requests flexibility in the implementation of this rule. As an integrated health care system, UnityPoint Health has taken great care in ensuring that Part 2 SUD treatment information remains segregated from other patient records within our EMR system. Currently, access to SUD records is highly restricted and limited to only those involved with treatment services, such as a treating provider, therapist, administrator, and other supportive staff on a strictly as-needed basis. We recognize the challenges this can create for patients who wish to integrate their overall health care needs with multiple treating providers. On balance though, this ensures that strict patient privacy requirements under HIPAA are met, and that patients may be assured their information will be kept confidential.

UnityPoint Health is generally supportive of the proposals, but requests that health care providers ultimately determine the best means to adopt this new permissive structure. Currently, our EMR system is configured in such a way to create a firewall between SUD records and a patient’s other PHI. It would present a technical challenge to create an additional permission structure that allows for broader sharing of information for certain patients while maintaining restrictions for others. Furthermore, should a patient wish to restrict or revoke sharing of information, additional burdens would ensue in reversing the permission structure for those records already established.

Additionally, the creation of a new single TPO authorization standard may itself create a barrier to patients seeking treatment. Currently, a significant hindrance to patients seeking care is their anxiety around others learning of their condition or decision to seek treatment. As a result, many patients consent to
treatment only after significant reassurances and explanations as to the strict confidentiality of their information. It is possible that simply offering this option to disclose information for ongoing TPO purposes as proposed will reinforce such additional anxieties, and we are concerned some patients may decline treatment as a result. While some patients will appreciate the additional flexibility and ease of sharing information, we expect others will refuse to do so.

We would also request clarity as to the interaction between the proposed consent standard and various state rules currently governing Release of Information (ROI) requirements. UnityPoint Health operates SUD treatment programs across multiple states, and as a result, we must comply with different state regulations around ROI standards. A single consent form for TPO purposes may conflict with these separate state regulations as many ROI standards require the naming of clear and specific recipients of SUD treatment records.

We are pleased to provide input on this NPRM and its impact on our patients and communities. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director Government and External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,

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