799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

January 31, 2023

Submitted electronically via: www.regulations.gov

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services (HHS)
200 Independence Ave. S.W.
Washington, D.C. 20201

Re: Confidentiality of Substance Use Disorder (SUD) Patient Records (Docket No. HHS-OCR-0018)

Dear Secretary Becerra,

Vizient, Inc. appreciates the opportunity to comment on the Department of Health and Human Services (HHS) proposed rule, "Confidentiality of Substance Use Disorder (SUD) Patient Records" (hereinafter, "Proposed Rule"). In the Proposed Rule, HHS proposes to modify portions of 42 CFR Part 2 (or Part 2) which currently impose different requirements for substance use disorder (SUD) treatment records that are protected by Part 2 (Part 2 records) than the Health Insurance Portability and Accountability Act of 1996 rules (HIPAA Rules) which apply to protected health information (PHI).

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 60% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

In our comments, we respond to various questions provided in the Proposed Rule. We thank HHS, particularly the Office for Civil Rights (OCR) and the Substance Abuse and Mental Health Services Administration (SAMHSA), for the opportunity to share recommendations related to SUD treatment records, including implementation of the CARES Act's provisions which aim to better align certain provisions of Part 2 with the HIPAA Privacy Rule.[1] We appreciate the agency's efforts to implement legislative changes that will help providers coordinate care while continuing to protect patient privacy.

Definitions

In the Proposed Rule, HHS proposes to define or modify several terms (e.g., business associate, covered entity, health care operations, HIPAA regulations, qualified service organization) under Part 2 to better align with existing HIPAA regulatory terms and provide greater clarity. Vizient is generally supportive of these changes, as they will help support a more consistent regulatory framework between Part 2 and HIPAA.

[1] https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E/section-164.520

Should HHS finalize the definitions as proposed, we encourage the agency to provide additional education to clarify circumstances in which an entity or person would be an "intermediary" and other related requirements, particularly as the agency notes that the term "intermediary" is based on the function of the person (i.e., receiving records and disclosing them to other providers as a key element of its role) rather than how an organization or business describes itself. Such information would be helpful, as HHS also notes that examples of an intermediary include "a health information exchange, a research institution that is providing treatment, an accountable care organization, or a care management organization", which may be providing many different functions. Although the Department does not propose changes to the requirements for intermediaries (i.e., providing patients with a list of disclosures made to a member or participant treating providers), we encourage HHS to provide additional resources to ensure intermediaries are appropriately identified given this would be a newly defined term.

Single Patient Consent for All Treatment, Payment, and Health Care Operations (TPO) Disclosures

In the Proposed Rule, HHS proposes that Part 2 Programs will be able to obtain a single consent for all future uses and disclosures for TPOs, until the patient revokes the consent in writing. Vizient appreciates that HHS has provided additional clarity regarding consent by specifying that the recipient may be described as "treating providers, health plans, third-party payers, and people helping operate this program" or a similar statement, which should limit the need to more frequently obtain consent. Vizient believes this will help ease administrative burden and support more effective communication and care.

In addition, the Proposed Rule eases consent requirement for permitted redisclosures of TPOs. Vizient appreciates this change, as it will also help minimize burden and streamline care by reducing the frequency in which consent needs to be obtained for key aspects of care. Vizient encourages HHS to work with stakeholders to clarify requirements related to lists of disclosures and intermediaries to ensure this does not negatively impact care and communication.

Regarding consent revocation, Vizient appreciates the clarification that a revocation would only be effective to prevent additional disclosures to a Part 2 program, covered entity or business associate (e.g., information would not be pulled back once disclosed). Vizient believes this clarification is important as it will help encourage care coordination by minimizing burdens on Part 2 programs should a patient revoke consent.

Notice Requirements

The Proposed Rule also includes a policy that would potentially require updating the HIPAA Notice of Privacy Practices (NPP) so that covered entities and Part 2 programs provide notice to individuals regarding privacy practices related to Part 2 records. For example, covered entities that receive and maintain Part 2 records would need to add a provision to their NPP that references the restrictions on use and disclosure of Part 2 records in civil, criminal, administrative, and legislative proceedings against the individual. The current NPP requirements would continue to apply, without change, to covered entities that do not receive or maintain Part 2 records. Vizient encourages HHS to engage broad groups of covered entities in educational efforts, as many may be unaware of the need to update the NPP based on whether they receive and maintain Part 2 records.

Data Segregation

In the Proposed Rule, regarding consent requirements and uses and disclosures permitted with written consent, HHS indicates that covered entities and businesses would no longer need to segregate SUD treatment data if permitted to follow only one set of federal regulations when making decisions about using and disclosing Part 2 records. Vizient encourages HHS to further emphasize this point in a final rule given the administrative burden currently associated with Part 2 records and the long-standing nature of this requirement.

Along those same lines, Vizient encourages additional education and information to be shared with providers and patients regarding alignment of Part 2 and HIPAA more generally. Providers may, rightfully, be cautious in what information is shared for a variety of reasons, including concerns of not adhering to HIPAA or Part 2. Therefore, it is also important that additional information and education be shared so providers are aware of circumstances in which information can be communicated and how this can benefit patient care. As such, Vizient suggests HHS, upon the final rule's release, consider broader educational efforts regarding HIPAA and Part 2 to limit any potential cooling effect these requirements may have on TPO disclosures.

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. In closing, on behalf of Vizient, I would like to thank HHS for providing us the opportunity to comment on this important Proposed Rule to help improve care and support communication. Please feel free to contact me, or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these recommendations.

Respectfully submitted,

Shoshana Krilow
Senior Vice President of Public Policy and Government Relations
Vizient, Inc.