



January 31, 2023

Melanie Fontes Rainer, Director  
Office for Civil Rights  
200 Independence Avenue, SW  
Washington, D.C. 20201

Re: HHS-OCR-0945-AA16; Confidentiality of Substance Use Disorder Patient Records

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

Dear Director Fontes Rainer,

Trinity Health appreciates the opportunity to comment on policies set forth in HHS-OCR-0945-AA16. Our comments and recommendations reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest not-for-profit, Catholic health care systems in the nation. It is a family of 123,000 colleagues and more than 26,000 physicians and clinicians caring for diverse communities across 26 states. Nationally recognized for care and experience, the Trinity Health system includes 88 hospitals, 135 continuing care locations, the second largest PACE program in the country, 136 urgent care locations and many other health and well-being services. Trinity Health has 15 medical groups with 1,324 primary care providers and 4,193 specialty care providers. Based in Livonia, Michigan, its annual operating revenue is \$21.5 billion with \$1.4 billion returned to its communities in the form of charity care and other community benefit programs.

Trinity Health has 17 Clinically Integrated Networks (CINs) that are accountable for approximately 2 million lives across the country through alternative payment models. Our health care system participates in 14 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes eleven markets partnering in one national MSSP Enhanced Track ACO, Trinity Health Integrated Care. All of these markets participated in the “enhanced track”, which qualifies as an advanced alternative payment model (AAPM). In addition, we have participated since 2014 in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative and the Comprehensive Care for Joint Replacement (CJR) program across 37 hospitals. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

#### General comments

Trinity Health urges HHS to align 42 CFR Part 2 (Part 2) with the Health Insurance Portability and Accountability Act (HIPAA) as much as possible, as operating on two different standards is not efficient and impedes critical care coordination for patients. It is imperative for providers to have complete medical histories for patients to coordinate care and provide the most effective treatment. In addition to patient safety concerns, Part 2 restrictions also result in great administrative burden for providers who must go to extraordinary lengths to comply with requirements.

Further, it is critical that HHS afford the same flexibilities to population health entities, such as accountable care organizations (ACOs), as they do for payers, especially when it comes to consent for disclosure. ACOs and coordinated care models are held accountable by CMS for coordinating care and outcomes of beneficiaries and they cannot do this without access to full patient data. Understanding a patient's behavioral health and access is key to supporting a comprehensive patient-centered care plan that improves outcomes for overall health and experience of care.

Our comments below are based on the current interpretation of HIPAA regulations, which clearly defines patient protections on authorizations. We understand there is an existing proposed HIPAA regulation and we urge HHS to further delay finalizing that regulation until they can assess interactions with this proposed alignment regulation.

#### Revisions to definitions of key terms under Part 2 to align with definitions from the HIPAA Rules

HHS proposes to add thirteen defined regulatory terms and modify the definitions of ten existing terms referenced in the Part 2 regulations. Most of these terms and definitions would be based on existing HIPAA regulatory terms and definitions; others would be modified for clarity and consistency. In addition, HHS also proposes to modify the definition of qualified service organization ("QSO") by adding HIPAA business associates to the Part 2 regulatory text.

The definition of QSO is broad and has created challenges—it's difficult to know which of our QSOs are receiving Part 2 data. Trinity Health supports the proposed changes for QSOs as long as the modifications mean compliance with the Business Association Agreement (BAA) obligations to comply with Part 2. Therefore, a business associate (BA) that is also a QSOA complies with Part 2 if they are HIPAA compliant with BAA requirements (the BAA requirements would satisfy QSOA). Such alignment would lighten operation burden and align HIPAA and Part 2.

HHS seeks comments on the number and type of third-party payers that would not be considered health plans (and therefore would be subject to limitations on redisclosures of Part 2 records). Participants in value-based care arrangements rely on sharing medical records and information to coordinate and integrate patient care. Trinity Health reiterates the need for HHS to ensure ACOs and population health providers have access to full Part 2 information for robust use without a beneficiary having to explicitly opt-in to data. Providers aim to improve patient care, which is a shared goal of the Administration's. CMS-regulated models, including ACOs, have the required leadership and governance structure needed to safeguard patient protections, as required under regulations.

#### New or modified requirements for patient consent and redisclosure of Part 2 records

HHS proposes elements of the written authorization forms for patient consent for Part 2 records to be modified to more closely track the core elements of a written authorization form under HIPAA and outlines how a recipient may further disclose Part 2 records.

Trinity Health applauds HHS for aligning patient consent and redisclosures with HIPAA, as this will lead to improved patient care. Providers have been pushing for this alignment for years and there have been several examples in the media outlining the negative consequences of uncoordinated care when acute care providers are not aware of substance use disorder concerns and cautions. The lack of alignment has been detrimental for patients.

Providing patients with a written copy of consent they signed would support the goal of making sure patients are informed about how their info will be further used and disclosed, and Trinity Health agrees patients shouldn't

have to provide consent every time their record is disclosed consistent with the patient's initial consent. To track disclosure agreements, we recommend entities post agreements in an easily accessed part of their website and/or maintain a copy in a patient's electronic medical record. Further, entities should be required to provide contact information in the event patients have questions and would like more information for how their data will be shared/used.

Trinity Health strongly recommends HHS approach these provisions with the goal of fully aligning Part 2 with HIPAA. We do not support the proposed two categories for redisclosure permissions as this is confusing and will be difficult to implement. Further, this goes against the stated intent of aligning Part 2 with HIPAA to ensure data can be used appropriately for care coordination and we recommend HHS not finalize this provision. In addition, HHS should clarify that the receiving party who is permitted under rules to obtain Part 2 data should be able to rely on the disclosure of the 42 CFR site to have had obtained consent for disclosure; the onus should not be on the receiving party to make sure the initial entity had proper consent.

#### New rights to obtain an accounting of disclosures made with consent and to request restrictions on disclosures

The proposed rule would require a Part 2 program to provide to a patient, upon request, an accounting of all disclosures made with consent in the six years prior to the date of the request. The regulation would also require that a Part 2 program provide a patient with an accounting of disclosures of records for treatment, payment, and health care operations where such disclosures are made through an electronic health record, and that a patient has a right to receive an accounting of these disclosures during the three years prior to the date on which the accounting is requested.

Further, the rule would incorporate two distinct patient rights into Part 2:

- A patient right to request restrictions on disclosures of records otherwise permitted for TPO purposes; and
- A patient right to obtain restrictions on disclosures to health plans for services paid in full by the patient, including a requirement for Part 2 programs to permit a patient to restrict uses or disclosures of the patient's records to carry out treatment, payment, or health care operations.

Trinity Health urges HHS to align the right to obtain disclosures made with consent and the right to restrict disclosures with requirements in HIPAA because Part 2 programs are HIPAA covered entities and the protections are already there in HIPAA. If there is a Part 2 entity that is not already a covered entity under HIPAA, we recommend HHS expand the HIPAA definition of covered entity rather than duplicate HIPAA provisions in this rule.

In addition, we caution the proposal to require Part 2 entities to provide 3 to 6 years of information accounting for disclosures would not be helpful for patients because it would include a significant amount of data.

#### Updates to the Notice of Privacy Practices requirements in the HIPAA Privacy Rule to address uses and disclosures of Part 2 records and individual rights with respect to those records

The rule would require all Part 2 programs, at the time of admission, to inform the patient that federal law protects the confidentiality of substance use disorder records. The rule also sets forth a detailed set of requirements for the Notice of Privacy Practices that Part 2 programs are required to provide. Notification requirements would now specify interaction between the HIPAA Notice of Privacy Practices (NPP) and the Part 2 NPP.

Revising the NPP would be a substantive change. HHS should clarify in the final rule the requirements for redistributing revised NPPS—Trinity Health recommends entities only need to redistribute NPPS to new patients to preserve their privacy and allow providers to obtain an acknowledgement of receipt of the up-to-date NPP the next time they interact with the system.

New requirements impose breach notification obligations

The proposed rule would apply the HITECH Act breach notification provisions that are currently implemented in the Breach Notification Rule to breaches of records for Part 2 programs. In addition, the proposed rule would require notification in the case of a breach of unsecured protected health information.

Trinity Health supports changes to the breach notification obligations as outlined in the proposed rule; however, we urge HHS to align as closely as possible to requirements under HIPAA. The Department asks whether it should consider a “safe harbor” from the imposition of civil or criminal monetary penalties under the Breach Notification Rule for the unintentional re-disclosure of Part 2 records by lawful holders that would have otherwise been a compliant disclosure of PHI under HIPAA TPO. We strongly advise HHS not to create a safe harbor as the onus should be on a covered entity to protect these records and comply with requirements.

Conclusion

Trinity Health appreciates the extent to which HHS is attempting to modernize 42 CFR Part 2; however, we urge HHS to more closely align Part 2 and HIPAA. We offer our support as a resource as HHS seeks to further align these privacy requirements. If you have any questions on our comments, please feel free to contact me at [jennifer.nading@trinity-health.org](mailto:jennifer.nading@trinity-health.org).

Sincerely,

/s/

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Director, Medicare and Medicaid Policy and Regulatory Affairs  
Trinity Health