
PARTNERSHIP TO AMEND 42 CFR PART 2

A COALITION OF NEARLY 50 HEALTH CARE STAKEHOLDERS COMMITTED TO ALIGNING 42 CFR PART 2 (PART 2) WITH HIPAA TO FOR TREATMENT, PAYMENT AND HEALTH CARE OPERATIONS (TPO) TO ALLOW APPROPRIATE ACCESS TO PATIENT INFORMATION THAT IS ESSENTIAL FOR PROVIDING WHOLE-PERSON CARE.

October 25, 2019

Elinore McCance-Katz, M.D., Ph.D.
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Confidentiality of Substance Use Disorder Patient Records Proposed Rule (SAMHSA 4162-20)

Dear Dr. McCance-Katz,

The Partnership to Amend 42 CFR Part 2 (Partnership) appreciates the opportunity to comment on (SAMHSA's) Confidentiality of Substance Use Disorder Patient Records Notice of Proposed Rulemaking (Proposed Rule).

The Partnership is a coalition of nearly 50 national health care organizations representing a range of stakeholders, including patients, clinicians, hospitals, biopharmaceutical companies, pharmacists, electronic health record (EHR)/health IT companies, and payers. The Partnership is committed to aligning 42 CFR Part 2 (Part 2) with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of treatment, payment, and health care operations (TPO) to allow appropriate access to patient information that is essential for providing whole-person care while protecting patient privacy.

The Partnership appreciates SAMHSA's proposals to update Part 2. Our comments focus on provisions within the Proposed Rule as well as other suggested changes to Part 2 and SAMHSA's authority to make these changes.

1. Provisions Within the Proposed Rule

• Non-Part 2 Providers

The Proposed Rule emphasizes that treatment records created by non-Part 2 providers based on their own patient encounters are not subject to Part 2, and clarifies the ability of non-Part 2 providers to segregate any patient records received from Part 2 programs in order to avoid subjecting their own records to Part 2. SAMHSA is making these changes due to confusion about how rules apply to information shared between Part 2 programs and non-Part 2 providers.

The Partnership appreciates SAMHSA’s efforts to reduce confusion about these provisions in Part 2 and increase coordinated care. We ask for further clarification regarding how these changes would be implemented. For example, if the non-Part 2 provider copies and pastes relevant information from the Part 2 program record into the patient’s record, would that meet the definition of the “recording” of substance use disorder (SUD) information and thus preclude the application of Part 2 to the non-Part 2 provider’s record? We also have questions about the technical feasibility of these changes given that electronic health records (EHRs) currently are not capable of easily segregating sensitive data from other patient data. SAMHSA should provide further guidance in the final rule or in sub-regulatory guidance about implementation of these regulations. While flexibility is important, it is also helpful to have definitive guidance to aid in compliance.

SAMHSA’s proposed change focuses on non-Part 2 providers, and we ask SAMHSA to clarify whether this would also apply to other entities such as health plans, health care clearinghouses and business associates that receive information from Part 2 providers for non-treatment purposes. For example, a payer entity may receive information for insurance claims, and then create their own records to process and pay the claim. Would these changes also apply to these types of records?

- **Consent Requirements**

Current rules preclude non-treating entities (other than third-party payers) from receiving Part 2 records unless the patient names the specific individual who would receive the record on behalf of the non-treatment entity. The Proposed Rule would eliminate the requirement for the disclosure consent form to name the specific individual to receive patient information on behalf of a given entity.

The Partnership supports these changes and agrees that it benefits patients to remove burdens from applying for and receiving non-medical benefits. In the Proposed Rule, SAMHSA provides a couple of examples of what is meant by “non-medical benefits and services.” We ask that in the final rule SAMHSA provide additional examples or categories of non-medical benefits and services to reduce potential confusion about what kinds of entities this provision applies to. The Partnership also recommends that the Proposed Rule allow for generalized consents, authorizing both disclosures and re-disclosures of Part 2 records for TPO purposes among HIPAA “covered entities,” Part 2 programs, and HIPAA “business associates.”

- **Disclosures for Payment and Health Care Operations**

The Proposed Rule codifies a list of 17 examples of “payment and health care operations” for which a legal holder may disclose Part 2 records to contractors, and clarifies that this list of activities is not intended to cover care coordination or case management. As part of this, SAMHSA interprets case management and care coordination to fall under “treatment, diagnosis, and referral,” and, therefore, requires patient consent for sharing information related to these activities in the same way as for treating providers.

While the Partnership appreciates clarification of what is considered payment and health care operations, we do not agree with SAMHSA’s interpretation that care coordination and case management fall under “treatment, diagnosis, and referral.” We support including care coordination and case management under the definition of health care operations as set forth under HIPAA.

Well-established definitions of “care coordination” and “case management” do not refer to treatment, but instead refer to more operational, or management, based activities. While there is no national definition of “care coordination,” the Department of Health and Human Services’ (HHS’s) Agency for Healthcare Research and Quality defines it as “the deliberate organization of patient care activities between two or more

participants (including the patient) involved in a patient's care to facilitate the appropriate delivery of health care services. Organizing care involves the marshalling of personnel and other resources needed to carry out all required patient care activities, and is often managed by the exchange of information among participants responsible for different aspects of care.”¹ Further, state Medicaid programs use similar interpretations for care coordination and care management. For example, Medicaid managed care contracts in South Carolina define care coordination as “[t]he manner or practice of planning, directing and coordinating health care needs and services of Medicaid MCO Members,” and care management as “a set of activities designed to assist patients and their support systems in managing medical conditions and related psychosocial problems more effectively, with the aims of improving patients’ functional health status, enhancing coordination of care, eliminating duplication of services and reducing the need for expensive medical services (NCQA).”² The federal Medicaid program defines case management as “services furnished to assist individuals, eligible under the State plan who reside in a community setting or are transitioning to a community setting, in gaining access to needed medical, social, educational, and other services . . .”³

Care coordination and case management are essential for whole-person, integrated approaches to care, which have been proven to produce the best outcomes for patients. However, these activities depend on the effective and timely sharing of information. Including care coordination and case management under the definition of health care operations in Part 2 would reduce the likelihood of barriers or delays, promoting more integrated care for patients.

- **Audit and Evaluation**

The Proposed Rule adds clarification and examples of permitted disclosures of Part 2 records without patient consent for audits and program evaluation. The Partnership supports clarification of these provisions, which are part of health care operations under HIPAA, and can help decrease administrative burden and potential confusion.

2. Request for Provisions not Included in the Proposed Rule

- **Protection of SUD Treatment Records.** As SAMHSA allows for increased flexibility to improve care coordination, we also urge you to enhance protections against substance use records being shared with law enforcement for non-treatment purposes. Part 2 information should also not be disclosed for non-treatment purposes to employers, divorce attorneys, or others seeking to use the information against the patient, which the HIPAA privacy framework already easily accommodates. Existing penalties for unauthorized release and use of confidential medical information should apply.
- **Align Part 2 with HIPAA for the purposes of TPO.** The Proposed Rule does not align Part 2 with HIPAA for the purposes of TPO. Access to a patient’s entire medical record, including addiction records, ensures that health care professionals have all the information necessary for safe, effective, high quality treatment and care coordination that addresses all of a patient’s health needs. Inability to have access to information can lead to risks and dangers to individual patients, such as contraindicated prescription medicines and problems related to medication adherence. Obtaining

¹ Agency for Healthcare Research and Quality, *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies*, June 2007. Available at <https://www.ncbi.nlm.nih.gov/books/NBK44015/>.

² <https://msp.scdhhs.gov/managedcare/sites/default/files/MCO%20PP%20October%202019.pdf>

³ 42 CFR §440.169(a).

multiple consents from the patient under the current requirement of Part 2 is challenging and obstructs whole-person, integrated approaches to care. Aligning Part 2 with HIPAA for the purposes of TPO will promote safe, effective, coordinated care for persons with SUDs. SAMHSA has the authority to align Part 2 with HIPAA for the purposes of TPO because 42 USC § 290dd-2 (the Confidentiality Statute) allows the Secretary of HHS to revise the Part 2 regulations. We outline the details of SAMHSA's authority to make this change in our attached legal memorandum.

- **Allow for disclosure and redisclosure of Part 2 records for the purposes of case management and/or care coordination by revising the definition of “qualified services organization” (QSO).** QSO's were created through regulation rather than through legislation, so SAMHSA could use the rulemaking process to change the definition of QSOs to explicitly include care coordination and/or case management services in the definition. This would allow for the disclosure of Part 2 information between a Part 2 program and a QSO for the purposes of care coordination and/or case management services furnished by the QSO for the Part 2 program. As stated previously, care coordination and case management are essential for whole-person, integrated approaches to care. Revising the definition and allowing disclosure and redisclosure of Part 2 records in this manner will facilitate the provision of safe and effective care.
- **Align the requirements for QSO agreements (QSOAs) with the standards for business associate agreements (BAAs) to align Part 2 with HIPAA.** As stated previously, QSOs were created through regulations rather than through legislation, so SAMHSA could use the rulemaking process to change the QSOA requirements so they align with the BAA requirements under HIPAA. Business associates under HIPAA can receive protected health information (PHI) from covered entities and can also disclose PHI to other business associates as long as BAAs are in place. The standards surrounding BAAs are robust and well-established, and SAMHSA could revise QSOAs so QSOs could also have the same ability to share information as HIPAA business associates. QSOs could then have the ability to provide and receive information about care management and care coordination services, with the same protections that HIPAA business associates have, allowing for more integrated care.

Alternatively, SAMHSA could allow QSOAs to be a multi-party agreement for the multi-directional sharing of information covered under Part 2. This agreement could establish a baseline of collective responsibilities for ensuring privacy of the disclosed information while enabling better care coordination.

- **Permit the use of an “opt out” consent process.** SAMHSA could amend Part 2 to allow an “opt out” consent process, where patient information can be used and disclosed like under HIPAA, and the patient would “opt out” if they want more stringent protection. The “opt out” consent process would have a default position where patient information would be permitted to be used and disclosed for TPO like under HIPAA. The patient would receive detailed information initially about the use and disclosures permitted, and if the patient did not want this to happen, they could sign a form that requires consent. This would also facilitate sharing of health information for safe, effective care.

Thank you for the opportunity to comment on the Proposed Rule. Individual members of the Partnership have positions on other provisions not discussed in this letter and their individual letters will address those issues. If you have questions about the Partnership's comment letter please contact me at (202) 449-7658 or gilmore@abhw.org.

Sincerely,

Maeghan Gilmore, Chair
Partnership to Amend 42 CFR Part 2

Cc: HHS Secretary Alex Azar
HHS Deputy Secretary Eric Hargan

Attachment: Legal Memorandum