October 23, 2019

Elinore McCance-Katz, M.D., Ph.D.
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
Department of Health and Human Services

Re: SAMSHA-4162-20: Confidentiality of Substance Use Disorder Patient Records Proposed Rule

Assistant Secretary McCance-Katz:

On behalf of the Premier healthcare alliance serving more than 4,000 U.S. hospitals and health systems and approximately 175,000 other providers and organizations to transform healthcare, we appreciate the opportunity to comment on the Confidentiality of Substance Use Disorder Patient Records proposed rule. With integrated data and analytics, collaboratives, supply chain solutions, and consulting and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Premier runs one the largest population health collaboratives in the country, the Population Health Management Collaborative, with more than 500 participating hospitals, in addition to an extensive Bundled Payment Collaborative with more than 200 participating facilities. Our comments primarily reflect the concerns of our hospitals and health systems, along with their employed and aligned independent physicians.

Premier has strongly advocated for 42 CFR Part 2 reform. Our members are leaders in the redesign of healthcare delivery, providing us unique insight into the importance of timely disclosure of patient information between healthcare providers. Without access to a complete record, providers cannot properly treat the whole person and may, unknowingly, endanger a person's recovery and his or her life. For example, a medical doctor in primary care may not know that he or she is prescribing pain medication to someone with a history of addiction. Premier supports the leadership by HHS and SAMSHA in proposing key Part 2 reform.

PROVISIONS OF THE PROPOSED RULE

Non-Part 2 Providers

The proposed rule clarifies that treatment records created by non-Part 2 providers based on their own patient encounters are not subject to Part 2 as long as any Part 2 records are segregated from the non-part-2 records. This will avoid classification of the entire record under Part 2 protections. SAMHSA is making these changes due to confusion about how rules apply to information shared between Part 2 programs and non-Part 2 providers.

Premier appreciates SAMHSA's efforts to provide clarity around Part 2 records protections and reduce barriers to coordinated care. We ask for further clarification regarding how these changes would be implemented. While flexibility is important, it is also helpful to have definitive guidance to aid in compliance. SAMHSA should provide further guidance in the final rule or in sub-regulatory guidance about how exactly providers could ensure they are complying with the regulations. One area where additional guidance is needed is identification of Part 2 and non-Part 2 providers. While the definition of a Part 2 program includes individuals and entities that "hold itself out" as providing SUD diagnosis,

treatment, or referral for treatment, there exists no requirement for Part 2 providers to identify themselves publicly as a Part 2 covered provider to patients and other stakeholders. Considering the intent of the Part 2 rules to encourage individuals to seek treatment for substance use disorders by imposing stricter requirements about disclosure of substance use-related information, it stands to reason that SUD patients would benefit from the ability to make informed choices about their selection of care provider, including whether that provider is subject to the Part 2 rules.

Additionally, we ask SAMHSA to clarify whether the proposed changes also apply to other entities such as health plans, healthcare clearinghouses and business associates that receive information from Part 2 providers for non-treatment purposes.

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. **Premier supports SAMSHA's proposal to eliminate the requirement for the disclosure consent form to name the specific individual to receive patient information and permit disclosure to organizations without a treating provider relationship.** Premier supports these changes and agrees that it benefits patients to remove burdens from applying for and receiving non-medical benefits. 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 to which this provision applies.

While the current regulations would permit CMS to disclose patient identifying information to providers in alternative payment models (APMs), CMS has removed this information from the monthly data feeds for APM participants. We request that SAHMSA work with CMS to provide claims data containing substance use diagnoses (whether it is the primary purpose of a visit or just listed as a comorbidity) to any providers in APMs. This will enhance the care coordination that APMs are intended to provide.

Disclosures for Payment and Healthcare Operations

The proposed rule codifies a list of 17 examples of "payment and healthcare 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. For SAMHSA, case management and care coordination fall under "treatment, diagnosis, and referral" and, therefore, requires patient consent in the same way as for other treating providers.

Premier does not agree with SAMHSA's interpretation that care coordination and case management fall under "treatment, diagnosis, and referral." We urge SAMSHA to include care coordination and case management under the definition of healthcare operations as set forth under HIPAA.

Definitions of "care coordination" and "case management" do not refer to treatment. There is no national definition of "care coordination" but the 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 healthcare 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 have their own interpretations of 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 healthcare 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 also has its own definition of 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. Including care coordination and case management under the definition of healthcare operations in Part 2 will reduce a barrier to integrated care.

Medical Emergencies

Disclosures of substance use disorder (SUD) treatment records without patient consent are currently permitted in a bona fide medical emergency. Although not a defined term under Part 2, a "bona fide medical emergency" most often refers to the situation in which an individual requires urgent clinical care to treat an immediately life-threatening condition, and in which it's not possible to seek the individual's consent to release of records prior to administering potentially life-saving care.

Premier supports SAMSHA's proposal to broaden the bona fide medical emergencies exception to include declared emergencies from natural disasters that disrupt treatment facilities and service. Major or natural disasters can disrupt access to and operation of treatment facilities and services, and patients should still be able to receive urgently needed services to prevent a medical emergency. Also, in a disaster records can be lost or misplaced and taking the time to find the consent form can have adverse consequences.

Research

Part 2 currently permits the disclosure of patient identifying information for research purposes without patient consent, if the recipient of the patient identifying information is a HIPAA-covered entity or business associate and has authorization from the patient, or a waiver or alteration of authorization (consistent with the HIPAA Privacy Rule) or the recipient is subject to the HHS regulations regarding the protection of human subjects under the Common Rule (at 45 C.F.R. Part 46).

Premier agrees with SAMSHA's proposal to broaden the research exception to include disclosures by a HIPAA-covered entity or business associate to individuals and entities who are not covered by HIPAA or the Common Rule. This will allow researchers to conduct more scientific and public health research on SUD care and SUD populations, and bring more understanding to this area. We do not have comments on the proposed provisions relating to employer-sponsored research or human subjects in clinical investigations.

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[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).

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. Premier supports clarification of these provisions, which can help decrease administrative burden and potential confusion.

REQUEST FOR PROVISIONS NOT INCLUDED IN THE PROPOSED RULE

Align Part 2 with HIPAA for 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 healthcare 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 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.

Disclosure and Redisclosure of Part 2 Records for Case Coordination

Qualified services organizations (QSO) 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 QSO Agreements (QSOAs) Standards with HIPAA Business Associate Agreement (BAA) Requirements

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 to grant QSOs the same ability to share information as HIPAA business associates. QSOs could then 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.

Covered Entity Allowance Reflecting HIPAA's "Friends and Family" Exception

This exception allows the HIPAA covered entity to talk to persons known to be involved in a patient's care, as long as the patient is given the opportunity to object and consent can be given verbally. This could involve the patient deciding to hand the phone to a family member, or the family member being asked if the patient can come to the phone and provide verbal approval for the covered entity to talk with the family member. Part 2 does not have a similar provision and does not allow for verbal consent. This may result in a situation where a patient may not be able to get information about a minor patient. If a state allows a minor to consent to treatment, information cannot be given to a parent unless the minor consents, even if the minor did not consent to treatment in the first place. This creates an unworkable framework for the exchange of healthcare information and coordination of care. Allowing this type of exception in Part 2 would help to facilitate the exchange of healthcare information and care coordination.

"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.

CONCLUSION

Premier supports SAMSHA's efforts to improve patient care and reduce barriers to effective coordination, while continuing to value patient confidentiality, through the proposed changes to behavioral health records. Thank you for the opportunity to comment on the proposed rule. If you have any questions regarding our comments or need more information, please contact Duanne Pearson, vice president, advocacy, at duanne_pearson@premierinc.com or 202.879.8008.

Sincerely,

Blair Childs
Senior vice president, Public Affairs
Premier healthcare alliance