



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 Association for Behavioral Health and Wellness (ABHW) appreciates the opportunity to comment on the Substance Abuse and Mental Health Services Administration's (SAMHSA's) Confidentiality of Substance Use Disorder Patient Records Notice of Proposed Rulemaking (Proposed Rule).

ABHW is the national voice for payers that manage behavioral health insurance benefits. ABHW member companies provide coverage to over 200 million people in both the public and private sectors to treat mental health, substance use disorders (SUDs), and other behaviors that impact health and wellness.

ABHW appreciates SAMHSA's proposals to update 42 CFR Part 2 (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, and would make these changes partially through making changes to definitions under 42 CFR § 2.11.

We appreciate the clarity provided by these changes and ask SAMHSA to also address confusion about whether or not payers are Part 2 providers. The regulations are not clear on this point, and further guidance on this issue would be helpful.

If payers are not considered Part 2 providers, we ask SAMHSA to clarify whether the proposed changes would also apply to entities such as health plans 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.

ABHW supports these changes. Eliminating the requirement for the disclosure consent form to name the specific individual will decrease frustration and delays in applying for and receiving non-medical benefits and services.

- **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. 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.

ABHW does 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 the Health Insurance Portability and Accountability Act (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.”<sup>1</sup> 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).”<sup>2</sup> 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 . . .”<sup>3</sup>

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

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<sup>1</sup> 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/>.

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

<sup>3</sup> 42 CFR §440.169(a).

the definition of health care operations in Part 2 will reduce a barrier to integrated care.

- **Disclosures to Prescription Drug Monitoring Programs**

In a previous 2011 guidance letter, SAMHSA encouraged opioid treatment program (OTP) staff to access state prescription drug monitoring programs (PDMPs), but stated that OTPs could not disclose patient identifying information to a PDMP unless an exception under the Part 2 statute applies. The Proposed Rule allows OTPs to enroll in PDMPs and submit data consistent with applicable state laws.

ABHW is in support of this change. Allowing OTPs to provide PDMPs with data on methadone and buprenorphine dispensed for the treatment of opioid addiction will enhance PDMPs and help in the prevention of SUDs.

ABHW also asks that health plans have access to PDMP data so they can have a more complete picture of the use of controlled substances in the community. If allowed access, these entities could identify patients at risk of overdose or complications and become a strategic partner in preventing and identifying abuse.

PDMPs collect, monitor, and analyze electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing practitioners. The data are used to support states' efforts in education, research, enforcement, and abuse prevention. PDMP data is provided only to entities authorized by state law to access the program, such as health care practitioners, pharmacists, licensing and regulatory boards, law enforcement agencies, state medical examiners or coroners, and research organizations that use de-identified data for analysis and research.

PDMPs are effective tools for states to intervene and prevent fraud, waste, and abuse for controlled substances. If properly implemented with real or recent data, PDMPs can be used to help understand and identify problem prescribers and individuals who are "doctor shopping" for multiple prescriptions. The most effective PDMPs provide real-time data that is easy to interpret and use and require providers to check them before prescribing. A *Health Affairs* article showed a 30% reduction in Schedule II opioid prescriptions when providers were mandated to check their state PDMPs, and this reduction was sustained over time.

Despite this success, very few states permit Medicaid managed care organizations (MCOs), insurance carriers, or private health plans access to PDMP data. If allowed access, these entities could identify patients at risk of overdose or complications because they are seeking prescriptions using multiple providers and paying for them through their insurance or with cash. Additionally, as critical components of an individual's care management, health plans should have access to PDMP data so they can have a more complete picture of the use of controlled substances in the community, including cash pay prescriptions, which they would not necessarily have from pharmacy claims. With access to PDMPs, payers can improve care coordination, clinical decision making, patient health care, and patient safety; they can also become a strategic partner in preventing and identifying abuse.

- **Medical Emergencies**

Currently, disclosures of SUD treatment records without patient consent are 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. The Proposed Rule broadens the bona fide medical emergencies exception to include declared emergencies from natural disasters that disrupt treatment facilities and service.

ABHW is in support of this change. 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 a consent form can have adverse consequences.

- **Research**

Currently, Part 2 allows 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). The Proposed Rule broadens 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 (regarding research on human subjects).

ABHW supports the alignment of Part 2 with HIPAA with regard to broadening the research exception to individuals or entities 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.

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

## **2. Request for Provisions not Included in the Proposed Rule**

- **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 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.


- Allow something similar to 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 health care information and coordination of care. Allowing this type of exception in Part 2 would help to facilitate the exchange of health care information and 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. Please feel free to contact me at [greenberg@abhw.org](mailto:greenberg@abhw.org) or (202) 449-7660 with any questions.

Sincerely,



Pamela Greenberg, MPP  
President and CEO

Cc: HHS Secretary Alex Azar  
HHS Deputy Secretary Eric Hargan

Attachment: Legal Memorandum