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October 25, 2019

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Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
Attn: SAMHSA-4162-20
5600 Fishers Lane, Room 13N02B
Rockville, Maryland 20857

RE: SAMHSA 4162-20: Confidentiality of Substance Use Disorder Patient Records

Altha J. Stewart, M.D.
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Dear Dr. McCance-Katz,

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The American Psychiatric Association (APA), the national medical specialty representing over 38,500 psychiatric physicians and their patients, is pleased to have the opportunity to comment on the proposed changes to the Confidentiality of Substance Use Disorder Patient Records, 42 CFR Part 2 (Part 2). We appreciate the work of the Substance Abuse and Mental Health Services Administration (SAMHSA) to improve care for patients with substance use disorders by recognizing the challenges Part 2 presents to clinicians providing comprehensive care. The administration has taken an important role in educating about the need for alignment of privacy protections for substance use disorder records with those for medical records. **While we support the proposal's intent to allow for better information sharing among Part 2 and non-Part 2 providers, we encourage additional modifications to allow for substance use disorder information to be integrated with the complete patient record in alignment with the Health Insurance Portability and Accountability Act (HIPAA) for treatment, payment, and health care operations (TPO). This would permit essential clinical information to follow the patient through the health system for treatment, payment and operations, while still ensuring proper privacy protections.** Such an approach would still allow preservation of essential features of Part 2, such as precluding law enforcement, employers, attorneys, and others access to patient information for non-treatment purposes.

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Our members are concerned about the impact of Part 2 on patient care. Under the current regulation, a Part 2 covered treatment program is not allowed to disclose a patient's treatment record without patient consent, including the type of information to be disclosed, for how long, and to whom. A disclosure must be accompanied by a notice prohibiting redisclosure. A clinician receiving Part 2 information from a Part 2 covered entity must abide by the Part 2 protections. While we recognize SAMHSA does "not intend this rule to result in the creation of separate servers or health IT

systems for Part 2 documents,” this requirement still creates major barriers to information sharing and is logistically difficult to manage within current Electronic Health Records systems. Although initiatives such as Data Segmentation for Privacy (DS4P) standards are a step in the right direction, these features are not widely available and a standard approach to electronic tagging and sequestration of sensitive information remains to be established. Without access to a complete record, providers cannot properly treat the whole person, and may, unknowingly, disrupt a person’s recovery or endanger their life. For example, a doctor may not know that he/she is prescribing pain medication to someone with a history of addiction or that can cause a potentially fatal drug/drug interaction. Furthermore, if a patient is being treated with an opioid agonist, a doctor in an acute care setting may not be able to verify this information and continue treatment, placing the patient at risk of relapse. The restrictions also make it difficult for a patient with substance use disorders (SUDs) to benefit from high-quality, coordinated-care models.

However, we do appreciate the steps taken in the proposal to address some of these challenges. Specifically:

- Clarifying which treatment records, created by a non-Part 2 provider, based on their own patient encounter, is not subject to Part 2.
- Clarifying emergencies resulting from natural disasters that disrupt treatment facilities and services will meet the definition of a “bona fide medical emergency”.
- Allowing information to be shared with an entity (e.g., the Social Security Administration) without naming a specific person as the recipient for disclosure.
- Allowing oral statements made by a Part 2 provider to a non-Part 2 provider (with the requisite patient consent) to be transcribed into a patient’s record without being covered by Part 2.
- Allowing legitimate stakeholders to obtain data from SUD treatment records for the purpose of conducting scientific research, including public health related research, in a manner that parallels research related data use under HIPAA and under the Common Rule.

In addition to the above, we recommend the following changes be included in future rulemaking to further facilitate the exchange of necessary information:

Definitions, Applicability, and Prohibition on Re-Disclosure (§2.11, §2.12, and §2.32)

We support the change in the definition of “records” in §2.11 that will allow an exception for a Part 2 provider to orally share information with a non-Part 2 program for treatment purposes, with patient consent, and for such information to be transcribed into a patient’s medical record. This flexibility will enhance patient safety and allow for necessary care coordination.

We urge you to provide further clarity on the definition of a Part 2 Program. The current definition is vague and leads to confusion and uncertainty as to applicability of Part 2. Specifically, of concern is how a Program is defined to include “an individual or entity who holds itself out as providing, and provides substance use disorder diagnosis, treatment, or referral for treatment; or ... Medical personnel or other staff in a general medical facility or general medical practice whose primary function is the provision of

substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.” **We strongly recommend the proposed rule explicitly state the “principal practice” standard established in a revised 2010 FAQ. The guidance clarified that primary care providers only meet Part 2’s definition of a program if their principal practice (over 50 percent) consists of providing the range of covered Part 2 services and they hold themselves out as providing the same.**

Consent Requirements (§2.31)

In the NPRM, SAMHSA proposes changes in §2.31 that would permit a patient to consent to the disclosure of his or her Part 2 treatment records to an entity, without naming a specific person as the recipient for the disclosure. **APA supports this change. We further recommend that SAMHSA consider additional revisions which would (1) permit generalized consents, authorizing both disclosures and re-disclosures of Part 2 records for purpose of TPO among HIPAA “covered entities,” Part 2 programs, and HIPAA “business associates” and (2) permit the use of an “opt out” consent process, where the Part 2 records could be disclosure and re-disclosed for TPO purposes, consistent with HIPAA, unless the patient “opted out.”** Nothing in 42 U.S.C. §290dd-2, itself, appears to impose a redisclosure prohibition or specify the unique criteria of a valid consent with the specificity that Part 2 currently requires. Therefore, such additional changes would further align Part 2 with HIPAA and the further integration of Part 2 records with other medical records, which we support.

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 (§2.11).

Qualified Service Organizations (QSO) were created through regulation rather than through legislation. Thus, **we recommend SAMHSA 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. 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.

Disclosures to Central Registries and PDMPs (§2.34 and §2.36)

SAMHSA’s proposed changes to §2.34 and §2.36 would allow non-OTP (opioid treatment program) providers to become eligible to query a central registry, in order to determine whether their patients are already receiving opioid treatment through a member program and prevent multiple enrollments. This change seems consistent with CMS proposals under the 2020 Outpatient Prospective Payment System (OPPS) rulemaking. Additionally, the proposed changes would allow OTPs to enroll in a state prescription drug monitoring program (PDMP) and report data into the PDMP when prescribing or dispensing medications on Schedules II to V, consistent with applicable state law. **The APA supports these changes to help prevent duplicative enrollments in SUD care, duplicative prescriptions for SUD treatment, and adverse drug events related to SUD treatment. We further recommend that PDMP systems notify**

PDMP users that information related to medications dispensed from OTPs may be incomplete. Protections should also be implemented to limit law enforcement access to data on a case-by-case basis, through a subpoena, and within a tightly regulated process.

Undercover Agents and Informants (§2.67)

SAMHSA proposes changes to §2.67 that would allow court-ordered placement of an undercover agent or informant within a Part 2 program to be extended to a total period of 12 months, starting on the date that the undercover agent or informant is placed within the program, and courts would also be authorized to further extend the period of placement through a new court order. **APA opposes this change. No provider or patient group is requesting this change. The change does not purport to improve care coordination or patient safety. There is no evidence that the current policy is encumbering ongoing investigations of Part 2 programs.**

Breach Notification

As changes are made to Part 2 to allow for improved information sharing, we urge you to align with the Health Insurance Portability and Accountability Act requirements for a breach of an individual's protected health information (PHI) and penalties. Currently, there is no requirement under Part 2 to report or inform if a breach has happened. **We strongly encourage SAMHSA to identify ways, such as this, to increase protections against the inappropriate sharing of information.**

Thank you again for your work to improve care coordination for patients with substance use disorders. It is our goal to ensure all patients have access to high-quality, evidenced-based integrated care. Reducing the barriers to providing such care is a main priority of the APA. If you have any questions or concerns, please contact Michelle Dirst, APA's Director of Practice Management and Delivery Systems Policy at mdirst@psych.org or at 202-559-3716.

Sincerely,



Saul Levin, MD, MPA, FRCP-E
CEO and Medical Director