American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

October 24, 2019

Re: SAMHSA–4162–20/ RIN 0930–AA32

Elinore F. 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
5600 Fishers Lane
Rockville, Maryland 20857

Re: 42 CFR Part 2: Confidentiality of Substance Use Disorder Patient Records Proposed Rule

Dear Dr. McCance-Katz:

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on a proposed rule from the Substance Abuse and Mental Health Services Administration (SAMHSA) that would modify the 42 CFR Part 2 ("Part 2") regulations. One of ACEP's top priorities is to ensure that patients with substance abuse disorder (SUD) receive timely and appropriate care. We are working to help reduce the stigma associated with SUD, which we believe impedes access to care and treatment of the disease. At the same time, it is essential to guarantee that the privacy and security of our patients' data are protected at all times. Overall, we appreciate SAMHSA's efforts to modernize Part 2 and provide access to vital data while still protecting patient privacy. We believe that the majority of the proposed changes in the proposed rule are appropriate and necessary to align the Part 2 requirements with how Part 2 programs and non-Part 2 providers currently exchange information and how non-Part 2 providers, including many of our members, provide treatment to their patients with SUD.

Non-applicability of Part 2 to Substance Use Disorder Treatment Records Created by Non-Part 2 Health Care Provider

To help mitigate confusion about whether medical records kept by non-Part 2 providers may in some cases be subject to Part 2 requirements, SAMHSA is proposing to amend the applicability provision to clarify that any new records created by the non-Part 2 provider in its direct patient encounter(s) would not be subject to Part 2 as long as the non-Part 2 provider segregates any Part 2 records previously received from the Part 2 program. ACEP appreciates this clarification as it would allow non-Part 2 providers to earmark their own records created from their interactions with patients as not subject to Part 2 requirements instead of being constantly confused about what part of a patient's record is subject to the Part 2 requirements. We believe that this policy could help facilitate meaningful communication between Part 2 programs and non-Part 2 providers.

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Consent Requirements

ACEP supports SAMHSA's proposal to amend the current Part 2 regulations to clarify that patients may consent to disclosures of Part 2 information to organizations withholding the specific names of individuals within that organization. Patients have noted that they want to provide written consent for the Part 2 program to share their Part 2 record but are unable to identify a specific person who would receive that information. This is especially true for patients who are seeking non-medical services or benefits, such as Social Security. We agree that it does not make sense for that patient to have to identify a specific person within the Social Security Administration to provide consent. Therefore, we urge SAMHSA to finalize the proposal as proposed.

Proposed Flexibility to Disclose Patient Records

Registries

The rule proposes two changes specifically aimed at the opioid crisis. First, SAMHSA proposes to allow all providers that have a treating relationship with a patient to access Part 2 central registry databases to determine whether that patient is enrolled in a SUD withdrawal management or treatment program, even if a provider is not an opioid treatment program (OTP). If finalized, this will prevent duplicative enrollments and prescriptions for excessive opioids, as well as prevent any adverse effects that may occur as a result of drug interactions with other needed medications.

Currently, a Part 2 program may seek written patient consent to disclose treatment records to a central registry. In turn, the central registry may only disclose patient contact information for the purpose of preventing enrollments in multiple Part 2 programs. Accordingly, ACEP strongly supports SAMHSA's proposal to change the current construct, along with SAMHSA's rationale that allowing non-OTP providers to consult registries would help "to ensure patient safety, and to prevent duplicative treatment plans and medications or medication doses that could place a patient receiving SUD treatment at risk."[1]

Disclosure to Prescription Drug Monitoring Programs (PDMPs)

The second proposed change aimed at the opioid crisis would allow disclosures of Part 2 records to state PDMPs that are set up to collect, analyze, and make available prescription data on controlled substances prescribed by practitioners and non-hospital pharmacies. Current SAMHSA policy is that OTPs are not required to report methadone or buprenorphine dispensing to their states' PDMP, and SAMHSA has previously released guidance stating that OTPs could not disclose patient identifying information to a PDMP unless an exception applies. However, SAMHSA no longer supports this prohibition, given the current public health crisis arising from opioid misuse and abuse. Therefore, SAMHSA is proposing to allow Part 2 programs, including OTPs and lawful holders, to enroll in PDMPs and submit the dispensing data for controlled substances required by states. SAMHSA would require Part 2 providers to obtain written consent from the patient whose identifying information will be disclosed prior to making such reports.

ACEP strongly agrees that this proposal would reduce duplicative enrollments in SUD care, duplicative prescriptions for SUD treatment, adverse drug events related to SUD treatment, and medication diversion. ACEP supports the

[1] 42 CFR Part 2: Confidentiality of Substance Use Disorder Patient Records Proposed Rule. 84 Fed. Reg. 44576 (August 26, 2019).

overall principle that the PDMP can simply inform the querying physician that a patient is currently receiving treatment in an OTP (without revealing any other information from the patient's OTP medical or counseling record).

However, in light of the current devastating opioid epidemic, ACEP believes that the proposal could potentially be strengthened to ensure that PDMPs are always informed of patient participation in OTPs (without revealing any further records or a patient's current OTP medication dosage). Patients treated in office-based opioid use disorder treatment programs (OBOTs) are already identified in PDMPs simply by a prescription for buprenorphine. Nevertheless, there is currently no way for a clinician to know that a patient is participating in an OTP (if the patient desires to conceal that information), before prescribing controlled substances. This information gap has had deleterious effects on patients in OTPs.

Disposition of Records

Part 2 regulations also address requirements for the disposition of records from a discontinued Part 2 program, stating specifically that records which are electronic must be "sanitized" – rendering the patient identifying information non-retrievable – within one year of the discontinuation of the program. SAMHSA clarifies that when a SUD patient sends an incidental message to the personal device of an employee of a Part 2 program, the employee will be able to fulfill the Part 2 requirement for "sanitizing" the device simply by deleting that message, rather than requiring that the phone or device is confiscated or destroyed. ACEP supports this proposal, as we believe that it would reduce unnecessary administrative burden.

Medical Emergencies

The current Part 2 regulation includes an exemption for medical emergencies. Specifically, disclosures of SUD treatment records are permitted without patient consent in a "bona fide medical emergency." While medical emergencies most often refer to individual life-threatening conditions that require immediate medical attention, SAMHSA proposes to expand this exemption to include major and natural disasters within the definition of medical emergencies. ACEPs supports this proposal, as we believe that expanding the current exemption is necessary to ensure that patients continue to have access to treatment when the Part 2 providers are unable to operationalize their existing policies for obtaining patient consent.

However, even with this regulatory change, ACEP still believes that more must be done to improve the flow of information during disasters. Emergency physicians and other emergency medical service (EMS) providers on the ground must have access to real-time data regarding all of the available health care resources in the affected region. Unfortunately, emergency physicians do not always know where or how to find this essential information. ACEP surveyed its members in May 2018 and found that over a quarter of emergency physicians did not have complete access to real-time data when responding to a natural or man-made disaster or mass casualty incident.[2] This is not acceptable, and we strongly encourage the Administration to help improve providers' access to clinical data and information on available health care resources during these devastating events.

[2] ACEP New Release, "Most Emergency Physicians Report Hospitals Lack Critical Medicines; Not "Fully Prepared" for Disasters, Mass Casualty Incidents," May 22, 2018, http://newsroom.acep.org/2018-05-22-Most-Emergency-Physicians-Report-Hospitals-Lack-Critical-Medicines-Not-Fully-Prepared-for-Disasters-Mass-Casualty-Incidents.

Research

SAMHSA proposes to allow the disclosure of Part 2 patient data by a HIPAA-covered entity to individuals and organizations that are neither HIPAA-covered entities, nor subject to the Common Rule, for the purpose of conducting scientific research. The agency stipulates that such disclosures must be consistent with the HIPAA Privacy rule, thus aligning the requirements of Part 2 "with the Privacy Rule around the conduct of research on human subjects."[3] SAMHSA also proposes to clarify that as part of employer-sponsored research, research disclosures may be made to the workforce of a HIPAA-covered entity provided that the covered entity meets all requirements of the Privacy Rule and/or Common Rule. The agency also proposes that research disclosures be permitted to recipients that are covered by FDA regulations governing the protection of human subjects in clinical investigations. ACEP applauds the proposal to allow disclosures for research to non-HIPAA covered entities provided that any such data will be disclosed in accordance with the HIPAA Privacy Rule. This will enable public health agencies and others, which are neither HIPAA covered entities nor business associates, to obtain Part 2 data to better research the impact of the opioid epidemic.

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org

Sincerely,

Vidor E. Friedman, MD, FACEP
ACEP President

[3] 84 Fed. Reg. 44578 (August 26, 2019).