October 25, 2019

Comments submitted electronically to Docket: HHS-OS-2019-0011

Re: Confidentiality of Substance Use Disorder Patient Records

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the efforts of the Department of Health and Human Services (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA) to propose changes to the Confidentiality of Substance Use Disorder Patient Records regulations ("Proposed Rule"). As noted in the Proposed Rule, advances in care delivery, particularly the need to facilitate information exchange for safe and effective substance use disorder care, should also consider privacy concerns of patients seeking treatment for substance use disorder.

Founded in 1852 as the American Pharmaceutical Association, APhA represents 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

Pharmacists are medication experts on care teams and are playing many different roles in caring for patients, including those with substance use disorders (SUDs). Pharmacists are well-positioned to help prevent adverse events and negative outcomes. As SAMHSA finalizes the Proposed Rule, APhA encourages the agency to determine whether efforts to prevent adverse events and improve care coordination achieve the desired outcomes and to monitor for unintended consequences. APhA offers the following responses to the Proposed Rule for SAMHSA's consideration.

I. Definition of "Records"

APhA appreciates SAMHSA's efforts to amend the definition of "records"[1] so that a non-part 2 provider who orally receives a protected SUD record from a part 2 program may communicate with a patient, without fear that the non-part 2 provider's own records would

[1] According to the Proposed Rule, "*Records* means any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient (*e.g.*, diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts), provided, however, that information conveyed orally by a part 2 program to a non-part 2 provider for treatment purposes with the consent of the patient does not become a record subject to this Part in the possession of the non-part 2 provider merely because that information is reduced to writing by that non-part 2 provider. Records otherwise transmitted by a part 2 program to a non-part 2 provider retain their characteristic as records in the hands of the non-part 2 provider, but may be segregated by that provider. For the purpose of the regulations in this part, records include both paper and electronic records."

become covered by part 2. Since SAMHSA is also proposing to enable OTP reporting to PDMPs, APhA anticipates health care providers may capture information learned in a PDMP in their own records. APhA encourages SAMHSA to consider clarifying that information reported to a PDMP by an OTP that is subsequently recorded by a non-part 2 providers is also not covered by part 2.

II. Disclosure to Prescription Drug Monitoring Programs (PDMPs)

APhA appreciates SAMHSA's efforts to address disclosures to PDMPs. While APhA is sensitive to privacy concerns when information is reported to a PDMP, our comments are limited to pharmacists' use of PDMPs when interacting with patients and other health care providers. APhA encourages SAMHSA to consider patient perspectives as it finalizes the Proposed Rule.

In the Proposed Rule, SAMHSA recognizes the importance of communicating certain information about a patient's treatment to help a patient's other care providers, including pharmacists, prevent adverse events and improve care. Currently, part 2 providers do not report opioid use disorder treatment information to a PMDP. As a result, pharmacists, including those working in community pharmacies and other settings, may not be aware that a patient is receiving opioid use disorder treatment from a part 2 provider unless the patient proactively provides such information. APhA's members have indicated that it would help improve care if information about a patient's medications for opioid use disorder was accessible, such as through a PDMP.

SAMHSA proposes to allow part-2 providers to report to their state's PDMP when furnishing medications if the patient's written consent is obtained. However, the Proposed Rule does not elaborate on written consent requirements when obtained for the purpose of reporting to a PDMP. While the Proposed Rule does address written consent being provided to individuals and entities (e.g., Social Security Administration), it is not clear how consent requirements should be applied for PDMP reporting, especially given the additional data sharing relationships most PDMPs have in place with other PDMPs and law enforcement access. APhA encourages SAMSHA to clarify written consent requirements for disclosures to a PDMP as this may help facilitate part-2 providers reporting to PDMPs and ensure patients understand how their information may be used if consent is provided.

III. Education

As SAMHSA is aware, part 2 requirements can be confusing to both part 2 and non-part 2 providers and health care entities. While several of the proposed changes aim to reduce such confusion, APhA encourages SAMHSA to provide education and resources to help improve awareness of the changes. In addition, APhA suggests SAMHSA follow-up with health care providers, including pharmacists, after the rule is finalized to determine whether communications have improved, any unintended consequences have been identified, and to ascertain future opportunities for rulemaking.

Thank you for the opportunity to provide comments to SAMHSA regarding the Proposed Rule. We support the SAMHSA's ongoing efforts to improve care for patients with SUDs. If you have any questions or require additional information, please contact Jenna Ventresca, Director, Health Policy at jventresca@aphanet.org or by phone at (202) 558-2727.

Sincerely,

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Executive Vice President and CEO