



American Pharmacists Association[®]
Improving medication use. Advancing patient care.

April 11, 2016

[Submitted electronically to <http://www.regulations.gov>]

The Substance Abuse and Mental Health Service Administration
Department of Health and Human Services
Attention: SAMHSA-4162-200
5600 Fishers Lane, Room 13No2B
Rockville, MD 20857

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

Dear Sir/Madam:

The American Pharmacists Association (“APhA”) appreciates the opportunity to provide feedback in response to the Department of Health and Human Services’ (HHS) Notice of Proposed Rulemaking Regarding “Confidentiality of Substance Use Disorder Patient Records” (hereinafter, the “Proposed Rule”). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 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, physicians’ offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA is committed to working with HHS’ Substance Abuse and Mental Health Services Administration (SAMHSA) and other health professionals and stakeholders to update and modernize regulations governing the confidentiality of substance abuse records which were last substantively updated in 1987. New delivery models focused on better integrating care has been a significant impetus for changes to privacy requirements in 42 CFR Part 2 due to the critical role communication and sharing of information between members of the health care system plays in optimizing patient care and outcomes. For example, pharmacists, as the medication expert on the patient’s health care team, rely on information from other sources, such as other health care professionals, health records and patients, when providing their services. Therefore, we applaud SAMHSA’s decision to modernize 42 CFR Part 2 and ease certain requirements so these patients are not unintentionally prevented from participating in alternative care delivery models that rely on care teams. In addition, APhA appreciates the Agency’s decision to seek public comment from pharmacists and the wide variety of stakeholders involved in organizations and networks designed to improve patient care and care coordination across the care spectrum.

I. Definition of program

APhA supports SAMHSA's effort to make sure patients with a history of substance use disorder are not discouraged from participating in alternative payment models. However, APhA is concerned that because of the Proposed Rule's definition of "Program,"¹ which describes the individuals and entities needing to comply with confidentiality requirements, pharmacists and pharmacies could unintentionally be subject to the requirements of 42 CFR Part 2.

As SAMHSA is aware, the pharmacist's role in helping curb prescription drug abuse is growing, in part, due to pharmacists' accessibility in communities. APhA is concerned that inadvertently including pharmacists and pharmacies under the Proposed Rule's requirements would discourage pharmacists and pharmacies from participating in efforts to help address our Nation's prescription drug abuse and misuse epidemic. Pharmacists, as medication experts, provide valuable insight regarding patients and their prescriptions and are well-positioned to help identify and refer patients in need of treatment for substance use disorder. Additionally, pharmacists and pharmacies are involved in dispensing buprenorphine and in some states, pharmacists can prescribe naloxone. Specifically, we believe that the Proposed Rule's scope over individuals or entities that "holds itself out as providing . . . substance use disorder diagnosis, treatment, or referral" could be interpreted to include pharmacists (and pharmacies) who dispense medications that could be used by persons receiving treatment, even though the pharmacist's primary practice is not substance abuse treatment and not intended to be covered by the Proposed Rule's requirements. Such an overly inclusive interpretation could have the unintended consequence of limiting options for persons in need of treatment and could further worsen the prescription drug abuse and misuse epidemic. Therefore, APhA requests that SAMHSA clarify that pharmacists and pharmacies are not covered by the Proposed Rule. However, if it is SAMHSA's intention to include pharmacies and pharmacists, APhA requests that the Proposed Rule apply only to pharmacists and pharmacies whose practice is primarily related to substance use disorder. In addition, SAMHSA should clarify that stocking or dispensing naloxone is not considered substance abuse treatment so as to encourage pharmacies to make these life-saving medications accessible.

Furthermore, if it were interpreted that pharmacists and pharmacies were broadly included under this Proposed Rule, implementation would create a significant financial burden to pharmacies, which are often small businesses. As noted in the Proposed Rule's Regulatory Impact Analysis, facilities that need to comply with 42 CFR Part 2 are expected to incur costs of approximately \$8,000 to add new functionality to existing medical records applications. We believe this is underestimated as existing pharmacy management system functionality may not be currently available due to the limited applications to date of electronic medical records in pharmacy practice. Thus the cost to pharmacies to add new functionality and applications would be significantly more than \$8,000. Also, the aforementioned cost does not include other software or security requirements, training, or other implementation costs associated with the Proposed Rule. Pharmacies' implementation cost is especially important to consider since pharmacies may have only a small proportion of patients with a history of substance use disorder, and the cost of adhering to the Proposed Rule essentially discourages pharmacies from dispensing needed medications like naloxone and buprenorphine. APhA suggests that SAMHSA consider methods that would significantly decrease the cost of implementation to entities affected by the Proposed Rule if pharmacists and pharmacies are to adhere to the Proposed Rule's requirements.

¹ The definition of "Program" as noted in §2.11 includes an individual or entity, (other than a general medical facility or general medical practice) who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment".

II. Education for health care professionals

As with many other changes in the health care industry, educating health care professionals will be an important step towards effective implementation of 42 CFR Part 2's privacy protections. Because of the pharmacy profession's growing role in substance abuse treatment, we ask that SAMHSA develop education materials targeted to pharmacists. APhA looks forward to working with SAMSHA and other stakeholders on the education efforts related to the Proposed Rule.

III. Disclosures and redisclosures

APhA agrees that restrictions on disclosures are necessary to help protect patient privacy. However, we are concerned that tracking and communicating disclosures securely will be difficult given current systems may not have the required functionality and as mentioned above, the costs associated with implementing security measures.

Regarding redisclosures, the Proposed Rule places a general prohibition on redisclosure of "information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a substance use disorder..." and "illnesses that are brought about by drug or alcohol abuse may reveal that a patient has a substance use disorder". APhA is concerned that it will be difficult for health care practitioners, including pharmacists, to determine which illnesses are typically "brought about" by drug or alcohol abuse. And more importantly, the potential harm that could result if such information, like that related to organ function, is not communicated.

Finally, any best practices SAMHSA considers related to securing patient information should take into account feasibility, such as time and cost to implement.

IV. E-prescribing and prescription drug monitoring programs

APhA was surprised to learn that SAMHSA intentionally left out regulations regarding e-prescribing and prescription drug monitoring programs (PDMPs). While we agree that it may be too early for sweeping regulations, we believe that some guidance should be provided as use of e-prescribing and PDMPs is unavoidable and often required by state law. For example, our interpretation of the Proposed Rule is that a pharmacy receiving an electronic prescription from a Part 2 Program must obtain patient consent to disclose that information, even if that disclosure is made to a PDMP. However, pharmacy systems do not distinguish Part 2 programs or providers, making compliance extremely difficult. Since several states require pharmacies to report such information to the PDMP, pharmacists would be forced to decide which to violate: SAMHSA regulation or state law. Thus, we request that SAMHSA provide guidance or issue a statement advising that they will not view disclosures related to e-prescribing or PDMPs as a violation of 42 CFR Part 2.

Thank you for your leadership and work on this issue. We look forward to supporting your efforts and working with SAMHSA to improve the care and treatment of individuals with a history of substance abuse. If you have any questions please contact, Jenna Ventresca, Associate Director for Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,

Thomas E. Menighan

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