American Hospital Association™
Advancing Health in America

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Deepa Avula
Chief of Staff/Director of Office of Financial Resources
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane, Room 17E41
Rockville, MD 20857

RE: SAMHSA-4162-20; Confidentiality of Substance Use Disorder Patient Records, Proposed Rule

Dear Ms. Avula:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the proposed revisions to the regulation governing the confidentiality of substance use disorder patients' records. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), the proposed revision will allow greater flexibility in sharing patient information to support new models of integrated care that require information exchange for care coordination, rely on an electronic infrastructure for managing and exchanging patient information, and focus on performance measurement and improvement within the delivery system.

The AHA recognizes that SAMHSA is statutorily constrained in making structural amendments to the regulations under 42 CFR Part 2 ("Part 2") and appreciates the revisions and clarifications proposed in this rule, which may improve aspects of care coordination for patients with substance use disorders (SUDs). Because the proposed rule would not change the basic framework of Part 2, which significantly impedes the robust sharing of patient information necessary for effective clinical integration, **we continue to urge full alignment of the Part 2 regulation with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulation as the proper and effective solution to eliminating barriers to the sharing of patient information.**

We understand that SAMHSA lacks the authority to circumvent the existing statutory structure; however, we believe that the agency could do more to align these two sets of requirements. Moreover, while reform of the statute remains the purview of the legislative branch, **we urge SAMHSA to prioritize educating Congress about the significant burdens the existing statutory framework imposes for the integration of SUD and physical health care, and to work with legislators to resolve the statutory conflicts that prevent full alignment of Part 2 with the HIPAA requirements that govern all other patient health information.**

PROPOSED REVISIONS

SAMHSA proposes steps to clarify existing requirements under Part 2 as well as amend a few sections to ease the burden on providers in both Part 2 and non-Part 2 programs.

Applicability and Re-disclosure. Much of the rule focuses on adding clarifying language to the existing regulations; one of these provisions would further explain the distinctions between records created by "non-Part 2 providers" and those disclosed by Part-2 providers to non-Part 2 providers. We agree with SAMHSA that the current restrictions on information sharing are so complex regarding who and what type of information is subject to certain requirements that many providers are reticent to take on patients with SUD; we also agree that further clarification is needed. However, the clarifications that SAMHSA proposes to codify would explain only that any records created by a non-Part 2 provider, even if they mention information about SUD status and treatment, are not automatically subject to Part 2 restrictions.

We appreciate this language; however, providers actually need additional clarity in the definition of a "Part 2" versus a "non-Part 2" provider. The statute defines Part 2 providers as alcohol and drug treatment programs that receive federal funds in any form, including Medicare or Medicaid funding or via their tax-exempt status, and "hold themselves out as providing" alcohol or drug abuse diagnosis, treatment or referral for treatment.

The proposed rule retains an overly broad applicability to treatment programs and providers in the definition of the regulation's applicable scope. While SAMHSA carved out general medical facilities and medical practices from the scope of the Part 2 regulation in what at first seems broad, the agency simultaneously restricts that carve out in the definition. Specifically, general facilities and practices are excluded from the scope of the Part 2 regulation, and thereby from complying with the significant regulatory constraints imposed on sharing a patient's behavioral health data, *only if* they do not "hold themselves out" as providing SUD diagnosis, treatment or referral for treatment and the "primary function" of their medical personnel or other staff is not the

provision of, and they are not identified as providing, such services. **We believe that further clarification on who is included in these definitions is needed.**

In the current care environment, where there is expanding emphasis on integration and coordination of behavioral health care with physical health care and where the prevailing location for delivery of that care is the general medical facility or medical practice, Part 2 requirements are likely to be interpreted by providers as applying to many more treatment settings and providers. We, therefore, urge SAMHSA to issue more detailed guidance about how providers should determine whether they are "holding themselves out," or whether the "primary function of their medical personnel or other staff is the provision of and they are identified as providing" the enumerated services. In other words, SAMHSA should provide definitions as to what "holding oneself out as providing" specifically entails — is this designation limited to organizations that advertise drug treatment services, or does it extend to those who are known to locals as providing these services? Does it extend to any organization that has billed for such services?

Opioid Treatment Program (OTP) Enrollment in Prescription Drug Monitoring Programs (PDMPs) and Non-OTP Querying of Central Registries. SAMHSA proposes to permit OTPs to report patient identifying information (PII) *with the patient's written consent* into a PDMP, and would allow non-OTP providers to query central registries to determine whether specific patients are receiving opioid use disorder (OUD) treatment.

PDMPs are centralized, statewide databases that collect, analyze and make available prescription data on controlled substances prescribed by practitioners and non-hospital pharmacies. Depending on state requirements, pharmacies must submit prescription data on Schedule II-V controlled medications (including opioids). More robust PDMP programs are associated with greater reductions in prescription opioid overdoses, as the data allows providers to ensure that a patient is not receiving multiple prescriptions.

Currently, OTPs (health care facilities like methadone clinics that primarily provide OUD treatment) are not required to report methadone or buprenorphine dispensing to PDMPs. In fact, in a 2011 guidance letter, SAMHSA stated that OTPs were prohibited from disclosing PII to a PDMP (with some exceptions). However, due to increasing prescription drug misuse, the lack of OTP data in a PDMP may put patients at risk for duplicate or contraindicated prescriptions. For example, a patient may be receiving buprenorphine as part of a medication-assisted course of therapy at an OTP, but a prescribing provider at an emergency department would not know that when prescribing an additional opioid for pain. Thus, SAMHSA would allow OTPs to enroll in a PDMP and contribute information about services they provide to their patients *with those patients' consent*.

The Centers for Disease Control and Prevention calls PDMPs "among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk." This proposal would improve the information contained in PDMPs. We note that the impact of PDMPs is limited by lack of comprehensive information and interoperability across states and, sometimes, by poor usability. All states can improve the usability of their PDMPs in additional ways, and federal guidelines can help promulgate best practices and highlight important data elements. We outline several recommendations in our recent comment letter in response to the Office of the Assistant Secretary for Planning and Evaluation's Request for Information on Ensuring Patient Access and Effective Drug Enforcement; we recommend SAMHSA review those recommendations to maximize the effectiveness of this proposed provision.

Disclosures to Entities without Naming a Recipient. SAMHSA would amend the regulations to no longer require a specific name within an organization in order to disclose records.

Under the current requirements, when disclosing protected information to entities that do not have a treating-provider relationship with the patient, patients must identify individuals to whom the disclosure may be made. However, patients may wish to disclose this information to entities for which they do not have a specific name, like when applying for assistance from government programs like Social Security or for halfway house programs. SAMHSA would remove the current requirement to name an individual, which can result in frustration and delays in receiving services. **The AHA supports this change and believes it will reduce the burden and delay associated with accessing necessary recovery services and benefits.**

Natural Disasters as "Bona Fide Medical Emergencies." In this proposed rule, SAMHSA would add declared major and natural disasters to the list of exceptions when it is permitted to disclose patient records without consent.

Disclosures of SUD records are permitted *without* patient consent in a "bona fide medical emergency," that is, when an individual requires immediate clinical care to treat a life-threatening condition and it is infeasible to seek written consent to release records. Disasters like hurricanes or wildfires may disrupt usual access to services, and patients may have to seek care at facilities that do not have full access to their records. In such cases, it would be overly burdensome to follow disclosure requirements. The proposed exception would apply only when a state or federal authority declares a state of emergency as a result of the disaster and the Part 2 program is closed and unable to provide services or obtain informed consent; the exception would be immediately rescinded once the Part 2 program resumes operations. **The AHA appreciates that SAMHSA acknowledges the need to quickly and safely share information during times of crisis and supports this change.**

ADDITIONAL RECOMMENDATIONS TO ALIGN PART 2 WITH HIPAA

The AHA has long advocated that the HIPAA requirements be the prevailing nationwide standard for protecting the privacy and security of all patient information. While by no means without its own regulatory impediments to the robust use and disclosure of patients' personal health information (PHI) necessary to support clinical integration and population health improvement, the HIPAA regulation generally permits covered entities, like hospitals and other health care providers, to share PHI for purposes of treatment, payment and health care operations without having to obtain each individual patient's authorization.

The AHA remains unwavering in its support for full federal preemption under HIPAA. Because HIPAA currently does not preempt other federal or state laws that require information be treated and handled differently, of which the Part 2 regulation is a prime example, the resulting patchwork of health information privacy requirements remains a significant barrier to the robust sharing of patient information necessary for coordinated clinical treatment and improving the quality of care and population health. In addition, the patchwork of differing requirements poses significant challenges for providers' use of a common electronic health record that is a critical part of the infrastructure necessary for effectively coordinating patient care and maintaining population health.

The separate privacy structure required by Part 2 stymies the integration of behavioral and physical health care because patient data related to SUD treatment cannot be handled like all other health care data. Estimates are that one in four Americans experiences a behavioral illness or SUD each year, and the majority of these individuals have comorbid physical health conditions. Moreover, primary care has become the prevailing location for patients to receive treatments that address all their health needs, behavioral as well as medical. Evidence confirms that integrating mental health, substance use and primary care services produces the best outcomes and proves the most effective approach to caring for people with multiple health care needs.

Furthermore, at the highest stage of care integration, the focus is not merely on improving outcomes for individual patients, but also on improving population health while reducing total costs for the overall health care system. To meet the needs of the many individuals with complex health needs, however, providers must be able to share patient SUD treatment information as easily as information related to physical health for purposes of treatment, payment and health care operations (i.e., without having to obtain each individual patient's authorization as HIPAA permits).

The requirement in the Part 2 regulation for individual patient consents to make sharing of SUD treatment information permissible seems to overemphasize the social harms that disclosing such clinical information is perceived to create, at the risk of medical harms and overdose deaths that are a consequence of poor coordination of care for such patients. Moreover, because the requirement to obtain individual patient consents significantly complicates the sharing of important patient information essential for

coordinating care and population health improvement, it contributes to higher health care costs for patients with complex health needs, who already are among the highest-cost utilizers in health care. A more effective approach to caring for and achieving the best outcomes for all patients is to allow providers to handle and treat patient data related to SUD treatment as simply another part of a patient's health care data protected by HIPAA.

We thank you for the opportunity to comment on this proposed rule. Please contact me if you have questions, or feel free to have a member of your team contact Caitlin Gillooley, senior associate director of policy, at cgillooley@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development