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HOSPITALS & HEALTH SYSTEMS

January 30, 2023
Miriam E. Delphin-Rittmon, PH. D.
Assistant Secretary for Mental Health and Substance Use
U.S. Department of Health and Human Services, Office for Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Dear Dr. Delphin-Rittmon:

On behalf of our more than 200 member hospitals and health systems, the Florida Hospital Association (FHA) appreciates the opportunity to comment on the proposed revisions to the regulations governing the confidentiality of substance use disorders (SUD) records, commonly known as 42 CFR Part 2 ("Part 2"). We appreciate that the Substance Abuses and Mental Health Services Administration (SAMHSA) is taking steps to align requirements under Part 2 regulations with those under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as we and many other stakeholders have requested.

Part 2 regulations are out-of-date and confusing, fail to protect patient privacy, and create barriers to providing coordinated, whole-person care to people with SUD. HIPAA requirements should serve as the single national standard for health information privacy protections. The HIPAA Privacy Rule generally permits covered entities, like hospitals, to share PHI for purposes of treatment, payment, and health care operations without having to obtain each individual patient's authorization. **FHA supports SAMHSA's proposal to align definitions as well as the requirement for only a single patient consent in perpetuity for appropriate use and disclosure.** SAMHSA is rightly attempting to balance patient information security, and privacy rights, with the need for improved care coordination between SUD treatment providers.

That said, the proposed rule does not address a number of significant regulatory barriers, including the requirement to segregate Part 2 data from other patient data, governing Part 2 programs and the information generated therein; those unresolved issues will continue to hinder the integration of behavioral and physical health care because the Part 2 patient data still cannot be used and disclosed like other health care data. In theory the proposed rule would allow much of this integration. However, the technology for health information technology platforms to distinguish between Part 2 and non-part 2 data does not exists, therefore rules that maintain segregation requirements will continue to impose burdens on integration.

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In addition to technological concerns, there are several operational issues that SAMHSA should address in the final rule. SAMHSA should provide additional clarity on the following:

Better Define Part 2 and non-Part 2 Provider When SAMHSA issued its 2019 rule to clarify requirements under Part 2 the agency failed to clarify the distinction between Part 2 and non-Part 2 providers. The statute defines Part 2 providers as: 1) alcohol and drug treatment programs that receive federal funds in any form, including Medicare or Medicaid funding or via their tax exempt status; and 2) "hold themselves out as providing" alcohol or drug abuse diagnosis, treatment or referral for treatment. However, the phrase "hold themselves out" is not well defined in the proposed regulations.

In the regulation, SAMHSA exempts general medical facilities and medical practices from information sharing restrictions, but limits that exemption for Part 2 providers. Essentially, a general provider is exempt from the Part 2 regulation, but 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 such services". Yet, many general facilities and providers not only offer these services but make their availability known to their communities. The vagaries of terms such as "hold themselves out" and "primary function" make interpretation difficult, and whether a specific medical facility or practice is exempt from Part 2 rules is not necessarily clear. **SAMHSA should provide further clarification in the final rule on the definitions of "holding themselves out" and "primary function…such services".**

Address Barriers to Alleviate Technical Challenges Segregation of Part 2 designated SUD records has proven an enormous technical challenge. Even the most sophisticated electronic health record (EHR) software lack the capability of automatically flagging or separating Part 2 records. There is currently no technical protocol for protecting SUD treatment information while integrating behavioral health records within current EHR systems. FHA believes that this capability is possible but current regulations stand in the way of implementation and SAMHSA has not addressed them in the proposed rule.

HIPAA Data Breach Enforcement Timeline The agency does propose to extend HIPAA enforcement penalties for information breaches; **without providing guidance, support and time for Part 2 providers to modify and enhance their health IT and HER capabilities, it is unreasonable to hold them to information protection standards beginning in 2024.** We recommend that SAMHSA work with the Office of the National Coordinator and the health IT vendor community to develop plans, verification criteria and support resources to ensure that patient information is meaningfully protected and providers have the resources to implement these protections without undue burden.

SAMHSA should also incorporate a phase-in period for enforcement, as the complex nature of compliance with Part 2 regulations is already a deterrent to take on patients with SUD without threat of monetary penalty. Providers are willing and committed to provide coordinated, whole-person care; they need the tools and capabilities to do it.

Patient Rights The balance of patient rights and the ability to deliver appropriate care are important questions and SAMHSA has made recommendations to ensure that patients are not left out of this rule. The proposal to allow for a single collection of patient consent for use and disclosure rather than individual consents for each instance of use or disclosure, will greatly ease barriers between providers and care coordination, as will the allowance for health insurers to access information as part of treatment, payment and operations. The proposal to allow disclosures of de-identified information for public health purposes is likely to improve population health efforts. To offset some of these "relaxation" of patient rights standards, SAMHSA has created new rights for patients, such as the right to request an accounting of all disclosures and a right to revoke consent at any time. **SAMHSA must provide guidance on what is expected of providers as they incorporate processes to ensure these patient rights.**

Finally, FHA is aware that some laws limiting the ability to integrate SUD records are statutory and beyond the scope of SAMHSA. **We urge SAMHSA to work with Congress to update the statutory framework to allow for meaningful integration of SUD and physical health care and to resolve the statutory conflicts that prevent full alignment of Part 2 with the HIPAA requirements that govern all other patient health information.**

FHA thanks you for your consideration of our comments. Please do not hesitate to contact me or reach out to Michael Williams, SVP Federal Affairs, at michaelw@fha.org.

Sincerely,

Mary C. Mayhew
President and CEO

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