AMERICAN ACADEMY OF FAMILY PHYSICIANS

January 30, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

The Honorable Melanie Fontes Rainer
Director
Office for Civil Rights
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

**RE: RIN: 0945-AA16; Confidentiality of Substance Use Disorder (SUD) Patient Records**

Dear Secretary Becerra and Director Rainer:

On behalf of the American Academy of Family Physicians (AAFP), representing more than 127,600 family physicians and medical students across the country, I write in response to the Notice of Proposed Rule Making (NPRM) "Confidentiality of Substance Use Disorder (SUD) Patient Records" as published in the Federal Register on December 2, 2022.

Family physicians provide comprehensive health care to patients of all ages, are tuned in to the needs of their community, and are often the first line of defense for primary care, chronic care management, and acute illness. To this end, family physicians play a crucial role in screening patients for SUD and providing appropriate treatment. Provisional data from the CDC indicates drug overdose rates continued to increase by 15% between 2020 and 2021. The AAFP shares HHS' concern with the unacceptable level of SUD in the U.S. and is committed to addressing the drug overdose epidemic. As such, the AAFP is pleased to offer the following detailed comments on this NPRM.

This NPRM, issued by the U.S. Department of Health & Human Services (HHS), through the Office for Civil Rights (OCR) and in coordination with the Substance Abuse and Mental Health Services Administration (SAMHSA), revises the regulations at 42 CFR part 2 ("Part 2"). Part 2 upholds patient confidentiality rights as it relates to SUD treatment, which allows patients to seek treatment without fear of discrimination or prosecution of substance use. Patient data for SUD must also comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Rules and the Health Information Technology for Economic and Clinical Health (HITECH) Act. Historically, Part 2 confidentiality requirements have been more stringent than HIPAA. Part 2 requires explicit, written consent from the patient to disclose specified SUD treatment information to specified recipients each time it is shared. This NPRM would more closely align Part 2 disclosure requirements with HIPAA's disclosure requirements.

The intent of this NPRM is to streamline regulations, support patient privacy, and facilitate appropriate and necessary data sharing when appropriate. **The AAFP applauds HHS, OCR, and SAMHSA for taking action to uphold patient privacy rights and streamline health data confidentiality requirements for physicians.** Specifically, this NPRM would make several changes to align Part 2 regulations with existing HIPAA and HITECH requirements. We have long advocated for the



1133 CONNECTICUT AVE., N.W., STE. 1100 | WASHINGTON, DC 20036-4305 | (800) 794-7481 | (202) 232-9033

harmonization of regulations governing the confidentiality and sharing of health data. The AAFP supports efforts to streamline regulatory language and simplify compliance requirements, which reduces the volume of administrative work physicians must do to comply with overlapping regulations and will allow physicians more time to treat patients.

Additionally, ensuring patients have and understand their rights to confidentiality of SUD treatment data is vital in encouraging patients to seek treatment. This NPRM facilitates the patient consent process by upholding important patient privacy rights while allowing a patient's care team greater latitude to coordinate care and make referrals after receiving consent. The AAFP supports this effort to improve and streamline care coordination when a patient approves of appropriate data sharing between physicians and other providers. The AAFP's confidentiality policy regards a patient's right to privacy as personal and fundamental, and confidentiality of health data that patients share with their physicians is essential for the free flow of information necessary for medical care and a trusting, long-term relationship. Access to and disclosure of health data should be based on the patient's expressed desires and consent, and patients should have the ability to raise a complaint if proper notice of disclosure was not provided.

**Despite the necessary improvements that would be made by this NPRM, the AAFP remains concerned about the feasibility and functionality of EHRs and other platforms to improve data sharing while protecting patient privacy.** As previously noted, we support aligning Part 2 disclosure requirements with HIPAA but note that this could pose additional confidentiality and privacy risks, particularly as health care data is increasingly being shared outside of HIPAA-covered entities. Additional functionalities, like data segmentation capabilities, must be made more widely available to Part 2 entities to ensure they can protect patients' data when requested. Modernization of current widely available technology is needed to ensure physicians and their practices can segment appropriate data elements, ensure timely and effective deidentification of data when needed, and uphold patient consent and privacy requirements.

Certain data like SUD treatment and status are especially sensitive. As a result, patients may request that their SUD treatment data not be shared with other clinicians or be accessible via various third-party applications. However, physicians generally lack the ability to segment out certain parts of a patient's record while maintaining the ability to meaningfully share the non-SUD treatment data across the patient's care team for the purposes of care coordination and management. This is a particular challenge for primary care physicians who may provide SUD treatment in addition to several other primary care services. This lack of granular data segmentation functionality increases administrative burden and creates challenges for clinicians who are complying with requests not to disclose SUD treatment data while still complying with HIPAA and information blocking requirements. As a result, clinicians must either place sensitive data in the normal record and institute policies and procedures outside of the EHR to protect this data or create a new location or shadow chart that houses and protects the data. These workarounds disrupt the flow of comprehensive health data among a patient's care team and increases administrative tasks. Confidentiality of SUD treatment is necessary and vital to maintaining trust between a patient and their physician. As such, the AAFP urges HHS to work with EHR vendors to modernize the functionality of healthcare data management platforms to ensure Part 2 programs can keep patients' data confidential when requested.

HHS and OCR also seek comment on the compliance date of 24-months after publication of the final rule. The AAFP appreciates this timeline for compliance and considers this to be appropriate given the current industry standards and length of time needed to update existing health IT software. The AAFP encourages HHS and OCR to consider additional time for compliance beyond the 24-month period for physicians and practices when compliance requires IT updates or new capabilities. Many

entities bound by these regulations are reliant on vendors for the necessary updates and should not be penalized if vendors are not compliant within the 24-month period. Moreover, it is critical that HHS and OCR also hold EHR vendors and other health IT entities accountable for compliance, not solely physicians.

§ 2.31—Consent requirements

Currently, Part 2 programs must seek patients' written consent each time they wish to disclose SUD treatment records. OCR proposes to allow a Part 2 program to use and disclose Part 2 records based on one-time signed consent from the patient. OCR also clarifies that "written" consent may include an electronic signature. This aligns Part 2 requirements with existing HIPAA requirements. This section also aligns revocation of consent with HIPAA requirements and requires a Part 2 entity to accept verbal revocation.

The AAFP supports streamlining consent requirements with existing HIPAA requirements and appreciates OCR providing clarity for electronic signatures. Telehealth and audio-only visits continue to be an important modality for SUD treatment, and clear guidance for the use electronic signatures will facilitate access to care. However, we urge SAMHSA to clarify that revocation only applies to information *going forward* from the time of revocation and that Part 2 entities are not required to withdraw data previously shared with consent.

§ 2.22 Notice to patients of federal confidentiality requirements; and 45 CFR 164.520—Notice of privacy practices for protected health Information

Currently, HIPAA regulations require a provider, payer, or other covered entity to provide an individual with a notice of privacy practices (NPP), which informs them of how their protected health information (PHI) is used and of their rights to provide or revoke consent to such use. These protections are more robust than the similar "patient notice" requirement for Part 2 programs. Many, but not all, entities are regulated by both of these notice requirements, and therefore already comply with the more robust NPP requirement.

Under § 2.22, HHS is proposing to modify the Part 2 "patient notice" requirements by incorporating nearly all of the NPP requirements. This would streamline compliance requirements for covered entities and ensure that Part 2 programs that are not covered by HIPAA are afforded as much notice and transparency as is provided to individuals in the NPP.

The AAFP supports the proposal to streamline the Part 2 "patient notice" and HIPAA NPP requirements to implement consistent, comprehensive and transparent notice processes without creating redundant and duplicative administrative work for practices subject to both regulations. **We urge HHS to provide physician practices with ample time to prepare for compliance and resources to streamline administrative changes for the few practices that are not already compliant with the existing HIPAA requirements.** This may include technical assistance, templates, and best practices, with additional and tailored support for small, independent, and otherwise under-resourced practices.

Additionally, under HIPAA NPP regulations, there is currently an exception for incarcerated individuals, which removes their right to information on their health information privacy rights and a covered entity's practices. HHS proposes to remove the exception for inmates and ensure that regulated entities provide an NPP to inmates consistent with what is provided to other individuals and retains the limitation on the right of access due to security concerns.

**The AAFP supports removing the exception to NPP requirements for incarcerated individuals**. The AAFP advocates for incarcerated individuals to have access to comprehensive medical services, including mental health and SUD treatment. These individuals will benefit from transparency on how their health information is used and shared to preserve their trust in the confidentiality of their health data. Incarcerated individuals should be provided the same privacy of their health care information as other patients in the community, and we applaud HHS for making this change.

Penalties and Complaints of Violations (§ 2.3 and §2.4)

Currently, punishment for violation of Part 2 regulations results only in criminal fines. Section 2.3 would allow both criminal and civil penalties for violating Part 2 regulations. Furthermore, HHS seeks comment on a safe harbor provision for SUD treatment providers who unknowingly hold and disclose Part 2 records.

The AAFP agrees that civil penalties may be more appropriate for Part 2 violations in some cases. The AAFP also supports adopting a safe harbor provision for SUD treatment providers who unknowingly hold and disclose Part 2 records. While all physicians and practices should ensure compliance with Part 2 regulations, certain functionality of patient records and data sharing make it difficult to ensure every reference to SUD care is removed in all cases, especially when a patient sees multiple physicians or care teams.

Currently, reports of violations of the Part 2 regulations should be directed to the U.S. Attorney for the judicial district in which the violation occurs and reports of any violation by an opioid treatment program may be directed to the U.S. Attorney and to SAMHSA.

HHS proposes to align this complaint process to that of HIPAA in Section 2.4. Specifically, HHS proposes to require a Part 2 program to implement a process to receive complaints concerning the program's compliance with the Part 2 regulations. This would provide that a program may not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against any patient for filing a complaint. HHS also proposes to prohibit a program from requiring patients to waive their right to file a complaint as a condition of the provision of treatment, payment, enrollment, or eligibility for any program subject to Part 2.

**The AAFP supports this proposal and reiterates our commitment to patient confidentiality as a key tenant of the patient-physician relationship.** The AAFP recognizes that most Part 2 practices already have a HIPAA-compliant complaint process in place and will likely only require minimal adjustments to come into compliance with this provision. We appreciate HHS ensuring complaint violation requirements are aligned across regulations to minimize administrivia. The AAFP encourages HHS to work with any remaining Part 2 programs to implement complaint processes, including by providing technical assistance and sample complaint processes that have proven to be effective and in compliance. **HHS should provide at least a six-month grace period for programs to address and rectify any complaints and otherwise come into compliance before imposing penalties for violating Part 2 regulations.**

Additional Comments

In Section 2.54, OCR proposes to allow Part 2 programs to disclose records without patient consent to public health authorities, so long as the information is de-identified. It has been noted that delays in

overdose data availability has limited the timely response from health care organizations, law enforcement, and federal agencies in acquiring the appropriate resources to respond.[i, ii]

**While the AAFP supports this provision to better facilitate public health data reporting, we note that the current standard for de-identification is significantly burdensome and time consuming for many practices.** De-identification standards are paramount for the protection of patient privacy, but many practices lack appropriate technology to facilitate de-identification of large quantities of Part 2 records. Moreover, practices that *do* have access to such technology have found that it can be insufficient to protect patient privacy. The AAFP has concerns that this provision could result in unintentional breaches in patient confidentiality without improvements to existing health IT and reporting technology. The AAFP strongly urges HHS to facilitate coordination between physicians and health IT entities to improve de-identification technology and make it more widely accessible for physician practices. This development will make public health reporting of SUD data more readily achievable while upholding important patient privacy rights.

In Section 2.15, OCR proposes to add health plans to the list of entities to which a Part 2 program may disclose records without consent when a patient lacks capacity to make health care decisions. The AAFP supports this inclusion to ensure Part 2 programs receive appropriate and timely payment for their services.

Thank you for the opportunity to provide these comments. The AAFP looks forward to working with OCR, HHS, and SAMHSA to streamline Part 2 regulations and uphold patient privacy. For additional information, please contact Meredith Yinger, Manager of Regulatory Affairs, at myinger@aafp.org.

Sincerely,

Sterling N Ransone, Jr MD FAAFP

Sterling Ransone, Jr., MD, FAAFP
American Academy of Family Physicians, Board Chair

[i] Sumner SA, Bowen D, Holland K, et al. Estimating Weekly National Opioid Overdose Deaths in Near Real Time Using Multiple Proxy Data Sources. *JAMA Netw Open.* 2022;5(7):e2223033. doi:10.1001/jamanetworkopen.2022.23033

[ii] Spencer MR, Ahmad F. Timeliness of death certificate data for mortality surveillance and provisional estimates. Centers for Disease Control and Prevention. Accessed January 5, 2022. https://www.cdc.gov/nchs/data/vsrr/report001.pdf