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January 31, 2023

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U.S. Department of Health and Human Services
Office of the Secretary
Office of Civil Rights (OCR)
Substance Abuse and Mental Health Services Administration (SAMHSA)
Attention: Lester Coffey, OCR

The American Psychiatric Association (APA), the national medical specialty society representing over 37,000 psychiatric physicians and their patients, appreciates the opportunity to comment on updates to confidentiality of substance use disorder (SUD) patient records. We applaud HHS's efforts to support care coordination, break down the silos of SUD treatment, and improve health outcomes through data-sharing while protecting patients. Increased regulatory alignment of 42 CFR Part 2 (*hereinafter Part 2*) SUD data protections with HIPAA health data protections is a valuable framework for reducing administrative burden with patients' best interests in mind. Further, we appreciate the Notice of Proposed Rulemaking's (NPRM) proposal to reduce unintended consequences of data access associated with law enforcement, civil proceedings, and discrimination. APA shares HHS's commitment to improving health outcomes for patients with SUD through data and technology.

However, this rule as written does not mitigate data segregation and segmentation obligations of Part 2 that challenge well-intentioned care coordination efforts. In particular, the revised regulation does not ease the burden of data management in integrated care and collaborative care settings. As health systems embrace value-based, whole-person care, creating data silos runs the risk of entrenching stigma and disparate outcomes among patients with SUD. At best, psychiatrists and other specialists may have significant administrative burden added to manage and maintain patient data in separate platforms, all without the intended outcome of coordination with colleagues to support shared patients. Facilities and providers may intentionally not "hold themselves out" as a Part 2 provider, choosing the lesser evil of data integration over the challenge of providing care within regulatory constraints. At worst, clinicians and facilities may avoid developing any critical SUD treatment programs or specialties to reduce liability and overhead. We recognize that the proposed updates are constrained by HHS's rulemaking authority; however, care coordination challenges will remain as long as data segregation and segmentation requirements are maintained.

Recognizing the original intent of Part 2 – protecting those seeking treatment from punitive treatment by law enforcement, social services, and their communities – and

recognizing the ongoing importance of protecting patients with SUD even from biases of non-SUD clinicians, the current reality of interoperable and integrated data systems reframes these efforts. Data that indicates a SUD diagnosis or treatment protocol are all over the medical record: in ED visits, claims data, referrals and treatment notes, prescription data, and prescription drug monitoring programs. In the case of health information exchanges, all-payer claims databases, and application programming interfaces (APIs) for interoperability, these data proliferate not just within but across systems. The simultaneous narrowness and ambiguity of the definition of a “Part 2 program” further entails that, while some data are likely protected to the benefit of the patient, in many cases, the data are not segregated. In summary, while we recognize the legal mandate to align 42 CFR Part 2 to HIPAA, we find that significant practical gaps exist in improving care coordination capacity while ensuring patient control over their data.

As the agency works to finalize the proposed rule, our recommendations to SAMHSA in revising Part 2 include:

- Provide one-on-one technical assistance to any clinician or facility wanting support in ensuring compliance with Part 2 regulations and work with the Office of Civil Rights and medical societies to provide comprehensive stigma reduction training and campaigns to clinicians. Engage in meaningful discussions about how data should be incorporated into EHRs to improve care and reduce stigma.
- Define Part 2 programs in a way that is comprehensible and actionable.
- Extend safe harbor protections to Part 2 programs and providers that are acting in good faith, not to investigative agencies. Enforce protections against discrimination.
- Work with ONC and HIT vendors to develop technical standards and feasible certification criteria to identify, tag, segregate, and remove specific data based on type of care, provider, and patient consent. Provide incentives and support to clinicians, practices, and EHR vendors – particularly those designed for specialty settings or small practices – in designing and adopting health IT that meets these objectives.
- Develop Part 2 consent materials usable by a wide range of clinicians in a wide range of settings, comprehensible to patients, that clearly delineate the difference between HIPAA- and Part 2-protected data and explains the patient’s right to consent to some disclosures and not others.
- Permit the use of an “opt out” consent process, where Part 2 records could be disclosed and re-disclosed for TPO purposes, consistent with HIPAA.

Effective Date

APA recommends that the agency delay finalization of the rule until root causes of burdens can be identified and fixed or allow for an additional 12 months on the proposed compliance date of 22 months after the effective date. Thirty-four months, following the 60-day effective date period (36 total months) would allow Part 2 providers greater time to make the necessary changes as well as give time for questions to and clarifications from the agency.

The updates to Part 2 outlined in the Notice of Proposed Rulemaking are not feasible based on the technology that currently exists. Effective execution of the proposed rule, reducing the administrative

burden associated with consent and redisclosure while allowing patient control over disclosures and retractions, is contingent on data management technology that can identify, tag, control, and retract SUD data as distinct from other data in the medical record. This technology does not exist and, if it were developed, would come at significant expense for facilities and Part 2 programs to integrate into their current systems. APA encourages the agency to allow additional time, over the 36 total months, if any major interoperability rules are added, to allow all Part 2 programs to update technology in their program. APA encourages the agency to communicate clarifications and guidance with Part 2 providers frequently throughout the implementation timeline to ensure revisions to existing policies and practices, complete additional training of workforce as needed, and successful implementation with the updated regulations. **APA recommends that technical assistance be provided to ensure consistent implementation and patient protections throughout the change management process.**

We further note that multiple efforts currently active in HHS, including the CMS Interoperability and Prior Authorization Requirement Draft Rule, ONC Information-Blocking Final Rule, and pending OIG Information-Blocking Draft Rule, along with ongoing implementation of HITECH Act provisions, are leading to increasing federal-led integration of health care data across systems. While we profoundly appreciate and support data modernization efforts, we caution HHS in moving policy faster than technology. Effective data management practices are a critical prerequisite to loosening data privacy standards.

The agency must also coordinate with the non-discrimination rule as mandated by the CARES Act to protect SUD data from discriminatory uses without adding increased burden to Part 2 programs and providers. The agency should use rulemaking and enforcement authority to stop discrimination based on SUD diagnosis or treatment status. Discrimination and stigma have a history of disproportionate harm particularly among historically marginalized populations, including in employment opportunities, child custody determinations, insurance discrimination, and criminal prosecution. Because of risks associated with access to SUD data, affording patient protection has also prevented SUD treatment and recovery from being treated as any other medical condition across the medical system. For these reasons, this sensitive information has been protected, and enhances the urgency with which the agency must act to release and align the non-discrimination rule. Through effective discrimination protections, data can be used to enhance medical care without risking patient well-being.

Core to patient protection is education of providers and patients on applicable privacy regulations. OCR and SAMHSA should collaborate to create multiple modalities of learning, including webinars, written guides, sample wording, and public awareness campaigns. Existing learning supports are valuable, but **APA recommends that the scope of education should expand to include public awareness of distinct protections around SUD data to empower patients to effectively consent to any disclosures.**

Section §2.11 Definitions

Definition of a Part 2 Program

The definition of a Part 2 Program has been a challenge throughout Part 2's history. While SAMHSA's efforts to support clinicians, health systems, and agencies in understanding who falls under Part 2's

regulations have been admirable, clearer definitions and determinations need to be established to reduce ambiguity, uncertainty, and liability.

This definitional challenge is compounded by administrative and technological challenges in appropriately segregating data based on Part 2 status. Applying Part 2 to individual clinicians rather than to facilities means that a handful of individuals within an institution may meet these criteria while the majority will not. However, EHRs and other data integration platforms are not designed to treat records of some clinicians within a practice or organization differently from others. They are also not designed to treat records of one location (e.g., emergency department) differently from another location on the same patient encounter. **APA urges SAMHSA to revise this definition to create an objective standard rather than subjective (“holds itself out as”); for example, the definition could include only those that are licensed SUD treatment providers.**

Records

The creation of a distinct class of psychotherapy notes in HIPAA provides an illustrative example of the challenge of implementing specific data protections within a medical record: although the “psychotherapy note” option was added to HIPAA to protect psychotherapist-patient privilege, this option specifically excludes the key elements of a psychotherapy session note that are required for routine clinical care as well as for billing purposes (e.g., medication prescription and monitoring, summary of diagnosis, treatment plan). A corollary of this is that, if a HIPAA-defined psychotherapy note is used, it must always be accompanied by a clinical note that includes the essential elements for routine clinical care and billing.

Accordingly, this option is rarely utilized by clinicians because it requires the provider to generate multiple records of the encounter. Options for segregating SUD records from other records that require manual or duplicative action by the clinician are likely not viable at scale. Further, the personnel time and infrastructure costs of configuring such an option in the EHR is not negligible.

Section §2.13 Confidentiality Restrictions and Safeguards

APA supports the alignment of redisclosure processes to HIPAA with the exception of uses for civil, criminal, administrative, and legal proceedings. Along with increased patient and provider education about disclosure and data protection, **APA recommends support for programs to understanding their role as a Part 2 program or lawful holder, and technological infrastructure to manage these data once disclosed.**

Section §2.16 Security for records and notification of breaches

While enforcement of Part 2 is important for meaningful data protection and incentivizes appropriate sharing of protected PHI, APA raises concern that if you bring 42 CFR Part 2 under the enforcement umbrella of HIPAA without making 42 CFR Part 2 clearer and more actionable, the risk increases of widespread litigation, system-level abandonment of efforts to address SUD in non-SUD settings, and even program closure. **When enforced without effective compliance supports, enforcement may decrease access to care and patient well-being instead of facilitating it.** Federal-level enforcement actions without infrastructural, technological, and definitional support of programs holding Part 2 data could penalize Part

2 programs and other providers without improving access to treatment for patients. **APA recommends the agency reduce penalties for instances for unintentional disclosures by Part 2 programs who may need additional time and technical assistance to comply with these updated regulations.**

Section §2.3 Civil and Criminal Penalties of Violations

APA supports the prohibition of Part 2 programs from intimidating, threatening, coercing, discriminating against, or taking other retaliatory action against any patient for the exercise of any right established, or for participation in any process provided for, in Part 2, including filing of a complaint. Moreover, APA supports the prohibition of a Part 2 program from requiring patients to waive their right to file a complaint as a condition of treatment, payment, enrollment, or eligibility for any program subject to Part 2.

However, APA does not support the changes to the safe harbor regulations for investigative agencies as written. Expanding law enforcement’s ability to access SUD records, with fewer guardrails, exposes patients to potential harm that Part 2 is intended to protect against. As written, there is concern that this would reduce access to care if Part 2 programs feel more at risk for acting in good faith than the investigative agencies who are not the business of patient care. Instead, **APA encourages HHS to write safe harbor rules for Part 2 programs who are helping ease addiction burden across the country.**

Section §2.6 Right to Request Privacy Protection for Records

While the intent behind segregating specific sensitive records behind data protections (e.g., Break the Glass functionalities) is sound, implementation poses challenges. Protecting these data requires the provider to identify the sensitive record and separate clinical data from pertinent claims or administrative data. Meanwhile, applying these protections creates an implication that there are SUD records hidden behind those protections. Tracking down a SUD/Part 2-protected piece of data throughout the medical record, or in the hands of other TPO associates, to remove it once disclosed is likely either extremely difficult or impossible, especially in clinically integrated settings. **APA recommends that SAMHSA work with ONC, and HIT vendors as appropriate, to operationalize policy through certification criteria.**

The NPRM does not account for patient protections in plans self-funded through an employer. **APA recommends clarity on how TPO information will be kept protected from the employer and how patients will be protected against discriminatory practices.** APA is concerned that without further clarification, patients will be hesitant to seek treatment if there is an assumption that an employer will have knowledge of a SUD.

Section §2.31 Consent Requirements

APA is pleased that the Part 2 rule is closer aligned with HIPAA and will allow patients to sign a single, written consent for all future uses and disclosures for treatment, payment, and healthcare operation purposes. However, **APA encourages SAMHSA to permit the use of an “opt out” consent process, where Part 2 records could be disclosed and re-disclosed for TPO purposes, consistent with HIPAA, unless the patient “opted out” – and was provided with comprehensible information around their rights to opt out.**

Notice to patients about their rights to privacy for protected health information must have clear and concise communications. The consent process must be aligned with existing HIPAA processes, ideally incorporated into the same document where feasible. Current notices are text-heavy and long documents, often written in “legalese,” that patients typically do not read nor fully understand. **APA recommends that HHS develop model consent language, limited to a paragraph and highly comprehensible, along with an option such as a QR code to find further information.**

Thank you for your review and consideration of these comments. If you have any questions or would like to discuss any of these comments further, please contact Abby Worthen (aworthen@psych.org), Deputy Director, Digital Health.

Sincerely,

A handwritten signature in black ink that reads "Saul Levin, M.D., M.P.A." in a cursive style.

Saul M. Levin, M.D., M.P.A., FRCP-E, FRCPsych
CEO and Medical Director
American Psychiatric Association