

January 31, 2023

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: SUD Patient Records
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: Docket No. HHS-OCR-2022-0018—Confidentiality of Substance Use Disorder
Patient Records

To Whom It May Concern:

On behalf of our 159,000 members, we would like to comment on the Department of Health and Human Services Notice of Proposed Rulemaking to implement section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act. The intent of this rulemaking is to better align the requirements of two federal laws governing the confidentiality and disclosure of patient records relating to substance use disorders. We offer these comments in response to your Federal Register notice of December 2, 2022 (87 FR 74216).

Dentists are generally considered covered entities under the Health Insurance Portability and Accountability Act of 1996, which governs what health care providers must do to protect the confidentiality of patient health records. However, a separate and more stringent set of rules exist to protect the confidentiality of information pertaining to substance use disorders. Those rules—Part 2 of Title 42 of the Code of Federal Regulations—are better known by facilities (and practitioners) whose primary function is to provide substance abuse treatment and who are licensed for that purpose.

There is usually little need for dentists to have detailed information about a patient's substance use disorder. Prior to surgery, a dentist may ask if a patient uses illicit substances or has (or is at risk of developing) an addiction. The information may shape decisions about administering anesthesia and/or prescribing controlled substances. A dentist may also voluntarily screen patients for potential substance use disorders and provide a brief intervention and referral for appropriate treatment. However, access to that information has historically (and sufficiently) been governed by HIPAA.

Enclosed you will find our detailed comments about the current proposal to clarify and better align the confusing and sometimes-conflicting requirements of HIPAA and Part 2. As you consider how to synchronize these two patient privacy laws for different types of providers, we offer the following recommendations:

- Exempt non-Part 2 providers from having to comply with the NPP changes, except in cases where the provider has knowingly received or expects to receive Part 2 records.

- Ease the compliance burden on non-Part 2 providers and those whose electronic record systems are not capable of segmenting or segregating Part 2 data.
- Exempt providers that are not covered by HIPAA from being penalized for making a use or disclosure of Part 2 records that a HIPAA covered entity could have made without penalty.
- Simplify and clarify the statements to be required in a revised notice of privacy practices, and provide sample language and comprehensive guidance well in advance of the effective date.
- Do not require HIPAA covered entities to notify individuals that a patient has a right to inspect and obtain copies of PHI at limited cost, or in some cases free of charge.
- Protect against dual liability under HIPAA and Part 2. (A single error must not result in enforcement actions and penalties under both HIPAA and Part 2.)
- Prohibit Part 2 programs from sharing Part 2 records with non-Part 2 providers, unless such records are critical to the patient's care.
- Require Part 2 programs to give health care providers adequate written notice well in advance of sharing any Part 2 record, clearly explaining that such records are subject to additional federal confidentiality regulations, and include clear guidance for non-Part 2 providers to understand their obligations and options concerning such records once received.
- Establish an effective date of no less than one year after publication of the final rule, and a compliance date of no less than one year after the effective date.
- Do not require the name and email address of the designated privacy officer be disclosed in a publicly available document. (Disclosing an individual's name in a publicly available document could put that person's privacy—and possibly their safety—at risk.)
- Do not change the current NPP header requirement
- Do not require covered entities to imply in their notices of privacy practices that all privacy practices are subject to the NPP.
- Modify the proposed NPP language from "...provided that such terms are not material or contrary to law..." to "...provided that such changes are not contrary to law".
- Eliminate the requirement to obtain an individual's written acknowledgment of receipt of a direct treatment provider's Notice of Privacy Practices.

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Thank you for providing us the opportunity to comment. We welcome the chance to work with you to minimize any unintended consequences for non-Part 2 providers. If you have any questions, please contact Mr. Robert J. Burns at 202-789-5176 or burnsr@ada.org.

Sincerely,

/s/

George R. Shepley, D.D.S.
President

/s/

Raymond A. Cohlma, D.D.S.
Executive Director

GRS:RAC:rjb
Enclosure

Detailed Comments

U.S. Department of Health and Human Services
Office of Civil Rights
Notice of Proposed Rulemaking
Docket No. HHS-OCR-2022-0018 / 87 FR 74216
Confidentiality of Substance Use Disorder Patient Records

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Regarding the Department of Health and Human Services Notice of Proposed Rulemaking to implement section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, the ADA supports the goals of:

- improving coordination of care for patients receiving treatment;
- ensuring individuals do not forego life-saving care due to concerns about records disclosure;
- better aligning Part 2 and HIPAA to decrease burdens on patients and providers;
- increasing access to care and treatment while protecting confidentiality of treatment records; and
- mitigating the discrimination and stigma that people with substance use disorders (SUD) experience.

The ADA notes that many dental practices are HIPAA covered entities, and that the U.S. Department of Health and Human Services (HHS) states in the executive summary to the proposed rule that HIPAA covered entities that maintain both HIPAA protected health information (PHI) and Part 2 records concerning substance use disorder (SUD) treatment at a Part 2 treatment provider are subject to both sets of rules. Thus, a dental practice could be subject to both HIPAA, with respect to PHI (or corresponding state law if the dental practice is not covered by HIPAA), and to the Part 2 confidentiality rules, with respect to Part 2 records.

Part 2 Confidentiality Requirements

Simplification and guidance. The ADA supports the efforts of HHS to align certain Part 2 requirements more closely to the requirements of the HIPAA rules, but only to the extent that doing so will benefit patients (for example, by enabling health care providers to have access to more complete information when treating patients) and health care providers (for example, by helping to eliminate confusion and ease the compliance burden on health care providers that are not Part 2 SUD treatment providers). However, the ADA urges HHS to consider the potential for the proposed rule to increase compliance burdens on non-Part 2 health care providers, particularly smaller ones that may rarely, if ever, receive Part 2 records. The ADA urges HHS to mitigate such burdens through rule simplification and by providing comprehensive HHS guidance well in advance of the effective date of the final rule.

Advance notice. In addition, the ADA urges HHS to require Part 2 programs to give health care providers adequate written notice in advance of providing any Part 2 record, and to require such notice to clearly explain that such records are subject to federal confidentiality regulations that are in some respects more stringent than HIPAA, along with links to clear and comprehensive

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HHS guidance sufficient to enable the health care provider to understand its obligations and options concerning such records once received.

Penalties. In the executive summary to the proposed rule, HHS states that the dual obligations of HIPAA and Part 2 create compliance challenges for HIPAA covered entities that are not also Part 2 SUD treatment providers. These challenges can impose daunting compliance burdens on such providers, particularly on small providers that rarely receive Part 2 records, or that could receive them unexpectedly, and that may lack a compliance department or compliance professionals on staff. This is especially concerning in light of the proposed civil penalties that could apply to violations of Part 2, which mirror those for HIPAA: depending on the level of culpability, a violation of the Part 2 confidentiality rules could result in penalties between \$100 and \$50,000 per violation, with an annual cap of up to \$1,500,000. It is not clear that the lower annual caps set by HHS through enforcement discretion would apply to Part 2 penalties. Moreover, as with HIPAA, criminal penalties for wrongful disclosure could apply as well, resulting in fines of up to \$50,000 and up to one year in prison (or more, depending on the level of culpability). The ADA urges HHS to ease the burden on HIPAA covered entities that are not Part 2 programs as much as possible and to provide clear and comprehensive guidance on how a non-Part 2 program can comply with applicable provisions of the Part 2 confidentiality requirements. In particular, the ADA urges HHS to provide administrative and technical guidance to health care providers whose electronic record system is not capable of segmenting or segregating Part 2 data, and comprehensive sample language for all documentation required under the final rule, such as any changes to the HIPAA notice of privacy practices. The ADA further urges HHS to protect HIPAA covered entities that are not Part 2 providers from double liability: a single error must not result in enforcement actions and penalties under both HIPAA and Part 2.

Effective date and compliance date. HHS proposes an effective date that is 60 days after the publication of a final rule, and a compliance date that is 22 months after the effective date. Such a time period is insufficient for dental practices to come into compliance with the changes, particularly if HHS has not provided clear and comprehensive guidance, including administrative and technical guidance, well in advance of the effective date. The effective date should be not less than one year after publication of the final rule, and the compliance date should be not less than one year after the effective date. HHS proposes tolling the compliance date of the Part 2 accounting of disclosures requirements until the effective date of changes to the HIPAA accounting of disclosures requirement. ADA urges HHS to delay proposing a Part 2 accounting of disclosures requirement until the effective date of changes to the HIPAA accounting of disclosures requirement, so that comments regarding the HIPAA requirement may inform the proposed Part 2 requirement.

Information critical to care. To further help protect patients receiving SUD treatment from a Part 2 provider, as well as to protect health care providers who are not Part 2 programs, ADA urges HHS to prohibit Part 2 programs from sharing Part 2 records with non-Part 2 program health care providers unless such records are critical to the patient's care.

Redisclosure. The ADA supports the proposal to permit redisclosure of Part 2 records in any manner permitted by the HIPAA Privacy Rule, with appropriate exceptions such as the use and disclosure of Part 2 records in civil, criminal, administrative, and legislative proceedings when not permitted under Part 2. However, the ADA urges HHS to permit such redisclosure whether or not a redisclosing health care provider is a HIPAA covered entity. Health care providers that

are not covered by HIPAA should not be penalized for making a use or disclosure of Part 2 records that a HIPAA covered entity could have made without penalty.

HIPAA Privacy Rule

New required information in the notice of privacy practices. The proposed rule would require HIPAA covered entities to add a substantial amount of information to their notices of privacy practices (NPP), some of which are vague. It would be difficult for a smaller covered entity to determine what language would suffice for the new requirements. In addition, the proposed rule would require HIPAA covered dental practices to undertake significant new obligations. For example, the NPP would be required to provide individuals subject to Part 2 records with adequate notice of the uses and disclosure of such Part 2 records; the covered entity's legal duties with respect to such records; any limitations on the use or disclosure of Part 2 records; and include a separate statement regarding the disclosure of substance use disorder treatment records for civil, criminal, administrative and legislative proceedings absent an appropriate court order or the consent of the patient. Such provisions would also require training staff to respond to questions about Part 2 records. The ADA urges HHS to simplify and clarify these requirements as much as possible while still providing individuals subject to Part 2 records adequate notice, and to publish guidance and sample provisions well in advance of the effective date. The ADA further urges HHS not to require HIPAA covered health care providers that are not Part 2 programs to implement any of the proposed changes to the NPP unless the health care provider has knowingly received or expects to receive Part 2 records.

Free copies. The proposed rule would require the NPP to state that individuals have the right to inspect and obtain a copy of PHI at limited cost, or in some cases, free of charge, which may create unrealistic expectations and misunderstandings, since HIPAA permits covered entities to charge a reasonable, cost-based fee for copies. The ADA urges HHS not to implement this proposed change.

Laws other than HIPAA. HHS proposes to delete the words "with respect to PHI" from 164.520(b)(1)(iv)(A), which would make this sentence overly broad:

The notice must contain (A) A statement that the covered entity is required by law to maintain the privacy of protected health information, to provide individuals with notice of its legal duties and privacy practices ~~with respect to PHI~~, and to notify affected individuals following a breach of unsecured protected health information... [proposed deletion indicated in strikethrough]

Covered entities may be subject to a variety of legal duties concerning privacy in addition to their duties related to PHI. For example, separate laws may apply to employee information, or to student information if the covered entity is an educational institution. The ADA urges HHS not to require covered entities to imply in their notices of privacy practices that all privacy practices are subject to the NPP.

Changes to the NPP. HHS proposes requiring a statement in the NPP that the covered entity reserves the right to change the terms of its notice, "provided that such terms are not material or contrary to law..." The ADA urges HHS to change the proposed language to "provided that such changes are not contrary to law" thus omitting the proposed word "material." A covered entity may be required to make material changes to the NPP in a number of situations; for example,

when regulations require a material change to the NPP, when a change is the result of new state law that is more stringent than HIPAA, or when the change is the result of a change of business practices.

Name and email address of a person who can provide information about privacy practices. HHS proposes requiring the NPP to include the name, title, telephone number and email for a designated person who is able to provide further information and answer questions about the covered entity's privacy practices. ADA urges HHS not to include persons' names in the NPP, because including a person's name in a publicly available document might put that person's privacy at risk, and perhaps even subject them to unwanted attention. In addition, two or more persons may share that responsibility, requiring the insertion of multiple names. Moreover, the NPP would need to be revised any time such a person left employment at the covered entity or changed job functions. The ADA further urges HHS not to require an email address to be included in the NPP, since this indirectly imposes a requirement on a covered entity to have an email address for privacy matters and to check emails with sufficient frequency, which may be a burden for a small covered dental practice and could take time away from patient care, particularly where the dental team is multifunctional and cross trains on workflows. Moreover, requiring covered entities to use email for this purpose could raise data security risks, or impose requirements to implement secure email for this purpose, which may be burdensome for both patients and the covered entity.

Obtaining records for a third party. HHS proposes a new provision that a covered entity may provide in its NPP information about how an individual who seeks to direct PHI to a third party, when the PHI is not in an electronic health record or is in a non-electronic format, can instead obtain a copy of PHI directly and send the copy to the third party themselves, or request the covered entity to send a copy of the PHI to a third party using a HIPAA valid authorization. ADA agrees with HHS that this provision should be optional for the covered entity.

NPP Header. HHS proposes changing the header requirement for the NPP. The current header requirement reads as follows:

“THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.”

The proposed new header would read:

NOTICE OF PRIVACY PRACTICES OF [NAME OF COVERED ENTITY, AFFILIATED COVERED ENTITIES, OR ORGANIZED HEALTH CARE ARRANGEMENT, AS APPLICABLE]

THIS NOTICE DESCRIBES:

HOW HEALTH INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED

YOUR RIGHTS WITH RESPECT TO YOUR HEALTH INFORMATION

HOW TO EXERCISE YOUR RIGHT TO GET COPIES OF YOUR RECORDS AT LIMITED COST OR, IN SOME CASES, FREE OF CHARGE

HOW TO FILE A COMPLAINT CONCERNING A VIOLATION OF THE PRIVACY, OR SECURITY OF YOUR HEALTH INFORMATION, OR OF YOUR RIGHTS CONCERNING YOUR INFORMATION, INCLUDING YOUR RIGHT TO INSPECT OR GET COPIES OF YOUR RECORDS UNDER HIPAA

YOU HAVE A RIGHT TO A COPY OF THIS NOTICE (IN PAPER OR ELECTRONIC FORM) AND TO DISCUSS IT WITH [ENTER [NAME OR TITLE] AT [PHONE AND EMAIL]] IF YOU HAVE ANY QUESTIONS.

ADA urges HHS not to change the current header requirement. The proposed header, in addition to the other proposed new NPP content, would make the NPP long and unwieldy, and even less likely to be read and understood by patients. Moreover, referring to obtaining records free of charge could cause confusion for the reasons explained above. Finally, inserting a person's name and email address could impose the risks discussed above.

Written acknowledgement. The ADA supports eliminating the requirement to obtain an individual's written acknowledgment of receipt of a direct treatment provider's NPP (and, if unable to obtain the written acknowledgment, to document their good faith effort to obtain the acknowledgment and the reason for not obtaining the acknowledgment), and to eliminate the requirement to retain copies of such documents for six years. The current requirement to obtain acknowledgement is confusing, time consuming, and burdensome for patients, who are often asked to sign the acknowledgement at a time when they are completing multiple documents such as health history, insurance, and other forms, and can confuse patients who may believe that they are being asked to agree to the terms of the NPP. The current requirement is also time consuming and burdensome for dental practices.

Inmates. HHS proposes eliminating the exception that currently deprives inmates from the right to obtain the NPP. ADA supports the rights of inmates to have access to information about their PHI and urges HHS to adopt this change, which would also help streamline health care provider compliance activities around providing the notice.