



LEGAL ADVICE FOR HEALTH PLANS

HEALTH LAW ALERT ***December 2, 2022***

HHS Proposes Revisions to Substance Use Disorder Rule Amendments to Better Align Part 2 Rule with HIPAA

Today, the Department of Health and Human Services (HHS) formally¹ published a proposed rule designed to address (among other things) “compliance challenges for HIPAA covered entities and business associates that maintain [both Protected Health Information] and Part 2 records.” The revisions to the Confidentiality of Substance Use Disorder Patient Records Rule (the Part 2 Rule) are required by Coronavirus Aid, Relief, and Economic Security (CARES) Act, which was enacted in March 2020. [Click here](#) for my Health Law Alert on the applicable CARES Act provisions.

The proposed rule is published at 87 *Federal Register* 74216 ([click here](#)).

Compliance Date for Proposed Rule. The proposed Rules are overdue. Under the Statute, rules to align the Part 2 Rule with the HIPAA Privacy Rule were required to *go into effect* by March 27, 2021. But such changes will not go into effect before a Final Rule’s “compliance date.” HHS proposes to make the compliance date for the Final Rule 24 months after the Final Rule is published. Since the Final Rule is not likely to be published for several months, the proposed rule indicates that any alignment of the Part 2 Rule to HIPAA would not go into effect for well over two years.

Effect of the Proposed Rule. The proposed rule would greatly simplify health plans’ Part 2 compliance obligations for the use, disclosure, and maintenance of Substance Use Disorder Patient Records. Under the proposed rule, when a health plan (or business associate) receives Part 2 Patient Records for payment or health care operations activities, it “may further use and disclose those records as permitted [by HIPAA].” The only exception to this broad relaxation of current requirements is that uses and disclosures for civil, criminal, administrative, and legislative proceedings *against the patient* would continue to be limited. Nevertheless, this exception dictates that Part 2 Patient Records would still need to be segregated or otherwise distinguishable from other protected health information.

¹ The Department informally published the proposed amendments and released them to the public on November 28 when they were filed with the Office of the Federal Register.

The proposed rule also distinguishes between “third-party payers” and “health plans.” Under the current Part 2 Rule (as well as the proposed rule), third-party payers must comply with the Rule with respect to any Part 2 Patient Records they receive directly from Part 2 Programs. Other parties must comply with the Rule only with respect to Records that are accompanied by a notice that redisclosure is prohibited by the Part 2 Rule. Thus, a third-party payer must determine whether information it receives is subject to the Part 2 Rule, whereas another party is not required to make that determination—another party (including a health plan under the proposed rule) must be notified whenever it receives information to which the Part 2 Rule applies. By excluding “health plans” from the definition of “third-party payers,” therefore, HHS would make it easier for health plans to determine which information is subject to the Part 2 Rule and which is not.

Enforcement of Part 2 Rule. Before the CARES Act passed, HHS had no regulatory authority to enforce the Part 2 Rule, so the only enforcement mechanism was through a criminal complaint. The proposed rule would use authority granted by the CARES Act to enforce violations of the Part 2 Rule using the same regulatory scheme that applies to the HIPAA Rules. Thus, penalties for violations of the Part 2 Rule would be the same as penalties for violations of the HIPAA Privacy and Breach Notification Rules.

HIPAA Privacy Practices Notice. In addition to proposing changes to the Part 2 Rule, HHS proposes related changes to the HIPAA Privacy Rule. Specifically, HHS proposes that any covered entity that maintains Part 2 Patient Records must revise its Privacy Practices Notice to explicitly address disclosure restrictions on the Records.

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