Compliance Today - January 2020
Proposed updates to 42 C.F.R. Part 2: Substance Use Disorder Privacy Rule

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On August 22, 2019, the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Department of Health and Human Services (HHS) announced proposed changes to the Confidentiality of Substance Abuse Disorder Patient Records regulations, set forth in 42 C.F.R. § 2 (Part 2). Part 2 protects, and prevents access to, patient records created by federally assisted substance abuse disorder (SUD) treatment programs. SUD is a defined term under Part 2, and includes cognitive, behavioral, and physiological symptoms indicating that an individual continues using a substance despite significant substance-related problems, such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal. SUD does not include tobacco or caffeine use.[1] Notably, Part 2 is limited in scope, because it applies only to certain programs that treat SUD and receive federal assistance, as such terms are defined within Part 2.

Legislative history

Initially, Part 2 was designed to protect SUD patient records so that patients would not be deterred from seeking SUD treatment. Specifically, Part 2's regulations specify that their intent is to ensure that a patient receiving SUD treatment in a program that is subject to Part 2 is not more vulnerable by virtue of the availability of their patient record than an individual with a SUD who does not seek treatment.[2] For that reason, Part 2 is more restrictive with regard to the disclosure of patient records than HIPAA and general state privacy laws.

However, Part 2 is outdated and creates barriers to treatment and coordination of care amidst the recent opioid crisis. According to HHS's press release, the proposed rule supports coordinated care among providers who treat SUD, while still maintaining privacy for patients who seek SUD treatment.[3] In addition, the proposed modifications are designed to clarify Part 2's protections and applicability in a manner intended to ensure that providers are not discouraged from treating SUD patients on account of what has historically been viewed as Part 2's onerous regulatory requirements.[4] Specifically, HHS states that: "the proposed rule is the first of four regulations that have been identified in HHS's *Regulatory Sprint to Coordinated Care* that seeks to promote value-based outcomes for patients by examining federal regulations that impede coordinated care among health providers."[5]

In sum, the proposed rule seeks to balance the need to both coordinate care among providers that treat SUD and maintain privacy for patients seeking such treatment. This article categorizes the types of changes sought by the proposed rule into the following broad categories: (1) changes intended to decrease the burden on patients, (2) changes intended to facilitate the coordination of care among providers who treat patients with SUD, (3) changes related to the use of SUD patient treatment records for research purposes, (4) changes intended to resolve existing ambiguities within Part 2, and (5) changes intended to provide further clarity with regard to Part 2 requirements. Interested parties were permitted to submit comments regarding the proposed rule to SAMHSA by

October 25, 2019.[6]