LEGAL ADVICE FOR HEALTH PLANS

HEALTH LAW ALERT
August 26, 2019

SAMHSA Proposes Changes to Part 2 Rule

Changes to Support Coordination of Care for Substance Use Disorder Patients

Today, the Substance Abuse and Mental Health Services Administration (SAMHSA), an agency of the Department of Health and Human Services (HHS), formally[1] published proposed amendments to the Confidentiality of Substance Use Disorder Patient Records Rule (Part 2 Rule). The proposal is designed to support coordination of care among Part 2 Programs (which treat patients for Substance Use Disorders) and other health care providers, by excluding from the scope of the Part 2 Rule records that these other providers create "in a direct patient encounter," even though the records may contain Substance Use Disorder information. Nevertheless, other health care providers would still be required to comply with the Part 2 Rule with respect to records received from a Part 2 Program (or another Lawful Holder of Part 2 records) and would need to keep the Part 2 Records "segregated or segmented" to distinguish them from other, non-Part 2 records.

Notwithstanding SAMHSA's emphasis on care coordination, however, the agency continues to stress in the proposed rule (as it has in the past) that "case management" and "care coordination" are not "health care operations" for purposes of the Part 2 Rule. This will make engaging in such activities extremely difficult for health plans. In addition to this change in how non-Part 2 health care providers may comply with the Part 2 Rule, the proposed rule would allow patient consents to name specific entities other than health care providers and third-party payers (*e.g.*, health plans) and clarify other provisions of the current Part 2 Rule.

The proposed rule is published at 84 *Federal Register* 44568 (click here).[2] Click here for my compilation of the Part 2 Rule (see second line under "Compiled Rules") (or see the "Resources" page at tbixbylaw.com).

[1] The Department informally published the proposed changes to the Part 2 Rule and released them to the public on August 22, when they were filed with the Office of the Federal Register.

[2] SAMHSA and HHS published two proposed rules today. This Alert addresses the proposed rule that addresses changes most likely to affect health plans. The second proposed rule addresses only court-ordered disclosures of patient identifying information "in connection with investigation or prosecution of an extremely serious crime, even if the . . . crime was not allegedly committed by the patient." This proposed rule is published at 84 *Federal Register* 44566 (click here).

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Care Coordination

SAMHSA explains that, as a result of the opioid crisis, "it has become increasingly important for primary care providers and general medical facilities not covered by [the Part 2 Rule] to be able to carry treatment and health care operations that sometimes involve creating new records that mention [Substance Use Disorder] status and care. Such records and activities are not covered by 42 C.F.R. part 2," as long as the non-Part 2 providers segregate records actually received from Part 2 Programs and maintain those records in accordance with the Part 2 Rule. Specifically, the proposed rule states:

> "a non-part 2 treating provider may record information about a substance use disorder (SUD) and its treatment that identifies a patient. This is permitted and does not constitute a record that has been re-disclosed under part 2, provided that any SUD records received from a part 2 program or other lawful holder are segregated or segmented."

Thus, this proposed change to the Part 2 Rule (as well as the discussion of the proposed change in the preamble to the proposed rule) clearly limit this greater flexibility to health care providers, meaning the proposed changes are not likely to affect how health plans comply with the Part 2 Rule.

Although HHS's media release touted "care coordination" as the most significant of the changes in the proposed rule, SAMHSA renewed its argument that "case management" and "care coordination" are not "health care operations" for purposes of the Part 2 Rule:

> "SAMHSA again clarifies that [the provision allowing disclosures of Patient Identifying Information to contractors to conduct payment activities and health care operations] is not intended to cover care coordination or case management, and disclosures to contractors, subcontractors, and legal representatives to carry out such purposes are not permitted [without a separate consent]."

SAMHSA's argument is based on its belief that case management and care coordination necessarily involve "patient diagnosis, treatment, or referral for treatment." Thus, in SAMHSA's view, providers may conduct case management or care coordination, but health plans generally cannot—health plans do not conduct "patient diagnosis, treatment, or referral for treatment." Moreover, SAMHSA makes clear that a Third-Party Payer (such as a health plan) cannot use the "audit and evaluation" exception for purposes of care coordination. "Information disclosed for the purpose of a program audit or evaluation may not be used to directly provide or support care coordination."

Proposed Revision to Consent Requirements

Under the current rule, a consent may name an entity (*i.e.*, a company or organization) as the permitted recipient of Patient Identifying Information only if the recipient is (i) a health care provider; (ii) a Third Party Payer; or (iii) a research institution, health information

exchange, or "other entity that facilitates the exchange of health information." 42 C.F.R. § 2.31(a)(4). Otherwise, a consent must name a ***specific individual*** who may receive Patient Identifying Information. Thus, for example, as currently written, "if a patient wants a part 2 program to disclose impairment information to the Social Security Administration for a determination of benefits," the consent must name ***a particular employee*** at the Social Security Administration to whom the information could be provided. SAMHSA acknowledged that the same problem arises in the context of disclosures of Patient Identifying Information to entities providing non-medical services to patients, such as local sober living or halfway house programs. SAMHSA is therefore proposing to allow patients to name ***any entity*** in a consent so as "to empower patients to consent to the release and use their health information in whatever way they choose."

Proposed Clarifications to Part 2 Rule

The current Part 2 Rule permits a Lawful Holder of Patient Identifying Information to disclose a patient's information to its business associates (or other "contractors" and "subcontractors"), provided that the patient has signed a consent allowing the Lawful Holder to use the patient's information for "payment and health care operations activities." SAMHSA has made clear that the payment and health care operations activities for which a Lawful Holder (or its business associates/contractors) may use Patient Identifying Information pursuant to this type of consent include many, but not all, of the payment activities and health care operations permitted under the HIPAA Privacy Rule. The preamble to the current Rule listed payment activities and health care operations that are permitted by these consents. The proposed Rule would not change the list of permitted activities, but it would include the list in the Rule itself in order to "clear up any remaining confusion" over what activities are permitted. SAMHSA stresses that the list (as previously published and as proposed) "is illustrative rather than exhaustive." Nevertheless, (as mentioned above) SAMHSA continues to insist that case management and care coordination are not health care operations for purposes of the Part 2 Rule.

The current Rule permits Third-Party Payers (as well as government entities and others) to conduct "audits" and "evaluations" of Lawful Holders of Patient Identifying Information. The Rule does not, however, define what an "audit" or "evaluation" is. In order to "clarify allowable program evaluation activities using patient identifying information," the proposed Rule would provide a non-exclusive list of the types of activities that qualify as audits and evaluations. Permitted audits and evaluations would include (but not be limited to) activities a Third-Party Payer conducts to:

(i) Identify actions it can take, to improve care and outcomes for part 2 programs, such as changes to its policies or procedures;

(ii) Target limited resources more effectively; or

(iii) Determine the need for adjustments to payment policies for the care of patients with Substance Use Disorders; and

(iv) Review the appropriateness of medical care, medical necessity, and utilization of services.

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