HEALTH LAW ALERT
January 3, 2018

SAMHSA Revises Substance Use Disorder Patient Confidentiality Rule

Revisions Designed to Better Align Part 2 with HIPAA

Today, the Department of Health and Human Services' Substance Abuse and Mental Health Services Administration (SAMHSA) formally[1] published a Final Rule revising the Confidentiality of Substance Use Disorder Patient Records Rule (42 C.F.R. Part 2) incorporating changes that make compliance with the Rule considerably easier for health plans and other third-party payers. The preamble to the revised Final Rule explains that "SAMHSA has attempted to align this final rule with HIPAA, the HITECH Act, and their implementing regulations to the extent feasible, . . . [given that the underlying statute] provides more stringent federal protections than other health privacy laws such as HIPAA."

The revised rules generally go into effect on February 2, 2018. SAMHSA will, however, permit health plans (and other lawful holders of information subject to the Rule) two years to come into compliance with a requirement that contractors and subcontractors be subject to provisions in written agreements that impose restrictions and limitations on how they use and disclose such information.

The revised Final Rule is published at 83 *Federal Register* 239 (click here). For my compilation of the Federal Confidentiality of Substance Use Disorder Patient Records Rule incorporating the amendments into previously-published rules, click here (*see* the last bullet under "Compiled Rules") (or see the "Resources" page at tbixbylaw.com).

Permitted Disclosures to Contractors and Subcontractors

Under previous versions of the Part 2 Rule, disclosure to a third party of information that is subject to the rule ("Patient Identifying Information") was generally permitted only with the patient's written consent that listed the name of the intended recipient. That made disclosure of information to a third-party payer's (such as a health plan's) contractors or

[1] The Department informally published the revised Final Rule and released it to the public on January 2, 2018 when it was filed with the Office of the Federal Register.

subcontractors problematic. Recognizing "the critical role that third-party payers . . . and their contractors, subcontractors, and legal representatives play in the provision of health care services," SAMHSA revised the rule to permit re-disclosure of Patient Identifying Information to these downstream entities based solely on a consent naming the third-party payer. As SAMHSA explained, "[t]his is because contractors, legal representatives, and subcontractors are acting on behalf of the lawful holders based on contracts, legal agreements or mandates in law."

The revised Final Rule will require third-party payers to engage contractors and subcontractors that receive Patient Identifying Information on behalf of the payer in provisions of a written agreement designed to safeguard the information and put these downstream entities on notice of their obligation to comply with the revised Final Rule.

(Certain) Payment Activities and Health Care Operations

SAMHSA stresses that a third-party payer must "ensure that the purpose section of the [patient's consent] is consistent with the . . . services provided by the contractor or subcontractor" to which the third-party payer plans to re-disclose Patient Identifying Information. Thus, a third-party payer cannot re-disclose Patient Identifying Information to a contractor or subcontractor to perform a service, unless the patient's consent permits the third-party payer to perform the service in the first place. The revised Final Rule allows a patient's consent to permit disclosure to a third-party payer (and therefore re-disclosure to a third-party payer's contractors and subcontractors) for "payment" activities and "health care operations," as those terms are defined in HIPAA.

Accordingly, a third-party payer that receives Patient Identifying Information for payment activities and health care operations pursuant to a consent may ***use*** that Patient Identifying Information as necessary to conduct payment activities and health care operations and ***disclose*** the information to its contractors or subcontractors as necessary for them to conduct payment activities or health care operations on the third-party payer's behalf. It is important to note, however, that the consent does ***not*** permit the third-party payer (or the downstream entities acting on third-party payer's behalf) to re-disclose the Patient Identifying Information to any other person or entity without additional consent.

The revised Final Rule limits the "payment" activities and "health care operations" to which a consent may apply, however. Specifically, a third-party payer may not re-disclose Patient Identifying Information to a contractor or subcontractor (or to any other person or entity) for purposes "such as substance use disorder patient diagnosis, treatment, or referral for treatment." SAMHSA explains in the preamble to the revised Final Rule that this restriction means a third-party payer is prohibited from re-disclosing Patient Identifying Information to a contractor or subcontractor for purposes of (and a contractor or subcontractor therefore cannot perform) "care coordination or case management."

Audit and Evaluation

The revised Final Rule also expanded the scope of the "audit and evaluation" provisions of Part 2. Under the previous versions of the Rule, audits were limited to Part 2 programs (*i.e.*, the health care provider treating patients for substance use disorders) and certain government-funded programs. The revisions published today will allow audits of any lawful holder of Patient Identifying Information, provided that the auditor agrees to comply with the revised Final Rule with respect to any Patient Identifying Information it reviews, among other requirements. Similarly, the revised Final Rule permits third-party payers (as well as other lawful holders of Patient Identifying Information) to disclose Patient Identifying Information to "[a]ny federal, state, or local governmental agency . . . authorized by law to regulate the activities of the . . . lawful holder," provided that the governmental agency agrees to the same restrictions as other auditors.

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