



LEGAL ADVICE FOR HEALTH PLANS

HEALTH LAW ALERT

January 18, 2017

Substance Use Disorder Patient Records Rule Published

Third Party Payers Must Implement Policies and Procedures

The Substance Abuse and Mental Health Services Administration (“SAMHSA”), a Department of Health and Human Services agency, formally¹ published final rules that update the “Federal Confidentiality of Alcohol and Drug Abuse Patient Records Rule,” often referred to as Part 2 (42 C.F.R. Part 2). The original rule was published over four decades ago and has undergone only minimal changes since, making the revisions among the most long-awaited of updates to HHS Rules. The new Confidentiality of Substance Use Disorder Patient Records Rule clarifies the requirements for the written consent necessary for disclosures to third-party payers (including health insurers and HMOs) of information subject to the Rule (“Patient Identifying Information”). The new Rule also provides some additional flexibility for third-party payer audits of providers of substance abuse treatment and for conducting research using patient records.

SAMSHA simultaneously published a Supplemental Notice of Proposed Rulemaking, which proposes to amend the new Rule to grant third-party payers flexibility to permit their business associates to access Patient Identifying Information for limited purposes, among other things.

The new Rule goes into effect on February 17, 2017 and is published at 82 *Federal Register* 6052 ([click here](#)). The proposed Supplemental rule is published at 82 *Federal Register* 5485 ([click here](#)). [Click here](#) for my version of the Federal Confidentiality of Substance Use Disorder Patient Records Rule (*see* the third bullet under “Compiled Rules”) (or see the “Resources” page at tbixbylaw.com).

Confidentiality of Substance Use Disorder Patient Records Rule

The Confidentiality of Alcohol and Drug Abuse Patient Records Rule applies to substance use disorder providers that receive federal financial assistance, including

¹ The Department informally published the Rules and released them to the public on January 13, when they were filed with the Office of the Federal Register.

reimbursements from Medicare, Medicaid, and other government programs, as well as receiving tax-exempt status from the IRS (“Substance Use Disorder Programs”). “Patient Identifying Information” that is subject to the Rule is limited, however, “to information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a substance use disorder.” Thus, information about a substance use disorder patient that relates to other health conditions is not Patient Identifying Information subject to the Rule, as long as the information does not indirectly identify the individual as a substance use disorder patient.

The Rule generally prohibits any disclosure of Patient Identifying Information without the patient’s written consent. Under the new Rule, a patient’s consent must name the specific third-party payer to which disclosure is permitted. Accordingly, a Substance Use Disorder Program must obtain consent from a patient for disclosures to a specific third-party payer before the Program submits a claim to the third-party payer, if the claim will include Patient Identifying Information. Recipients of Patient Identifying Information, such as third-party payers, are subject to the Rule once they receive Patient Identifying Information.

Formal Policies and Procedures

The Confidentiality of Substance Use Disorder Patient Records Rule requires all “lawful holders” of Patient Identifying Information to “have in place formal policies and procedures to reasonably protect against unauthorized uses and disclosures of patient identifying information and to protect against reasonably anticipated threats or hazards to the security of patient identifying information.” A third-party payer that has received Patient Identifying Information is a “lawful holder,” as is any other “individual or entity who has received such information as the result of a part-2-compliant patient consent.”

The policies and procedures required by the Rule must address, among other things, the manner in which electronic records are created, received, maintained, and transmitted; the destruction of the records; and use or and access to the records. SAMSHA stresses, however, an entity that “already has security practices and policies in place that meet the requirements of [the new Rule] . . . may not need to take additional action on this issue.”

Provider Audits and Research

The Confidentiality of Substance Use Disorder Patient Records Rule permits a third-party payer to conduct an audit of a Substance Use Disorder Program, provided that the third-party payer (i) covers patients in the Program and (ii) agrees in writing to specified safeguards related to the Patient Identifying Information. The third-party payer must conduct the audit itself, however, and cannot hire an outside contractor to perform the audit on its behalf.²

² Medicare, Medicaid, CHIP, and certain other CMS-regulated entities may use vendors to perform audits.

The new Rule also permits third-party payers (and other lawful holders of Patient Identifying Information) to conduct research in accordance with the HIPAA Privacy Rule requirements for research under 45 C.F.R. § 164.512. The new Rule does not, however, permit the use of Patient Identifying Information for research under the Privacy Rule’s Limited Data Set provisions.

Supplemental Notice of Proposed Rulemaking

In the preamble to the new Rule, SAMHSA explained that it had received comments concerning the important role of contractors and subcontractors have in “carrying out payment, health care operations, and other health care related activities” for third-party payers. SAMHSA went on to propose modifications to the new Rule to address contractors and subcontractors because of “this feedback and given the critical role third-party payers, other lawful holders, and their contractors and subcontractors play in the provision of health care services.”

Under the proposed rule, a patient could provide written consent to allow his/her specific third-party payer to receive Patient Identifying Information for payment activities and health care operations. This consent would be sufficient to permit that third-party payer’s contractors and subcontractors to receive and use Patient Identifying Information about the patient for most (but not all) payment activities and health care operations (as defined by the HIPAA Privacy Rule) on the third-party payer’s behalf. These contractors and subcontractors would need to be subject to contractual provisions (presumably added to a business associate agreement) that address specific requirements of the proposed Rule.

SAMHSA is soliciting comments on the proposed rule, which must be submitted by February 17, 2017.

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