HEALTH LAW ALERT
February 9, 2016

HHS Proposes Changes to Federal Substance Abuse Rules

"Modernization" of Rule Unlikely to Resolve Health Plan Issues

The Department of Health and Human Services' Substance Abuse and Mental Health Services Administration ("SAMHSA") formally[1] published proposed modifications to the Federal Substance Abuse Rules, which severely restrict the use and disclosure of information concerning treatment of alcohol and drug-abuse patients. The Federal Substance Abuse Rules, codified at 42 C.F.R. Part 2 ("Part 2" or "FSAR"), were drafted in 1975 and have changed little since then. SAMHSA's goal in proposing the changes was to "modernize" the rules and "to better align them with advances in the U.S. health care delivery system while retaining important privacy protections." But, the proposed changes are unlikely to make it any easier for health plans to maintain, use, or disclose information that is subject to the Rules.

The proposed rules are published at 81 *Federal Register* 6987 (click here). Comments on the proposed rules are due on or before April 11.

Consent Requirements Under the Federal Substance Abuse Rules

FSAR protects records that "identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a substance use disorder" ("FSAR Records"). Health care providers, health plans, and others that create or receive FSAR Records generally cannot disclose the records without the patient's written consent. Under the current rule, a consent is not valid unless the document includes the "name of the organization to which disclosure is to be made." Thus, a consent permitting disclosure to "my health insurer" is not valid. And a consent that includes the name of the health insurer would not be valid for disclosures to the health plan's business associates, such as a pharmacy benefit manager (PBM), claims processer, or care manager.

The proposed rule would relax this requirement for individuals or entities that have a "treating provider relationship" with the patient. But, the requirement that the consent

[1] The Department informally published the Rules and released them to the public on February 5th when they were filed with the Office of the Federal Register.

include the name of the specific organization to which FSAR Records may be disclosed would continue to apply to any entity that does not have a "treating provider relationship" with the patient. A provider cannot, therefore, submit a claim that includes FSAR Records to a health plan without a patient consent that specifies the health plan's name; and the health plan could not disclose FSAR Records to its business associates without a consent that states the name of each business associate. The proposed rules would not change this situation in any way.

Qualified Service Organizations

FSAR permits certain health care providers that operate programs to treat patients for substance abuse (Part 2 Programs) to disclose FSAR Protected Records to vendors that provide the Part 2 Programs services, such as data processing, bill collection, and legal, medical or accounting professional services. These vendors, called Qualified Service Organizations, may only receive FSAR Records when performing services for a Part 2 Program. Thus, the exception is not applicable to a health plan's business associates. Again, the proposed rules do not provide relief to health plans from this restriction.

Proposed Requirement for Formal Policies and Procedures

SAMHSA proposes to require that any "lawful holder" of FSAR Records implement "formal policies and procedures" designed "to reasonably protect against unauthorized uses and disclosures of [FSAR Records] and protect against reasonably anticipated threats or hazards to the security of [FSAR Records]." The policies and procedures would be required to address, for example:

- Maintenance of paper FSAR Records "in a secure room, locked filing cabinet, safe, or other similar container, or storage facility when not in use"; and

- Provisions for "copying, downloading, forwarding, transferring, . . . [and] destroying [electronic FSAR Records], including sanitizing the electronic media on which it was stored."

Because health plans will receive FSAR Records in claims (at least), they will need to implement such policies and procedures if the proposed rules are finalized.

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