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HHS Issues Proposed Rule to Modify 42 CFR Part 2 Privacy and Security Standards for Substance Use Disorder Information

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On February 9, 2016, the Substance Abuse and Mental Health Services Administration (“SAMHSA”) of the Department of Health and Human Services (HHS) published new proposed regulations¹ to modify the special privacy and security standards relating to certain drug and alcohol abuse records under 42 CFR Part 2. Since their enactment in 1975, the regulations under 42 CFR Part 2 have not been substantively updated since 1987. If the proposed regulations are finalized, healthcare providers subject to the regulations will need to update policies and procedures and may also need to update consent/authorization forms to address the regulatory changes.

Background:

The regulations under 42 CFR Part 2 establish special standards for use and disclosure of certain information that would identify an individual as receiving or needing treatment for alcohol or drug abuse. The standards under 42 CFR Part 2 are more stringent than those under HIPAA and require consent/authorization from the patient for a number of uses and disclosures that are otherwise permitted under HIPAA without patient consent. For example, 42 CFR Part 2 does not include a broad exception allowing disclosures to other healthcare providers for treatment and patient consent/authorization is often required even for payment activities of the treating provider and some basic healthcare operations.

Proposed Regulations:

SAMHSA states that its goal in updating the regulations is to increase opportunities for individuals with “substance use disorders”² to participate in new and emerging healthcare models by facilitating the sharing of information within the healthcare system while still honoring the privacy of patients seeking treatment. In what would be the first substantive update in nearly 30 years, the proposed regulations, if finalized, would modify a number of standards including the following:

- *Security Policies and Procedures* – The proposed regulations include new standards that would mandate that covered programs and other holders of information have in place formal policies and procedures addressing a number of security standards.
- *Standards for Disposition of Records by Discontinued Programs* – The proposed regulations include additional specific standards relating to management of covered records where a program covered by 42 CFR Part 2 discontinues operations or is taken over or acquired by another program.

¹ 81 Fed. Reg. 6988 (Feb. 9, 2016).

² The proposed regulations would define “substance use disorder” as encompassing drug abuse, alcohol abuse, and other disorders associated with altered mental status that have the potential to lead to risky and/or socially prohibited behaviors. 81 Fed. Reg. 6994.

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- *Privacy Notices* – The proposed regulations would modify standards relating to privacy notices given to patients of a covered program.
- *Consents for Use and Disclosure* – The proposed regulations would modify the current standards for consent/authorization for disclosure of covered information to facilitate sharing of information within a health information exchange (HIE) and in connection with certain research activities. Under current standards, the consent/authorization must typically include the name or title of the individual or the name of the organization to which covered information is to be disclosed. The revisions are intended to facilitate provision of covered information to a HIE and to address similar issues where covered information may be included in an electronic health record.
- *Notices Accompanying Records* – The regulations would update the language that must be included in notices furnished with records covered by 42 CFR Part 2.
- *Research* – The proposed regulations would permit certain disclosures for research purposes without special patient consent under 42 CFR Part 2, subject to certain special standards and compliance with HIPAA.
- *List of Disclosures* – The proposed regulations include provisions allowing a patient to obtain a list of disclosures made under a “general consent designation” during the two year period prior to the patient’s request.

Comments to the proposed regulations must be received by HHS no later than 5:00 p.m. on April 11, 2016. If you have any questions about 42 CFR Part 2 or this proposed rule, please contact Bill Hall, Mary Malone, or Molly Huffman at 804-967-9604.

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