March 29, 2016

Significant Proposed Changes Seek to Modernize Regulations on Confidentiality of Drug and Alcohol Abuse Patient Records under Part 2

On February 9, the Substance Abuse and Mental Health Services Administration ("SAMHSA") published proposed rule changes relating to the confidentiality of drug and alcohol abuse patient records in 42 CFR Part 2 ("Part 2"). The proposed changes are intended to update and modernize the regulations, which have not been substantively updated since 1987. Most notably, in the past 25 years, health care in the United States has become more integrated and digitized, and SAMHSA "wants to ensure that patients with substance abuse disorders have the ability to participate in, and benefit from new integrated health care models without fear of putting themselves at risk of adverse consequences" such as loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrest, prosecution, and incarceration. The proposed changes would significantly alter how facilities subject to Part 2 must comply with the regulations in the modern age of health care technology, integration and delivery.

Below is a summary of the most significant proposed changes:

- **General Medical Practice Applicability:** An identified unit within a general medical facility or a general medical practice itself would be subject to Part 2 *only* if it holds itself out as providing, and provides, substance abuse use disorder diagnosis, treatment, or referral for treatment, or if the primary function of medical personnel or other staff in the general medical facility or general medical practice is the provision of such services and they are identified to the public as providing such services. The Proposed rules also clarifies that "holds itself out" means any activity that would lead one to reasonably conclude that the individual or entity provides substance abuse disorder diagnosis, treatment or referral for treatment, including but not limited to (a) authorization by the state or federal government to provide such services, (b) advertisements, notices or statements related to such services, or (c) consultation activities relative to such services.

- **Disclosures:** In certain circumstances, a patient would be permitted to include a general designation in the "To Whom" section of the consent form, provided the form includes an explicit description of the amount and kind of substance use disorder treatment information that may be disclosed, and the "From Whom" section specifically names the Part 2 program or other lawful holder of the patient identifying information permitted to make the disclosure.

- **List of Disclosures:** Upon request, patients who choose to include a general designation in the "To Whom" section of their consent form must be provided a list of entities to which their information has been disclosed under the general designation (referred to as the "List of Disclosure" requirement). Such requests would have to be made in writing, and would be limited to disclosures made in the past two years.

- **Electronic Records:** The proper disposition of records by discontinued programs would explicitly address electronic and paper records, as well as requirements for sanitizing associated media.
- **Consent:** Patients would be permitted to electronically sign consent forms to the extent permitted by applicable law.
- **Prohibitions on Re-disclosure:** The prohibition on re-disclosure of patient information would apply only to information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a substance use disorder, such as indicated through standard medical codes, descriptive language, or both, and allows other health related information shared by the Part 2 program to be re-disclosed, if permissible under other applicable laws.
- **Medical Emergency:** The medical emergency exception would give providers more discretion to determine when a "bona fide medical emergency" exists. This exception would also allow medical personnel to disclose Part 2 patient information in the context of a bona fide medical emergency when patient consent cannot be obtained.
- **Clinical Research:** Information protected by Part 2 would be permitted to be disclosed to qualified personnel for the purpose of conducting scientific or clinical research by a Part 2 program or any other individual or entity that is in lawful possession of Part 2 data if the researcher provides documentation of meeting certain requirements related to other existing protections for human subjects research. SAMHSA is also seeking comment on whether researchers holding Part 2 data should also be permitted to link to data sets from federal data repositories, and possibly also non-federal data repositories.
- **Audits and Evaluations:** Provisions for audits and evaluations would address electronic as well as paper patient records.

In addition, the following changes to definitions are proposed:

- To clarify applicability of Part 2, a new defined term, "**Part 2 Program**," would be defined as a federally assisted alcohol or drug abuse program that is also a "Program" under the regulations, and "Part 2 Program" would replace the term "Program" where appropriate throughout the regulations.
- The definitions of "Alcohol abuse" and "Drug abuse" would be deleted and combined into a new definition referring collectively to "**Substance use disorder**," which would cover substance use disorders that can be associated with altered mental status that has the potential to lead to risky and/or socially prohibited behaviors, including, but not limited to, substances such as, alcohol, cannabis, hallucinogens, inhalants, opioids, sedatives, hypnotics, anxiolytics, and stimulants, but specifically excluding tobacco and caffeine.

- A new definition of "**Treating provider relationship**" would be added, relevant to the proposed revisions to the consent form to allow a general description of the individuals or entities to which a disclosure is made, but only if they have a "Treating provider relationship" with the patient. Under the proposed changes, a "Treating provider relationship" would mean, regardless of whether there has been an actual in-person encounter, that "a patient agrees to be diagnosed, evaluated and/or treated for any condition by an individual or entity, and the individual or entity agrees to undertake diagnosis, evaluation and/or treatment of the patient, or consultation with the patient, for any condition."
- The definition of "**Records**" would be updated to include electronic records as well as paper records.

These proposed changes are not final, and a public comment period is open until April 11, 2016. The proposed effective date of the changes would not be for two years after the effective date of the final rule, providing time for Part 2 providers to implement any final changes, including updating IT systems, updating consent forms, compiling the "List of Disclosures," and training staff. Nonetheless, Part 2 providers should be aware of these potential changes and what steps would need to be taken ensure compliance.

Practically speaking, if the proposed changes go into effect, patients who participate in from Part 2 programs will gain from alternative reimbursement models and health care delivery models as their records will be able to be used in quality improvement studies. Additionally, Part 2 patients will be able to allow their information to be included in that which goes to health information exchange organizations. Part 2 patients will also benefit from being able to participate in clinical research protocols that they might otherwise not be able to. And finally, practitioners practicing at general medical practices will finally have clarification that Part 2 requirements only apply to their practices in specific circumstances.

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