

SAMHSA Overhauls Federal Rule Governing Privacy of Patients Seeking Treatment for Substance Use Disorders

The federal regulations codified at 42 CFR Part 2 (“Part 2”) protect the confidentiality of patients seeking treatment for substance use disorders (“SUD”). The Substance Abuse and Mental Health Services Administration (“SAMHSA”) enforces Part 2. On January 18, 2017, SAMHSA published a final rule (“Final Rule”) revising Part 2. SAMHSA had not amended Part 2 since 1987 despite advances in health information technology and delivery systems. Due to the recognition of the treatment benefits achieved through prompt transmission of SUD information from one provider to another, SAMHSA has attempted to balance privacy rights with critical treatment needs. Below is a summary of the major changes contained in the Final Rule.

1. CONSENT REQUIREMENT

Part 2 previously required SUD patients to list the name of each provider to whom they wanted to disclose SUD information on a written consent form (e.g., “Dr. Thomas Smith”). This requirement made it nearly impossible for patients to participate in a health information exchange or accountable care organization because naming all participating providers was impracticable or impossible. The Final Rule lets patients use a general designation in the “To Whom” section of their consent form (e.g., “my treating providers”) provided they also specify the amount and kind of SUD information to be disclosed (e.g., “all of my SUD information” or “records of my Suboxone treatment”). This new general designation allows patients to participate in clinically integrated networks, health information exchanges, and accountable care organizations because all participating providers may access the patient’s information based on a single designation.

2. PROHIBITION ON RE-DISCLOSURE

Part 2 programs disclosing SUD information must send a specific written notice notify-

ing the recipient that the information produced is not subject to re-disclosure without the patient’s consent. Previously, all data disclosed by a SUD program was protected from re-disclosure by the recipient. The Final Rule adds language to the re-disclosure notice clarifying that only data which directly or indirectly identifies a patient as suffering from a SUD (e.g., diagnosis codes, etc.) is subject to the prohibition on re-disclosure. Given that nearly all information disclosed by a Part 2 program identifies a patient as suffering from a SUD, this change may be a distinction without a difference.

3. QUALIFIED SERVICE ORGANIZATIONS

Part 2 programs may share SUD information with third party contractors known as “Qualified Service Organizations” or “QSOs” (e.g. data processing, billing, collection, etc.). Although the Final Rule expands the definition of QSO by including population health management entities, it narrows the definition by excluding care coordination and medication management services. This narrowing may prevent Part 2 programs from sharing SUD information with existing contractors in the absence of a patient authorization.

4. SCIENTIFIC RESEARCH

The Final Rule permits any lawful holder of SUD information to disclose it to “qualified personnel” for purposes of conducting scientific research as long as the researchers provide proof of compliance with various legal requirements such as HIPAA. Researchers are bound by the Final Rule to the same extent as Part 2 programs.

5. SUPPLEMENTAL NOTICE OF PROPOSED RULEMAKING

SAMHSA also published a Supplemental Notice of Proposed Rulemaking seeking comments on the ability of Part 2 programs and



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their contractors, subcontractors, and legal representatives to disclose SUD information for payment and health care operations as well as re-disclosures for audit and evaluation activities. The comment period is now closed. SAMHSA will likely make further changes to Part 2 based on the comments received.

CONCLUSION

The Final Rule took effect on March 21, 2017. Part 2 programs should take immediate steps to comply such as amending outdated policies and notices, training staff, and communicating with their QSOs. Part 2 programs should consult with legal counsel where necessary to ensure compliance, and stay tuned for further action from SAMHSA.

Balancing access to information and patient privacy is extremely important given the unfortunate rise of opioid addiction in New Hampshire and nationwide. Overall, it appears that the Final Rule paves the way for SUD patients to participate in integrated health care models that ideally will lead to a better, more cost-effective health care system, while safeguarding essential privacy rights.

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