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HEALTH LAW
A SHIPMAN & GOODWIN® ALERT

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SAMHSA Modernizes Regulations Governing the Confidentiality of Substance Use Disorder Records

After nearly thirty years since the last substantive change to the law, on January 18, 2017, the Substance Abuse and Mental Health Services Administration (SAMHSA) published its final rule[1] (the "Final Rule") implementing substantive amendments to the Confidentiality of Alcohol and Drug Abuse Patient Records regulations at 42 C.F.R. part 2 (the "Part 2 Regulations"), which restrict the disclosure and use of substance use disorder patient records.[2]

Please note that the Final Rule was set to take effect on February 17, 2017; however, due to the Executive Branch's 60-day "regulatory freeze," the effective date has been delayed until no sooner than March 21, 2017.[3]

A. Background

Under the existing Part 2 Regulations, a "federally assisted program" ("Program") may not disclose any information about a patient's diagnosis, treatment, or referral for treatment for a substance use disorder ("Patient Identifying Information"), unless the patient has consented in writing on a form that satisfies the requirements set forth in the Part 2 Regulations, there is a valid court order authorizing the disclosure, or another limited exception applies. The purpose of the Part 2 Regulations is to ensure that fear of disclosure of Patient Identifying Information is not a deterrent to treatment for substance use.

B. SAMHSA's Final Rule

The following sections summarize the key revisions to the Part 2 Regulations set forth in the Final Rule. For additional information regarding selected changes to the existing Part 2 Regulations, please see the Summary Chart we have prepared [http://shipmangoodwin.com/webfiles/SummaryChartSMHSA.pdf].

1. Applicability

Notably, the Final Rule did not substantively change what entities are considered Programs under the Part 2 Regulations. However, SAMHSA does clarify that both "Programs" and "other lawful holders" of Patient Identifying Information[4] (e.g., a patient's

1 Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. 11, 6052 (Jan. 18, 2017), available at https://www.gpo.gov/fdsys/pkg/FR-2017-01-18/pdf/2017-00719.pdf.

2 The Final Rule is the product of the federal regulators' attempt to keep pace with health care providers' increasing reliance on electronic health records and the growing number of integrated care initiatives in the country.

3 On January 20, 2017, the administration of President Donald J. Trump issued a memorandum asking the heads of executive departments and agencies to "temporarily postpone" the effective date of regulations that had been published in the *Federal Register b*ut had not yet taken effect for 60 days from the date of the memorandum "for the purpose of reviewing questions of fact, law, and policy they raise." Memorandum, Reince Priebus to the Heads of Executive Departments and Agencies, "Regulatory Freeze Pending Review" (Jan. 20, 2017), https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies.

4 A 'lawful holder' of patient identifying information is an individual or entity who has received such information as the result of a part 2-compliant patient consent (with a prohibition on re-disclosure notice) or as permitted under the part 2 statute, regulations, or guidance and, therefore, is bound by 42 CFR part 2." 82 Fed. Reg. 11, 6068. It is important to note that the requirements under the Part 2 Regulations apply to information maintained and

treating provider, a hospital emergency room, an insurance company, or an individual/entity performing an audit or conducting scientific research) are subject to the Part 2 Regulations, including the restrictions on use and disclosure and the requirement to have formal security policies and procedures in place. Thus, any party that receives the Patient Identifying Information may not redisclose the information unless it receives the proper patient authorization or an exception applies (e.g., disclosure to "qualified service organizations").

2. Consent Requirements

Some of the most significant revisions to the Part 2 Regulations in the Final Rule pertain to the requirements for a valid patient consent for disclosure of Patient Identifying Information. Under the existing Part 2 Regulations, the Program must obtain written consent from the patient on a form that includes: the specific name or general designation of the Part 2 Program or person permitted to make the disclosure; the recipient's name; the patient's name; the purpose of the disclosure; how much and what kind of information is to be disclosed; the patient's signature; the date on which the consent is signed; a statement that the consent is subject to revocation at any time except to the extent that the Program or person making the disclosure has already acted in reliance on it; and the date, event, or condition upon which the consent will expire if not revoked before.[5]

The Final Rule amends two of the aforementioned elements in the patient consent form. Specifically, the Final Rule requires that the patient consent form include an "explicit description" of the types of Patient Identifying Information that may be disclosed. SAMHSA explains that the entity creating the consent form may provide options for the patient with respect to the type of Patient Identifying Information that that is authorized to be disclosed. "All my substance use disorder information" may be an option provided to the patient, as long as more granular options are also included on the consent form.

In addition, in order to encourage patients to participate in organizations that coordinate care, the Final Rule provides patients with the option of providing a general designation in the "To Whom" section of the consent form, so long as the recipients within the intermediary have a treatment relationship with the patient (i.e., "past," "current," and/or "future" treating providers). SAMHSA clarifies that a consent form can include multiple authorizations in the "To Whom" section. For example, patients may designate by name one or more individuals with whom they do not have a treating provider relationship, along with a general designation for their treating providers, as being authorized to receive or access their information (i.e., Dr. Smith at Blue Hospital, and all past, current, or future treating providers under Red ACO).

Lastly, the Final Rule provides patients with the right to receive, upon request, from the entity that serves as the intermediary (e.g., HIE, ACO, CCO) a list of entities to which their information has been disclosed pursuant to the general designation. SAMHSA clarifies that intermediaries may not disclose Patient Identifying Information pursuant to a general designation on a consent form until they have the ability to comply with the list of disclosures requirement.

3. Research

SAMHSA revises the existing research exception so that researchers are subject to specific regulatory requirements. The Final Rule permits Patient Identifying Information to be disclosed to qualified personnel for the purpose of conducting scientific research by a Program or any other "lawful holder" of Patient Identifying Information if the individual designated as the director determines that the researcher satisfies

disclosed by a Part 2 Program or a "lawful holder" of Patient Identifying Information. Therefore, "'[a] patient who has obtained a copy of their records or a family member who has received such information *from a patient* would not be considered a 'lawful holder' of patient identifying information in this context." Id. at 6070.

5 42 C.F.R. § 2.31.

the following requirements, as applicable: (i) has obtained and documented patient authorization or a waiver of authorization consistent with HIPAA; and (ii) has complied with the Department of Health and Human Services ("HHS") regulations regarding the protection of human subjects.[6]

4. Electronic Records

SAMHSA revises the definition of "records" to clarify that the confidentiality protections under the Part 2 Regulations are not limited to paper records, but also extend to electronic records containing Patient Identifying Information. SAMHSA further revises the definition of "records" to include verbal communications created, received, or acquired by a Part 2 Program relating to a patient. Additionally, revisions in the Final Rule address: (i) the security and disposition of electronic records, including a requirement for sanitizing associated media; (ii) the permitted distribution of the required notice setting forth the federal confidentiality requirements to patients in electronic format; (iii) the permitted use of electronic signatures on consent forms to the extent they are not prohibited by any applicable law; and (iv) the inclusion of both paper and electronic records in the audit and evaluation requirements.

C. Additional Guidance from SAMHSA

SAMHSA simultaneously issued a Supplemental Notice of Proposed Rulemaking[7] ("SNPRM") to seek further comments and information regarding the use and disclosure of Patient Identifying Information by "lawful holders" and their contractors, subcontractors, and legal representatives[8] for purposes of carrying out payment, health care operations, and other health care related activities. Comments are due by 5:00 p.m. on February 17, 2017.

D. Next Steps for Providers

Although the "regulatory freeze" has delayed the effective date of the Final Rule, providers should be aware of these pending changes and should consider developing an action plan to achieve full compliance with the Part 2 Regulations. Providers subject to the Part 2 Regulations should consider taking the following actions:

- Monitor for future changes and effective dates
- Revise consent forms
- Review and revise existing privacy and security policies

Questions or Assistance

If you have any questions about this alert or the SAMHSA Part 2 regulations, please contact Joan Feldman (jfeldman@goodwin.com or 860.251.5104), Vincenzo Carannante (vcarannante@goodwin.com or 860.251.5096), William Roberts (wroberts@goodwin.com or 860.251.5051), or Stephanie Gomes-Ganhão (sgomesganhao@goodwin.com or 860.251.5239).

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6 The Final Rule also permits researchers to link to federal and non-federal data repositories holding Patient Identifying Information if the request has been reviewed and approved by an Institutional Review Board registered with HHS.

7 The Supplemental Notice of Proposed Rulemaking may be found at: Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. 11, 5485 (Jan. 18, 2017), available at https://www.gpo.gov/fdsys/pkg/FR-2017-01-18/pdf/2017-00742.pdf.

8 Upon receipt of Patient Identifying Information, the contractors, subcontractors, and legal representatives of "lawful holders" are themselves considered "lawful holders," and thus subject to the Part 2 Regulations. 82 Fed. Reg. 11, 5487.

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