The Network for Public Health Law

Snap Shot

Substance Abuse and Mental Health Services Administration

Federal Law: Substance Abuse and Mental Health Services Administration (SAMHSA): Confidentiality of Substance Abuse Disorder Patient Records

Theme: Substance abuse treatment and diagnosis

Citation: 42 U.S.C. § 290dd- 2, 42 C.F.R. Part 2

Protects all identifiable information of treatment participants.

THE LAW

What does the law do?

The SAMHSA confidentiality legal provisions protect all identifiable information about any person receiving diagnosis, treatment, or referral for treatment for a substance use disorder at a federally assisted substance abuse disorder program. With limited exceptions, regulated programs may not use or disclose any information about a patient unless the patient consents in writing.

To whom does the law apply?

The protections apply to any federally assisted program covered by 42 C.F.R. Part 2, including treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners who hold themselves out as providing, and provide substance use disorder diagnosis, treatment, or referral for treatment.

How is "identifiable" information defined?

The law defines "patient identifying information" as information that can identify a patient with reasonable accuracy either directly or by reference to other information. The law includes the following examples of patient identifiers: name, address, social security number, fingerprints, and photographs.

SHARING OF IDENTIFIABLE DATA

Does this law allow identifiable data to be shared?

The law strictly restricts data use and disclosure without written patient consent. A few exceptions permit data sharing under limited circumstances, including to disclosures relating crimes on program premises or against program personnel, child abuse reporting, medical emergencies, court-ordered disclosures, disclosures to accreditation bodies, audit and evaluation, and research.

Among who?

The law limits internal data sharing to individuals whose duties require the information. The law also permits data sharing to Qualified Service Organizations (i.e., individuals or entities that provide services to the

program). Limited exceptions allow disclosure to various entities (e.g., healthcare, child welfare agencies, judicial officers, accreditation bodies, researchers).

What are the prerequisites and conditions?

The law requires written patient consent for any information use or disclosure with few exceptions. The written consent must conform to specific requirements. Generally, once information is disclosed, it cannot be disclosed again without consent. Qualified Service Organizations must have an agreement between the Part 2 program and the Qualified Service Organization. If a disclosure occurs in response to a medical emergency, all the circumstances surrounding the disclosure must be immediately documented in writing.

SHARING OF DE-IDENTIFIED DATA

Does this law allow de-identified information to be shared?

The law does not prohibit disclosures that do not identify a patient as an alcohol or drug abuser or someone who was a patient in a 42 C.F.R. Part 2 substance abuse disorder treatment program.

Does this law define de-identification or standards to render the data de-identified?

The law does not contain specific standards for de-identifying information. 42 C.F.R. § 2.16, which establishes security requirements, provides removing direct identifiers as an example of "[r]endering patient identifying information non-identifiable in a manner that creates a very low risk of reidentification." However, in the preamble to the 2017 final rule (pages 6064-6065), SAMHSA suggested that HIPAA's list of 18 direct and indirect identifiers applies to 42 CFR §2.11's definition of "patient identifying information.''

DATA SHARING IMPLICATIONS FOR PUBLIC HEALTH

Does this law support data sharing to improve the health of communities?

The law contains strict non-disclosure provisions with few limited exceptions. The law does not contain a generalized exception permitting the disclosure of identifying patient information without patient consent to improve the health of communities. The law contains a limited exception for disclosures to the Federal Food and Drug Administration (FDA) if there is a reason to believe that the health of an individual is at risk based on an error in the manufacture, labeling, or sale of a product under FDA jurisdiction.

How does this law hinder data sharing to improve the health of communities?

There are documented examples of the 42 C.F.R. Part 2 provisions hindering the use of data to address public health issues related to substance abuse. The law requires patient consent for most data uses and disclosures. The few exceptions to this general rule do not include an exception for disclosure to public health authorities. Moreover, the law permits states to enact laws with additional confidentiality provisions while prohibiting states from enacting laws that authorize or compel additional disclosures.

Does this law establish prerequisites, conditions, or limitations for data sharing, not previously identified?

Part 2 programs can only disclose the amount of information necessary to carry out the purpose of the disclosure. Each disclosure made pursuant to a patient's consent must include a prohibition on re-disclosure.

Substance abuse disorder programs that do not receive federal assistance are not covered by these regulations.

What other terms apply to sharing this data?

If a patient consents to disclosures to entities under a general designation (as opposed to a list of named entities or individuals that will receive confidential information), a Part 2 substance abuse disorder program must provide the patient, on request, a list of entities who have received their identifying information under the general designation.

What remedies or solutions might be employed to support data sharing while complying with this law?

The 2017 amendments to 42 C.F.R. Part 2 allow patients to consent to disclose confidential information to entities with a general designation (as opposed to a list of named entities or individuals that will receive confidential information). These amendments facilitate disclosures to organizations that enable the exchange of health information or coordinate care (e.g., HIEs, ACOs, and CCOs). Some organizations might reduce the burden associated with patient consent and increase data sharing flexibility by adapting existing forms to these new regulations.

What ethical considerations apply to the exercise of discretion to share data under this law?

Substance abuse disorders are frequently associated with stigma and illegal behaviors. The law's protections are intended to encourage patients to seek treatment by shielding them from the risk of prosecution and discrimination. Disclosures of patient identifying information increase the risk that an individual patient will be harmed by identification.

Additional information on the SAMHSA confidentiality provisions can be found here.

SUPPORTERS

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