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ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

May 7, 2018

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Improving the Coordination and Quality of Substance Use Disorder Treatment"

On **Tuesday, May 8th, 2018 at 1:00 p.m., in room 2123 of the Rayburn House Office Building,** the Subcommittee will hold a hearing entitled "Improving the Coordination and Quality of Substance Use Disorder Treatment." The bill under consideration is the AINS to H.R. 3545, Overdose Prevention and Patient Safety Act, submitted for the April 25th Subcommittee on Health markup.

I. BACKGROUND

The Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 and the Drug Abuse Prevention, Treatment, and Rehabilitation Act of 1972, including subsequent amendments to these laws, and their implementing regulations in Title 42 of the Code of Federal Regulations Part 2 (Part 2), were motivated by "great concern about the potential use of substance use disorder information against individuals," which could cause these individuals to not seek treatment.[1] According to the Substance Abuse and Mental Health Services Administration (SAMHSA), the purpose of Part 2 is "to ensure that a patient receiving treatment for a substance use disorder in a Part 2 program is not made more vulnerable by reason of the availability of their patient record than an individual with a substance use disorder who does not seek treatment."[2]

[1] Substance Abuse and Mental Health Services Administration (SAMHSA), *Confidentiality of Substance Use Disorder Patient Records, 42 CFR Part 2 final rule* (Jan. 18, 2017) (https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records).

[2] *Id.*

Because of the unique nature of substance use disorders, individuals may be discouraged from seeking treatment out of fear of the negative outcomes that could result, including loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrest, prosecution, and incarceration.[3] Further, a lack of confidence in the privacy and security of medical records appears to influence individuals to engage in privacy protective behaviors, including not seeking treatment or not disclosing relevant information to health providers.[4]

Part 2 governs the disclosure and use of substance use disorder treatment records of Part 2 programs, such as records related to the treatment of opioid use disorder and alcohol use disorder. Part 2 protections apply to any individual or entity that is federally assisted and "holds itself out" as providing alcohol or drug use disorder diagnosis, treatment, or referral for treatment. Part 2 restricts the disclosure, re-disclosure, and use of substance use disorder patient treatment information that would identify an individual as having had or having a substance use disorder. With few exceptions, Part 2 specifically requires written patient consent for disclosures of Part 2 medical records related to the treatment of substance use disorders. Accordingly, patients are exclusively permitted to decide when, what, and with whom to share their treatment records. One exception to the consent requirement is that Part 2 information can be disclosed without consent to medical personnel to the extent necessary to meet a bona fide medical emergency.[5]

II. 2017 AND 2018 PART 2 RULE CHANGES

In 2017 and 2018, SAMSHA substantially updated Part 2 for the first time since 1987.[6] The purpose of the 2017 rulemaking was to "ensure that patients with substance use disorders have the ability to participate in, and benefit from health system delivery improvements, including from new integrated care models while providing appropriate privacy safeguards."[7] The purpose of the 2018 final rule was to "better align the regulations with advances in the U.S.

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[3] SAMHSA, *Confidentiality of Substance Use Disorder Patient Records, 42 CFR Part 2 final rule* (Jan. 18, 2017) (https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records).

[4] Israel T. Agaku et al, *Concern about security and privacy, and perceived control over collection and use of health information are related to withholding of health information from healthcare providers*, Journal of the American Informatics Association (Mar. 2014) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3932467/pdf/amiajnl-2013-002079.pdf).

[5] Public Health Service Act, Section 543(b)(2)(A).

[6] American Psychiatric Association, *Final Rule: 42 CFR Part 2, Confidentiality of Substance Use Disorder Patient Records* (2017) (https://www.psychiatry.org/psychiatrists/practice/practice-management/hipaa/42-cfr-part-2).

[7] SAMHSA, *Confidentiality of Substance Use Disorder Patient Records, 42 CFR Part 2 final rule* (Jan. 18, 2017) (https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records).

health care delivery system while retaining important privacy protections for individuals seeking treatment for substance use disorders."[8]

A. General Consent Designation

Most notably, the 2017 final rule allows patients to designate a general "To Whom" their records may be disclosed. Under the final rule, patients may disclose their medical records to individuals or entities, such as a hospital, health care clinic, or a private practice, by naming such entity so long as the entities have a treating relationship with the patient. [9] Under Part 2, a treating provider relationship means that, regardless of whether there has been an actual in-person encounter: (1) a patient is, agrees to, or is legally required to be diagnosed, evaluated, and/or treated, or agrees to accept consultation for any condition by an individual or entity, and (2) the individual or entity undertakes or agrees to undertake diagnosis, evaluation, and/or treatment of the patient, or consultation with the patient, for any condition.[10] Additionally, in the cases where a patient does not have a treating provider relationship such as with a health information exchange (HIE), a patient can consent to share with the HIE so long as the patient identifies names of individuals; names of entity participants with a treating provider relationship with the patient; or a general designation of individual participants, entity participants, or class of participants with a treating provider relationship in which the patient has agreed to whom the HIE can share their patient identifying information.[11] Under the rule, when patients grant consent using a general designation, upon request, the patient must be provided a list of entities to which their information has been disclosed pursuant to the general designation.[12]

B. Permitted Disclosures with Written Patient Consent

The 2018 final rule establishes circumstances under which lawful holders and their legal representatives, contractors, and subcontractors may use and disclose patient identifying information for purposes of payment, health care operations, and audits and evaluations.[13] The final rule updated the regulations to allow lawful holders who receive Part 2 records based on patient consent to a disclosure of their records for payment and/or health care operation purposes, to further disclose these Part 2 records to their legal representatives, contractors, and subcontractors in order to perform the payment and/or health care operations functions

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[8] SAMHSA, *Confidentiality of Substance Use Disorder Patient Records, 42 CFR Part 2 final rule* (Jan. 18, 2017) (https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records).

[9] *Id.*

[10] 42 C.F.R. §2.11

[11] 42 C.F.R. §2.31

[12] 42 C.F.R. §2.13

[13] SAMHSA, *Confidentiality of Substance Use Disorder Patient Records, 42 CFR Part 2 final rule* (Jan. 18, 2017) (https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records).

designated on the patient consent form.[14] As part of such disclosures, the lawful holder must include a notice of prohibition of re-disclosure of the disclosed Part 2 record.[15]

III. CONSENT2SHARE

Technology exists that allows for the electronic sharing of a patient's medical record in compliance with Part 2. For example, SAMHSA supported the development of Consent2Share, an open-source software application for consent management and data segmentation that complies with Part 2.[16] Prince Georges County, Maryland Health Department piloted the Content2Share software to enable patients to electronically consent to share Part 2 data with providers.[17] The system, for example, would allow a user to give advanced, online consent to an out of town provider to ensure continuous coverage of substance use treatment.[18] The Consent2Share program can connect with other health information technology and segment data into appropriate Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Part 2 protected information. Users can choose which information covered under Part 2 they consent to share with which providers. Notably, all of the patients who participated in the Prince Georges County pilot blocked at least some information to some providers.[19]

IV. PROTECTIONS FOR INDIVIDUALS WITH SUBSTANCE USE DISORDERS UNDER CIVIL RIGHTS LAWS

Federal civil rights protections do not always apply to those with substance use disorders. Therefore, people who seek treatment for a substance use disorder are at greater risk of losing employment or housing than they would be if they had another health condition, such as HIV, which has complete protection under federal civil rights laws. The Americans with Disabilities Act (ADA) and Fair Housing Act (FHA), for example, have exclusions that do not protect individuals who currently use illegal substances (e.g., illicit opioids) from discrimination.[20]

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[14] *Id.*

[15] *Id.*

[16] SAMHSA, *Confidentiality of Substance Use Disorder Patient Records, 42 CFR Part 2 final rule* (Jan. 18, 2017) (https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records).

[17] Joseph Conn, *County Health Department Takes Major Step Forward on Privacy,* Modern Healthcare (Sept. 16, 2014) (http://www.modernhealthcare.com/article/20140916/BLOG/309169995).

[18] SAMHSA, *Consent2Share: Managing Patient Consent* (Apr. 20, 2015) (https://ncc.expoplanner.com/files/13/SessionFilesHandouts/E13_Wetherby_1.pdf).

[19] Joseph Conn, *County Health Department Takes Major Step Forward on Privacy,* Modern Healthcare (Sept. 16, 2014) (http://www.modernhealthcare.com/article/20140916/BLOG/309169995).

[20] Department of Justice, *Fair Housing Act* (Dec. 21, 2017) (https://www.justice.gov/crt/fair-housing-act-1); 42 U.S.C. §§12111-12117.

Although former or sufficiently rehabilitated drug addiction may be considered a disability for the purposes of both laws, and therefore protected, those with a substance use disorder, who may just be entering treatment or who have a relapse after a period of recovery, are not protected from housing discrimination under the FHA or discrimination in a broad range of areas under ADA. For example, an employer may discharge or deny employment to anyone who currently uses illegal substances and not violate the ADA.[21] As a result, federal laws do not prevent a person with a substance use disorder, who actively uses illegal drugs, from losing their housing or their job, or being excluded from public services or places of public accommodation such as doctors' offices, homeless shelters, or social service establishments, if information about them were accidentally, maliciously, or otherwise disclosed without authorization.

V. HIPAA AND HIPAA EXCEPTIONS

HIPAA establishes a set of national standards for the protection of certain health information that addresses the use and disclosure of individuals' health information by certain entities.[22] Specifically, the Privacy Rule protects all "individually identifiable health information" held or transmitted by a covered entity or its business associates, in any form or media, whether electronic, paper, or oral (referred to as protected health information (PHI)).[23]

HIPAA establishes the "federal floor" for privacy protections applied to PHI within covered entities. In instances where privacy laws, including state laws and Part 2, require heightened protections above the HIPAA standard for certain types of medical records, the heightened standards apply to the protections of such records, including for PHI held by covered entities. In such cases, the HIPAA standard would still apply for covered entities for protections that don't conflict with the heightened protections of the controlling standard.

Covered entities include health plans, health care providers, and health care clearinghouses who transmit health information electronically.[24] In general, business associates are people or organizations, other than a member of the covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of PHI.[25]

Under HIPAA, a covered entity is permitted to use, disclose, or re-disclose PHI to covered entities, without a patient's written consent, for a number of purposes and situations, including for treatment, payment, and health care operation activities (TPO exception). Under

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[21] United States Commission on Civil Rights, *Sharing the Dream: Is the ADA Accommodating to All?* (June 2016) (http://www.usccr.gov/pubs/ada/ch4.htm); 42 U.S.C. §12114.

[22] Department of Health and Human Services, *Summary of the HIPAA Privacy Rule* (July 26, 2013) (https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html).

[23] *Id.*

[24] *Id.*

[25] *Id.*

HIPAA treatment is defined as "the provision, coordination, or management of health care and related services for an individual by one or more health care providers, including consultation between providers regarding a patient and referral of a patient by one provider to another."[26] Payment is defined as "activities of a health plan to obtain premiums, determine or fulfill responsibilities for coverage and provision of benefits, and furnish to or obtain reimbursement for health care delivered to an individual and activities of a health care provider to obtain payment or be reimbursed for the provision of health care to an individual."[27] Health care operations are any of the following: "(a) quality assessment and improvement activities, including case management and care coordination; (b) competency assurance activities, including provider or health plan performance evaluation, credentialing, and accreditation; (c) conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs; (d) specified insurance functions, such as underwriting, risk rating, and reinsuring risk; (e) business planning, development, management, and administration; and (f) business management and general administrative activities of the entity, including but not limited to: de-identifying protected health information, creating a limited data set, and certain fundraising for the benefit of the covered entity."[28]

In general, within the TPO exception, a patient does not have the ability to stop a covered entity from sharing their information with another covered entity or business associate. A patient can ask a provider to not share their information with a particular covered entity or business associate, but the provider does not have to agree. However, if a provider does agree to not share that information, a provider must comply with that agreement. A major exception to this rule relates to the psychotherapy note exception under HIPAA which requires consent before such a record could be shared with a covered entity or business associate under the TPO exception.

Another limited exception in which a patient can prevent their medical records from being shared with a health plan for payment or healthcare operations; the patient can request the information not be shared and pay cash for the service. Within the TPO exceptions, covered entities are not required to provide an accounting of covered entities or business associates who have received an individual's PHI, even if a patient requests such information. Therefore under HIPAA, a patient does not have a way to determine how covered entities disclosed their medical records pursuant to the TPO exception.

VI. SECTION BY SECTION OF AINS TO H.R. 3545, OVERDOSE PREVENTION AND PATIENT SAFETY ACT

The bill under consideration is a discussion draft that mirrors the AINS to H.R. 3545, introduced by Rep. Mullin (R-OK), at the Subcommittee on Health markup on April 25, 2018.

A. Subsection (a): Substance Use Disorder Defined

[26] *Id.*

[27] *Id.*

[28] *Id.*

This section would put an amended form of the definition of substance use disorder currently included in regulations into statute.

B. Subsection (b): Disclosures by Covered Entities Consistent with HIPAA

This section would create a new exception to the Part 2 patient consent requirement allowing a covered entity or a Part 2 program to share Part 2 information with a covered entity without patient consent for purposes of treatment, payment, and health care operations under the HIPAA privacy regulation as long as the disclosures are made in accordance with HIPAA.

C. Subsection (c): Disclosures of De-Identified Health Information to Public Health Authorities

This section would create a new exception to the Part 2 patient consent requirement allowing a Part 2 program to share Part 2 data with a public health authority without patient consent as long as the data does not include any PHI and meets the HIPAA standards for creating de-identified information.

D. Subsection (d): Definitions

This section would insert definitions of certain terms by referencing the HIPAA privacy regulation.

E. Subsection (e): Use of Records in Criminal, Civil, or Administrative Investigations, Actions, or Proceedings

This section would amend the existing section pertaining to the use of Part 2 records in criminal cases to add measures related to civil and administrative proceedings.

F. Subsection (f): Penalties

This section would amend the current penalty applied to a violation of Part 2, a fine in accordance with title 18, U.S. Code, to be the same penalties that apply for a violation of HIPAA.

G. Subsection (g): Antidiscrimination

This section prevents an entity that receives information through a permissible disclosure of Part 2 information from using such information to discriminate against an individual in admission or treatment for health care, hiring or terms of employment, the sale or rental of housing, or access to Federal, State, or local courts. This section also prevents a recipient of federal funds who receives information through a permissible disclosure of Part 2 information from using such information to discriminate against an individual in affording access to services provided with such funds. This section requires the Secretary to issue regulations enforcing these antidiscrimination requirements.

H. Subsection (h): Notification in Case of Breach

This section applies HIPAA breach notification requirements to Part 2 programs.

I. Subsection (i): Sense of Congress

This section establishes that it is the Sense of Congress that providers in Part 2 programs should check the applicable state-based prescription drug monitoring program (PDMP) as a precaution against substance use disorder.

J. Subsection (j): Development and Dissemination of Model Training Programs for Substance Use Disorder Patient Records

This section incorporates the text of Sec. 509 of the bipartisan S. 2680, the Opioid Crisis Response Act of 2018, introduced by Sen. Alexander (R-TN) and Sen. Murray (D-WA) and reported out of the Senate Health, Education, Labor and Pensions Committee. This section would require the Secretary to identify model programs and materials. In the event that none exists, the Secretary would be required to recognize entities to develop such programs and materials to educate health care providers, patients, and families on Part 2 within 1 year of enactment. The Secretary is required to periodically update the program and materials that are disseminated.

VII. WITNESSES

Panel I:

Congressman Earl Blumenauer (D-OR)

Panel II:

Dr. H. Westley Clark, MD, JD, MPH
Dean's Executive Professor
Public Health Program, Santa Clara University

Patty McCarthy Metcalf
Executive Director
Faces & Voices of Recovery

Gerald DeLoss
Officer
Greensfelder, Hemker & Gale, P.C.

Dustin McKee
Director of Policy
National Alliance of Mental Illness Ohio

Jeremiah Gardner
Manager, Public Affairs and Advocacy
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