May 5, 2018

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing entitled "Improving the Coordination and Quality of Substance Use

Disorder Treatment"

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Tuesday, May 8, 2018, at 1:00 p.m. in 2123 Rayburn House Office Building. The hearing is entitled "Improving the Coordination and Quality of Substance Use Disorder Treatment."

II. WITNESSES

The following panels of witnesses have been invited to testify. The makeup and order of the panels are subject to change.

PANEL ONE

• Earl Blumenauer (D-OR), Member, U.S. House of Representatives.

PANEL TWO

- Gerald (Jud) E. DeLoss, Officer, Greensfelder, Hemker and Gale, P.C.;
- Jeremiah Gardner, Manager of Public Affairs and Advocacy, Hazelden Betty Ford Foundation;
- Dustin McKee, Director of Policy, National Alliance on Mental Illness of Ohio;
- H. Westley Clark, M.D., J.D., M.P.H., Dean's Executive Professor, Public Health Program, Santa Clara University; and
- Patty McCarthy Metcalf, Executive Director, Faces and Voices of Recovery.

III. BACKGROUND

Federal confidentiality law and regulations (42 C.F.R. Part 2, or Part 2) were enacted in the 1970s after Congress recognized that extreme stigma associated with substance use disorder

Majority Memorandum for May 8, 2018, Subcommittee on Health Hearing Page 2

(SUD) and fear of prosecution decreased the likelihood patients would enter into treatment. ^{1,2} Patients with SUD can be reluctant to get treatment because of fear that disclosure of information about their condition could lead to prosecution, discrimination, loss of employment, housing, or child custody. The statute authorizing Part 2 was originally intended to protect patients seeking SUD treatment from these negative repercussions.

Part 2 regulations provide stronger protections for substance use disorder treatment records than do most other federal and state health privacy laws, including the *Standards for Privacy of Individually Identifiable Health Information* (Privacy Rule) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).³ The HIPAA Privacy Rule sets national standards for the protection of health information, and applies broadly to identifiable health information that is created or received by payers and providers of health care. It also applies to the business associates of these covered entities that provide specific services (e.g., claims processing, data management) for covered entities to help them operate and meet their responsibilities to patients. Under the HIPAA Privacy Rule, health information may be used or disclosed by covered entities (health providers, payers, and business associates) for the purposes of treatment, payment, and other healthcare operations—including case management, care coordination, and outcomes evaluation. The Privacy Rule also outlines other various circumstances under which covered entities may use or disclose health information.

Compared to the HIPAA Privacy Rule, Part 2 is much narrower in scope and permits fewer uses and disclosures of patient information without written consent. Under Part 2, any information regarding "the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States" is confidential. This information may be disclosed <u>only</u> with the patient's written consent, pursuant to a court order, or if the disclosure falls within one of a few statutory exceptions. The regulations apply to holders, recipients, and seekers of this information.

Part 2 also places very strict limitations on the redisclosure of such records. Anyone who receives such information from a SUD treatment program may not redisclose it without consent or as otherwise authorized by the regulations and may not use it except for certain purposes. Part 2 technically applies only to federally assisted organizations and individual practitioners that specialize in providing SUD treatment or referral for treatment. However, with the exception of a small few that are supported completely by private pay, most of the nation's alcohol and drug treatment programs are somehow federally assisted.

According to the Substance Abuse and Mental Health Services Administration (SAMHSA), individuals with mental and substance abuse disorders die decades earlier than the average person — mostly from untreated chronic illnesses that are aggravated by poor health habits. SAMHSA has stated that integrating mental health, substance abuse, and primary care

¹ Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970, P.L. 91-61

² Drug Abuse Office and Treatment Act of 1972, P.L. 92-255

³ Health Insurance Portability and Accountability Act of 1996, P.L. 104-191

⁴ 42 U.S.C. § 290dd–2. Confidentiality of records

services produces the best outcomes and proves the most effective approach to caring for people with multiple healthcare needs. However, Part 2 can be a barrier for initiatives that promote enhanced access and care continuity, such as health information exchanges, integrated care networks, health homes, and accountable care organizations. In addition, Part 2 is not uniformly applied to all providers treating patients with SUD. Patient information maintained in connection with the Veterans' Health Administration is not subject to Part 2. For profit treatment providers that do no receive any Federal assistance do not have to comply with Part 2. Buprenorphine prescribers may or may not be subject to Part 2 depending on whether the provider considers itself as an entity that specifically provides SUD diagnosis, treatment, or referral for treatment.

Because of disparities between HIPAA and Part 2, the health provider community has become increasingly frustrated with the restrictions that Part 2 places on their ability to improve the coordination and quality of care by sharing SUD treatment records. Access to a patient's entire medical record, including addiction records, ensures that providers and organizations have all the information necessary for safe, effective, high quality treatment, and care coordination that addresses all a patient's health needs. Failure to integrate services and supports can lead to risks and dangers to individual patients, such as dangerous drug interactions⁷ and problems related to medication adherence. Obtaining multiple consents from a patient can often be challenging and creates barriers to whole person, integrated approaches to care.

SAMHSA revised the Part 2 regulations in 1987 and in 2017. The most recently released final regulations and supplemental notice of proposed rulemaking were an attempt to align Part 2 with the HIPAA Privacy Rule to the extent feasible under current law by making it easier to share these records within accountable care organizations and health information exchanges. SAMHSA has stated that the agency is encouraged that this Committee is reviewing the issue and has made clear that any further changes to Part 2 would require an act of Congress.⁸

IV. LEGISLATION

The Subcommittee will review a discussion draft entitled "Overdose Prevention and Patient Safety Act," which was authored by Rep. Markwayne Mullin (R-OK) and Rep. Earl Blumenauer (D-OR). The discussion draft will permit SUD records to be shared between covered entities (health providers, payers, and business associates) in accordance with the HIPAA Privacy Rule, for the purposes of treatment, payment, and healthcare operations. The bill will also enhance the penalties in the event of disclosure SUD treatment records, add breach notification requirements, and provide discrimination prohibitions to protect individuals seeking and receiving SUD treatment.

⁵ SAMHSA-HRSA Center for Integrated Health Solutions. "What is integrated care?" 2016. Available at http://www.integration.samhsa.gov/resource/what-is-integrated-care.

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

⁷ McCance-Katz EF, Sullivan L, Nallani S, Drug Interactions of Clinical Importance among the Opioids, Methadone and Buprenorphine, and other Frequently Prescribed Medications: A Review. *Am J Addict*. 19: 4-16 (2010). Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3334287/.

⁸ McKance-Katz, Elinore F. (Substance Abuse and Mental Health Services Administration) Letter to the Honorable Markwayne Mullin. March 19, 2018. Available at https://docs.house.gov/meetings/IF/IF14/20180321/108049/HHRG-115-IF14-20180321-SD100.pdf.

Majority Memorandum for May 8, 2018, Subcommittee on Health Hearing Page 4 $\,$

V. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Kristen Shatynski or Paul Edattel of the Committee staff at (202) 225-2927.