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REVAMPING PART 2: AN ANALYSIS OF REVISIONS TO THE FEDERAL SUBSTANCE USE DISORDER TREATMENT CONFIDENTIALITY REGULATIONS

*MICHELLE RACKISH**

INTRODUCTION

In 2020, the United States Substance Abuse and Mental Health Services Administration (SAMHSA) loosened its confidentiality requirements for substance use treatment records.[1] SAMHSA's substance use-specific regulations exist alongside broader Health Insurance Portability and Accountability Act (HIPAA) regulations, which govern the confidentiality of most medical records.[2] In justifying the revisions, SAMHSA highlighted a goal of aligning the confidentiality regulations with HIPAA to make coordinated care easier for substance use patients.[3] Public response to the revisions varied. Some commenters emphasized the benefits of a more flexible care structure.[4] Others expressed concerns about potential patient confidentiality breaches, which could put patients at risk of backlash due to the criminalization and stigmatization of substance use in the U.S.[5]

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1. *See infra* Section II.D (referring to 42 C.F.R. Part 2, "Confidentiality of Substance Use Disorder Patient Records," discussed in depth later).

2. *See infra* Section II.C.

3. *See infra* Section II.D.

4. *See infra* Section II.E.

5. *See infra* Section II.E.

SAMHSA was correct to loosen its confidentiality restrictions.[6] Aligning substance use confidentiality regulations with HIPAA facilitates integration of substance use care with other medical care, allowing health care providers to work together across disciplines to better serve patients.[7] Loosening treatment-level disclosure requirements also creates an opportunity to address drug use stigmatization by normalizing substance use disorder treatment within primary care.[8] Furthermore, the revisions retain key provisions relating to criminalization that differ from HIPAA.[9] Taken as a whole, SAMHSA's revisions to its substance use record confidentiality regulations bolster patient care while retaining protections against the legal and social consequences of substance use disorder disclosure.[10]

I. BACKGROUND

SAMHSA's substance use treatment record privacy regulations protect patients from involuntary confidentiality breaches.[11] The confidentiality rules are codified in 42 C.F.R. Part 2 and commonly referred to as "Part 2." The regulations govern healthcare provider interactions and require that disclosures outside the medical space, for example with law enforcement, be recorded.[12] The following sections survey SAMHSA's regulations and the historical context from which the regulations grew. Like any other federal regulatory scheme, Part 2 has undergone multiple revisions since its implementation in 1975.[13] The most recent revisions aim to align Part 2 with HIPAA, a more general federal health information privacy statutory scheme.[14] This background section will address the distinctions between HIPAA and Part 2, the newest revisions, and the public response to bridging the gaps between HIPAA and Part 2.

A. Part 2 provides confidentiality protections for substance use disorder treatment records.

The federal government created confidentiality rules for substance use treatment records in 1975 amidst growing criminalization and societal

6. *See infra* Section III.

7. *See infra* Section III.A.

8. *See infra* Section III.C.

9. *See infra* Section III.BA.

10. *See infra* Section III.B.

11. 42 C.F.R. §§ 2.1–2.67 (2022).

12. *Id.* at §§ 2.35–2.36, 2.64–2.65.

13. *See* Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 42986–97 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2) (summarizing the history of Part 2 revisions).

14. *Id.* at 42987.

condemnation of drug use.[15] These confidentiality rules outlined procedures for disclosure of substance use treatment records, focusing on written patient consent.[16] The rules also created safeguards to protect patients from disclosures that could cause them legal or social harm, including provisions barring law enforcement from acquiring treatment records without following specific procedures.[17]

Part 2 was the first set of regulations governing confidentiality and security standards for patient health information records.[18] The protections were, in part, created to combat the discrimination that substance use disorder patients experience based on their condition.[19] Part 2 also aimed to alleviate concerns about the use of substance use treatment records in criminal, administrative, or domestic proceedings.[20] Drafters of the original 1975 version of Part 2 wanted patients to be able to seek treatment for substance use disorder without fearing backlash in other areas of their lives.[21] This goal lead to the creation of Part 2's strict confidentiality safeguards.[22] Part 2 applies solely to substance use disorder treatment, protecting patient health information from involuntary disclosure.[23] Establishing its narrow scope, Part 2 defines *substance use disorder* as a "cluster of cognitive, behavioral, and physiological symptoms indicating that an individual continues using a substance, despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal."[24] This definition excludes tobacco and caffeine as substances.[25]

15. Confidentiality of Alcohol and Drug Abuse Patient Records, 40 Fed. Reg. 27802 (July 1, 1975) (to be codified at 42 C.F.R. pt. 2). The 1975 rule was authored jointly by the U.S. Department of Health, Education, and Welfare and the U.S. Special Action Office for Drug Abuse and Prevention. *Id.* Part 2 predates SAMHSA, which was established by Congress in 1992 and since gained jurisdiction over Part 2. *Frequently Asked Questions*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVS. ADMIN., https://www.samhsa.gov/about-us/frequently-asked-questions (last updated Jan. 24, 2023).

16. Confidentiality of Alcohol and Drug Abuse Patient Records, 40 Fed. Reg. at 27802.

17. *Id.*

18. Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. at 42986. *See generally* Health Insurance Portability and Accountability Act, Pub. L. No. 104–191, 110 Stat. 1936 (1996) (demonstrating that Congress enacted HIPAA in 1996, more than two decades after Part 2).

19. Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. at 42986 (addressing the antidiscrimination purpose of Part 2 while discussing 2016 revisions).

20. *Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me?*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVS. ADMIN. 1, https://www.samhsa.gov/sites/default/files/does-part2-apply.pdf (last accessed Feb. 23, 2023) [hereinafter SAMHSA).

21. *Id.*

22. *Id.*

23. 42 C.F.R. § 2.2(b)(2) (2022).

24. *Id.* § 2.11.

25. *Id.*

In addition to narrowly defining substance use disorder, Part 2 applies only to treatment information produced by *federally assisted programs*.[26] The regulations define "federally assisted" broadly to include programs that receive funding or licensing from a U.S. department or agency.[27] A "program" encompasses entities, units, and medical personnel or staff providing substance use diagnosis, treatment, or referral.[28] Substance use treatment programs that do not meet the criteria for a "federally assisted program" under Part 2 are not required to comply with Part 2 regulations concerning protected health information.[29] However, these programs are subject to the HIPAA and state medical records confidentiality laws.[30]

Part 2 covers a wide range of record-keeping confidentiality issues for substance use disorder patients, but this article will primarily focus on restrictions within treatment settings and provisions barring law enforcement acquisition of records. In treatment settings, Part 2 requires a patient's written consent specifying information and records meant to be shared.[31] Part 2 privacy protections apply to disclosed substance use treatment records, meaning that recipients of Part 2-protected records are as bound to follow the confidentiality protections of Part 2 as an initial provider.[32] Part 2 also places barriers between law enforcement and substance use treatment records.[33] Part 2 records are not admissible in court without a special court order.[34] Subpoenas, search warrants, official requests, and even general court orders are not sufficient for disclosure under Part 2.[35] Barriers between law enforcement and record disclosure will be discussed in more detail in Section III.B.[36]

B. Part 2 protections arose from a history of drug criminalization in the United Staes.

As mentioned briefly above, rulemakers enacted the original Part 2 in response to drug criminalization and stigmatization in the U.S. Substance use

26. SAMHSA, *supra* note 20, at 1.

27. 42 C.F.R. § 2.12(b) (2022).

28. *Id.* § 2.11.

29. *Id.* § 2.12(e)(2).

30. Deborah A. Reid, et al., *Fundamentals of 42 CFR Part 2*, LEGAL ACTION CTR. (Oct. 2022), https://www.lac.org/resource/the-fundamentals-of-42-cfr-part-2; *see* 42 U.S.C. § 1320d(3) (defining HIPAA covered entities to include "provider[s] of medical or other health services").

31. 42 C.F.R. § 2.31(a)(3) (2022).

32. *Id.* § 2.32.

33. *Id.* § 2.35.

34. *Id.* § 2.65; *see also* Reid et al., *supra* note 30.

35. Reid et al., *supra* note 30.

36. *See infra* Section III.B.

treatment confidentiality regulations aimed to encourage patients to seek treatment without the fear of social or legal backlash.[37] Since Part 2's 1975 inception, medical understanding of substance use disorder has evolved, and substance use disorder is now viewed as a treatable health condition. Though views have progressed, the stigma and criminal consequences of substance use disorder disclosure remain.

1. The foundations of substance use stigma and criminalization in the United States.

Although the 1970s "War on Drugs" widely publicized criminalization of drug use in the U.S., state action against drug use began long before President Nixon declared drug abuse "public enemy number one."[38] Regulations, taxes, and drug bans date back to the 1800s.[39] Many substances that are illegal today began as widely accepted medical treatments that produced negative side effects. Eventually, these side effects led to public condemnation and criminalization.[40] One early example is the rise and fall of heroin in the United States.[41] When first introduced into the market, heroin was an accepted medication approved by the American Medical Association.[42] However, the long-term effects of the drug quickly emerged, and Congress outlawed heroin in the Heroin Act of 1924.[43]

Scholars characterize the progression of attitudes towards many now-illicit substances as a pendulum, swinging from "open embrace" of medication to prohibition and disgust.[44] The pendulum swing from medication to illicit substance for drugs like heroin paved the way for broader criminalization efforts in the U.S.[45] In the 1970s, President Nixon took sweeping action by beginning

37. Confidentiality of Alcohol and Drug Abuse Patient Records, 40 Fed. Reg. 27802 (July 1, 1975) (to be codified at 42 C.F.R. pt. 2).

38. Morning Edition, *A Brief History of the War on Drugs*, NPR, at 0:07 (Apr. 26, 2019), https://www.npr.org/2019/04/26/717389563/a-brief-history-of-the-war-on-drugs; *see generally War on Drugs*, HISTORY.COM (Dec. 17, 2019), https://www.history.com/topics/crime/the-war-on-drugs (summarizing the history of government control of drug use prior to the 1970s).

39. *War on Drugs*, HISTORY.COM (Dec. 17, 2019), https://www.history.com/topics/crime/the-war-on-drugs.

40. *See A History of the Drug War*, DRUG POLICY ALL., https://drugpolicy.org/issues/brief-history-drug-war (last visited Feb. 28, 2023) (noting that many now-illegal substances, such as opium, were initially used as medicines); *see also* TRAVIS RIEDER, IN PAIN 48–49 (2019) (giving the example of the drug heroin).

41. *Id.*

42. *Id.*

43. *Id.* at 49.

44. *Id.*

45. Morning Edition, *supra* note 38; *War on Drugs*, *supra* note 39.

the "War on Drugs."[46] During this time, emphasis was placed on mandatory sentencing for drug-related crimes and then mandatory minimums for those sentences.[47] In 1973, President Nixon created the Drug Enforcement Administration (DEA).[48] Since the 1970s, the federal government has taken continuous steps to punish drug offenders.[49]

Criminalization of drug use furthers societal stigmatization of substance use disorder. One bioethicist noted that "by . . . driving use underground, society turned addiction and opioid use into something to be spurned and reviled" rather than a medical issue.[50] As a result, individuals living with substance use disorder face broad consequences should their condition be disclosed.[51] Beyond fears of arrest and incarceration, disclosure of a person's substance use disorder can affect housing, employment, government benefits, and child custody.[52] The historical criminalization of drug use perpetuates the idea that substance use is a "moral failing."[53] Treating substance use disorder as a moral issue, rather than a medical issue, lead to discriminatory treatment of individuals suffering from substance use disorder in everyday life.[54] For example, disabilities stemming from substance use disqualify an individual from federal social security benefits.[55] Concerns about stigma and criminal consequences may dissuade patients from seeking substance use treatment.[56] These concerns laid the foundation for the 1975 Part 2 protections.

46. *A History of the Drug War*, *supra* note 40.

47. *War on Drugs*, *supra* note 39.

48. *Id.*; *see also* Reorganization Plan No. 2 of 1973, Pub. L. No. 93–253, §1, 88 Stat. 50 (1973) (prepared by President Nixon and transmitted to Congress, this plan included the establishment of the DEA).

49. *War on Drugs*, *supra* note 39 (summarizing President Reagan's continuation of the War on Drugs, an increase in nonviolent drug crime incarcerations, and Congressional facilitation of the Warn Drugs through the Anti-Drug Abuse Act of 1986).

50. *Id.*

51. Karla Lopez & Deborah Reid, *Discrimination Against Patients with Substance Use Disorder Remains Prevalent and Harmful: The Case for 42 C.F.R. Part 2*, HEALTH AFFS. (Apr. 13, 2017), https://www.healthaffairs.org/do/10.1377/hblog20170413.059618/full/.

52. *Id.*

53. Stephanie Desmon & Susan Morrow, *Drug Addiction Viewed More Negatively than Mental Illness, Johns Hopkins Study Shows*, JHU HUB (Oct. 1, 2014), https://hub.jhu.edu/2014/10/01/drug-addiction-stigma/ (recapping a Johns Hopkins study surveying 709 participants and their views on drug addiction and mental illness. Results showed more contempt for drug addiction than other conditions). *See also* Lopez & Reid, *supra* note 51 (detailing the harmful stigmatization of substance use disorder); Rieder, *supra* note 40 at 49 (summarizing dehumanization of "addicts").

54. Desmon & Morrow, *supra* note 53.

55. CONGRESS. RSCH. SERV., SOCIAL SECURITY DISABILITY INSURANCE (SSDI) AND SUPPLEMENTAL SECURITY INCOME (SSI): ELIGIBILITY, BENEFITS, AND FINANCING 37–38 (2018).

56. Desmon & Morrow, *supra* note 53.

2. Modern medical and societal trends towards acceptance of substance use as a disorder.

Amidst the criminalization and stigmatization of substance use disorder in the U.S., public opinion has shifted to focus on patient health instead of individual moral failings.[57] Public opinion increasingly recognizes the importance of substance use treatment and health reform.[58] One study, surveying media reports between 1998 and 2012, found a slow but significant reframing of substance use disorder as a public health concern instead of a law enforcement concern.[59]

Though the destigmatizing shift is slow in popular media, the medical profession recognizes substance use disorder as a chronic health condition.[60] In 2008, the American Medical Association wrote a position paper characterizing substance use disorder as a "chronic disease, attributable in part to long-term changes in the patterns of neuronal activity and connections."[61] In 2017, the American College of Physicians followed suit and stated that substance use disorder is a chronic medical condition and "should be managed as such."[62]

Even though the medical community is treating substance use disorder as a health condition, Part 2 protections remain relevant. Based on the most recent SAMHSA data published in September 2020, an estimated 40.3 million Americans are living with substance use disorder.[63] 165.4 million Americans have used a substance[64] without developing substance use disorder, and 35.8 million of those Americans have used an illicit (criminalized) drug.[65] Though millions live with substance use disorder, drug use is still widespread and criminalized. These are the very conditions that led to Part 2's adoption.[66]

57. *See A History of the Drug War*, *supra* note 40 (noting a growing emphasis on healthcare reform in substance use disorder treatment); Rieder, *supra* note 40, at 231 (summarizing studies indicating a shift from a law enforcement focus to a public health focus surrounding substance use disorder).

58. *A History of the Drug War*, *supra* note 40.

59. Emma E. McGinty et al., *Criminal Activity or Treatable Health Condition? News Media Framing of Opioid Analgesic Abuse in the United States*, *1998–2012*, 67 PSYCH. SERV. 405, 409 (2016).

60. Ryan Crowley et al., *Health and Public Policy to Facilitate Effective Prevention and Treatment of Substance Use Disorders Involving Illicit and Prescription Drugs: An American College of Physicians Position Paper*, 166 ANNALS OF INTERNAL MED. 733 (2017).

61. COUNCIL ON SCI. AND PUB. HEALTH, AM. MED. ASS'N, REPORT 8: SUBSTANCE USE AND SUBSTANCE USE DISORDERS (2008).

62. Crowley et al., *supra* note 60 at 734.

63. SUBSTANCE ABUSE & MENTAL HEALTH ADMIN., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2019 NATIONAL SURVEY ON DRUG USE AND HEALTH 3 (2020).

64. *Id.* SAMHSA categorizes a substance as "tobacco, alcohol, kratom, or an illicit drug." *Id.*

65. *Id.* at 1.

66. *See supra* Section II.B.1.

C. Part 2 and HIPAA differ in their requirements for health information confidentiality.

While Part 2 was enacted in 1975, the Health Insurance Portability and Accountability Act (HIPAA) was signed into law in 1996.[67] HIPAA sets out minimum mandatory federal privacy standards for protected health information (PHI).[68] Since HIPAA creates a minimum standard for patient protection, Part 2 generally requires stricter protective measures for patient records than HIPAA.[69] HHS advises providers subject to both Part 2 and HIPAA to adhere to Part 2 provisions, since Part 2 provisions require greater protections for patient information than the HIPAA baseline.[70]

More entities are required to adhere to HIPAA protections than Part 2 protections.[71] HIPAA applies to "covered entities," including healthcare providers, health plans, healthcare clearinghouses, and business associates.[72] In contrast, Part 2 only applies to the aforementioned federally assisted programs.[73] Most health treatment facilities must abide by HIPAA protections, including substance use disorder treatment facilities, and Part 2 provisions are tacked on top of HIPAA protections for federally assisted programs.[74]

HIPAA and Part 2 differ most drastically in their treatment of patient record disclosure and law enforcement.[75] Under Part 2, special court orders are required to admit substance use treatment records, and records must be anonymized.[76] In contrast, HIPAA permits patient record disclosure in

67. *Health Insurance Portability and Accountability Act of 1996 (HIPAA)*, CTRS. FOR DISEASE CONTROL AND PREVENTION https://www.cdc.gov/phlp/publications/topic/hipaa.html (last reviewed June 27, 2022).

68. *Id.*

69. *How Does HIPAA Interact with the Federal Confidentiality Rules for Substance Use Disorder Treatment Information in an Emergency Situation–Which Rules Should Be Followed?* HHS.GOV (Jan. 9, 2023), https://www.hhs.gov/hipaa/for-professionals/faq/3005/how-does-hipaa-interact-federal-confidentiality-rules-substance-use-disorder-treatment-information-in-emergency/index.html [hereinafter *Which Rules Should Be Followed?*].

70. *Id.*

71. *Health Insurance Portability and Accountability Act of 1996 (HIPAA)*, *supra* note 67.

72. *Id.* (explaining that health plans refer to entities providing payment for medical care, like insurers, while business associates perform functions for covered entities like billing, data analysis, and claims processing).

73. 42 C.F.R. § 2.12 (2022).

74. *Which Rules Should Be Followed?, supra* note 69.

75. *See generally* 42 C.F.R. §§ 2.61–2.67 (2022) (commonly referred to as Subpart E, these sections of Part 2 address disclosure requirements for law enforcement); Lopez & Reid, *supra* note 51 (highlighting how Part 2 and HIPAA address law enforcement acquisition of patient records).

76. 42 C.F.R. §§ 2.61–2.67 (2022).

accordance with procedures set forth under state law, which are often less robust than Part 2 requirements.[77]

D. SAMHSA's most recent revisions to Part 2 aim to enable coordination of substance use treatment with other medical care.

SAMHSA published a Notice of Proposed Rulemaking (NPRM) on August 26, 2019, to amend Part 2.[78] The purpose of the revisions was to "continue aligning the regulations with advances in the U.S. health care delivery system, while retaining important privacy protections for individuals seeking treatment for substance use disorders."[79] After the Notice and Comment period, SAMHSA published the amended regulations in the July 15, 2020, edition of the Federal Register with an effective date of August 14, 2020.[80]

In the Final Rule, SAMHSA focused on coordinated care.[81] Prominent revisions affected how and to what extent records may be disclosed.[82] In making these revisions, SAMHSA aimed to align disclosure requirements with HIPAA standards.[83]

SAMHSA revised the definition of "records" to omit oral communication between Part 2 providers and non-Part 2 providers made for treatment purposes.[84] Pursuant to this change, a patient's substance use treatment provider may discuss a care plan with another provider for the patient, like a primary care physician.[85] This change does not leave patients unprotected regarding provider communications.[86] Though provider communications are not "records" within Part 2, Part 2 still requires preliminary patient consent for discussion between providers.[87]

The Final Rule also allows non-Part 2 records (i.e., medical records unrelated to substance use treatment) to be stored separately from Part 2 records (i.e., substance use treatment records).[88] Non-Part 2 records are still subject to

77. Lopez & Reid, *supra* note 51.

78. Confidentiality of Substance Use Disorder Patient Records, 84 Fed. Reg. 44568, 44568 (proposed Aug. 26, 2019) (to be codified at 42 C.F.R. pt. 2).

79. *Id.*

80. Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 42986 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2).

81. *Id.* at 42987.

82. *Id.*

83. *Id.*

84. *Id.* at 43036 (amending 42 C.F.R. § 2.11).

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.* (amending 42 C.F.R. § 2.12).

HIPAA and other applicable privacy standards.[89] Furthermore, Part 2 records disclosed to non-Part 2 providers may be redisclosed by those providers with written consent by the patient.[90] Regarding consent, patients can now authorize disclosure through written consent to an entire entity without naming an individual recipient.[91] The Final Rule also allows for broader research-related disclosures of patient data to organizations not subject to HIPAA.[92]

In the 2020 Final Rule, SAMHSA noted plans to amend Part 2 again to align the regulations with the Coronavirus Aid, Relief, and Economic Security (CARES) Act.[93] Section 3221 of the CARES Act, effective March 27, 2021, aimed to further align Part 2 with HIPAA by amending 42 U.S.C. § 290dd-2, Part 2's authorizing statute.[94] This section modified consent requirements to allow a patient's written consent to disclose records to treating providers who would then be subject to HIPAA, not Part 2.[95] Congress also changed the penalties for Part 2 violation to align with sections 1176 and 1177 of the Social Security Act.[96] Section 3221 also broadened the prohibition on using substance use disorder patient records in criminal proceedings to include civil actions, discussed in greater detail in Section III.B, and expressly banned discrimination based on substance use disorder treatment record disclosure.[97] SAMHSA proposed changes to address Section 3221 in December 2022.[98]

E. Public comments on the 2020 Part 2 revisions varied.

SAMSHA received 684 comments on the 2019 proposed changes to Part 2.[99] Support for the Final Rule largely followed SAMHSA's own purpose

89. *Id.*

90. *Id.* at 43037 (amending 42 C.F.R. § 2.32).

91. *Id.* (amending 42 C.F.R. § 2.31).

92. *Id.* at 43038 (amending 42 C.F.R. § 2.52).

93. *Id.* at 42987.

94. *Id.*; *see also* Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116–136 § 3221, 134 Stat. 281, 376–79 (2020) (outlining the new consent and disclosure guidelines for health information to public health authorities; medical records used in criminal, civil, or administrative contexts; and penalties for those who violate § 290dd-2).

95. § 3221, 134 Stat. at 376.

96. *Id.* at 377.

97. *Id.* at 377–78 (stating that "[n]o entity shall discriminate against an individual on the bases of information received by such entity pursuant to an inadvertent or intentional disclosure of records" in treatment, employment, housing, court proceedings, or government benefits).

98. Confidentiality of Substance Use Disorder (SUD) Patient Records, 87 Fed. Reg. 74216 (proposed Dec. 2, 2022) (to be codified at 42 C.F.R. pt. 2).

99. Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 42989 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2).

statement regarding the necessity of the revisions: enhancing coordinated care.[100] Commenters emphasized an integrated care model allowing "more seamless[]" substance use treatment alongside other medical treatment.[101] Commenters also felt that the new regulations would increase efficiency and decrease the burden on providers sharing treatment information.[102] They noted that this increased efficiency and flexibility would not sacrifice Part 2's strictness.[103]

While comments supporting the Final Rule focused on easing administrative burdens in healthcare delivery, comments opposing the Final Rule focused on substance use disorder patient privacy and concerns about discrimination.[104] The comments opposing the Final Rule expressed fears that loosened regulations would create new avenues to invade patient privacy and expose patients to societal stigma surrounding drug use.[105] Additional concerns included problems with the U.S.'s criminalization of drug use as well as daily social consequences, such as the housing and employment considerations raised above.[106]

II. ANALYSIS

SAMHSA's Part 2 revisions present an opportunity to treat substance use disorders as a medical condition while also retaining criminalization protections for patients. The revisions loosen provider restrictions in ways that promote coordinated patient care, addressing health issues holistically rather than separating substance use treatment from other medical care.[107] The revisions do not alter Subpart E, the provisions within Part 2 preventing disclosure to law enforcement, protecting patients seeking treatment from legal backlash.[108] Finally, the revisions take a step towards fighting drug use stigma by breaking down some HIPAA-Part 2 regulatory barriers, allowing for integrated substance use care within traditional medical spaces, like primary care offices and hospitals.[109]

100. *Id.*

101. *Id.*

102. *Id.* (recapping comments pertaining to flexibility of information sharing. SAMHSA also noted that some commenters did not find the new regulations flexible enough, advocating for further revisions for better coordination of care).

103. *Id.*

104. *Id.*

105. *Id.*

106. *Id*; *see also* Lopez & Reid, *supra* note 51.

107. *See infra* Section III.A.

108. *See infra* Section III.B.

109. *See infra* Section III.C.

A. The 2020 Part 2 revisions take needed steps towards bolstering coordinated care, a goal supported by the medical profession.

The 2020 Final Rule makes necessary revisions to loosen privacy standards within the treatment relationships, thus advancing coordinated care.[110] Both SAMHSA and public comments on the final rule emphasize integrating care teams treating substance use disorder with care teams for other health issues.[111] Research and publications within the medical field also support changing policy and practice to treat substance use disorder like any other disease.[112] Part 2 revisions to the definition of "records" and the broadness of how patients can disclose their records to treatment facilities and other entities further this coordinated care approach.[113]

Part 2 revisions to records disclosure reinforce the growing understanding that substance use disorder is a medical condition to be treated rather than a character flaw, moral failing, or problem for criminal law.[114] Under the 2020 revisions, patients may consent to records disclosure to entire healthcare entities, not just individual providers.[115] This change allows care teams to access records and coordinate treatment, facilitating the inclusion of multiple healthcare professionals helping to treat a patient. Substance use disorder does not exist in a vacuum – patients often have other comorbid conditions that may be more effectively treated in an integrated manner rather than individually.[116] For example, a patient's substance use care team could collaborate with their general practitioner team for a more holistic healthcare approach. Integrated healthcare teams are the ideal standard in other areas of medical care, promoting collaboration.[117] Collaboration seeks to improve patient care by addressing all health issues a patient has at once and building a treatment plan to maximize recovery and wellbeing.[118]

110. Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 42986 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2).

111. *Id,* at 42987.

112. *Id.*

113. *Id.* at 43036–37.

114. Nora D. Volkow, *Addiction Should Be Treated, Not Penalized*, HEALTH AFFS. (Apr. 27, 2021), https://www.healthaffairs.org/do/10.1377/hblog20210421.168499/full/.

115. 42 C.F.R. § 2.31 (2022). For example, a patient can now permit disclosure to the University of Maryland Medical System instead of a specific provider.

116. *See generally* Maria Jimenez-Lara, *Reaping the Benefits of Integrated Health Care,* STAN. SOC. INNOVATION REV. (Sept. 2, 2016), https://ssir.org/articles/entry/reaping_the_benefits_of_integrated_health_care# (discussing the benefits of integrated health care).

117. *Id.*

118. *Id.*

Beyond institution-wide disclosure measures, Part 2 revisions to the definition of "records" also promote treatment collaboration.[119] The 2020 Final Rule removes restrictions on oral communication between Part 2 providers and non-Part 2 providers for treatment purposes, as long as the patient consents.[120] Pursuant to this change, substance use treatment providers can speak with a patient's other healthcare providers to further treatment goals.[121] These permitted communications may be used to strengthen treatment plans to address all of a patient's health concerns, instead of having each provider attempt to remedy concerns independently.

Revisions to the definition of "records" and the scope of entity disclosure not only advance an idealistic integrated care team model, they also align with the medical field's understanding of how to treat substance use disorder.[122] In the same position paper in which the American College of Physicians (ACP) announced that substance use disorder is a "chronic medical condition" that "should be managed as such," ACP urged a treatment focus.[123] Looking to a 2014 U.S. survey, ACP found that sixty-seven percent of Americans think "the government should focus more on providing treatment" for substance use disorder than pursuing criminal charges.[124] ACP advocated for increases in education, research, and prevention related to substance use disorder as well as efforts towards diagnosis and treatment.[125] The position paper also called for more health professionals in the substance use treatment field and the implementation of substance use treatment training in medical school.[126] Medical professionals understand the science behind addiction and its effects on the brain. Given this knowledge, medical treatment should be the primary focus for substance use disorder.[127] The Part 2 revisions facilitate a focus on substance use disorder as a "medical condition" that "should be managed as such"[128] by

119. 42 C.F.R. § 2.11 (2022).

120. Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 42991 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2).

121. *Id.* at 42990.

122. *See* COUNCIL ON SCI. AND PUB. HEALTH, AM. MED. ASS'N, *supra* note 61, at 7 (emphasizing treatment of substance use disorder like any other chronic medical condition); Crowley et al., *supra* note 60 at 734 (highlighting the importance of integrated care).

123. Crowley et al., *supra* note 60 at 734.

124. *Id.* at 733 (citing *America's New Drug Policy Landscape*, PEW RSCH. CTR.(Apr. 2, 2014), https://www.pewresearch.org/politics/2014/04/02/americas-new-drug-policy-landscape/).

125. Crowley et al., *supra* note 60, at 734.

126. *Id.* at 735.

127. *See generally id.* at 741 (discussing treatment focused programs and the importance of medical treatments for substance use disorders).

128. *Id.* at 733.

removing some of the rigidity surrounding substance use treatment record confidentiality.[129]

The Part 2 revisions also align with the public health and treatment focus advanced by the United Nations in 2016.[130] The 2016 UN General Assembly on drugs unanimously approved that "'drug addiction [is] a complex multifactorial health disorder characterized by chronic and relapsing nature' that is preventable and treatable and not the result of moral failure or a criminal behavior."[131] The UN decision adopted recommendations from the Informal International Scientific Network, which is comprised of addiction experts.[132] The recommendations encourage public health responses to substance use disorder.[133] One recommendation addressed the implementation of evidence-based substance use treatment.[134] The recommended treatment would mirror standards of care for chronic illnesses like diabetes and cardiovascular disease.[135] A chronic care model requires "integrat[ion] into the general health care system."[136] This integration would make substance use disorder screening as routine as any other health check-up tasks. The UN decision also emphasized making integrated substance use treatment affordable and accessible.[137] The Part 2 revisions bring U.S. substance use treatment a step closer to the UN integrated model, facilitating options for providers to work together in holistic treatment teams.[138]

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129. Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 43036-39 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2).

130. Nora D. Volkow et al., *Drug Use Disorders: Impact of a Public Health Rather than a Criminal Justice Approach*, 16 WORLD PSYCHIATRY 213 (2017).

131. UNITED NATIONS OFF. ON DRUGS AND CRIME, OUTCOME DOCUMENT OF THE 2016 UNITED NATIONS GENERAL ASSEMBLY SPECIAL SESSION ON THE WORLD DRUG PROBLEM 6 (2016) [hereinafter OUTCOME DOCUMENT] (quoted in Volkow et al., *supra* note 131, at 213).

132. *Id.*

133. Volkow et al., *supra* note 131, at 213 (describing interactions between research and policymaking organizations that set agenda for 2016 U.N. General Assembly Special Session on drugs).

134. OUTCOME DOCUMENT, *supra* note 132, at 6; Volkow et al., *supra* note 131, at 213–14.

135. Volkow et al., *supra* note 131, at 214.

136. *Id.*

137. OUTCOME DOCUMENT, *supra* note 132, at 6; Volkow et al., *supra* note 131, at 214.

138. *See* Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 42987 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2) (explaining that proposed changes to Part 2 regulations will "better align with the needs" of patients, those who treat them, and those who "facilitate the provision of well-coordinated care").

B. The 2020 Part 2 revisions do not remove protections separating law enforcement from substance use disorder patient records, and they should not do so.

A common concern about loosening Part 2 protections relates to criminalization.[139] Critics of Part 2 revisions fear that the revisions will increase the probability of involuntary disclosure and thus increase possible legal backlash on patients seeking substance use treatment.[140] However, although the Part 2 revisions loosen regulations related to coordinated care, the revisions do not loosen any provisions related to law enforcement.[141] The Part 2 revisions correctly retain strict protections for substance use patient records to bar law enforcement from accessing records, which allow patients to seek treatment without fear of legal consequences.

The Part 2 provisions relating to law enforcement are located in Subpart E.[142] The 2020 Final Rule does not alter Subpart E protections against disclosure to law enforcement and litigation.[143] Subpart E is unique to Part 2 – there is no HIPAA equivalent.[144] Although Part 2 revisions align with HIPAA in a treatment context, SAMHSA was correct to leave Subpart E unaltered. Subpart E reflects the important criminal law difference between substance use treatment and other medical treatment. In order for patients to seek care safely, they must be assured that seeking care will not bring them legal backlash.[145] This need to prevent legal backlash for patients seeking care is as necessary today as it was at Part 2's 1975 inception.

Subpart E limits the ways a court may obtain substance use treatment records.[146] For example, a court may only obtain substance use treatment records through a special court order after a provider is subpoenaed.[147] Subpart E provides specific circumstances where a court can compel disclosure of

139. *Id.* at 43027.

140. *See id.* (responding to public commenters concerned that revisions could lead to loss of insurance coverage, "a more defined or interfering role" for third party payers in treatment decisions, and greater risk of criminalization or stigma of patients).

141. *Id.* at 43036–43038.

142. 42 C.F.R. §§ 2.61–2.67 (2021) (titled "Court Orders Authorizing Disclosure and Use").

143. Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 43036–38 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2).

144. *See* 45 C.F.R. § 164.512 (2022) (listing situations in which "[a] covered entity may disclose protected health information for a law enforcement purpose").

145. *See* 42 C.F.R. § 2.2 (2022) (stating regulations limiting law enforcement access to substance use treatment records "are intended to ensure that a patient receiving treatment for a substance use disorder . . . 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").

146. *Id.* §§ 2.61–2.67.

147. *Id.* § 2.61.

physician-patient communications concerning substance use disorder treatment.[148] Detailed regulations guide disclosures for noncriminal purposes,[149] criminal investigation and prosecution of a patient,[150] and investigation of a Part 2 program or practitioner.[151] The final section of Part 2 addresses undercover agents within Part 2 programs.[152] The 2020 Final Rule edited the provisions about undercover agents, amending § 2.67(d)(2) to limit placement of undercover agents or informants to 12 months without a court-ordered extension.[153] Other existing Subpart E protections were left untouched.[154]

Concerns about aligning Part 2 with HIPAA often mention the elimination of Subpart E.[155] One article cautioning revision or deletion of Part 2 referred to HIPAA as a "false equivalent," largely focusing on criminalization protections.[156] The authors noted that HIPAA protections, unlike Subpart E protections, allow for disclosures in court pursuant to general state law permissions.[157] These state laws may allow disclosure of certain records under HIPAA through subpoenas or discovery requests.[158] Subpoenas or discovery requests contrast with Part 2 requirements of a special court order and protections surrounding the identity of the patient in disclosure to a court.[159] These concerns deeming HIPAA a "false equivalent" are substantial but inapplicable to the Part 2 revisions. The 2020 Final Rule has not changed or taken away Subpart E protections.[160]

Alignment of Part 2 provisions with HIPAA can only work in our society with strict retainment of Subpart E. Even if the medical profession and some of society adopts the view that substance use disorder is a chronic, treatable health

148. *See id.* § 2.63 (listing three situations where court order under Part 2 can compel disclosure as (1) protecting against serious harm or bodily injury, (2) in connection with a list of serious crimes related to loss of life or serious bodily injury, and (3) in litigation or administrative proceedings where the patient themselves testifies about the communications).

149. *Id.* § 2.64.

150. *Id.* § 2.65.

151. *Id.* § 2.66.

152. *Id.* § 2.67.

153. Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 42988 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2).

154. *Id.* at 43036–39.

155. *Id.* at 42997. *See also* Lopez & Reid, *supra* note 51 (explaining the potential for harm of fully equating Part 2 to HIPAA and deleting Subpart E protections).

156. Lopez & Reid, *supra* note 51.

157. *Id.*

158. *Id.*

159. 42 C.F.R. § 2.65 (2022).

160. Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 43036–39 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2).

condition, much of the drug use leading to substance use disorder remains heavily criminalized in the U.S.[161] The most robust and integrated care team would not be able to overcome the treatment barrier created if substance use treatment records were freely attainable for prosecution. Opposing commenters on the Final Rule were reasonably wary of any loosened restrictions, because eliminating Subpart E would likely be an insurmountable problem for treatment retention and success.[162]

Subpart E protections are also necessary because the effect of incarceration on substance use treatment outcomes is alarmingly bleak.[163] A 2018 study found that there was no statistically significant correlation between drug imprisonment rates and mitigating state drug problems.[164] Another study followed prisoners for a year after release and found that drug use tends to increase significantly, though Medicaid expansion and access to care was a mitigating factor.[165] Even more concerning, a third study found that drug overdose was the leading cause of death after prison release.[166] Based on these findings, incarceration does not help the treatment outcomes of substance use patients – it is much more likely to harm them.[167] Subpart E protections provide a crucial barrier between seeking treatment for a chronic medical condition and facing legal action that could be detrimental to the health of substance use patients.[168]

In the context of the above criminalization data, the 2020 Final Rule correctly does not revise Subpart E protections.[169] If SAMHSA plans to take additional steps to align Part 2 with HIPAA, SAMHSA must retain Subpart E.

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161. *See A History of the Drug War*, *supra* note 40 (outlining drug criminalization in the United States from the nineteenth century to the present).

162. *See* Lopez & Reid, *supra* note 51; Volkow et al., *supra* note 131.

163. Volkow et al., *supra* note 131.

164. PEW CHARITABLE TRS., MORE IMPRISONMENT DOES NOT REDUCE STATE DRUG PROBLEMS 5 (2018), https://www.pewtrusts.org/-/media/assets/2018/03/pspp_more_imprisonment_does_not_reduce_state_drug_problems.pdf.

165. Bruce Western & Jessica T. Simes, *Drug Use in the Year After Prison*, 235 SOC. SCI. & MED. 1, 5 (2019).

166. Elizabeth Needham Waddell et al., *Reducing Overdose After Release From Incarceration (ROAR): Study Protocol for an Intervention to Reduce Risk of Fatal and Non-fatal Opioid Overdose Among Women After Release from Prison*, HEALTH & JUST. 1, 2 (2020) (citing Ingrid A. Binswanger et al., *Clinical Risk Factors for Death After Release from Prison in Washington State: A Nested Case Control Study*, 111 ADDICTION 499 (2016)).

167. *See* Waddell et al., *supra* note 167, at 2 (noting that "risk for drug-related death is significantly elevated in the 4 weeks following release from prison"); *see also* Western & Simes, *supra* note 166, at 5 (finding "evidence of a high and increasing rate of drug use through the first year after prison release").

168. Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 43036-39 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2).

169. *Id.*

While the U.S. still criminalizes drug use, patients seeking treatment for substance use disorder must be protected against law enforcement actions, otherwise patients will not seek treatment. If patients are dissuaded from seeking treatment out of fear of legal repercussions, the movement towards integrated care and chronic-care-modeled treatment of substance use disorder is immeasurably impeded. Subpart E is a necessary component of Part 2 to make any treatment efforts realistic.

It is unlikely that Subpart E will be weakened in future SAMHSA revisions because Congress *strengthened* Subpart E provisions in the CARES Act.[170] As mentioned above, Section 3221 of the CARES Act expanded prohibitions on using Part 2 records in criminal proceedings to all criminal, civil, administrative, and legislative actions on the federal, state, and local level.[171] This provision does have some exceptions, including if a patient consents to disclosure.[172] However, Congress expanding the protections for Part 2 record disclosure demonstrates intent to further safeguard patients, not loosen regulations. SAMHSA has yet to revise Part 2 to incorporate Section 3221 of the CARES Act and future proposed revisions addressing the CARES Act would likely strengthen Subpart E.[173]

Based on these considerations of Subpart E, critics of Part 2 revisions should be reassured that SAMHSA retains protections separating substance use disorder patient records from the U.S. criminal legal system. The 2020 Final Rule did not eliminate any Subpart E protections against records disclosure to law enforcement.[174] Exactly opposite, future revisions are needed to align Part 2 with Section 3221 of the CARES Act, in which Congress broadened legal protections against disclosure.[175] The 2020 Final Rule carries no greater criminal disclosure

170. Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116–136, § 3221, 134 Stat. 281, 375 (2020).

171. *Id.* (stating that "a record … may not be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority, against a patient, including with respect to the following activities: (1) such record or testimony shall not be entered into evidence in any criminal prosecution or civil action before a Federal or State court[,] (2) Such record or testimony shall not form part of the record for decision or otherwise be taken into account in any proceeding before a Federal, State, or local agency[,] (3) Such record or testimony shall not be used by any Federal, State, or local agency for a law enforcement purpose to conduct any law enforcement investigation[,] (4) Such record or testimony shall not be used in any application for a warrant").

172. *Id.*

173. Confidentiality of Substance Use Disorder (SUD) Patient Records, 87 Fed. Reg. 74216 (proposed Dec. 2, 2022) (to be codified at 42 C.F.R. pt. 2).

174. Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 43036–39 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2).

175. Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat. 281 (2020).

concern than the iterations of Part 2 before it, and the future seems to hold stronger Subpart E protections.

C. The 2020 Part 2 revisions may decrease substance use treatment stigma by demonstrating that substance use treatment is a regular component of healthcare.

The Part 2 revisions present a new avenue for destigmatizing substance use disorders by integrating substance use patient records with general medical records. The Part 2 revisions retain strict record privacy rules while creating parity with HIPAA.[176] As a result, the Part 2 revisions seek to allow providers to integrate records and healthcare teams, creating an opportunity to normalize substance use disorder as a medical condition, instead of a moral failing.[177]

Integrating substance use disorder care into general medical care presents a unique opportunity to fight drug use stigmatization. The continued stigmatization of drug use in the U.S. is perpetuated by the clear divide between substance use treatment and all other medical treatment.[178] Substance use treatment is often physically separated from other medical care services and is not fully accessible in hospitals or primary care settings.[179] This separation advances the idea that substance use treatment is not routine medical treatment. Breaking down drug use stigma requires substance use treatment integration into the everyday healthcare system.[180]

The Part 2 revisions facilitate healthcare integration by lessening record-keeping obstacles for providers.[181] Since most, if not all, healthcare providers work under HIPAA,[182] integrating substance use care into general medical care requires providers to comply with HIPAA and Part 2 simultaneously. Historically complying with both schemes proved challenging and prevented the integration of substance use care into other healthcare settings.[183] The 2020 Final

177. Jerome M. Adams & Nora D. Volkow, *Ethical Imperatives to Overcome Stigma Against People With Substance Use Disorders*, 22 AMA J. ETHICS 702, 703 (Aug. 2020).

177. Jerome M. Adams & Nora D. Volkow, *Ethical Imperatives to Overcome Stigma Against People With Substance Use Disorders*, 22 AMA J. ETHICS 702, 703 (Aug. 2020).

178. Adams & Volkow, *supra* note 178.

179. *Id.*

180. Adams & Volkow, *supra* note 178.

181. Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 43036–39 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2).

182. *Who Must Comply with HIPAA Privacy Standards?*, U.S. DEP'T OF HEALTH & HUM. SERVS., (last reviewed Dec. 28, 2022), https://www.hhs.gov/hipaa/for-professionals/faq/190/who-must-comply-with-hipaa-privacy-standards/index.html.

183. *Id.*

Rule bridges the HIPAA-Part 2 gap and reduces the regulatory burden on providers.

Though Part 2 was not revised to mirror HIPAA completely, the revisions take important steps to bring substance use treatment into the same arena as other medical treatment.[184] Treating substance use disorder in primary care facilities, emergency departments, or even hospitals, rather than in a separate facility, has the power to normalize substance use disorder as an ordinary, treatable medical condition.[185] Though imperfect, one of the best ways to fight stigma is to bring a condition "out of the shadows."[186]

The Part 2 revisions encourage integrating substance use treatment into the broader medical space, but the revisions do not fully ameliorate the societal stigma surrounding drug use. SAMHSA and the Health Resources and Services Administration (HRSA) have published various guides to help implement integrated care between traditional medical care, mental health care, and substance use care.[187] Issues spread beyond record privacy regulations. Additionally, HHS recognizes that substance use stigma is part of a multifaceted issue that requires widespread intervention.[188] Scholars addressing avenues for alleviating drug use stigma in the U.S. urge steps to reach integrated care, like Part 2 revisions and physician training, and public education on substance use, history, stigma, and medical knowledge.[189] The Part 2 revisions are one step in the right direction to fight stigma and normalize substance use disorder as a medical condition as treatable as any other disease.

III. CONCLUSION

Seeking treatment for substance use disorder can be a risk for patients based on societal stigma and drug criminalization.[190] SAMHSA's confidentiality requirements establish a barrier against disclosure, aimed to protect patients and allow them to seek treatment with less hesitance.[191] SAMHSA's 2020 revisions to Part 2 correctly aim to increase feasibility of coordinated care.[192] The revisions enhance coordinated care by aligning Part 2 with more general HIPAA

184. *Id.* at 703.

185. *Id.* at 704–05.

186. *Id.* at 705.

187. *A Quick Start Guide to Behavioral Health Integration for Safety-Net Primary Care Providers*, NAT'L COUNCIL FOR MENTAL WELLBEING, https://www.thenationalcouncil.org/wp-content/uploads/2020/01/Website-Resources.pdf?daf=375ateTbd56 (last visited Jan. 29, 2023).

188. Adams & Volkow, *supra* note 178.

189. *Id.* at 704.

190. *See supra* Section II.B.1.

191. *See supra* Section II.A.

192. *See supra* Section II.D.

requirements, which in turn may lead to better, more holistic outcomes for patients[193] and normalization of substance use disorder as a medical condition treatable alongside other conditions.[194] While treatment-level requirements have loosened slightly to enhance integrated care systems, the revisions necessarily retain Subpart E law enforcement provisions to protect patients from disclosure to prosecution and other legal consequences.[195] Moving forward, SAMHSA will revise Part 2 again to meet the requirements of the CARES Act, likely strengthening protections for patients with substance use disorder.[196] Though revised, Part 2 remains an effective protective scheme for patients seeking substance use disorder treatment.

193. *See supra* Section III.A.
194. *See supra* Section III.C.
195. *See supra* Section III.B.
196. *See supra* Section II.D.