pennsylvania
DEPARTMENT OF HEALTH
PRESCRIPTION DRUG MONITORING PROGRAM

RESEARCH & EVALUATION GROUP
at PHMC

August 2019

Protecting Patients with SUDs: The Relationship of PDMPs and 42 CFR Part 2

Introduction

The opioid overdose epidemic has been sustained in large part by prescription opioid misuse. Patients have been able to obtain prescription opioids at a high rate, partially due to limited communication between prescribers and dispensers. Doctor shopping and prescription forgery have also contributed to overprescribing and misuse of prescription drugs. Historically, patients have obtained Schedule II-V controlled substances from prescribers and subsequently from dispensers without the prescriber or dispenser being aware of whether the patient already possessed the controlled substance. To address these issues, states have implemented Prescription Drug Monitoring Programs (PDMPs). State PDMPs electronically track patients' prescription medication history, allowing prescribers and dispensers to identify potential dangers related to treatment determinations.

Despite increased national attention and the historical safeguards of anonymity, substance use disorder (SUD) remains highly stigmatized. As such, many patients who seek SUD treatment require substantial privacy protections. To address the need for discrete SUD treatment, the federal government regulates substance abuse treatment programs through the Confidentiality of Alcohol and Drug Abuse Patient Records regulations (42 Code of Federal Regulations ("CFR") Part 2),[1] which implement the Federal Drug and Alcohol Confidentiality Law.[2] 42 CFR Part 2 works to ensure that "a patient 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,"[3] since "unauthorized disclosure of substance use disorder patient records can lead to a host of negative consequences, including loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrest, prosecution, and incarceration."[4] In other words, to ensure patients can pursue treatment without fear of discrimination or unintended legal consequences, 42 CFR Part 2 prevents treatment programs, and all providers working in treatment programs, from disclosing specific information regarding patient treatment to a program or individual without consent.

In an effort to modernize the Confidentiality of Alcohol and Drug Abuse Patient Records regulations (42 CFR Part 2), the Substance Abuse and Mental Health Services Administration (SAMHSA) published a Notice of Proposed Rulemaking (NPRM) in early 2016 that proposed policy changes to update 42 CFR Part 2 for the first time since 1987. After consideration of comments, SAMHSA concurrently issued a final rule[5] detailing the changes, and a separate Supplemental Notice of Proposed Rulemaking (SNPRM) was created in early 2017, providing further guidance.[6] Many comments submitted to SAMHSA in response to the NPRM and SNPRM focused on the relationship between the safeguards of 42 CFR Part 2 to protect patients treated for SUDs with prescription drugs and the objectives of state PDMPs to reduce prescription drug abuse and diversion.

Overview and Application of 42 CFR Part 2

42 CFR Part 2 applies to any "individual or entity (other than a general medical facility) who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment."[7] The regulations also extend to medical staff in a general medical facility "whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers."[8] Most drug and alcohol treatment programs are federally assisted; therefore, most programs and providers working in them, including DATA waivered providers,[9] are

subject to the requirements of 42 CFR Part 2. For-profit programs and private practitioners that do not receive federal assistance of any kind are not subject to 42 CFR Part 2, unless a state licensing or certification agency requires them to comply. However, any clinician who uses a controlled substance for detoxification or maintenance treatment of a SUD is required to have a federal DEA registration, and becomes subject to 42 CFR Part 2 pursuant to the DEA license.

Regulation of Patient Information Disclosures

42 CFR Part 2 states that all patient information disclosures ''must be limited to that information which is necessary to carry out the purpose of the disclosure.''[10] While federally assisted SUD treatment programs may disclose information to "lawful holders," or individuals or entities with access to patient identifying information based on patient consent, there are specific circumstances in which lawful holders are also allowed to disclose patient information.[11] The SNPRM was created to provide lawful holders with a better understanding of appropriate organizations that can receive patient information, based on those organization's activities. The SNPRM provides a non-exhaustive list of permissible activities that constitute payment and health care operations activities.[12] This list includes examples such as "patient health safety activities," "clinical professional support services" and "third party liability coverage," with no further explanation.[13]

Proponents of the SNPRM believe "the proposed payment and health care operations activities represent significant progress toward SAMHSA's stated goal of modernizing 42 CFR Part 2 to increase opportunities for individuals with SUDs to participate in new and emerging health care models and health information technology."[14] Additionally, supporters proposed adding care coordination and case management to the list of permissible activities. In comments submitted to SAMHSA, proponents emphasized the role of these activities "in the operational and treatment responsibilities in serving patients, including those with a dual diagnosis of mental health and substance use disorder."[15] This interest in supporting an integrated healthcare model is similar to the objective of a PDMP in maintaining a database of the prescribed medications of a patient. Ultimately, care coordination and case management were not added to the non-exhaustive list provided by the preamble. SAMHSA reasoned that this provision is not intended to cover care coordination or case management, stating conclusively, "disclosures may not be made under proposed 2.33(b) for activities related to the patient's diagnosis, treatment, or referral for treatment."[16]

Regulation of Disclosures in Pennsylvania: 4 Pa. Code § 255.5

To safeguard the integrity of client treatment-related information, Pennsylvania law generally requires client consent before disclosure, except in limited situations wherein releasing client treatment information is necessary to determine compliance with a condition of a sentence, parole and/or probation. The Pennsylvania Code establishes appropriate instances for the disclosure of "client oriented data" in Title 4, Section 255.5. The law permits disclosure of client information in certain situations, generally related to determining a client's compliance with mandated treatment as a condition of a judicially imposed sentence, probation and/or parole. Information that may be disclosed in these situations includes: whether the client is in treatment, the prognosis and nature of treatment, a description of the progress made thus far, and a statement detailing any relapse.[17] Such information may be released, with or without consent of the client, to judges and probation or parole officers that are provided with client treatment information to support or contest compliance with an imposed sentence, proposed treatment plan, or conditional release option.[18]

Disclosures that require a client's written consent include release of information to a client's attorney, to employers considering the client for employment or to support an employee's rehabilitation, as well

as to a judge who needs additional information to initiate a conditional release program for the client.[19] Pennsylvania's law also includes stipulations for disclosure of client information, with client consent, to health care insurance companies or plans, as well as to governmental officials to obtain governmental benefits related to drug abuse or dependence. Client records may be released without consent in emergency medical situations "where the life of the client is in immediate jeopardy" to provide appropriate medical treatment.[20] The law limits disclosure of medical records to client admission forms, treatment/discharge forms, and treatment discharge summaries. Before release of records, the client must "fully understand the nature of the information, the purpose of the record transfer, and the identity of the recipient of the information."[21]

PDMPs and Risk of Treatment Information Re-Disclosure

In response to the SNPRM, Attorneys General from 32 states and the District of Columbia recommended that the Department of Health and Human Services revise 42 CFR Part 2 to permit substance abuse treatment programs to submit prescription and dispensing information to state PDMPS, in order to allow for comprehensive drug treatment.[22] Currently, 42 CFR Part 2 prohibits providers and programs providing substance abuse treatment from reporting patient-identifying information to PDMPs, including information regarding dispensations of controlled substances for SUD treatment.[23] Therefore, pharmacists that search PDMPs for patients will not have any indication that a patient is receiving treatment for a SUD via a substance abuse treatment program or provider. As methadone is often administered to patients at federally regulated opioid treatment programs (OTPs) and in hospital settings without a prescription, "PDMPs do not contain data regarding patients receiving methadone [without a prescription], even when the same patients are treated by other providers [outside of OTPs] who do participate in the PDMPs."[24] This statement is limited to methadone received by patients at an OTP without a prescription; PDMPs do monitor prescriptions of methadone that are dispensed by pharmacies. The state Attorneys General expressed concern that this disconnect between methadone dispensed by OTPs to patients without a prescription, which are not dispensations monitored by PDMPs, may lead to adverse drug interactions. Alternatively, since pharmacies are not subject to 42 CFR Part 2 restrictions, and prescriptions for buprenorphine or methadone are filled at pharmacies, pharmacists must submit this patient-identifying information to PDMPs (and, likewise, may access it as PDMP users). The state Attorneys General reasoned that this "arbitrary and dangerous distinction" between tracking Medication Assisted Treatment (MAT) based upon whether a provider or dispenser is subject to 42 CFR Part 2 privacy restrictions might lead to inferior treatment for individuals in methadone treatment programs, as they may have a greater chance of abusing their medications.[25] Hartford Healthcare echoed these concerns, believing that the lack of communication between medical providers would prevent seamless and effective care to patients.[26]

In a 2011 "Dear Colleague" letter, SAMHSA provided guidance to federally assisted substance abuse programs with respect to maintaining patient privacy and the role of the PDMP in the pursuit of better patient care.[27] Numerous state laws regulating PDMPs require any provider who dispenses more than a 48-hour supply of a schedule II-V controlled substance to report such transactions to the state PDMP.[28] However, 42 CFR Part 2 prohibits federally assisted substance abuse treatment programs from disclosing patient records that could directly or indirectly be used to identify a patient as receiving treatment for an SUD without patient consent, unless one of the regulation-specific exceptions apply.[29] Although a patient may provide written consent to disclose treatment information to a non-federally assisted substance abuse program, 42 CFR Part 2 prohibits re-disclosure of treatment information, including to PDMPs. In other words, federally assisted substance abuse programs cannot provide patient information to PDMPs, as any later access of the information by a PDMP user would constitute re-disclosure, a violation of 42 CFR Part 2.[30] However, 42 CFR Part 2 does not explicitly state what, if any, actions that

federally assisted substance abuse programs must take when confronted with state PDMP laws that mandate reporting of substances used for treatment.

States have varied in managing the seemingly contrasting requirements of 42 CFR Part 2 and adherence to PDMPs. The Vermont Department of Health and the Maryland Department of Health and Human Services both recommend that 42 CFR Part 2 permit re-disclosure for the purpose of treatment and care coordination, reasoning that it may limit "avoidable poor patient outcomes like adverse drug interactions, or even death."[31] The states' Departments of Health further assert that opioid treatment providers should be allowed to disclose information to state PDMPs with patient consent, as reports have noted links in some states between implementation of the state PDMP and a decline in drug overdose deaths.[32]

Alternatively, the Legal Action Center (LAC), a leading expert in SUD policy, maintains its opposition to the disclosure of opioid treatment information to state PDMPs.[33] In comments to SAMHSA, LAC has recommended that SAMHSA retain the full notice requirement, which states that a standard explanation of 42 CFR Part 2 be included in every disclosure of patient information.[34] Currently, SAMHSA allows federally assisted substance abuse treatment programs to provide an abbreviated notice when disclosing patient information, as it "provides more flexibility and efficiency in meeting the notice requirement."[35] The abbreviated notice permits treatment programs to provide patient information with an accompanying notice letter that states, "42 CFR Part 2 prohibits unauthorized disclosure of these records."[36] LAC reasoned that this notice may not be sufficient to prevent unauthorized disclosures, since many non-federally assisted drug abuse programs or "lawful holders" may not be familiar with 42 CFR Part 2.

Additionally, SAMHSA declined to implement suggestions made by LAC and other organizations to extend 42 CFR Part 2 requirements to third parties who receive patient information from lawful holders. LAC asserts that allowing further disclosure of patient information by lawful holders would be a risk to patient privacy.[37] The broad term "health care operations," LAC notes, could be interpreted to permit activities that are detrimental to the purpose of 42 CFR Part 2.[38] LAC recommended that 42 CFR Part 2 require lawful holders that disclose information to third parties for payment or healthcare operations to enter a relationship similar to that of Qualified Service Organizations (QSO). As a QSO, the third party would be able to provide services to the lawful provider but would be bound to the legal requirements of 42 CFR Part 2. SAMHSA ultimately did not propose to revise QSOs in the SNPRM.

Conclusion

42 CFR Part 2 regulates all federally assisted substance abuse programs, with the overarching goal of maintaining patient privacy. In order to ensure that a patient who seeks treatment "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,"[39] federally assisted drug abuse programs may not disclose patient information without written consent.[40] Even with written consent, these programs cannot disclose information to organizations that may re-disclose information under 42 CFR Part 2. In other words, federally assisted substance abuse programs cannot provide PDMPs with patient information, even with consent, as any later access of the information would be a re-disclosure.[41] The latest iteration of 42 CFR Part 2 includes a SNPRM, which acts as a guideline for when lawful holders can disclose information to third parties such as legal representatives, contractors, and subcontractors. This non-exhaustive list of third parties includes "patient health safety activities," "clinical professional support services" and "third party liability coverage," among others.[42] Care coordination and care management were intentionally excluded from the list, as 42 CFR Part 2 states, "disclosures may not be made under proposed 2.33(b) for activities related to the patient's diagnosis, treatment, or referral for treatment."[43]

There is a continuing debate on the implications of 42 CFR Part 2, as an interest in retaining patient privacy is balanced with advancing integrated health care.

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[1] 42 Code of Federal Regulations § 2 ("42 CFR Part 2"); hereinafter 42 CFR § 2.
[2] 42 U.S.C. §290dd-2.
[3] 82 FR 6052.
[4] *Id.*
[5] Department of Health and Human Services (HHS), *Final Rule: Confidentiality of Substance Use Disorder Patient Records* (Jan. 18, 2017), https://www.regulations.gov/document?D=HHS-OS-2016-0005-0377.
[6] Office of the Federal Register, *82 FR 5485 - CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS* (Jan. 18, 2017), https://www.gpo.gov/fdsys/granule/FR-2017-01-18/2017-00742; hereinafter 82 FR 5485.
[7] 42 CFR § 2.11.
[8] *Id*.
[9] Qualifying providers, following required training and waiver application, can obtain a DATA waiver (pursuant to the Drug Addiction Treatment Act of 2000, or DATA 2000). Waiver holders are permitted to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications - medications that have a lower risk for abuse, such as buprenorphine - in settings other than an opioid treatment program (OTP), such as a methadone clinic. See SAMHSA, *Buprenorphine Waiver Management* (January 18, 2018), https://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/buprenorphine-waiver.
[10] 42 C.F.R. § 2.13(a).
[11] *Id.*
[12] 82 FR 5485.
[13] 42 C.F.R. §2.33(b).
[14] 82 FR 6052.
[15] *Id.*
[16] *Id.*
[17] 4 Pa. Code § 255.5(b).
[18] 4 Pa. Code § 255.5(a).
[19] *Id.*
[20] *Id. at (a)(7)-(9).*
[21] *Id. at (c).*
[22] *AG: Methadone Clinics Should Report to Prescription Drug Monitoring Program* (April 12, 2016), https://www.nmag.gov/uploads/PressRelease/48737699ae174b30ac51a7eb286e661f/Methadone_Clinics_Should_Report_to_Prescription_Drug_Monitoring_Program_1.pdf.
[23] SAMHSA, *Dear Colleague Letters for Medication Assisted Treatment (MAT) Providers: Letter on the illicit use of prescription drugs and State Prescription Drug Monitoring Programs (PDMPs)* (Sept. 27, 2011), https://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/dear_colleague_letters/2011-colleague-letter-state-prescription-drug-monitoring-programs.pdf. [hereinafter *Dear Colleague Letter*]
[24] State Attorneys General, *Confidentiality of Substance Use Disorder Patient Records, 81 Federal Register 6988 (February 9, 2016) Comments to Proposed Rulemaking* (April 11, 2016), https://www.regulations.gov/document?D=HHS-OS-2016-0005-0333.
[25] *Id.*
[26] Hartford Healthcare, *File Code SAMHSA 4162-20* (April 1, 2016), https://www.regulations.gov/document?D=HHS-OS-2016-0005-0341.
[27] *Dear Colleague Letter*, *supra* note 18.
[28] *Id*.
[29] 42 C.F.R. §2.12.
[30] 42 C.F.R. §2.32; *Dear Colleague Letter*, *supra* note 18.
[31] State of Vermont, Department of Health, *Comment on the Confidentiality of Substance Use Disorder Patient Records* (April 11, 2016), https://www.regulations.gov/document?D=HHS-OS-2016-0005-0210.

[32] Prescription Drug Monitoring Program Center of Excellence at Brandeis, *Briefing on PDMP Effectiveness* Sept. 2014), http://www.pdmpassist.org/pdf/COE_documents/Add_to_TTAC/Briefing%20on%20PDMP%20Effectiveness%203rd%20revision.pdf.
[33] Legal Action Center, *Comments of the Legal Action Center in Response to U.S. Dept. of Health & Human Services, Substance Abuse & Mental Health Services Administration, Notice of Public Listening Session* (June 25, 2014), https://lac.org/wp-content/uploads/2014/12/LAC_COMMENTS.pdf.
[34] *Id.*; Legal Action Center, *Legal Action Center Comments on Supplemental Notice of Proposed Rulemaking regarding 42 CFR Part 2 (SAMHSA-4162-20; RIN 0930-AA21)* (Feb. 13, 2017), https://lac.org/wp-content/uploads/2017/02/SNPRM-Comments-REVISED-2-13-17.pdf.
[35] 82 FR 6052.
[36] *Id.*
[37] Legal Action Center, *Legal Action Center Comments on Supplemental Notice of Proposed Rulemaking regarding 42 CFR Part 2 (SAMHSA-4162-20; RIN 0930-AA21)* (Feb. 13, 2017), https://www.regulations.gov/document?D=HHS-OS-2016-0005-0384.
[38] *Id.*
[39] 82 FR 6052.
[40] 42 C.F.R. §2.33.
[41] 42 C.F.R. §2.32.; *Dear Colleague Letter*, *supra* note 18.
[42] 42 C.F.R. §2.33(b).
[43] *Id.*