

The Substance Abuse and Mental Health Services Administration  
Department of Health and Human Services  
Attn: SAMHSA - Deepa Avula  
5600 Fishers Lane, Room 17E41  
Rockville, Maryland 20857

Re: 42 CFR Part 2 - Confidentiality of Substance Use Disorder Patient Records Proposed Rule (SAMHSA 4162-20; RIN 0930-AA32)

## **Overview**

As a public health policy think tank focused on addiction and overdose prevention, the Health in Justice Action Lab and the Electronic Frontier Foundation writes in strong opposition to the changes proposed in SAMHSA-4162-20 to 42 CFR 2.31(a)(4)(i). Allowing substance use treatment programs currently covered by 42 CFR Part 2 to expose dispensing information to state prescription drug monitoring programs (PDMPs) is a step in the wrong direction because it will:

1. Expose highly-sensitive, compromising, and potentially-incriminating information to a broad array of law enforcement and other public and private entities;
2. Negatively impact patient help-seeking, retention, and survival because of real and perceived risk of surveillance, stigma, and criminalization;
3. Fail to mitigate real and perceived threats to confidentiality through the proposed consent mechanism.

In the context of the nation's deadliest drug overdose crisis, better integration and coordination of care for people affected by substance use disorder (SUD) is a worthy goal. But merging Part 2 data into state PDMPs fails to substantially advance this imperative, while materially eroding the privacy, security, and wellbeing of vulnerable patients. Rather than pursuing a privacy race to the bottom, we must work to improve integration by bolstering data protections for sensitive health information across the board.

## **I. Substance Use Disorder Treatment: Vital, But Stigmatized and Criminalized**

We trust the information we share with our health care providers to be received in confidence and without judgment. This is why the patient's right to confidentiality is fundamental to the provision of medical care. The very fact that a patient has sought medical assistance typically comes under the scope of restricted information. These protections derive their justification in patients' expectation of privacy, agency, and control over information (including possibly embarrassing, incriminating, or otherwise damaging facts) revealed during the health care encounter.

Substance use treatment—especially treatment currently covered under 42 CFR Part 2—is vital to addressing today’s opioid crisis. Methadone and buprenorphine maintenance reduce overdose risk by 50-80%.<sup>1</sup> Yet, such life-saving care remains highly stigmatized and criminalized. There are myriad ways in which ongoing stigma harms people receiving opioid agonist therapy (OAT) in the medical system.<sup>2</sup> Patronizing an opioid treatment program (OTP) can trigger cascades of negative legal consequences, including criminal, family law, and housing policy sanctions. Stripping SUD patients from privacy protections leaves them even more vulnerable to discriminatory practices both within and outside the health care system.

In the criminal-legal context, removing privacy protections from Part 2 care creates an especially acute risk of harm. For instance, individuals with opioid use disorder (OUD) under community supervision are frequently mandated to adhere to specific conditions of pharmacotherapy.<sup>3</sup> Often, this means enrolling in abstinence-based treatment that affect de-facto bans on OAT or on a regimen of extended-release injectable naltrexone (Vivitrol), which is not compatible with OAT. Although such conditions are coming under increasing number of legal challenges, they remain widespread. The violation of such conditions is customarily punishable by automatic incarceration.<sup>4</sup> Evidence that an individual is a patient at an OTP could technically constitute a violation, triggering such a result. In addition to the trauma and disruption to the individual’s recovery process, incarceration also translates into an extremely high risk of overdose upon re-entry.<sup>5</sup> In the midst of the nation’s deadliest overdose crisis in recorded history, the stakes for safeguarding this highly sensitive information could not be higher.

## II. PDMPs Facilitate OAT Patients’ Vulnerability to Stigma, Criminalization

---

<sup>1</sup> Nora D. Volkow & Eric M. Wargo, *Overdose Prevention Through Medical Treatment of Opioid Use Disorders*, ANN 169 INTERN MED 190-192 (2018).

<sup>2</sup> United States Department of Justice, *Justice Department Reaches Settlement with Selma Medical Associates Inc. to Resolve ADA Violations*, U.S. DEPARTMENT OF JUSTICE (Jan. 31, 2019), <https://www.justice.gov/opa/pr/justice-department-reaches-settlement-selma-medical-associates-inc-resolve-ada-violations> (describing the case where, in January 2019, the Justice Department’s Civil Rights Division sued a privately owned medical facility located in Winchester, Virginia for refusing to accept a prospective patient on the basis that he was lawfully prescribed Suboxone).

<sup>3</sup> Harlan Matusow et al. *Medication assisted treatment in US drug courts: results from a nationwide survey of availability, barriers and attitudes*. 44 J SUBST ABUSE TREAT 473-480 (2013).

<sup>4</sup> Jake Horowitz & Amy Solomon, *Community Supervision Too Often Leads to Incarceration*, PEW CHARITABLE TRUSTS (Jan. 19, 2019), <https://www.pewtrusts.org/en/about/news-room/opinion/2019/01/19/community-supervision-too-often-leads-to-incarceration>.

<sup>5</sup> In addition to real risks, individuals who can benefit from the services covered under 42 CFR Part 2 also carry substantial amounts of trauma from their encounters with the criminal-legal and health care systems, increasing distrust and making robust privacy protections that much more vital to incentivise help-seeking.

In the context of the overdose crisis, nearly all United States jurisdictions have rapidly adopted PDMPs.<sup>6</sup> The purported benefits of PDMPs remain elusive: narrative and systematic reviews have painted a mixed picture of impact, on balance finding that PDMP deployment has been associated with both decreases in prescription drug-involved overdoses, as well as increases in overdoses involving illicit opioids,<sup>7</sup> in particular heroin.<sup>8</sup> Users of PDMPs have also expressed concerns that these systems may be affecting population-level collateral consequences evidenced in epidemiological data.<sup>9</sup> In troubling ways, these concerns reflect those about invasive “drug user registration” schemes standard in totalitarian settings like the Soviet Union and China.<sup>10</sup> Nevertheless, the various policy and functionality shortcomings and pitfalls of PDMPs have received little attention.

The extent to which PDMPs provide police and other law enforcement agencies broad access to highly-sensitive data remains poorly understood. Only 14 states currently have a warrant requirement for law enforcement access, and even these requirements include a number of exemptions.<sup>11</sup> In a sample of 16 states from 2013 to 2019, the volume of law enforcement queries shows a persistent upward trend, with many thousands of searches per annum in some states.<sup>12</sup> This trend is reversed in those jurisdictions after the enactment of a relatively low-threshold warrant safeguard. For instance, after the Utah Legislature adopted a warrant requirement in 2015, law enforcement searches demonstrated a drastic decrease in PDMP queries by law enforcement, falling by over 99 percent (See Appendix 1).

Even in states where access is contingent upon the presence of an “active investigation” or “probable cause,” PDMP systems may run searches and deploy predictive algorithms that trigger investigations, functionally circumventing these access requirements. Typically designed by commercial entities, such algorithms are intended to flag “problematic” patterns in patient, provider, and pharmacy practice. Risk scoring and other functionality in these black-box analytical systems are not transparent and have raised substantial concerns about fidelity, validity, and bias.<sup>13</sup> At a time when limitations of—and equity risks posed by—predictive

---

<sup>6</sup> Prescription Drug Abuse Policy System, *PDMP Reporting and Authorized Use*, <http://pdaps.org/datasets/prescription-monitoring-program-laws-1408223416-1502818373>.

<sup>7</sup> Leo Beletsky, *Deploying Prescription Drug Monitoring to Address the Overdose Crisis: Ideology Meets Reality*, 15 INDIANA HEALTH LAW REVIEW 139 (2018); *See also* David S. Fink et al, *Association between prescription drug monitoring programs and nonfatal and fatal drug overdoses: a systematic review*, 168 ANN INTERN MED 783-790 (2018).

<sup>8</sup> Silvia S. Martins et al., *Prescription drug monitoring programs operational characteristics and fatal heroin poisoning*. 74 Int J Drug Policy 174-180 (2019).

<sup>9</sup> Alden Yuanhong Lai et al., *Perceived Unintended Consequences of Prescription Drug Monitoring Programs*. 54 SUBST USE MISUSE 345-349 (2018).

<sup>10</sup> Daniel Wolfe, MP Carrieri, D Shepard. *Treatment and care for injecting drug users with HIV infection: a review of barriers and ways forward*, 376 LANCET 355, (2010).

<sup>11</sup> PDMP Access and Registration, *The Policy Surveillance Program: A Law Atlas Project*, LAW ATLAS (2016), <http://www.lawatlas.org/query?dataset=prescription-monitoring-program-laws-1408223332>.

<sup>12</sup> These data are a result of a national effort to understand the extent of law enforcement use of PDMPs, the Health in Justice Action Lab has filed Freedom of Information Act (FOIA) requests with all 50 states. So far, 16 states have provided information.

<sup>13</sup> Beletsky, *see supra* note 7.

analytical are increasingly recognized in criminal justice and other domains, PDMPs have cavalierly embraced algorithmic functionality without sufficient scrutiny or transparency.<sup>14</sup>

Law enforcement access is a significant issue, but not the only concern in merging Part 2 medication dispensing data with PDMPs. A wide range of other parties may also interact with PDMP information, in part due to the creep of information use and commercialization by companies that run PDMP infrastructure. Appriss, a private firm that frequently collaborates with law enforcement agencies, is involved with PDMP infrastructure and analytics in 42 states and territories.<sup>15</sup> There are wide-ranging implications of this commercialization potentially impacting health or life insurance, among other systems. But these risks must be better understood before proposed rulemaking can proceed.

Despite the broad scope of information collected by PDMPs, these databases have never captured all dispensations of scheduled controlled substances. Although care provided in office-based settings is included in PDMPs, OTP information is not because medications dispensed through OTPs are an exception.<sup>16</sup> Federal law has long provided heightened privacy protections for OTP patient records, expressly prohibiting disclosure of this information without patient consent or one of a narrowly defined set of exceptions (such as providing information to medical personnel in an emergency situation).<sup>17</sup>

Even when patients do consent to disclosure, federal regulations prevent disclosed OTP records from being subsequently redisclosed unless the patient also consents to the subsequent disclosure.<sup>18</sup> Consequently, as the Director of SAMHSA's Center for Substance Abuse Treatment has previously clarified, the privacy protections afforded to OTP patients under 42 CFR Part 2 are incompatible with the level of information sharing that occurs in PDMP programs, stating that "one of the goals of PDMPs is to make information available to authorized users, currently it would not be feasible to ensure that the information will not be redisclosed."<sup>19</sup>

Although office-based opioid treatment (OBOT) prescription information is already collected by PDMPs, two wrongs don't make a right. This unfortunate fact must not serve as a rationale for further erosion of privacy protections. This is a classic example of surveillance creep. Indeed, given the trajectory of these databases and analytical tools they increasingly employ, privacy

---

<sup>14</sup> *Id.*

<sup>15</sup> Appriss Health, *PMP AWARe*, APPRISS HEALTH (last visited Oct. 21, 2019), <https://apprisshealth.com/solutions/pmp-awarxe/>.

<sup>16</sup> Substance Abuse and Mental Health Services Administration, *Certification of Opioid Treatment Programs*, SAMHSA (Sep. 28, 2015), <https://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs>.

<sup>17</sup> 42 CFR Part 2.

<sup>18</sup> 42 CFR § 2.32.

<sup>19</sup> Substance Abuse and Mental Health Services Administration, *Letter Encouraging Use of PDMPs*, SAMHSA (Sep. 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](https://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/dear_colleague_letters/2011-colleague-letter-state-prescription-drug-monitoring-programs.pdf).

issues are only likely to get worse as technology implementing PDMPs continue to become more sophisticated.

Better integration and coordination of substance use treatment services is a valid concern. Substance use disorder is a complex disease, often enmeshed with co-occurring physical and mental health conditions. By ignoring this complexity, the historical segregation of SUD care in the United States bears substantial responsibility for the system's failure to meet the needs of so many patients. In some ways, OTPs represent a codification of the stigma of addiction and its treatment, so it is imperative to identify ways to lower the barriers to integration. However, including OTP information in PDMPs will only exacerbate these harms.

### **III. Implications of Proposed Regulatory Changes**

SAMHSA now proposes to change the long-standing privacy protections provided to OTP patient records through integration with state PDMPs. These changes would further expose the private information of an already extensively surveilled group and risk public health in the midst of the ongoing crisis by disincentivizing OTP participation.

SAMHSA's contention that these privacy harms will be minimal because law enforcement would be required to obtain a court order satisfying 42 U.S.C. 290dd-2(c) prior to seeking additional patient records from OTPs fails to account for the sensitive inferences that can be made from prescription records alone, and the potential downstream effects on law enforcement efforts to obtain OTP information.

#### *A. Aggravating surveillance and stigmatization burden on traumatized, criminalized patients*

Confidential medical care is not equally distributed: There is a growing, global body of empirical data documenting the disparities in systemic violations to confidentiality and other rights of patients belonging to marginalized groups. Although poorly-regulated law enforcement access to PDMP data risks the privacy of all who receive health care, these threats are particularly salient to OTP participants.

Reflecting the power imbalance that affects these groups in other domains, confidentiality violations disproportionately impact these patients because they are subject to increased state control, surveillance, and stigmatization. People who use drugs are highly vulnerable to deleterious outcomes that can cascade from receiving care in Part 2 covered entities. Even though the information collected is narrow in scope, it raises significant privacy risks that can result in severe criminal penalties. Furthermore, legal risks created by allowing OTPs to report information to PDMPs extend far beyond the criminal context: Child protective services, employment, and immigration are just some of the enforcement structures that could access PDMPs and their analytical functionality. Actual and perceived access by governmental agencies for the purposes of surveillance could precipitate harmful consequences, deterring help-seeking and precipitating harm among already vulnerable patients.

## B. Fueling morbidity and mortality

There is still significant stigma attached to participation in SUD treatment programs across a wide variety of communities and institutions.<sup>20</sup> Consequently, protecting the privacy and confidentiality of OTP information—especially information related to dispensing—is a crucial step in reducing the barriers to participation in OAT programs. As described by one recovery advocate, “[w]e would not have put our careers, reputation or families at risk of stigma and discrimination if we were not assured that information about our substance use disorder was safe and would only be shared with our consent.”<sup>21</sup>

Opioid agonist therapy is the gold standard in treatment of opioid use disorder. Engaging patients on OAT using methadone and buprenorphine (especially the buprenorphine-naloxone combination, e.g. Suboxone®) effectively staves off OUD withdrawal symptoms, controls cravings, and stabilizes patients, helping them regain control of their lives.<sup>22</sup> Much like other chronic and relapsing conditions, OUD typically requires long-term (even life-long) pharmacotherapy.<sup>23</sup>

Decades of research have demonstrated these medications to be safe, effective, and cost-effective in the treatment of OUD. Methadone and buprenorphine maintenance have been especially positively evaluated across a variety of geographical and institutional settings, demonstrating unequivocal public health, social, family, and crime-prevention benefits.<sup>24</sup> Of vital relevance in the current crisis, OAT holds enormous overdose prevention potential and is enormously cost-effective.<sup>25</sup> Changes currently proposed risk increasing barriers to this care, however, endangering the very same people SAMHSA is tasked with protecting.

Finally, 42 CFR Part 2 already allows sharing of OTP records in the circumstances most likely to result in direct public health benefits: the prevention of duplicative enrollment. Under 42 CFR §

---

<sup>20</sup> Sarah E. Wakeman & Josiah D. Rich, *Barriers to Medications for Addiction Treatment: How Stigma Kills*, 53 SUBST USE MISUSE 330 (2018).

<sup>21</sup> Alison Knopf, *SAMHSA proposes significant changes to 42 CFR Part 2*, 31 ALCOHOLISM & DRUG ABUSE WEEKLY 1-5 (Sept. 2019).

<sup>22</sup> M.T. Brugal et al., *Evaluating the Impact of Methadone Maintenance Programmes on Mortality Due to Overdose and Aids In A Cohort Of Heroin Users In Spain*, 100 ADDICTION 981, 985-86 (2005); Louisa Degenhardt et al., *Mortality Among Regular Or Dependent Users Of Heroin And Other Opioids: A Systematic Review and Meta-Analysis of Cohort Studies*, 106 ADDICTION 32 (2011).

<sup>23</sup> DEP'T HEALTH & HUM. SERVS., (describing the parallel between MAT and insulin in chronic disease management).

<sup>24</sup> Amy Gibson et al., *Exposure to Opioid Maintenance Treatment Reduces Long-Term Mortality*, 103 ADDICTION 462, 462-63 (2008); Avram Goldstein & James Herrera, *Heroin Addicts and Methadone Treatment in Albuquerque: A 22-year Follow-Up*, 40 DRUG ALCOHOL DEPEND 139, 139-40 (1995); Robert Schwartz et al., *Opioid agonist treatments and heroin overdose deaths in Baltimore, Maryland, 1995-2009*, 103 AM J PUB HEALTH 917, 921 (2013); Luis Sordo et al., *Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies*, 357 BRIT MED J 1, 1 (2017).

<sup>25</sup> Mark McInerney, *Opioid Use Disorder Treatment and Mortality: Evidence from Variation in Services Offered* (U. Conn. Dep't of Economics, Working Paper No. 2018-2021, 2018).

2.34, OTPs can disclose information to other OTP programs or a central registry when a patient begins or ends treatment, or when the medication used to treat them is changed. However, unlike the broad information sharing allowed by PDMPs, information sharing between OTPs under 42 CFR Part 2 is tightly constrained to protect both public health and information privacy. Disclosures may only be made to a central registry or a treatment program within 200 miles and is limited to patient identity, medication type/dosage, and applicable dates.<sup>26</sup> Furthermore—in sharp contrast to the ever-expanding use of information collected by PDMPs—information disclosed between OTP providers under 42 CFR Part 2 may not be redisclosed, and “patient identifying information” may not be used “for any purpose other than the prevention of multiple enrollments without a court order.”<sup>27</sup>

### *C. Spurring additional law enforcement activity targeting OTP patients*

SAMHSA has argued that the potential privacy threats posed by incorporating OTP dispensing information into PDMPs—where they can be accessed by law enforcement officers without a warrant in a majority of jurisdictions—is mitigated by the fact that law enforcement is still required to obtain a court order satisfying 42 U.S.C. 290dd-2(c) in order to access covered records from any patient of an OTP. However, adding OTP dispensing information to PDMPs is likely to have downstream consequences on how—and how often—law enforcement officers request information directly from OTPs. In other contexts, surveillance scholars have noted that law enforcement can use information obtained through less-costly and less-regulated forms of surveillance to form the basis for requests for more-costly and more-regulated forms of surveillance.<sup>28</sup> Therefore, law enforcement may use more resource-intensive and invasive forms of surveillance less often when their precursor forms of surveillance are more strictly regulated.<sup>29</sup> Similarly, although the legal standard for obtaining OTP dispensing information remains the same, including OTP records in PDMPs reduces the outlays of meeting that standard, and therefore may increase the frequency with which law enforcement requests information directly from OTPs.

The requirements for obtaining a court order under 42 U.S.C. 290dd-2(c) are robust, but reasonable: law enforcement must demonstrate “good cause...including the need to avert a substantial risk of death or serious bodily harm” based on consideration of “the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services.”<sup>30</sup> OTP dispensing information will severely erode the legal and

---

<sup>26</sup> 42 CFR § 2.34(a).

<sup>27</sup> 42 CFR § 2.34(b).

<sup>28</sup> James X. Dempsey, *The Path to ECPA Reform and the Implications of United States v. Jones*, 47 U.S.F. L. Rev. 225, 234 (2012) (“ECPA must preserve the building blocks of the investigative process...It is important that investigators have the ability to work their way up that ladder of authority, gaining access to more sensitive data as the standard increases.”).

<sup>29</sup> Anne E. Boustead, *Police, Process, and Privacy: Three Essays on the Third Party Doctrine*, 31 (2016) (presenting evidence that law enforcement requests fewer wiretaps when they are required to obtain a warrant prior to obtaining phone records).

<sup>30</sup> 42 U.S.C. § 290dd-2(b)(2)(C).

other barriers to meeting this standard, as knowledge of the type and frequency of prescriptions received by an individual provides uniquely powerful insight into the relationship between the individual, his or her physician, and the treatment program. It bears emphasis that, in the majority of states, law enforcement *are not required to obtain a court order* prior to obtaining PDMP information. In turn, knowledge gained through OTP dispensing information would greatly facilitate law enforcement in meeting the legal standard to obtain other forms of OTP information, creating a back door to undermine the entire confidentiality framework.

#### **IV. Consent Cannot Mitigate Risks, is Impracticable**

SAMHSA purports to mitigate the privacy harms created by their proposed changes to 42 CFR Part 2 by requiring OTPs to obtain written consent from an individual prior to reporting their information to a state PDMP.<sup>31</sup> While this is a well-intentioned, it is wholly insufficient to mitigate the risks created by allowing OTP dispensing information to be reported to PDMPs. Because PDMPs engage in broad and wide-ranging information sharing, patients (and even providers) cannot be adequately informed of how the information provided to PDMPs will be used at the time they are asked to provide consent.

Across many contexts, meaningful consent requires not just that a formal individual assent to a course of action, but that they provide this assent after being fully informed of the implications of their decision. Informed consent in the medical context generally mandates disclosure of the material risks and benefits of treatment;<sup>32</sup> the Fair Information Practice Principles (FIPPs) protects personal information by requiring information collectors to provide “clear and conspicuous notice” of how information will be used, disclosed, and shared.<sup>33</sup> In line with these practices, 42 CFR Part 2 currently requires that consent to information disclosure specify what information will be shared and with whom.<sup>34</sup> Moreover, 42 CFR Part 2 goes beyond many other information protection schemes by prohibiting subsequent redisclosure of information without specific patient consent.<sup>35</sup>

Given the big data analytics, commercialization, and other evolving elements of PDMPs, OTPs will be unable to provide patients with a meaningful and comprehensive explanation of how information disclosed to these state databases will be used. This will render patient consent to

---

<sup>31</sup> Confidentiality of Substance Use Disorder Patient Records, 84 Fed. Reg. 44568, 44577 (Aug. 26, 2019) (“Therefore SAMHSA proposes to add a new section § 2.36, permitted OTPs and other lawful holders to report the required data to their respective state PDMPs when dispensing medications. The proposed rule would require part 2 providers to obtain written consent from the patient whose identifying information will be disclosed prior to making such reports.”).

<sup>32</sup> Erica S. Spatz, Harlan M. Krumholz, & Benjamin W. Moulton, *The New Era of Informed Consent: Getting to a Reasonable-Patient Standard Through Shared Decision Making*, 315 JAMA 2063 (2016).

<sup>33</sup> Federal Trade Commission, *Privacy Online: Fair Information Practices in the Electronic Marketplace* (2000), <https://www.ftc.gov/sites/default/files/documents/reports/privacy-online-fair-information-practices-electronic-marketplace-federal-trade-commission-report/privacy2000.pdf>.

<sup>34</sup> 42 CFR § 2.31.

<sup>35</sup> 42 CFR § 2.32.

information sharing meaningless. Additionally, because some of the less transparent uses of PDMP information, such as use of decision making tools based on proprietary black box algorithms such as NarxCare, it will be *technically impossible* to explain to patients how their information will be used at the time they are asked to provide consent.<sup>36</sup>

Reliance on consent to mitigate privacy shortcomings also raises questions about how to handle circumstances when use of PDMP data is expanded after consent is provided. It is also not clear what information about PDMPs will be provided at the time consent is sought. As willingness to share health information has been shown to depend on the context in which it will be used,<sup>37</sup> an OTP patient's willingness to provide information to a PDMP may change depending on how and with whom the information will be shared. Unless OTPs are able to provide a full accounting of PDMP information sharing at the time consent is sought, the patient will not be able to make an informed decision about whether it is in their best interest to share their sensitive, potentially stigmatizing health information.

## V. Pursue Integration Through More, Not Less, Privacy

Improving integration of prescribing information and care-coordination is a plausible pathway to better health services for people with SUD. Integration by no means guarantees such improvement; however, there is mounting evidence that personal health information integration does not, in and of itself, lead to improved health outcomes.<sup>38</sup> A variety of factors influence provider decisions to integrate SUD care into their primary care practice. For instance, user-driven design can help inform the configuration of electronic health records and other decision support tools to facilitate screening, diagnosis, and treatment.<sup>39</sup>

Similarly, technologically-driven “nudges,” such as electronic reminders, algorithms, and deliberate setting of default options can steer providers towards desired action. Conversely, systems-level barriers to providing SUD care, including technological and regulatory hurdles (such as the buprenorphine waiver requirement), disincentivize care integration.

Questions about its instrumental value aside, we should not pursue integration at the expense of privacy. A key hurdle is the enormous gap that currently exists between protections afforded under HIPAA and those affected by 42 CFR Part 2. To achieve integration, we need to extend

---

<sup>36</sup> For example, NarxCare has been implemented on the state level in 20 states, and some pharmacy chains have implemented it in their outlets in some states but not others. Christine Blank, *Chains Implementing Tech to Help Track Opioid Misuse*, DRUG TOPICS (Oct. 14, 2019), <https://www.drugtopics.com/opioid-epidemic/chains-implementing-tech-help-track-opioid-misuse>.

<sup>37</sup> Catherine L. Anderson & Ritu Agarwal, *The Digitization of Healthcare: Boundary Risks, Emotion, and Consumer Willingness to Disclose Personal Health Information*, 22 INF SYST RES 469, 483 (2011).

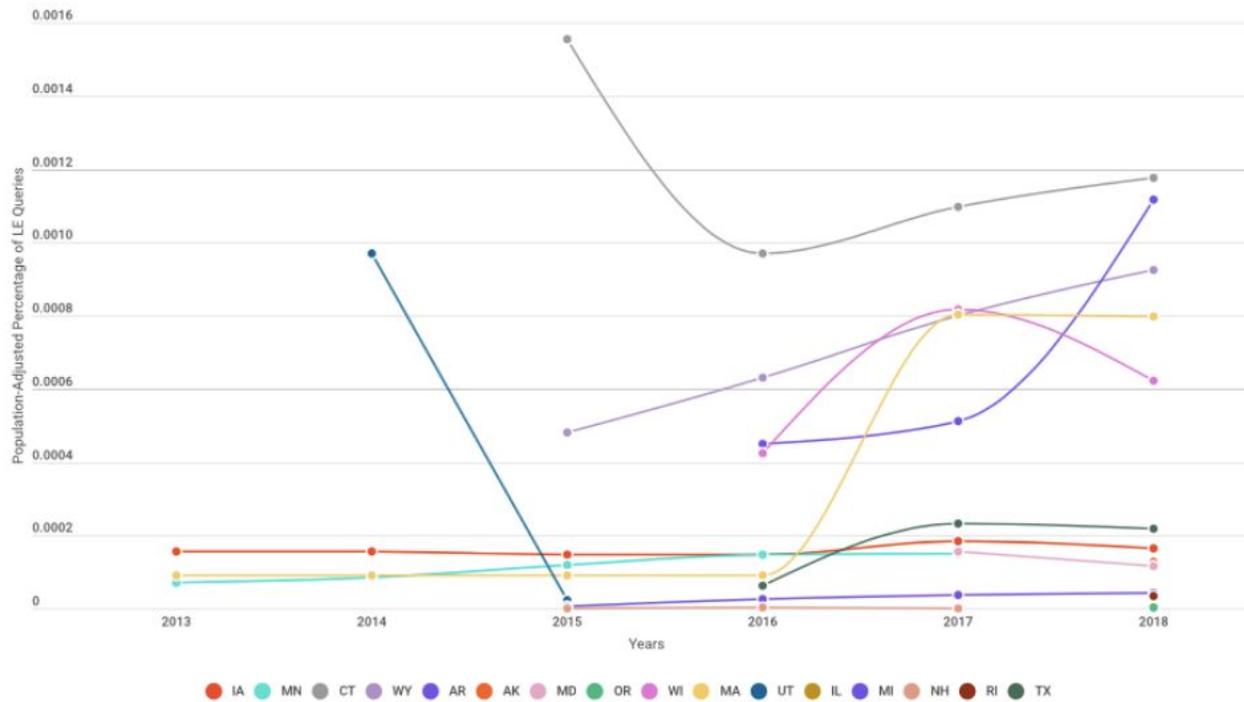
<sup>38</sup> Dori A. Cross, Jeffrey S. McCullough, Jane Banaszak-Holl, Julia Adler-Milstein. *Health information exchange between hospital and skilled nursing facilities not associated with lower readmissions*. HEALTH SERVICES RESEARCH, <https://doi.org/10.1111/1475-6773.13210>.

<sup>39</sup> Leo Beletsky, *Using Choice Architecture to Integrate Substance Use Services with Primary Care*. 12 J ADDICTION MEDICINE 1 (2018).

protections provided to prescriptions dispensed by OTP to other forms of prescription information, rather than the other way around. This would have potential public health benefits because protecting privacy builds trust, encourages help-seeking, and can improve care coordination. Conversely, if the rule is promulgated, consent should articulate an accurate assessment of risk of PDMP integration including law enforcement and other agency access.

Appendix 1.

**Figure 1. Law Enforcement Queries of PDMP in 16 States, Adjusted for Population**



\* Massachusetts Averages Span an Older and Newer Iteration of PDMP

\*\* Data constitute incomplete annual statistics to Q2