Leveraging Data Sharing for Overdose Prevention

Legal, Health, and Equity Considerations

June 2020





ACKNOWLEDGMENTS

This publication was supported by Cooperative Agreement Number NU380T000307 awarded to ChangeLab Solutions and funded by the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or the US Department of Health and Human Services.

ChangeLab Solutions is a nonprofit organization that provides legal information on matters relating to public health. The legal information provided in this document does not constitute legal advice or legal representation. For legal advice, readers should consult a lawyer in their state.

Contents

Introduction and Background	3
The Overdose Epidemic Persists	4
Access to Timely Data Can Inform Overdose Prevention Efforts	5
The Effects of Stigma on Health	6
Who Is This Document for?	7
How Is This Document Organized?	7
Guiding Principles	8
Legal Landscape	9
Health Insurance Portability and Accountability Act (HIPAA)	9
42 CFR Part 2	12
Legislative Amendments to the Federal Confidentiality Rule	16
Overdose-Related Data Collection and Sharing	17
Law Enforcement and Other First Responders	17
Diversion Programs and Correctional Settings	20
Prescription Drug Monitoring Programs (PDMPs)	25
Additional Opportunities	27
Conclusion	30
Appendix A: Key Terminology and Abbreviations	31
Appendix B: Applicability of HIPAA and Part 2 in Various Data-Sharing Situations	33
Appendix C: Resources on Data Sharing to Prevent Overdose and Reduce Drug-Related Harm	34
Notes	35

Those involved in the collection, use, and sharing of overdose-related data must keep privacy considerations in mind and ensure that data are directed toward improving public health and reducing drug-related harm rather than exposing individuals to additional risk factors such as social stigma, trauma, and involvement in the criminal justice system.

Introduction and Background

Massachusetts provides an example of how a state has successfully leveraged a comprehensive approach to collecting and using public health and other relevant data to address the overdose epidemic. Massachusetts' experience underscores why it is critical for jurisdictions to use data and data sharing to improve their understanding of the evolving landscape of drug-related harm as well as to inform and target policies and programs aimed at overdose prevention.

Amid a rapid increase in opioid overdose deaths and other drug-related harm, Massachusetts recognized that despite the numerous state agencies that were collecting and maintaining overdose-related data, the incomplete and fragmented nature of these data impeded the state's ability to design, implement, and target effective overdose prevention interventions. In 2015, the state legislature sought to address this gap by enacting legislation that requires the Massachusetts Department of Health to operate a central hub for collecting disparate overdose-related datasets and to analyze those data to help public health officials, policymakers, and communities identify trends in and risk factors for overdoses.¹

Insights uncovered through Massachusetts' analyses include the fact that opioid-related overdose death rates are 30 and 120 times greater among individuals without permanent housing and those involved with the criminal justice system, respectively, compared with the general population.² In response, the state prioritized partnerships with the criminal justice system and implemented policies to connect individuals experiencing homelessness with social services and treatment.³ Other findings from Massachusetts' data include, for example, that fatal overdoses involving both opioids and stimulants rather than opioids alone are more common among non-Hispanic black individuals, non-rural populations, and persons experiencing homelessness.⁴

The Overdose Epidemic Persists

The overdose epidemic resulted in more than 67,000 US deaths in 2018, nearly 47,000 of which involved an opioid.⁵ Opioids are substances that "reduce the intensity of pain signals and feelings of pain" by acting on a person's opioid mu receptors. Opioids include legal prescription medications such as oxycodone and morphine as well as illegal drugs such as heroin and illicitly manufactured fentanyl.⁶ The World Health Organization classifies certain prescription opioids as essential medications, given their efficacy in palliative care and treating some cancers, human immunodeficiency virus (HIV), and acute pain.⁷ But opioids also present substantial risks, including dependence, addiction, overdose, and death. Overdoses involving a combination of opioids and other drugs are also increasing and can pose a more substantial risk of death or long-term injury than overdoses involving only non-opioid drugs.^{8,9,10}

Federal, state, and local governments have taken a variety of approaches in order to address the overdose epidemic, including efforts to increase access to the opioid antidote naloxone, expand syringe access programs, facilitate evidence-based treatment, and implement prescription drug monitoring programs. ^{11,12} Despite these efforts, opioid- and other drug-related harm continues at a high rate; emergency room admissions for opioid overdose climbed 30% from July 2016 to September 2017. ¹³ Moreover, increases in overdoses related to drugs other than opioids underscore the need for more comprehensive overdose prevention efforts that do not focus exclusively on opioids. ¹⁴

Information about opioids and the overdose epidemic

Opioid overdose

Centers for Disease Control and Prevention cdc.gov/drugoverdose/index.html

Understanding the epidemic

Centers for Disease Control and Prevention cdc.gov/drugoverdose/epidemic/index.html

The triple wave epidemic: supply and demand drivers of the US opioid overdose crisis

Daniel Ciccarone

sciencedirect.com/science/article/pii/S0955395919300180

Access to Timely Data Can Inform Overdose Prevention Efforts

The timely exchange and use of data among public safety officials, public health officials, health care systems and providers, and social service agencies can help stem the tide of drug-related harm in the United States by reducing the number of overdoses and keeping overdoses that occur from becoming fatal.¹⁵ Understanding the shifting scope, direction, and contours of the overdose epidemic requires access to complete, accurate, and timely data.

Law enforcement officers, emergency medical personnel, and firefighters are often the first trained professionals to respond to fatal and non-fatal overdoses, and as a result, they collect substantial quantities of overdose-related data. However, public health officials and medical professionals are typically better equipped to leverage those data for overdose prevention initiatives.

Efforts to use data to address overdose and other drug-related harm have often failed to keep pace with data use in other fields and are hampered by barriers to data availability and access, as well as by privacy concerns. Public health professionals frequently lack access to actionable data, including data related to prescribing, illicit opioid use, and non-fatal and fatal overdoses. Even when these data exist, misconceptions about when and how federal and state privacy laws apply can impede the sharing of such data for public health purposes.¹⁶

Addressing gaps in data availability, access to data, and understanding of applicable law is critical in order to inform and target overdose prevention and response efforts.

Resources on using data and data sharing for public health purposes

Data Across Sectors for Health

dashconnect.org

Health information and data sharing

Network for Public Health Law

networkforphl.org/resources/topics/health-information-and-data-sharing/

All In: Data for Community Health

allindata.org

Strengths and weaknesses of existing data sources to support research to address the opioids crisis

Rosanna Smart et al.

doi.org/10.1016/j.pmedr.2019.101015

The Effects of Stigma on Health

Data and data sharing can provide critical insights to inform the design and implementation of overdose prevention initiatives. However, the sensitive nature of overdose-related data and stigma associated with substance misuse and addiction necessitate careful consideration of potential unintended consequences. For example, research shows that people with substance use disorders (SUD) such as opioid use disorder (OUD) "internalize or anticipate the public stigma attached to their illness" and that such internalized or anticipated stigma is "associated with psychological distress and poorer quality of life, continued substance use, and reduced engagement with substance use treatment."¹⁷ Even when people with SUD seek treatment, stigmatizing beliefs held by health professionals may result in substandard care.^{18,19}

Negative stereotypes about people with SUD can also result in punitive policy responses such as criminal prosecution and exclusionary measures that limit or prevent the operation of proven public health interventions such as evidence-based SUD treatment programs and syringe access programs. Moreover, a 2019 study examining stigma and the opioid overdose epidemic noted that "these types of [punitive and exclusionary] policies . . . reinforce the ways in which people with OUD[] are treated separately from others" and "implicitly classify people with OUD[] as being unworthy of investment and undeserving of treatment – thereby potentially having direct effects on health outcomes."²⁰

Given the robust evidence connecting stigma with negative health outcomes, those involved in the collection, use, and sharing of overdose-related data must keep privacy considerations in mind and ensure that data are directed toward improving public health and reducing drug-related harm rather than exposing individuals to additional risk factors such as structural discrimination, trauma, and involvement in the criminal justice system.

Resources on stigma, the overdose epidemic, and health outcomes

Stigma as a fundamental hindrance to the United States opioid overdose crisis response

Alexander C. Tsai et al. doi.org/10.1371/journal.pmed.1002969

Language and stigma

Evidence on how language can contribute to stigma about substance use, addiction, and overdose has evolved over time. Amendments to the federal law governing confidentiality of substance use treatment records, for example, replaced the term *substance abuse* with *substance use disorder*. This document aims to use non-stigmatizing, person-first language, but it incorporates the language used in statutes or regulations when that language affects the interpretation or application of those laws. For more information on how language and framing can reinforce stigma and for research on less stigmatizing language, see the following resources:

Expanding language choices to reduce stigma

Robert David Ashford, Austin Brown, Brenda Curtis emerald.com/insight/content/doi/10.1108/HE-03-2018-0017/full/html

Changing the Narrative

Health in Justice Action Lab ChangingTheNarrative.news

Who Is This Document for?

This resource provides an overview of relevant legal, health, and equity considerations in collecting, using, and sharing overdose-related data. It is intended to help individuals and organizations such as state and local health departments, first responders, public safety officials, social service providers, correctional facilities, health care systems, health care providers, and health insurers move closer to a public health–focused approach to leveraging data and data sharing for overdose prevention. This resource can also help government and private-sector legal and data security professionals navigate the data-sharing landscape for overdose prevention.

Determining whether and how privacy laws apply in any scenario requires a case-specific analysis of factors such as the type of information and the individuals or entities involved. Readers should consult with an attorney licensed to practice in their state when determining whether and how data privacy laws apply to them.

How Is This Document Organized?

This document

- Provides a general overview of data sharing for overdose prevention;
- Sets forth guiding principles for designing and implementing initiatives to leverage data and data sharing for overdose prevention;
- Outlines how two federal laws the Health Insurance Portability and Accountability
 Act (HIPAA) and the federal confidentiality rule, 42 CFR Part 2 (hereafter referred to as
 Part 2) regulate data privacy and sharing, including their applicability to overdoserelated data;
- Discusses overdose-related data collection and sharing by various entities involved in overdose prevention and response, including when and by whom overdose-related data are collected and whether and how HIPAA and Part 2 apply to the use and sharing of such data;
- Identifies available tools and resources on data collection for overdose prevention; and
- Defines key terms and abbreviations (see Appendix A).

Guiding Principles

This resource adopts the 4 guiding principles set forth in the 2018 Centers for Disease Control and Prevention (CDC) resource *Evidence-Based Strategies for Preventing Opioid Overdose: What's Working in the United States*. ²¹ These principles can help guide the design, implementation, and use of effective person-centered and equity-focused initiatives to leverage data and data sharing for overdose prevention.

1. Know your epidemic, know your response

"'Know your epidemic, know your response' reminds us that we must have a clear understanding of the causes and characteristics of local public health problems before we can know how to tackle them. It reminds us that our choices must be driven by evidence and data; that we must employ strategies we know to be effective; and that we must remain vigilant in maintaining a holistic and grounded understanding of who is at risk of fatal overdose, how that risk is constructed, and what can be done to reduce that risk as much as possible."

2. Make collaboration your strategy

"Effectively responding to the opioid overdose crisis requires that all partners be at the table and that we 'make collaboration our strategy' by ensuring that all community entities are able to fulfill their necessary roles."

3. Nothing about us without us

"In the context of today's opioid overdose epidemic, 'nothing about us without us' speaks to the fact that prevention strategies need to take into account the realities, experiences, and perspectives of those at risk of overdose. Those affected by opioid use and overdose risk should be involved in the design, implementation, and evaluation of interventions to assure those efforts are responsive to local realities and can achieve their desired goals."

4. Meet people where they are

"Meeting people where they are requires understanding their lives and circumstances, what objectives are important to them personally, and what changes they can realistically make to achieve those objectives. . . . [It] means more than showing compassion or tolerance to people in crisis. This principle also asks us to acknowledge that all people we meet are at different stages of behavior change. Furthermore, recognition of these stages helps us set reasonable expectations for that encounter."

Legal Landscape

Two primary sources of federal law govern access to and sharing of health-related data in the context of overdose prevention:

- 1. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations, including the Privacy Rule
- 2. Provisions within the Public Health Service Act specific to federally assisted SUD treatment programs, commonly referred to as the *federal confidentiality rule*, 42 CFR Part 2, or simply Part 2

Despite limitations imposed by HIPAA and Part 2 on the use and dissemination of certain overdose-related data, both public and private entities have ample opportunities to leverage such data to prevent overdose and reduce other drug-related harm. In fact, many purported barriers to collecting, using, and sharing overdose-related data result from common misconceptions about the applicability and scope of these federal laws. For this reason, it is critical for all overdose prevention stakeholders to understand the scope and application of these laws.

State and local laws may establish more robust privacy protections than federal law does. Additionally, other federal laws such as the Family Educational Rights and Privacy Act of 1974 (FERPA) regulate data use and sharing in specific contexts, such as schools. Although this resource does not address the applicability of state and local privacy laws or federal laws other than HIPAA and Part 2, agencies, groups, and individuals seeking to leverage data for overdose prevention should familiarize themselves with all applicable laws. For more information about these additional federal, state, and local laws, readers should consult an attorney licensed to practice in their state.

Health Insurance Portability and Accountability Act (HIPAA)

The Health Insurance Portability and Accountability Act establishes minimum national standards for use and disclosure of **protected health information**ⁱⁱ (PHI).²² By design, HIPAA aims to balance protection of sensitive health information from unauthorized disclosure with the need to use and share such information in the provision of and payment for health services as well as outside the health service delivery context (eg, research, public health surveillance, and law enforcement).

To those ends, HIPAA sets forth detailed standards, requirements, and restrictions applicable to certain entities and individuals who collect, store, use, or disclose PHI. The US Department of Health and Human Services' regulation *Standards for Privacy of Individually Identifiable Health Information* (commonly referred to as the *Privacy Rule*), which became effective in 2001, establishes the requirements and limitations most commonly applicable in the overdose prevention context.²³

The Network for Public Health Law may be available to provide legal technical assistance on leveraging data and data sharing
for overdose prevention and harm reduction. For additional information about the availability of technical assistance, visit the
Network for Public Health Law's website at <u>networkforphl.org</u>.

ii. Protected health information includes information that "relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual" and either the information explicitly "identifies the individual" or "there is a reasonable basis to believe the information can be used to identify the individual." 45 C.F.R. § 160.103.

Who is covered by HIPAA?

HIPAA's Privacy Rule applies to both **covered entities** and **business associates**. Covered entities include health plans, health care clearinghouses, and health care providers that transmit electronic health information connected to regulated transactions such as submitting health care claims, enrolling or disenrolling in a health plan, or coordinating benefits.^{24,25} Business associates include individuals who are not members of the covered entity's workforce and who create, receive, maintain, or transmit PHI on behalf of a covered entity.²⁶ Additionally, a single legal entity that engages in both covered and non-covered operations may designate itself a **hybrid entity**.²⁷ Within a hybrid entity, the Privacy Rule applies only to those operations that would qualify the entity as a covered entity or business associate.

Example: A university hospital system, which operates as a single legal entity, provides health care services and conducts laboratory research. Those engaged in the laboratory research do not function as health care providers. By default, the entire university hospital system and its employees qualify as a covered entity subject to the Privacy Rule. However, if the university hospital properly designates itself a hybrid entity, the Privacy Rule would apply only to those engaged in providing health care services, not to those engaged only in laboratory research.²⁸

HIPAA's applicability to overdose prevention stakeholders varies considerably.

Examples

- Emergency medical service (EMS) providers generally qualify as a covered entity subject to HIPAA's Privacy Rule, but most law enforcement officials and other first responders do not, even if they provide basic medical care, including emergency overdose reversal.
- The Privacy Rule may apply to all or parts of jails and prisons that provide medical treatment, depending on their organizational structure and whether they have designated themselves a hybrid entity, whereas courts and diversion programs generally do not qualify as a covered entity.
- Although prescription drug monitoring programs (PDMPs) do not themselves qualify as a covered entity, the entities that house such programs may be subject to the Privacy Rule. For example, some states house their PDMP within the state health department, which may qualify as a covered entity, while other states locate their PDMP within an agency that generally does not qualify as a covered entity, such as a law enforcement agency or a licensing agency that regulates health professionals.²⁹

What information does HIPAA protect?

Covered entities and business associates may not use or disclose PHI unless the disclosure is explicitly permitted by the Privacy Rule.³⁰ For example, the Privacy Rule authorizes covered entities to use and disclose PHI for treatment, payment, and health care operations.³¹ To qualify as PHI, information must

- 1. Relate to an individual's physical or mental health condition or health care services (including payment); and
- 2. Directly identify the individual or provide sufficient detail such that a reasonable basis exists to believe that someone could use the information to identify the individual.³²

When does HIPAA authorize disclosure of protected information?

The Privacy Rule regulates when a covered entity (and, in some instances, business associates) may use and disclose PHI – and specifies any applicable requirements or limitations. For example, the Privacy Rule authorizes otherwise prohibited disclosures of PHI when a patient *authorizes the disclosure*.³³ Several exceptions permit the use and disclosure of PHI without patient authorization:³⁴

- **Required by law:** When local, state, or federal law requires such use or disclosure and the use or disclosure is limited to the requirements of such law.³⁵
- **Public health activities:** Disclosures to public health authorities authorized by law to receive such information for public health purposes (eg, preventing or controlling disease, injury, or disability). Public health authorities include any local, state, federal, tribal, or territorial government agency that is responsible for public health matters as part of its official mandate. Public health matters as
- Serious health and safety threats: If the covered entity, in good faith, believes that the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health and safety of a person or the public and the disclosure is to a person or persons reasonably able to prevent or lessen the threat.³⁸

Examples

- Arizona state law requires first responders, health professionals, administrators of health care institutions, pharmacists, medical examiners, and correctional facilities to report encounters with an individual with a suspected opioid overdose to the Arizona Department of Health Services.^{39,40} Although many of these mandated reporters qualify as covered entities and the reports include PHI, the disclosures fall within the Privacy Rule's required by law and public health activities exceptions.
- A health care provider who treats a patient for an opioid overdose may disclose the
 patient's misuse of opioids to family, friends, or caregivers if the provider determines
 that the patient's continued misuse of opioids following discharge poses a serious and
 imminent threat to the patient's health.⁴¹

Except when otherwise required by law, covered entities must limit the use and disclosure of PHI to the minimum necessary to achieve the intended purpose.⁴²

Even though the Privacy Rule allows covered entities to share PHI for public health and other purposes, individuals and entities often decide against disclosing personal information due to uncertainty about whether an exception applies.⁴³

Surveillance strategy report — **syndromic reporting** Centers for Disease Control and Prevention cdc.gov/surveillance/initiatives/symptoms-signal.html

The impact of law on syndromic disease surveillance implementation Jonathan Purtle et al. ncbi.nlm.nih.gov/pmc/articles/PMC5534386/

iii. The Privacy Rule defines required by law as "a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law." 45 C.F.R. § 164.103. The Privacy Rule also provides examples of when a disclosure is required by law, including "court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits." 45 C.F.R. § 164.103.

iv. The Privacy Rule exception for public health activities would, for example, generally allow emergency departments to disclose overdose-related syndromic surveillance data to public health authorities authorized by law to receive such information. Additionally, most emergency rooms do not qualify as a Part 2 program. This means that Part 2 generally does not prevent the disclosure of overdose-related emergency department data for syndromic surveillance. For additional information on syndromic surveillance, see the following resources:

Resources on HIPAA and the Privacy Rule

HIPAA guidance materials

US Department of Health and Human Services

hhs.gov/hipaa/for-professionals/privacy/guidance/index.html

HIPAA Privacy Rule

Network for Public Health Law

networkforphl.org/resources/resource-collection-federal-privacy-laws/federal-laws-hipaa-privacy-rule/

42 CFR Part 2

Commonly known as the *federal confidentiality rule*, 42 CFR Part 2 (often referred to as *Part 2* or *42 CFR*) governs the use and disclosure of patient records maintained by federally assisted programs that diagnose, treat, or make treatment referrals for substance use disorder. Originally issued in 1975, Part 2 regulations provide heightened privacy protections for those seeking or receiving assistance with a substance use disorder (SUD) and generally prohibit covered treatment programs from disclosing patient records – or the fact that an individual received SUD treatment – without the patient's consent.

These protections are intended to prevent the use of "[SUD] information against individuals [for example, in criminal, civil, administrative, or legislative proceedings], causing individuals with [SUD] to not seek needed treatment."⁴⁴ Indeed, Part 2 includes a near-categorical prohibition on the use of patient-identifying information in such proceedings. ^{45,46} Absent patient consent, Part 2 also generally prevents patients' non-SUD health care providers from knowing that a patient is receiving or has received SUD treatment. ⁴⁷

Who is covered by Part 2?

Part 2 applies only to federally assisted SUD treatment programs that provide or hold themselves out as providing SUD diagnosis, treatment, or referral for treatment (Part 2 programs).^{48,49} Treatment programs that do not receive federal assistance, thus, are not required to comply with Part 2 unless they operate in a state that requires them to follow Part 2 as a condition of state-based licensing or other state-based regulatory regimes.^{50,51} However, Part 2 broadly defines federal assistance, thereby making the regulations applicable to the majority of SUD treatment programs, including, for example, any program that

- Is operated by a federal agency (except the Department of Veterans Affairs and the Armed Forces);
- Receives federal financial support in any form (eg, tax-exempt status under the federal tax code);
- Is a participating provider in Medicare; or
- Provides maintenance treatment or withdrawal management including the use of methadone or buprenorphine to treat OUD – that requires a license, certification, registration, or other authorization granted by a federal department or agency.⁵²

In some cases, individuals or units operating in a medical facility may constitute a Part 2 program even if the entire medical facility does not.⁵³ For example, most emergency rooms do not qualify as a Part 2 program because they are a general medical facility and do not hold themselves out as providing SUD diagnosis, treatment, or referral for treatment. General medical facilities also do not generally become subject to Part 2 solely because they provide Screening, Brief Intervention, and Referral to Treatment (SBIRT) services related to SUD.⁵⁴ However, within general medical facilities, Part 2 does apply to units that specialize in SUD diagnosis or treatment if the unit receives federal assistance and the unit holds itself out as providing SUD diagnosis, treatment, or referral for treatment.⁵⁵ Within general medical facilities, Part 2 also applies to individual practitioners and staff who receive federal assistance if their primary function is to provide SUD diagnosis, treatment, or referral for treatment (eg, an addiction medicine specialist treating a patient in the emergency room) and they are identified as providing SUD diagnosis, treatment, or referral for treatment.⁵⁶

Part 2 regulations prohibit individuals and organizations from re-disclosing patient-identifying information if they (1) obtained the patient-identifying information from a Part 2 program or an entity lawfully possessing the information; and (2) received a specified notice^v informing them of the prohibition on re-disclosure.^{57,58}

v. The Part 2 regulations require this notice to include at least one of the following written statements:

^{1. &}quot;This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see § 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65; or

^{2. 42} CFR part 2 prohibits unauthorized disclosure of these records."

⁴² C.F.R. §§ 2.32(a)(1)-(2).

What information does Part 2 protect?

Part 2 programs are prohibited from disclosing any information that would directly or indirectly identify a person as having or having had a SUD, including information related to diagnosis, treatment, or referral for treatment for SUD, unless the regulations explicitly authorize such disclosures. ^{59,60} Moreover, with very limited exceptions, Part 2 prohibits the use of any patient-identifying information obtained from a Part 2 program for the purpose of conducting a criminal investigation or initiating or substantiating a criminal charge. ^{61,62,63} When Part 2 authorizes disclosure, the information must be limited to the minimum necessary to accomplish the purpose of the disclosure. ⁶⁴

When does Part 2 authorize disclosure of patient-identifying information?

Unlike HIPAA, which often allows use and disclosure of certain PHI without patient authorization, Part 2 almost always requires patients to consent, in writing, to the disclosure of patient-identifying information – including disclosure of patient-identifying information to third-party payers such as health insurers.⁶⁵ Indeed, the regulations include only limited exceptions authorizing the disclosure of patient-identifying information without patient consent:

- Between or among personnel within a Part 2 program or between a Part 2 program and an entity with direct administrative control over the program to the extent that the personnel or entity has "a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of patients with SUD":66
- Reports of suspected child abuse or neglect;67
- Medical emergencies in which a Part 2 program discloses patient-identifying information "to medical personnel to the extent necessary to meet a bona fide medical emergency in which the patient's prior informed consent cannot be obtained",68
- Conducting scientific research, subject to certain requirements and limitations;⁶⁹
- Certain audits and evaluations of a Part 2 program; 70 and
- Pursuant to a **court order** issued in accordance with Part 2 regulations.⁷¹ Unlike typical court orders, court orders issued pursuant to Part 2 do not *compel* the disclosure or use of patient-identifying information but, rather, only *authorize* such disclosure or use.⁷² Additional requirements and limitations apply based on the intended purpose of the court order (eg, whether the order authorizes disclosure or use of patient-identifying information for non-criminal purposes or whether it authorizes disclosure or use for the purpose of criminally investigating or prosecuting patients).⁷³

Part 2 also authorizes the disclosure and use of patient-identifying information without patient consent to qualified service organizations⁷⁴ when the information is related to crimes on the premises of a Part 2 program or against Part 2 program personnel⁷⁵ and when information is exchanged within a Part 2 program or between a Part 2 program and an entity that has direct administrative control over the Part 2 program.⁷⁶

The regulations include specific requirements on when and how patients must provide consent.⁷⁷ Additionally, whereas HIPAA's Privacy Rule authorizes otherwise prohibited disclosures when required by state or local law, Part 2 prohibits state and local governments from authorizing or compelling the disclosure of any Part 2 patient-identifying information.⁷⁸

${\bf Change Lab \, Solutions}$

Historically, Part 2 required patients to provide consent for each recipient of patient-identifying information. However, 2017 amendments to Part 2 allow patients to provide broader consent for disclosure of patient-identifying information to "treating providers" within entities that coordinate care and to entire entities that provide treatment.⁷⁹ These changes are intended to facilitate coordination between SUD treatment programs and other entities with a treating provider relationship with a patient, including disclosure of patient-identifying information to providers who do not themselves provide SUD treatment (eg, primary care providers and emergency department personnel).⁸⁰

Even after these amendments, however, Part 2's requirements may be burdensome for the transmission of patient information. Nevertheless, Part 2's enhanced privacy protections help ensure that individuals are not dissuaded from obtaining SUD treatment due to negative repercussions that could result from disclosure of their SUD-related medical and treatment information.

Resources on the federal confidentiality rule (42 CFR Part 2)

Substance abuse confidentiality regulations

Substance Abuse and Mental Health Services Administration samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs

Substance use: confidentiality resources

Legal Action Center

lac.org/resources/substance-use-resources/confidentiality-resources/

Overcoming data-sharing challenges in the opioid epidemic

California Health Care Foundation

chcf.org/publication/overcoming-data-sharing-challenges-opioid-epidemic/

Legislative amendments to the federal confidentiality rule

The federal Coronavirus Aid, Relief, and Economic Security Act (CARES Act), signed into law on March 27, 2020, amended the statute governing the federal confidentiality rule.81 The revised statute continues to require a patient in a Part 2 program to provide their initial written consent to the use or disclosure of patient-identifying information held by the Part 2 program. Under the new law, however, once a patient provides their initial written consent, their SUD records may be used, disclosed, or redisclosed for the purposes of treatment, payment, and health care operations in accordance with HIPAA regulations. This consent remains valid unless and until the patient revokes it in writing. As in the previous version of the law, a patient may also include specific limitations on their consent (ie, disallow the use or disclosure of patient-identifying information in specific circumstances detailed in their written consent). Although the CARES Act reduces restrictions on a Part 2 program using or disclosing patient-identifying information for treatment, payment, and health care operations, the act also clarifies and expands protections against the use of such information for other purposes. Specifically, absent patient consent or a court order issued in accordance with the federal confidentiality rule, a Part 2 program record or testimony relaying information contained within a Part 2 program record may not be disclosed or used in any civil, criminal, administrative, or legislative proceeding conducted by any federal, state, or local government. The act includes a specific prohibition on such records or testimony being

- 1. Entered into evidence in any criminal prosecution or civil action before a federal or state court;
- 2. Taken into account in any proceeding before a federal, state, or local agency;
- 3. Used by any federal, state, or local agency for a law enforcement purpose or to conduct any law enforcement investigation; or
- 4. Used in any application for a warrant.

The CARES Act also enacts broad new antidiscrimination protections. More specifically, the act prohibits any entity from discriminating against an individual on the basis of information contained in a Part 2 program record, regardless of whether such information was intentionally or inadvertently disclosed, in

- 1. Admission, access to, or treatment for health care;
- 2. Hiring, firing, terms of employment, or receipt of worker's compensation;
- 3. Sale, rental, or continued rental of housing;
- 4. Access to federal, state, or local courts;
- 5. Access to, approval of, or maintenance of social services and benefits provided or funded by federal, state, or local governments; or
- 6. Access to any services that receive federal funding.

In addition, the CARES Act allows disclosure of information to a public health authority if the information is de-identified in accordance with HIPAA. The US Department of Health and Human Services is required to issue regulations implementing these changes, which must be effective on or before March 27, 2021.

This document provides information about the scope and applicability of Part 2 as the law existed on April 1, 2020. Upon the issuance and effective date of regulations implementing the changes contained in the CARES Act, readers should consult with an attorney licensed to practice in their state to ascertain whether and how the new regulations affect the information in this resource.

Overdose-Related Data Collection and Sharing

The preceding section has provided a general overview of the federal legal landscape for collecting, using, and sharing data for overdose prevention. It explained the purpose, applicability, and operation of HIPAA and Part 2. The following sections provide specific examples of how stakeholders can use data and data sharing to inform and target overdose prevention efforts, as well as how HIPAA and Part 2 apply to various stakeholders and types of overdose-related data.

Law Enforcement and Other First Responders

Data can offer critical insights to inform public health-driven overdose response efforts. 82,83 EMS dispatch data, for instance, have shown promise as an effective public health surveillance resource because they provide a comprehensive, timely, and location-specific accounting of all overdoses to which EMS providers respond. 84,85,86 Many law enforcement departments also collect relevant data such as written reports documenting overdoses to which officers respond, including whether they administered naloxone. 87,88 Information drawn from 911 call data, naloxone administration data, mortality data, or data related to social determinants of health can assist overdose response actions.

Some local governments, often in conjunction with non-governmental organizations, have initiated programs that connect people who experience a non-fatal overdose with peer coaches or other trained individuals shortly after the overdose.^{89,90} These overdose response teams can leverage law enforcement or EMS data to help target overdose prevention programming and interventions such as providing referrals to treatment, naloxone rescue kits, or other supports.⁹¹ Because individuals who experience an overdose are more likely to experience a subsequent overdose, including a fatal overdose, these interventions have the potential to reach some of the highest-risk individuals.⁹² Although overdose response programs vary, they generally begin with law enforcement and other first responders (eg, fire and EMS), who share data (such as names and locations of individuals who have overdosed) with public health officials, other government agencies, and, in some instances, non-governmental outreach groups.⁹³

Law enforcement officials and first responders also increasingly rely on data mapping tools in order to share collective intelligence about the overdose epidemic. For example, the Overdose Detection Mapping Application Program (ODMAP) allows first responders to report fatal and non-fatal overdoses and enables authorized users to access near real-time de-identified surveillance data. ^{94,95} By using these mapping tools to identify hot-spot areas with a high incidence of overdoses, jurisdictions can better focus overdose prevention programming and resources. ⁹⁶

Despite the advantages of using data in overdose prevention efforts, concerns related to patient privacy and the applicability of federal health information privacy laws can affect timely collection, dissemination, and use of the data that are needed to inform rapid response actions. Understanding whether, when, and how HIPAA and Part 2 apply to data can help address these concerns and facilitate deployment of resources, including overdose response teams led by public health professionals.

HIPAA applicability

Whether HIPAA applies to overdose-related data collected by first responders depends on several factors, including the entity that holds the data. For example, law enforcement agencies generally do not qualify as a covered entity.⁹⁷ As a result, HIPAA's Privacy Rule does not restrict the ability of most law enforcement agencies to collect, use, and disseminate identifiable information about people who have overdosed. It is important to note, however, that state and local laws as well as internal department policies may impose more stringent privacy protections that restrict the use and sharing of such data. Although HIPAA may not prohibit law enforcement agencies from using or disclosing identifiable health information, those agencies should nevertheless remain cognizant of potential harms that could result from the misuse of such information (eg, increased stigma and criminalization) and take steps to ensure that such data are used only to reduce drug-related harm.

In contrast, EMS providers generally qualify as covered entities and must comply with HIPAA's Privacy Rule.⁹⁸ Nevertheless, several exceptions to the Privacy Rule enable EMS providers to use and share otherwise protected information, subject to any additional limitations in state or local law. For example, the Privacy Rule authorizes use and disclosure of PHI when state or local law requires such use or disclosure,⁹⁹ and some states have enacted laws requiring EMS providers to report overdose-related data.¹⁰⁰ State laws authorizing EMS providers to report data to public health authorities also allow EMS providers to disclose PHI under the Privacy Rule's exception for public health activities.¹⁰¹

Part 2 applicability

Part 2 generally does not apply to first responders such as law enforcement, EMS, and fire department personnel because they do not hold themselves out as providing SUD diagnosis, treatment, or referral to treatment.¹⁰² First responders such as EMS also do not qualify as general medical facility staff whose primary function is the provision of SUD diagnosis, treatment, or referral for treatment.¹⁰³ Rather, the primary function of EMS personnel is responding to and treating emergent health conditions, some of which involve substance use. Moreover, even if first responders met these criteria, Part 2 is unlikely to apply to most overdose-related information they collect because Part 2 protects only information that identifies an individual as having a SUD or having been referred for SUD treatment, and evidence of an overdose, without more information, is likely insufficient to meet this threshold.¹⁰⁴ Part 2 does, however, regulate when and how law enforcement agencies may obtain and use information held by a Part 2 program.¹⁰⁵

It remains unclear whether Part 2 would apply to specialized EMS programs that both provide SUD-related services and take steps to publicize that they provide such services. For example, in June 2019, the New Jersey Health Commissioner authorized certain statelicensed Mobile Intensive Care Units (MICUs) to administer buprenorphine following administration of naloxone to reverse an overdose. Although no court has addressed whether or how Part 2 applies in this context, this type of specialized program potentially meets the criteria of a Part 2 program. More specifically,

- 1. New Jersey EMS agencies do not specialize in SUD diagnosis, treatment, or referral for treatment and thus likely qualify as a general medical facility;
- 2. Although SUD treatment is not their primary purpose, MICUs may qualify as an identified unit within a general medical facility (ie, the EMS agencies);
- 3. New Jersey widely publicized that certain EMS first responders may offer buprenorphine following an opioid overdose (ie, they "held themselves out" as providing SUD treatment); and
- 4. The provision of buprenorphine constitutes SUD treatment, and information about a person receiving buprenorphine could identify the individual as having an SUD.

If Part 2 applies to New Jersey MICUs that provide buprenorphine following an overdose, the MICU will be required to comply with disclosure limitations, which may substantially limit their ability to share patient-identifying information for overdose prevention interventions.

Example

In 2019, **Washington State** enacted legislation requiring EMS providers to report data on suspected drug overdoses to a statewide electronic EMS data system, with the intent to use these data to identify individuals in order "to engage [SUD] peer professionals, patient navigators, outreach workers, and other professionals as appropriate to prevent further overdoses and to induct into treatment and provide other needed supports as may be available."¹⁰⁷

HIPAA permits the disclosure of these data because state law requires such disclosures. Part 2 does not apply to these disclosures because the EMS providers do not qualify as a Part 2 program, given that they neither hold themselves out as providing SUD diagnosis, treatment, or referral nor are they general medical facility staff whose primary function is SUD diagnosis, treatment, or referral.

Resource on public health data sharing, law enforcement, and first responders

Information sharing in criminal justice-mental health collaborations: working with HIPAA and other privacy laws

Council of State Governments Justice Center bja.gov/Publications/CSG_CJMH_Info_Sharing.pdf

Diversion Programs and Correctional Settings

A public health approach to overdose prevention should prioritize linking individuals who experience a non-fatal overdose or who use drugs and witness an overdose with evidence-based treatment over punitive or coercive responses.¹⁰⁸ Nevertheless, individuals who experience a non-fatal overdose are sometimes arrested and placed in the criminal justice system. It is particularly important to connect justice-involved persons with evidence-based care because a substantial percentage of justice-involved individuals meet the criteria for SUD and are at greater risk of fatal overdose.^{109,110}

Law enforcement agencies, courts, correctional facilities, and related entities seeking to reduce the rate of overdose among individuals in custody, under supervision, awaiting trial, and after release have many opportunities to strengthen access to and use of evidence-based care through coordinated services informed by overdose- and SUD-related data. However, given that these new types of services require increased coordination and collaboration among community partners, SUD treatment programs, and the criminal justice system, clear principles and procedures are necessary to ensure patient privacy, improve health outcomes, and prevent the misuse of SUD-related data.

Diversion programs (eg, drug courts)

Diversion programs such as drug courts have expanded rapidly in the wake of the overdose epidemic, with the intention to channel individuals with SUD into treatment rather than incarceration. Because the successful implementation of these programs often requires SUD treatment providers and the supervising court or diversion program to coordinate and share data about an individual's SUD treatment, these programs must carefully consider when, how, and to what extent patient privacy protections apply to such data and any mandated restrictions, requirements, or procedures.

Substantial gaps exist in the availability of high-quality empirical research on whether diversion programs like drug courts improve health outcomes. 111,112,113,114,115 The more than 4,000 drug courts that currently operate in the United States vary substantially in their implementation of and adherence to evidence-based best practices. 116,117,118 A 2019 SAMHSA report, for example, found that less than "50% of drug court participants with OUD . . . received [medication treatment]" and some [drug courts] require participants to cease using prescribed MOUD such as methadone and buprenorphine. 119 Furthermore, despite their widespread use, programs and policies that rely on coercion to link people to treatment services continue to spur ethical debate. 120,121 Existing research focuses primarily on whether and how diversion programs and drug courts affect costs and recidivism rates rather than assessing health outcomes. 122,123 More comprehensive empirical research is needed to assess whether diversion programs and drug courts have the potential to reduce drug-related morbidity and mortality when implemented in an evidence-based, public health-focused, and non-punitive manner.

HIPAA applicability

Diversion programs, including drug courts, are generally not covered entities subject to the Privacy Rule because they generally do not electronically transmit PHI in covered transactions (eg, to secure treatment authorization or receive payment from a health plan). The Privacy Rule does, however, restrict when and how covered entities may disclose PHI about an individual participating in a diversion program (eg, when a health care provider may share information about a participant's adherence to a treatment plan with a court).

Two exceptions to the Privacy Rule can facilitate information sharing between covered entities and diversion programs:

- Covered entities may disclose PHI to a diversion program when state law requires such disclosures. Also, covered entities may disclose PHI in response to an order issued by a court or administrative tribunal such as a drug court.¹²⁴
- 2. More commonly, however, covered entities may share PHI with a diversion program based on participants' explicit consent to such disclosures, and most drug courts and diversion programs condition participation on an individual's providing such consent.

Part 2 applicability

In general, courts and diversion programs do not qualify as Part 2 programs. However, conflicting interpretations suggest that Part 2 regulations may apply to specialized diversion programs and drug courts that engage in SUD screening and treatment referral, 125,126 and some state and local drug courts have opted to comply with Part 2 even if they do not qualify as a Part 2 program under federal law. 127,128,129,130 Regardless of whether a diversion program or drug court itself qualifies as a Part 2 program, many participants in these programs receive treatment from Part 2 programs that are subject to restrictions on the use and disclosure of patient-identifying information.

Part 2 programs may disclose otherwise protected patient-identifying information to individuals within the criminal justice system when patients' participation in the Part 2 program is a condition of their eligibility for the diversion program and the patient provides written consent authorizing such disclosures.¹³¹ Individuals within the criminal justice system who receive patient-identifying information from a Part 2 program may use and disclose the information only to carry out their official duties with respect to the patients' participation in the diversion program or other actions to which the patient has consented.¹³² Additionally, although Part 2 regulations generally allow a patient to revoke their consent to disclose patient-identifying information at any time, the provisions specific to the criminal justice system allow for revocation of consent only after a specific amount of time or event (eg, completion of the diversion program) has occurred.¹³³

Examples

- Michigan has provided grant funding for drug courts to ensure that participants with OUD receive medications to treat their OUD.¹³⁴ The Michigan court system also provides guidance to drug courts that emphasizes the importance of coordination with treatment providers and public health agencies, as well as the confidentiality and consent requirements that come along with transmitting data protected by Part 2.¹³⁵
- Colorado's Fourth Judicial District also provides guidance for administration of medications for OUD in collaboration with outpatient treatment providers, as part of its Family Treatment Drug Court model.¹³⁶ The same guidance suggests that "updated releases of information must be completed as needed," to maintain "regular and routine communication" between the drug court and treatment providers.¹³⁷
- **Buffalo, New York's** Opioid Intervention Court (OIC) presents a model that connects people who have been arrested with SUD treatment within 24 hours of arrest and then suspends prosecution for at least 30 days while the individual undergoes treatment (including medication treatment). Ongoing case management and other coordination of care, which involve communication of data between multiple entities, occur during the period immediately following arrest. Several other jurisdictions within the state are now adopting the OIC model. Several other jurisdictions within the state are

Correctional institutions (eg, jails and prisons)

Given the limited availability of diversion programs and the barriers to participation, many justice-involved individuals with SUD do not have a meaningful opportunity to participate in diversion programs. Instead, most justice-involved individuals with SUD are incarcerated in more traditional correctional institutions such as jails and prisons. Justice-involved individuals face a substantially higher risk of overdose than the general population, particularly during the period immediately following their release from a correctional setting.^{141,142,143} Providing evidence-based treatment to individuals while they are in custody and coordinating treatment and other services (eg, Medicaid enrollment) upon their release can substantially reduce such risk.¹⁴⁴

Professional organizations such as the American Society of Addiction Medicine (ASAM) and the American Correctional Association (ACA) support SUD screening and treatment for justice-involved individuals, including collaborative relationships between treatment programs and community supervision teams.¹⁴⁵ ASAM and ACA also recommend that individuals be linked to an appropriate treatment provider at least 1 month in advance of release from a correctional setting.¹⁴⁶ However, providing SUD treatment to justice-involved individuals in custody and linking them to treatment and other services upon their release involves the collection, use, and sharing of protected information, thereby requiring consideration of HIPAA and 42 CFR Part 2.

HIPAA applicability

Correctional institutions such as jails and prisons may qualify as covered (or hybrid) entities subject to the Privacy Rule if they engage in a covered function (eg, provide or pay for health care) and electronically transmit PHI in a covered transaction (eg, to secure treatment authorization or receive payment from a health plan). A correctional institution will also qualify as a covered entity if it contracts with a health care provider who electronically transmits PHI. Additionally, health care providers that treat individuals within a correctional institution qualify as a covered entity even if the correctional institution itself does not.

Even if a correctional institution qualifies as a covered entity, the Privacy Rule generally will not prevent the institution from obtaining, using, or disclosing PHI for treatment and other purposes that further public health objectives. For example, a correctional institution that qualifies as a covered entity may still use and disclose PHI in accordance with Privacy Rule exceptions such as disclosures required by law,¹⁴⁷ to public health authorities,¹⁴⁸ or for certain law enforcement purposes.¹⁴⁹ Additionally, provisions within the Privacy Rule specific to criminal justice settings authorize covered entities to share PHI with correctional institutions or law enforcement officials when

- 1. The PHI concerns an individual under the lawful custody of the correctional institution or law enforcement official; and
- 2. The correctional institution or law enforcement official represents that the PHI is necessary for 150
 - a. Providing health care to an inmate or other individual under the lawful custody of a correctional institution or law enforcement official;
 - b. Protecting the health and safety of inmates and other individuals under the lawful custody of a correctional institution or law enforcement official;
 - c. Protecting the health and safety of others (eg, officers and employees) at the correctional institution;
 - d. Protecting the health and safety of persons responsible for transporting inmates or transferring an inmate from one institution, facility, or setting to another;
 - e. Law enforcement on the premises of the correctional institution; or
 - f. Administration and maintenance of the safety, security, and good order of the correctional institution.

Importantly, however, this exception applies only to individuals currently in the lawful custody of a correctional institution or law enforcement official. The exception ceases to apply immediately upon an individual's release from custody, including when an individual is released on parole, probation, or supervised release, ¹⁵¹ and a covered entity may not disclose PHI about a justice-involved individual following their release unless the Privacy Rule otherwise authorizes the disclosure. As a result, correctional institutions that wish to share PHI to link individuals with treatment programs following their release must either obtain the individual's consent or ensure that one or more Privacy Rule exceptions apply to the disclosure.

Part 2 applicability

Unlike HIPAA, Part 2 does not include provisions specific to correctional settings such as prisons and jails. Therefore, Part 2 programs operating within correctional settings must comply with the regulation's general requirements and limitations on the use and disclosure of patient-identifying information, including patient consent requirements.¹⁵²

Example: A person is set to be released from state prison, and the person received SUD treatment from a federally assisted SUD program during their incarceration. To ensure that the person continues to receive care following their release, the SUD program seeks to link the individual to a SUD treatment program outside the prison. To do so, the program must obtain the person's consent, in the manner specified by Part 2, prior to disclosing any patient-identifying information about them to the outside SUD treatment program.

Example

Pima County, Arizona, uses multiple health information exchange systems to ensure that correctional institutions can access an individual's medical records upon their incarceration as well as that community-based providers can access correctional health records upon the individual's release. The exchanges include both general and mental health treatment records, to help ensure continuity of care as individuals transition to and from justice-involved settings. 153,154

Resources on data sharing in criminal justice settings

Information sharing in criminal justice-mental health collaborations: working with HIPAA and other privacy laws

Council of State Governments Justice Center bja.gov/Publications/CSG_CJMH_Info_Sharing.pdf

Corrections and reentry: protected health information privacy framework for information sharing

National Institute of Corrections

 $\underline{nicic.gov/corrections-and-reentry-protected-health-information-privacy-framework-information-sharing}$

Prescription Drug Monitoring Programs (PDMPs)

Forty-nine states, the District of Columbia, Guam, Puerto Rico, and some counties in Missouri have implemented PDMPs – electronic databases that track the dispensing of many controlled substance prescriptions.^{155,156,157} The specific controlled substances tracked by PDMPs vary among jurisdictions, and some PDMPs also track non-controlled substances such as naloxone and other information such as ICD-10 diagnosis codes.^{158,159} Given the quantity and timeliness of information gathered by PDMPs across the country, these databases can help to "facilitate a nimble and targeted response" to the overdose epidemic.¹⁶⁰ If designed and operated with public health goals in mind, PDMPs have the potential to provide clinicians and health authorities with timely information about prescribing and patient behaviors that contribute to the epidemic, as well as provide public health advocates with an opportunity to identify and proactively offer support to individuals who might benefit from targeted risk reduction initiatives.

CDC has identified PDMPs as "among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk." Although research on the overall efficacy of PDMPs is mixed, "evaluations of PDMPs have illustrated changes in prescribing behaviors, use of multiple providers by patients, and decreased substance [use] treatment admissions." CDC has also encouraged states to adopt several features that show promise in improving the use of PDMPs for public health surveillance and response, including real-time data collection, universal access and use, integration of PDMP data with other health systems data such as electronic health records and health information exchanges, and linkage of PDMP data to other data systems within a jurisdiction. 162,163

Importantly, evidence suggests that simply increasing access to PDMP data is insufficient to reduce opioid and other drug-related harm. Maximizing the efficacy of PDMPs for public health purposes requires that such access be accompanied by education about appropriate responses to individuals identified as potentially having a SUD and by increased availability of appropriate evidence-based treatment. Education and linkages to care are particularly important in order to address patient privacy concerns and potential unintended consequences associated with the implementation and use of PDMPs, such as individuals moving into the illicit opioid market.^{164,165}

HIPAA applicability

HIPAA does not impede the sharing of PDMP data for public health purposes because PDMPs generally do not qualify as a covered entity within the meaning of the Privacy Rule. How Moreover, even if PDMPs qualified as a covered entity, disclosure of PDMP data likely falls within one or more exceptions to the Privacy Rule. For example, because many state laws require various entities to provide data to the PDMP, such disclosures would fall within the Privacy Rule's exemption for disclosures required by law. Similarly, the sharing of PDMP data with public health officials is likely to fall within the Privacy Rule exception for disclosures to an authorized public health authority. Although HIPAA does not prevent the disclosure of PDMP data for public health purposes, state laws often impose additional restrictions on PDMP data, including limitations on whether, when, and how public health officials can access the data. How we have the data and the purpose of PDMP data and the purpose of PDMP data and how public health officials can access the data.

Part 2 applicability

Similar to HIPAA, Part 2 does not impede the use and disclosure of PDMP data for public health purposes. PDMPs do not qualify as Part 2 programs because they neither purport to provide referrals for SUD treatment nor possess the technical capability to make diagnoses of or provide treatment for SUD. However, some entities that receive and use PDMP data (eg, health departments and health professionals) may qualify as a Part 2 program and therefore must comply with Part 2's heightened privacy protections when they use or further disclose PDMP data that identify a patient as having or having had a SUD. Part 2 also limits the collection of some data by PDMPs. Current SAMHSA guidance explains that "OTPs [opioid treatment programs] and [physicians authorized to prescribe buprenorphine for OUD treatment] should not disclose patient-identifying information to PDMPs" because, even though patient-identifying information may be disclosed with written consent, redisclosure of such information remains prohibited and one of the purposes of PDMPs is to further disclose patient information.¹⁶⁸

Examples

Several federally funded initiatives have sought to improve access to PDMP data, including pilot programs in 6 states.¹⁶⁹ These efforts focused on streamlining user workflows to make it easier to access PDMP data and incorporate those data into the clinical decisionmaking process.¹⁷⁰ Because many providers do not check the PDMP unless required to do so, efforts to streamline clinician access to PDMP data and, in some cases, mandating that they check the PDMP may improve prescribing decisions.¹⁷¹

Evidence also suggests that efforts to streamline and mandate provider access to PDMP data are associated with reductions in potentially harmful prescribing practices. State health officials in **Pennsylvania**, for example, report that the state's PDMP curbed both the number of multiple-provider episodes and the number of high-dose opioid prescriptions.¹⁷²

Resources on PDMPs

What states need to know about PDMPs

Centers for Disease Control and Prevention cdc.gov/drugoverdose/pdmp/states.html

What healthcare providers need to know about PDMPs

Centers for Disease Control and Prevention cdc.gov/drugoverdose/pdmp/providers.html

Prescription drug monitoring program legal datasets

Prescription Drug Abuse Policy System (PDAPS) pdaps.org/

Prescription drug monitoring programs

National Alliance for Model State Drug Laws namsdl.org/topics/pdmp/

Prescription Drug Monitoring Program Training and Technical Assistance Center

Institute for Intergovernmental Research

pdmpassist.org/

Additional Opportunities

Mapping tools

The section on law enforcement and other first responders highlighted how they use mapping tools such as ODMAP to identify and track overdose events and responses. Governmental and non-governmental actors have developed several mapping tools to better understand trends in opioid prescribing and increase community awareness of the overdose epidemic and available resources. For example, the Centers for Medicare & Medicaid Services (CMS) developed the Medicaid Opioid Prescribing Mapping Tool, which presents geographic information about opioid prescribing rates at the state level, 173,174 and the Medicare Part D Opioid Prescribing Mapping Tool, which provides similar data at both state and local levels. 175

Other user-friendly data mapping tools include maps that identify naloxone access locations, drop-off boxes for unused or expired medications, and treatment centers, as well as "story maps" for public education campaigns. (Story maps are interactive resources that combine textual and visual elements such as maps to contextualize information and provide a narrative.)¹⁷⁶ Some jurisdictions, such as the Tri-County Health Department in Colorado, use mapping tools to overlay opioid-related data with other health information such as reported mental health distress and suicide rates, allowing officials to identify broader trends and engage in a more holistic approach to community health improvement.¹⁷⁷ Additionally, the Opioid Mapping Initiative has sought to create a community of practice for local governments in order to leverage data and mapping tools to address the overdose epidemic.¹⁷⁸

These mapping tools generally do not implicate HIPAA or Part 2 because they use deidentified or otherwise unprotected data.

Resources on mapping tools related to overdose prevention

Overdose Detection Mapping Application Program (ODMAP)

odmap.org

Opioid Mapping Initiative

opioidmappinginitiative-opioidepidemic.opendata.arcgis.com

Social determinants of health (SDOH)

Existing efforts to leverage data and data sharing for overdose prevention have focused primarily on the more acute drivers and consequences of substance misuse. These acute drivers and consequences include opioid prescriptions, naloxone administration, emergency room admissions, and overdose-related morbidity and mortality, as well as linking individuals to downstream resources such as SUD treatment. Such efforts remain critical to reducing opioid- and other drug-related harm. However, data and data sharing can also be used to understand and inform efforts to address the many underlying social and environmental determinants of substance misuse and addiction. These determinants include lack of safe, stable housing; childhood trauma; economic inequality; structural discrimination and racism; toxic stress; social isolation; and lack of access to quality education.^{179,180} Social and environmental factors can also present substantial barriers to access to, retention in, and efficacy of evidence-based SUD treatment.¹⁸¹

For example, research shows that individuals experiencing housing instability or homelessness have a significantly greater overdose risk and lower enrollment and retention in treatment programs. ¹⁸² Likewise, lack of reliable transportation is a well-established barrier to health care access, which would include access to treatment for SUD. ¹⁸³ Individuals receiving medication treatment for OUD report substantial travel times and costs, as well as employment challenges resulting from such travel. ¹⁸⁴

Data and data sharing can provide state and local governments with insight into these social determinant-based risk factors and barriers to treatment, as well as allow governments to use such data to more effectively direct resources, target interventions, and inform policy change.

HIPAA applicability

Most SDOH-related data sources do not contain personally identifiable health information protected by HIPAA's Privacy Rule, nor do most entities that collect and disseminate such data qualify as a covered entity, because they generally are not a health plan, health care clearinghouse, or health care provider.¹⁸⁵ The Privacy Rule generally does not, for instance, apply to governmental and non-governmental social service entities such as housing authorities, transportation departments, public benefit offices, and community-based organizations that do not provide and electronically bill insurers for direct medical services.

Nevertheless, HIPAA remains an important consideration in leveraging SDOH-related data for overdose prevention because such efforts will often require linking these data with PHI held by a covered entity, and the Privacy Rule will apply to a covered entity's subsequent use or disclosure of the linked data. Covered entities may also use SDOH-related data for treatment purposes, thereby implicating the Privacy Rule.

Jurisdictions have several opportunities to use SDOH-related data for overdose prevention while remaining in compliance with the Privacy Rule. For example, state and local governments can authorize an entity that is already subject to the Privacy Rule and that has an existing infrastructure for handling PHI (eg, a health department) to coordinate data collection, aggregation, linking, and analysis. Such an entity would be well positioned to address the various legal and privacy considerations as well as to operationalize the data for public health-oriented overdose prevention efforts. By designating a public health agency as the lead entity, state law can authorize or require covered entities to disclose otherwise protected information under the Privacy Rule's public health or required by law exceptions. Jurisdictions can also use de-identified data to identify SDOH-related trends, common risk factors, and barriers to overdose prevention and treatment.

Part 2 applicability

Entities that collect and disseminate SDOH-related data generally do not qualify as Part 2 programs. Part 2 programs may not, however, disclose patient-identifying information for the purpose of linking such information with SDOH-related data absent patient consent for each disclosure. As a result, jurisdictions thus far have not attempted to integrate Part 2 records into their data collection efforts.¹⁸⁹

Examples

- Allegheny County, Pennsylvania, operates a data warehouse that aggregates individual-level demographic and human services utilization data, including data related to substance use, mental health, child welfare, housing, schools, criminal justice involvement, and public benefits. Per Researchers used these data to identify demographic and service utilization trends as well as overdose-related risk factors, including recent interaction with the criminal justice system and SUD treatment programs.
- The **National Opioid Misuse Community Assessment Tool** overlays county-level overdose mortality data with demographic and social determinant data, including race and ethnicity, age, educational attainment, disability status, median household income, poverty rate, unemployment rate, and accident-prone employment rates.¹⁹²
- In 2015, **Massachusetts** enacted legislation that required the state's Department of Health to collect, analyze, and publish overdose-related data based on 10 datasets from 5 state agencies. A report from the Association of State and Tribal Health Officers (ASTHO) indicates that Massachusetts is beginning to look at data from mental health, the [Supplemental Nutrition Assistance Program (SNAP, formerly known as *food stamps*)], and other sectors to build predictive models that can address the social determinants of health or indicate risk for addiction. 194
- The **Maryland** Department of Health uses Local Overdose Fatality Review Teams to provide "a detailed understanding of the circumstances surrounding a[n] [overdose] death and the ways in which it could have been prevented."¹⁹⁵ The reviews include SDOH-related data such as involvement in the criminal justice system, use of social services and public assistance programs, housing status, history of domestic violence, and mental health history.¹⁹⁶
- Although not specific to overdose or drug-related harm, the California Healthy Places Index illustrates the use of SDOH data to identify health-related trends. The index linked health outcome data with data related to economics, education, health care access, neighborhood conditions, pollution/clean environment, social connection, transportation, and racial residential integration, among other factors. The initiative also developed interactive online tools to allow public access to the data; related policy briefs; and communication recommendations for advocates and community-based organizations seeking to leverage the data to inform policy change.¹⁹⁷
- The 2018 SUPPORT for Patients and Communities Act authorizes the Centers for Disease Control and Prevention to collect and report data on adverse childhood experiences (a known risk factor for developing SUD) and appropriates funds to support such efforts.¹⁹⁸

Information about how social determinants of health affect overdose

Opioid crisis: no easy fix to its social and economic determinants

Nabarun Dasgupta, Leo Beletsky, Daniel Ciccarone ajph.aphapublications.org/doi/10.2105/AJPH.2017.304187

Conclusion

As the scope and direction of the overdose epidemic continues to evolve, ensuring that public health officials have access to complete, accurate, and timely data remains critical to the identification, implementation, and targeting of effective evidence-based interventions. Stakeholders such as public safety officials, health care providers, and social service agencies often collect and maintain substantial quantities of overdose-related data. Federal and state privacy laws, including HIPAA and Part 2, impose requirements and limitations on the disclosure of certain health information. (See Appendix B for a summary of how HIPAA and Part 2 apply in the situations detailed in this document.) Nevertheless, government agencies and other entities have ample opportunities to share data with the public health officials best positioned to use those data to prevent overdose and reduce drug-related harm. (See Appendix C for a list of resources on data sharing to reduce drug-related harm.)

By working together, stakeholders can ensure that overdose-related data are collected, shared, and used in a manner that preserves patient privacy and protects patients from exposure to additional risk factors while improving public health and helping to stem the tide of overdose and other drug-related harm.

Appendix A: Key Terminology and Abbreviations

Business associates are entities that engage in certain functions on behalf of a covered entity (eg, claims processing and billing) that involve creation, receipt, maintenance, transmission, or disclosure of protected health information.

CDC refers to the Centers for Disease Control and Prevention, a component of the US Department of Health and Human Services.

Correctional institution, for the purposes of the Privacy Rule, is defined as "any penal or correctional facility, jail, reformatory, detention center, work farm, halfway house, or residential community program center operated by, or under contract to, the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other persons held in lawful custody. Other persons held in lawful custody includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses, or others awaiting charges or trial." ¹⁹⁹

Covered entity is an individual or organization subject to the Privacy Rule. Covered entities include health plans, health care clearinghouses, and health care providers who transmit health information in electronic form.

HIPAA, the Health Insurance Portability and Accountability Act of 1996, is a federal law that requires the US Department of Health and Human Services to establish regulations about health information privacy.

Hybrid entity is a covered entity that engages in both conduct subject to the Privacy Rule and conduct not subject to the Privacy Rule and that designates itself a hybrid entity in accordance with federal law.

Medications for opioid use disorder (MOUD) are FDAapproved medications used to treat individuals with OUD, including methadone, buprenorphine, and naltrexone.

ODMAP refers to the Overdose Detection Mapping Application Program, which "provides real-time overdose surveillance data across jurisdictions to support public safety and health efforts to mobilize an immediate response to an overdose spike."²⁰⁰

Opioids are substances that "reduce the intensity of pain signals and feelings of pain" by acting on a person's opioid mu receptors. Opioids include legal prescription medications

such as oxycodone and morphine as well as illegal drugs such as heroin and illicitly manufactured fentanyl.²⁰¹

Opioid treatment programs (OTPs) are federally registered programs that use medications such as methadone and buprenorphine to treat OUD.

Opioid use disorder (OUD), as defined by the *Diagnostic* and *Statistical Manual of Mental Disorders,* 5th edition, is "a problematic pattern of opioid use leading to clinically significant impairment or distress, manifested by at least two defined criteria occurring within a year."²⁰²

Part 2 refers to federal regulation 42 CFR Part 2, which restricts the disclosure and use of certain health information created or maintained by federally assisted providers of treatment for substance use disorder.

Prescription drug monitoring programs (PDMPs) are statelevel electronic databases that track the dispensing of many controlled substances.

Privacy Rule refers to the federal regulation ("Standards for Privacy of Individually Identifiable Health Information") that implements HIPAA requirements for health data privacy. The Privacy Rule regulates how covered entities and business associates may use and disclose individually identifiable health information.

Protected health information (PHI) is individually identifiable health information that meets specified criteria and is transmitted or maintained in any form or medium.

SAMHSA refers to the federal Substance Abuse and Mental Health Services Administration.

Social determinants of health (SDOH), as defined by CDC, are "conditions in the places where people live, learn, work, and play [that] affect a wide range of health risks and outcomes."²⁰³ SDOH include housing, education, environmental quality, employment opportunities and financial security, discrimination, transportation, and access to healthy food, among other factors.

Substance use disorder (SUD), as defined by the Substance Abuse and Mental Health Services Administration (SAMHSA), is "recurrent use of alcohol and/or drugs [that] causes clinically significant impairment, including health problems, disability, and failure to meet major responsibilities at work, school, or home."²⁰⁴

42 CFR Part 2 Terminology

Disclosure means "to communicate any information identifying a patient as being or having been diagnosed with a substance use disorder, having or having had a substance use disorder, or being or having been referred for treatment of a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person."²⁰⁵

Federally assisted, in the context of Part 2, means a program that is

- Conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (except the Department of Veteran Affairs or the Armed Forces);²⁰⁶
- Carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States, including but not limited to a participating provider in the Medicare program, authorization to conduct maintenance treatment or withdrawal management, or registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of SUD;²⁰⁷
- Supported by funds provided by any department or agency of the United States by being either (1) a recipient of federal financial assistance in any form, including financial assistance that does not directly pay for the SUD diagnosis, treatment, or referral for treatment; or (2) conducted by a state or local government unit that, through general or special revenue sharing or other forms of assistance, receives federal funds that could be (but are not necessarily) spent for a SUD treatment program;²⁰⁸ or
- Assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deduction for contributions to the program or through the granting of tax-exempt status to the program.²⁰⁹

General medical facility: Federal law does not define *general medical facility,* but SAMHSA guidance indicates that it includes hospitals, trauma centers, federally qualified health centers, practices comprised of primary care providers, and similar institutions.

Holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment:

Part 2 does not define the phrase holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment, but SAMHSA guidance includes a non-exhaustive list of conduct that may qualify: "state licensing procedures, advertising or the posting of notices in the offices, certifications in addiction medicine, listings in registries, internet statements, consultation activities for non-'program' practitioners, information presented to patients or their families, or any other activity that would lead one to reasonably conclude that the provider is providing or provides alcohol or drug [misuse] diagnosis, treatment, or referral for treatment."²¹⁰

Part 2 program means an individual or entity that is federally assisted and meets any of the following criteria:

- A provider or entity, other than a general medical facility, that holds itself out as providing and provides SUD diagnosis, treatment, or referral for treatment;
- An identified unit within a general medical facility that holds itself out as providing and provides SUD diagnosis, treatment, or referral for treatment; or
- A provider or other staff in a general medical facility whose primary function is providing SUD diagnosis, treatment, or referral for treatment and is identified as providing such services.

Patient-identifying information means "the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a [Part 2 program] patient . . . can be determined with reasonable accuracy either directly or by reference to other information."²¹¹

Records means "any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient (e.g., diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts)." Records include both paper and electronic records.²¹²

Treating provider relationship means that "(1) A patient is, agrees to, or is legally required to be diagnosed, evaluated, and/or treated, or agrees to accept consultation, for any condition by an individual or entity, and; (2) The individual or entity undertakes or agrees to undertake diagnosis, evaluation, and/or treatment of the patient, or consultation with the patient, for any condition." A treating provider relationship may exist regardless of whether the patient and provider have had an in-person encounter.²¹³

Appendix B:

Applicability of HIPAA and Part 2 in Various Data-Sharing Situations

	HIPAA Privacy Rule	Part 2
Law Enforcement	Generally Inapplicable Law enforcement agencies generally do not qualify as a covered entity subject to HIPAA's Privacy Rule. The Privacy Rule does not restrict the ability of law enforcement to collect, use, and disseminate individually identifiable health information, including information related to overdose.	Generally Inapplicable Part 2 does not apply to law enforcement agencies directly. Part 2 does regulate when and how law enforcement agencies may obtain and use information held by a Part 2 program.
EMS	Generally Applicable EMS providers generally qualify as a covered entity and must comply with HIPAA's Privacy Rule. EMS providers may not disclose protected health information unless they receive patient consent or a Privacy Rule exception applies.	Generally Inapplicable Part 2 generally does not apply to EMS providers. It remains unclear whether Part 2 would apply to specialized EMS programs that both provide SUD-related services and publicize that they provide such services.
Diversion Programs (eg, Drug Courts)	 Generally Inapplicable Diversion programs generally do not qualify as a covered entity. The Privacy Rule restricts when and how covered entities may share protected health information with diversion programs. Exceptions to the Privacy Rule can facilitate information sharing between covered entities and diversion programs. 	 Generally Inapplicable Part 2 generally does not apply to diversion programs, but conflicting interpretations exist. Many participants in diversion programs receive treatment from Part 2 programs. Patient consent is required for a Part 2 program to disclose patient-identifying information to a diversion program, but many diversion programs condition participation on individuals' providing such consent.
Correctional Institutions	Potentially Applicable Correctional institutions may qualify as a covered or hybrid entity subject to the Privacy Rule. The Privacy Rule contains specific regulations about when a covered entity may share with a correctional institution certain protected health information about an individual who is in the custody of that correctional institution.	Potentially Applicable Part 2 does not include provisions specific to correctional institutions. Part 2 applies to a Part 2 program that operates within a correctional institution.
PDMPs	Generally Inapplicable PDMPs generally do not qualify as a covered entity subject to the Privacy Rule.	Generally Inapplicable PDMPs do not qualify as a Part 2 program. If an entity receiving or using PDMP data is a Part 2 program, they must comply with Part 2 when using or further disclosing patient-identifying information obtained from the PDMP. A Part 2 program may not disclose patient-identifying information to a PDMP.
Mapping Tools	Generally Inapplicable • Mapping tools generally use de-identified or otherwise unprotected data that are not subject to the Privacy Rule.	Generally Inapplicable Mapping tools generally use de-identified or otherwise unprotected data that are not subject to Part 2.
Social Determinants of Health (SDOH)	 Applicability Varies The Privacy Rule does not protect most SDOH-related data, and most entities that collect and disseminate such data do not qualify as a covered entity. The Privacy Rule may apply when Linking SDOH-related data with protected health information held by a covered entity; A covered entity uses or discloses linked data; or A covered entity uses SDOH-related data for treatment purposes. 	Generally Inapplicable Entities that collect and disseminate SDOH-related data generally do not qualify as a Part 2 program. Part 2 programs may not disclose patient-identifying information for the purpose of linking such information with SDOH-related data unless the patient has consented.

Appendix C: Resources on Data Sharing to Prevent Overdose and Reduce Drug-Related Harm

Opioid overdose Centers for Disease Control and Prevention cdc.gov/drugoverdose/index.html

Understanding the epidemic Centers for Disease Control and Prevention cdc.gov/drugoverdose/epidemic/index.html

The triple wave epidemic: supply and demand drivers of the US opioid overdose crisis

Daniel Ciccarone

sciencedirect.com/science/article/pii/S0955395919300180

Data Across Sectors for Health dashconnect.org

Health information and data sharing Network for Public Health Law <u>networkforphl.org/resources/topics/health-information-and-data-sharing/</u>

All In: Data for Community Health <u>allindata.org</u>

Strengths and weaknesses of existing data sources to support research to address the opioids crisis Rosanna Smart et al.

doi.org/10.1016/j.pmedr.2019.101015

Stigma as a fundamental hindrance to the United States opioid overdose crisis response
Alexander C. Tsai et al.

doi.org/10.1371/journal.pmed.1002969

Changing the Narrative Health in Justice Action Lab ChangingTheNarrative.news

HIPAA guidance materials
US Department of Health and Human Services
https://hipaa/for-professionals/privacy/guidance/index.html

HIPAA Privacy Rule
Network for Public Health Law
networkforphl.org/resources/resource-collection-federal-privacylaws/federal-laws-hipaa-privacy-rule/

Substance abuse confidentiality regulations
Substance Abuse and Mental Health Services Administration
samhsa.gov/about-us/who-we-are/laws-regulations/confidentialityregulations-fags

Substance use: confidentiality resources Legal Action Center lac.org/resources/substance-use-resources/confidentiality-resources/

Overcoming data-sharing challenges in the opioid epidemic
California Health Care Foundation

 $\frac{chcf.org/publication/overcoming-data-sharing-challenges-opioid-epidemic/$

Information sharing in criminal justice-mental health collaborations: working with HIPAA and other privacy laws Council of State Governments Justice Center bia.gov/Publications/CSG_CIMH_Info_Sharing.pdf

Corrections and reentry: protected health information privacy framework for information sharing National Institute of Corrections

<u>nicic.gov/corrections-and-reentry-protected-health-information-privacy-framework-information-sharing</u>

What states need to know about PDMPs Centers for Disease Control and Prevention cdc.gov/drugoverdose/pdmp/states.html

What healthcare providers need to know about PDMPs Centers for Disease Control and Prevention cdc.gov/drugoverdose/pdmp/providers.html

Prescription drug monitoring program legal datasets Prescription Drug Abuse Policy System (PDAPS) pdaps.org/

Prescription drug monitoring programs National Alliance for Model State Drug Laws namsdl.org/topics/pdmp/

Prescription Drug Monitoring Program Training and Technical Assistance Center Institute for Intergovernmental Research pdmpassist.org/

Overdose Detection Mapping Application Program (ODMAP)

odmap.org

Opioid Mapping Initiative
opioidmappinginitiative-opioidepidemic.opendata.arcgis.com

Opioid crisis: no easy fix to its social and economic determinants

Nabarun Dasgupta, Leo Beletsky, Daniel Ciccarone ajph.aphapublications.org/doi/10.2105/AJPH.2017.304187

Notes

- 2015 Mass. Acts ch. 55. <u>malegislature.gov/Laws/SessionLaws/Acts/2015/Chapter55</u>.
- Data Brief An Assessment of Opioid-Related Overdoses in Massachusetts 2011-2015. Boston: Massachusetts Department of Public Health; 2017. mass.gov/files/documents/2017/08/31/data-brief-chapter-55-aug-2017.pdf. Accessed July 19, 2019.
- See Bharel M. Massachusetts Responds to the Opioid Epidemic: Using Data to Inform Policy and Programs. Boston: Massachusetts Department of Public Health; 2018. <u>bu.edu/ctsi/files/2018/03/BUSM-CTSI-5_18-Bharel-for-Website.pdf</u>. Accessed March 6, 2020.
- Barocas JA, Wang J, Marshall BD, et al. Sociodemographic factors and social determinants associated with toxicology confirmed polysubstance opioid-related deaths. *Drug Alcohol Depend*. 2019;200:59-63. doi:10.1016/j.drugalcdep.2019.03.014.
- Wilson N, Kariisa M, Seth P, Smith H IV, Davis NL. Drug and opioidinvolved overdose deaths — United States, 2017–2018. Morb Mortal Wkly Rep. 2020;69(11):290–297. doi:10.15585/mmwr.mm6911a4.
- Opioid overdose: opioid basics commonly used terms. Centers for Disease Control and Prevention website: <u>cdc.gov/drugoverdose/opioids/terms.html</u>. Reviewed February 12, 2019. Accessed July 19, 2019.
- Davis CS, Anderson ED. Breaking the cycle of preventable suffering: fulfilling the principle of balance. *Temple Int Comp Law* J. 2010;24(2):329-364. papers.ssrn.com/sol3/papers.cfm?abstract id=2011197.
- Opioid overdose: data other drugs. Centers for Disease Control and Prevention website: <u>cdc.gov/drugoverdose/data/otherdrugs.html</u>. Reviewed August 12, 2019. Accessed January 20, 2020.
- 9. Cicero TJ, Ellis MS, Kasper ZA. Polysubstance use: a broader understanding of substance use during the opioid crisis. *Am J Public Health*. 2020;110(2):244-250. doi:10.2105/ajph.2019.305412.
- Barocas JA, Wang J, Marshall BD, et al. Sociodemographic factors and social determinants associated with toxicology confirmed polysubstance opioid-related deaths. *Drug Alcohol Depend*. 2019;200:59-63. doi:10.1016/j.drugalcdep.2019.03.014.
- Saloner B, McGinty EE, Beletsky L, et al. A public health strategy for the opioid crisis. *Public Health Rep.* 2018;133(1_suppl):24S-34S. doi:10.1177/0033354918793627.
- 12. Cicero TJ, Ellis MS, Kasper ZA. Polysubstance use: a broader understanding of substance use during the opioid crisis. *Am J Public Health*. 2020;110(2):244-250. doi:10.2105/ajph.2019.305412.
- Opioid overdoses treated in emergency departments. Centers for Disease Control and Prevention website: <u>cdc.gov/vitalsigns/opioid-overdoses/</u>. Reviewed March 16, 2018. Accessed July 19, 2019.
- Opioid overdose: data other drugs. Centers for Disease Control and Prevention website: cdc.gov/drugoverdose/data/otherdrugs.html. Reviewed August 12, 2019. Accessed January 20, 2020.
- Modernizing drug death data: improving the timeliness and quality of drug mortality data and the interoperability of state electronic death registration systems. Centers for Disease Control and Prevention website: cdc.gov/surveillance/projects/improving-data-on-drug-overdose-deaths.html. Reviewed April 9, 2019. Accessed July 19, 2019.
- McCarthy D, Rieckmann T, Baker RL, McConnell KJ. The perceived impact of 42 CFR Part 2 on coordination and integration of care: a qualitative analysis. *Psychiatr Serv.* 2017;68(3):245-249. doi:10.1176/ appi.ps.201600138.
- 17. Tsai AC, Kiang MV, Barnett ML, et al. Stigma as a fundamental hindrance to the United States opioid overdose crisis response. *PLoS Med.* 2019;16(11):e1002969. doi:10.1371/journal.pmed.1002969.
- van Boekel LC, Brouwers EP, van Weeghel J, Garretsen HF. Stigma among health professionals towards patients with substance use disorders and its consequences for healthcare delivery: systematic review. *Drug Alcohol Depend*. 2013;131(1-2):23-35. doi:10.1016/j. drugalcdep.2013.02.018.
- 19. Allen B, Harocopos A, Chernick R. Substance use stigma, primary care, and the New York State prescription drug monitoring program. *Behav Med.* 2019;46(1):52-62. doi:10.1080/08964289.2018.1555129.

- 20. Tsai AC, Kiang MV, Barnett ML, et al. Stigma as a fundamental hindrance to the United States opioid overdose crisis response. *PLoS Med.* 2019;16(11):e1002969. doi:10.1371/journal.pmed.1002969.
- Carroll JJ, Green TC, Noonan RK. Evidence-Based Strategies for Preventing Opioid Overdose: What's Working in the United States: an introduction for public health, law enforcement, local organizations, and others striving to serve their community. Atlanta, GA: National Center for Injury Prevention and Control, Centers for Disease Control and Prevention; 2018. cdc.gov/drugoverdose/pdf/pubs/2018-evidencebased-strategies.pdf. Accessed March 6, 2020.
- 22. 45 C.F.R. §§ 164.500-164.534.
- Standards for Privacy of Individually Identifiable Health Information, 65
 Fed. Reg. 82462 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164).
- 24. 45 C.F.R. § 160.103.
- Covered entities and business associates. US Department of Health and Human Services website: https://his.gov/hipaa/for-professionals/covered-entities/index.html. Reviewed June 16, 2017. Accessed July 19, 2019.
- 26. 45 C.F.R. § 160.103.
- 27. 45 C.F.R. § 164.103.
- 28. When does a covered entity have discretion to determine whether a research component of the entity is part of their covered functions, and therefore, subject to the HIPAA Privacy Rule? US Department of Health and Human Services website: https://hipaa/for-professionals/faq/315/when-does-a-covered-entity-have-discretion-to-determine-covered-functions/index.html?language=en. Updated March 14, 2006. Accessed July 19, 2019.
- Prescription Drug Abuse Policy System. PDMP administration [database online]. Philadelphia, PA: Policy Surveillance Program, Center for Public Health Law Research, Temple University Beasley School of Law. <u>pdaps.org/datasets/prescription-monitoring-program-laws-1408223428-1502818371</u>. Updated July 1, 2016. Accessed July 26, 2019.
- 30. 45 C.F.R. § 164.502(a).
- 31. 45 C.F.R. § 164.506.
- 32. 45 C.F.R. § 160.103.
- 33. 45 C.F.R. § 164.508(a)(1).
- 34. 45 C.F.R. § 164.512.
- 35. 45 C.F.R. § 164.512(a)(1).
- 36. 45 C.F.R. § 164.512(b)(1).
- 37. 45 C.F.R. § 164.501.
- 38. 45 C.F.R. § 164.512(j)(1)(i).
- 39. Ariz. Admin. Code §§ 9-4-602(A)-(F) (2019).
- 40. See also Ariz. Admin. Code § 9-4-602(G) (2019) (requiring that collected information remain confidential).
- 41. How HIPAA Allows Doctors to Respond to the Opioid Crisis.

 Washington, DC: Office for Civil Rights, US Department of Health and Human Services; 2017. hhst.gov/sites/default/files/hipaa-opioid-crisis.pdf. Accessed March 6, 2020.
- 42. 45 C.F.R. § 164.502(b).
- 43. Wilson A. Missing the mark: the public health exception to the HIPAA Privacy Rule and its impact on surveillance activity. *Houston J Health Law Policy*. 2009: 9:131-156. *law.uh.edu/hjhlp/volumes/Vol* 9 1/Wilson. pdf.
- 44. Confidentiality of Alcohol and Drug Abuse Patient Records, 82 Fed. Reg. 6052, 6053 (Jan. 18, 2017) (noting that "the disclosure of records of individuals with substance use disorders has the potential to 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").
- 45. 42 C.F.R. § 2.13(a) ("The patient records subject to the regulations in this part may be disclosed or used only as permitted by the regulations in this part and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority").

- 46. The Part 2 regulations include limited exceptions to the general prohibition on disclosure. See 42 C.F.R. §§ 2.12(c)(5)-(6) (authorizing the use and disclosure of protected information related to crimes on Part 2 Program premises or against Part 2 Program personnel and reports of suspected child abuse and neglect); 42 C.F.R. § 2.35 ("Disclosures to Elements of the Criminal Justice System Which Have Referred Patients"); 42 C.F.R. § 2.64 ("Procedures and Criteria for [Court] Orders Authorizing Disclosures for Noncriminal Purposes"); and 42 C.F.R. § 2.65 ("Procedures and Criteria for [Court] Orders Authorizing Disclosure and Use of Records to Criminally Investigate or Prosecute Patients").
- 47. Wakeman SE, Friedmann P. Outdated privacy law limits effective substance use disorder treatment: the case against 42 CFR Part 2. *Health Affairs Blog. healthaffairs.org/do/10.1377/hblog20170301.058969/full/*. Published March 1, 2017. Accessed July 19, 2019.
- 48. 42 C.F.R. § 2.11.
- 49. 42 C.F.R. § 2.12(b).
- 50. See, e.g., Conn. Gen. Stat. § 17a-688(c).
- 51. See, e.g., Ind. Code Ann. § 16-39-1-9.
- 52. 42 C.F.R. § 2.12(b).
- 53. Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me? Rockville, MD: Substance Abuse and Mental Health Services Administration; 2018. samhsa.gov/sites/default/files/does-part2-apply.pdf. Accessed July 19, 2019.
- 54. Substance abuse confidentiality regulations. Substance Abuse and Mental Health Services Administration website: samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs. Updated April 18, 2019. Accessed January 20, 2020.
- 55. 42 C.F.R. §§ 2.11, 2.12.
- 56. 42 C.F.R. §§ 2.11, 2.12.
- 57. 42 C.F.R. § 2.12(d)(2)(i)(C).
- 58. 42 C.F.R. § 2.32(a).
- 59. 42 C.F.R. § 2.11.
- 60. 42 C.F.R. § 2.12.
- 61. 42 C.F.R. § 2.12(d)(1).
- 62. 42 C.F.R. § 2.13(a).
- 63. See 42 C.F.R. § 2.65.
- 64. 42 C.F.R. § 2.13(a).
- 65. 42 C.F.R. § 2.31(a)(4)(iii)(A).
- 66. 42 C.F.R. § 2.12(c)(3).
- 67. 42 C.F.R. § 2.12(c)(6).
- 68. 42 C.F.R. § 2.51.
- 69. 42 C.F.R. § 2.52.
- 70. 42 C.F.R. § 2.53.
- 71. 42 C.F.R. §§ 2.61-2.65.
- 72. 42 C.F.R. § 2.61(a).
- 73. Part 2 establishes separate procedures and criteria for orders authorizing the disclosure and/or use of Part 2 program records (1) for non-criminal purposes (42 C.F.R. § 2.64); (2) to criminally investigate or prosecute patients (42 C.F.R. § 2.65); and (3) to investigate or prosecute a Part 2 program or a person holding records (42 C.F.R. § 2.66). The regulations also address orders "authorizing the use of undercover agents and informants to investigate employees or agents of a Part 2 program in connection with a criminal matter" (42 C.F.R. § 2.67).
- 74. 42 C.F.R. § 2.12(c)(4).
- 75. 42 C.F.R. § 2.12(c)(5).
- 76. 42 C.F.R. § 2.12(c)(3).
- 77. 42 C.F.R. § 2.31.
- 78. 42 C.F.R. § 2.20.
- 79. 42 C.F.R. § 2.33.
- Confidentiality of Alcohol and Drug Abuse Patient Records, 82 Fed. Reg. 6052 (Jan. 18, 2017).

- 81. Coronavirus Aid, Relief, and Economic Security Act (CARES Act), H.R. 748, 116th Cong. § 3221 (2020) (enacted).
- 82. See Jay J. Tapping local data to fight drug overdoses: Part II, dispatch your own data. Data-Smart City Solutions, Harvard Kennedy School website: dispatch-your-own-data-1. Published August 28, 2017. Accessed July 19, 2019.
- 83. HealingNYC: Preventing Overdoses, Saving Lives. New York, NY: The City of New York Office of the Mayor; 2017. www1.nyc.gov/assets/home/downloads/pdf/reports/2017/HealingNYC-Report.pdf. Accessed July 19, 2019.
- 84. Garza A, Dyer S. EMS data can help stop the opioid epidemic. *J Emerg Med Serv.* 2016;41(11). *jems.com/articles/print/volume-41/issue-11/features/ems-data-can-help-stop-the-opioid-epidemic.html*. Accessed April 23, 2019.
- 85. Cutts E. Overdose calls, deaths in Northampton dip in 2017. *Daily Hampshire Gazette*. gazettenet.com/Northampton-Police-release-information-on-Narcan-use-in-the-city-15073000. Published January 29, 2019. Accessed July 19, 2019.
- 86. Knowlton A, Weir BW, Hazzard F, et al. EMS runs for suspected opioid overdose: implications for surveillance and prevention. *Prehosp Emerg Care*. 2013;17(3)317-329. doi:10.3109/10903127.2013.792888.
- Reichert J, Charlier J. Exploring Effective Post-Opioid Overdose Reversal Responses for Law Enforcement and Other First Responders. Chicago: Illinois Criminal Justice Information Authority Research Hub; 2017. icjia.illinois.gov/researchhub/articles/exploring-effective-post-opioid-overdose-reversal-responses-for-law-enforcement-and-other-first-responders. Accessed March 7, 2020.
- 88. Department Policies, Emergency Procedures: FC No. 923 Opiate Overdose Response Program. Gaithersburg, MD: Montgomery County, Maryland, Police Department; 2014. montgomerycountymd.gov/POL/Resources/Files/PDF/Directives/900/FC923%20Opiate%20Overdose%20Response%20Program.pdf. Accessed March 7, 2020.
- 89. Formica SW, Apsler R, Wilkins L, Ruiz S, Reilly B, Walley AY. Post opioid overdose outreach by public health and public safety agencies: exploration of emerging programs in Massachusetts. *Int J Drug Policy*. 2018;54:43-50. doi:10.1016/j.drugpo.2018.01.001.
- Davis CS, Carr DH. Legal and policy changes urgently needed to increase access to opioid agonist therapy in the United States. *Int J Drug Policy*. 2019;73:42-48. doi:10.1016/j.drugpo.2019.07.006.
- 91. Now What? The Role of Prevention Following a Nonfatal Opioid Overdose. Rockville, MD: Center for the Application of Prevention Technologies, Substance Abuse and Mental Health Services Administration; 2018. edc.org/sites/default/files/uploads/role_of_prevention_following_and_overdose-v02.pdf. Accessed March 8, 2020.
- 92. Stoové MA, Dietze PM, Jolley D. Overdose deaths following previous non-fatal heroin overdose: record linkage of ambulance attendance and death registry data. *Drug Alcohol Rev.* 2009;28(4)347-352. doi:10.1111/j.1465-3362.2009.00057.x.
- 93. See Now What? The Role of Prevention Following a Nonfatal Opioid Overdose. Rockville, MD: Center for the Application of Prevention Technologies, Substance Abuse and Mental Health Services Administration; 2018. edc.org/sites/default/files/uploads/role_of_prevention_following_and_overdose-v02.pdf. Accessed March 8, 2020.
- Overdose Detection Mapping Application Program (ODMAP). ODMAP website: <u>odmap.org/#home</u>. Accessed July 22, 2019.
- 95. Beeson J. ODMAP: a digital tool to track and analyze overdoses. National Institute of Justice website: nij.gov/publications/Pages/notes-from-the-field-opioid-epidemic-beeson.aspx. Published May 14, 2018. Accessed July 22, 2019.
- 96. SAMSHA's Center for the Application of Prevention Technologies provides an overview of the different types of coordinated prevention programs that could be employed after an EMS handoff following a nonfatal opioid overdose and also discusses specific governmental and nongovernmental programs currently in place throughout the United States. See generally Now What? The Role of Prevention Following a Nonfatal Opioid Overdose. Rockville, MD: Center for the Application of Prevention Technologies, Substance Abuse and Mental Health Services Administration; 2018. edc.org/sites/default/files/uploads/role_of_prevention_following_and_overdose-v02.pdf. Accessed March 7, 2020.

- 97. Petrila J, Fader-Towe H. Information Sharing in Criminal Justice–Mental Health Collaborations: Working with HIPAA and Other Privacy Laws. New York, NY: Council of State Governments Justice Center; 2010. bja.gov/Publications/CSG_CJMH_Info_Sharing.pdf. Accessed March 7, 2020.
- 98. See Emergency Medical Services (EMS) Data Integration to Optimize Patient Care: An Overview of the Search, Alert, File, Reconcile (SAFR) Model of Health Information Exchange. Washington, DC: Office of the National Coordinator for Health Information Technology, US Department of Health and Human Services; 2017. healthit.gov/sites/default/files/emr.safer.knowledge.product_final.pdf. Accessed March 6, 2020.
- 99. 45 C.F.R. § 164.512(a)(1).
- 100. Davis CS, Green TC, Hernandez-Delgado H, Liberman AJ. Status of US state laws mandating timely reporting of nonfatal overdose. *Am J Public Health*. 2018;108(9)1159-1161. *ajph.aphapublications.org/doi/abs/10.2105/AJPH.2018.304589*. Accessed July 22, 2019.
- 101. 45 C.F.R. § 164.512(b)(1)(i).
- 102. 42 C.F.R. § 2.11.
- 103. 42 C.F.R. § 2.11.
- 104. Part 2 protects only information that "would identify a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person." 42 C.F.R. § 2.12(a)(1)(i). However, experiencing an overdose is not a listed criterion for substance use disorder in DSM-5. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed. Washington, DC: American Psychiatric Publishing; 2013. dsm.psychiatryonline.org/doi/book/10.1176/appi.books.9780890425596.
- 105. 42 C.F.R. §§ 2.12(d)(1), 2.35, 2.61-2.67.
- 106. N.J. Dep't of Health Exec. Directive No. 19-004 (June 24, 2019). <u>state.</u> <u>nj.us/health/news/2019/NJDOH%20Executive%20Directive%2019-004.pdf.</u>
- 107. S.S.B. 5380, 66th Leg., Reg. Sess. (Wash. 2019).
- 108. Saloner B, McGinty EE, Beletsky L, et al. A public health strategy for the opioid crisis. *Public Health Rep.* 2018;133(1_suppl):24S-34S. doi:10.1177/0033354918793627.
- 109. Owens MD, Chen JA, Simpson TL, Timko C, Williams EC. Barriers to addiction treatment among formerly incarcerated adults with substance use disorders. Addict Sci Clin Pract. 2018;13:19. ncbi.nlm.nih.gov/pmc/ articles/PMC6102909/. Accessed March 5, 2020.
- 110. Krawczyk N, Picher CE, Feder KA, Saloner B. Only one in twenty justice-referred adults in specialty treatment for opioid use receive methadone or buprenorphine. *Health Aff (Millwood)*. 2017;36(12):2046-2053. <u>ncbi.nlm.nih.gov/pmc/articles/PMC6035729/</u>. Accessed March 5, 2020
- 111. Shaffer, DK. Looking inside the black box of drug courts: a metaanalytic review. *Justice Q.* 2011;28(3):493-521. doi:10.1080/ 07418825.2010.525222.
- 112. Adult Drug Courts: Evidence Indicates Recidivism Reductions and Mixed Results for Other Outcomes. GAO-05-219. Washington, DC: US Government Accountability Office; 2005. <u>digital.library.unt.edu/ark:/67531/metadc302987/m2/1/high_res_d/245455.pdf</u>.
- 113. Fendrich M, LeBel TP. Implementing access to medication assisted treatment in a drug treatment court: correlates, consequences, and obstacles. *J Offender Rehabil*. 2019;58:1-21. doi:10.1080/10509674.2019.1582573.
- 114. Marlowe DB, Hardin CD, Fox CL. Painting the Current Picture: A National Report Card on Drug Courts and Other Problem-Solving Court Programs in the United States. Alexandria, VA: National Drug Court Institute; 2016. <u>ndci.org/wp-content/uploads/2016/05/Painting-the-Current-Picture-2016.pdf</u>. Accessed March 9, 2020.
- 115. Szalavitz M. How America overdosed on drug courts. *Pacific Standard.* psmag.com/news/how-america-overdosed-on-drug-courts. Published May 18, 2015. Updated May 3, 2017. Accessed March 9, 2020.
- 116. See Use of Medication-Assisted Treatment for Opioid Use Disorder in Criminal Justice Settings. HHS Publication No. PEP19-MATUSECJS. Rockville, MD: National Mental Health and Substance Use Policy Laboratory, Substance Abuse and Mental Health Services Administration; 2019. <u>store.samhsa.gov/sites/default/files/d7/priv/pep19-matusecjs.pdf.</u> Accessed April 1, 2020.

- 117. See Fendrich M, LeBel TP. Implementing access to medication assisted treatment in a drug treatment court: correlates, consequences, and obstacles. J Offender Rehabil. 2019;58(3):1-21. doi:10.1080/ 10509674.2019.1582573.
- 118. See National Drug Court Resource Center. Drug treatment court programs in the United States [database online]. Wilmington: Social Science Applied Research Center, University of North Carolina Wilmington; 2017. <u>ndcrc.org/database/</u>. Accessed March 9, 2020.
- 119. Use of Medication-Assisted Treatment for Opioid Use Disorder in Criminal Justice Settings. HHS Publication No. PEP19-MATUSECJS. Rockville, MD: National Mental Health and Substance Use Policy Laboratory, Substance Abuse and Mental Health Services Administration; 2019. store.samhsa.gov/sites/default/files/d7/priv/pep19-matusecjs.pdf. Accessed April 1, 2020.
- 120. Opsal A, Kristensen Ø, Vederhus JK, Clausen T. Perceived coercion to enter treatment among involuntarily and voluntarily admitted patients with substance use disorders. *BMC Health Serv Res.* 2016;16:656. doi:10.1186/s12913-016-1906-4.
- 121. Drug Courts Are Not the Answer: Toward a Health-Centered Approach to Drug Use. New York, NY: Drug Policy Alliance; 2011. <u>drugpolicy.org/sites/default/files/Drug%20Courts%20Are%20Not%20the%20Answer_Final2.pdf</u>. Accessed March 6, 2020.
- 122. Shaffer, DK. Looking inside the black box of drug courts: a metaanalytic review. *Justice Q.* 2011;28(3):493-521. doi:10.1080/ 07418825.2010.525222.
- 123. Adult Drug Courts: Evidence Indicates Recidivism Reductions and Mixed Results for Other Outcomes. GAO-05-219. Washington, DC: US Government Accountability Office; 2005. digital.library.unt.edu/ark:/67531/metadc302987/m2/1/high_res_d/245455.pdf.
- 124. 45 C.F.R. § 164.512(e)(1).
- 125. Petrila J, Fader-Towe H. Information Sharing in Criminal Justice–Mental Health Collaborations: Working with HIPAA and Other Privacy Laws. New York, NY: Council of State Governments Justice Center; 2010. <u>bja.gov/Publications/CSG_CIMH_Info_Sharing.pdf</u>. Accessed March 7, 2020.
- 126. See Tauber J, Weinstein SP, Taube D. Federal Confidentiality Laws and How They Affect Drug Court Practitioners. Alexandria, VA: National Drug Court Institute; April 1999, which discusses ambiguities in the interpretation of federal confidentiality laws and offers regulatory analysis for drug courts. <u>ndci.org/wp-content/uploads/federalconfidentiality.pdf</u>. Accessed July 22, 2019.
- 127. See, e.g., Or. Rev. Stat. Ann. § 3.450(3).
- 128. See also Bowler PC. Drug Treatment Courts Confidentiality and Ethics. Lansing: Michigan State Court Administrative Office & Michigan Association of Treatment Court Professionals; 2017. matcp.org/uploads/8/3/0/0/83009324/confidentiality_matcp_2017.pdf. Accessed March 7, 2020.
- 129. See also Adult Drug Court Standards, Best Practices, and Promising Practices. Lansing: Michigan State Court Administrative Office & Michigan Association of Treatment Court Professionals; 2019. courts.michigan.gov/Administration/SCAO/Resources/Documents/bestpractice/ADC-BPManual.pdf. Accessed March 7, 2020.
- 130. See also Mader L. Evaluating the Technical Needs of Montana's Problem-Solving Courts. Helena: Montana Judicial Branch; 2016. courts.mt.gov/portals/189/drugcourt/docs/DRAFT%20Evaluation%20 of%20Montana%20Drug%20Court%20Technical%20Needs.pdf. Accessed March 7, 2020.
- 131. 42 C.F.R. § 2.35(a).
- 132. 42 C.F.R. § 2.35(d).
- 133. 42 C.F.R. § 2.35(c).
- 134. Drug court legislation. National Center for State Courts website: ncsc.org/Topics/Court-Management/Leadership-and-Change-Management/Opioids-and-the-Courts/Legislation-categories/Drug-Court-Legislation-aspx. Published November 8, 2018. Accessed July 22, 2019.

- 135. Developing and Implementing a Drug Treatment Court in Michigan. Lansing: State Court Administrative Office, Michigan Supreme Court; 2012. <u>courts.michigan.gov/Administration/SCAO/Resources/Documents/Publications/Manuals/Specialty/DC-PlanningImplementation.pdf</u>. Accessed July 22, 2019.
- 136. Vigil J. Medication assisted treatment in drug court. *Colorado Lawyer*. 2017;46:20.
- 137. Vigil J. Medication assisted treatment in drug court. *Colorado Lawyer*. 2017;46:20.
- 138. Heitler SK. New York courts respond to the opioid epidemic. New York State Bar J. 2018;90:30.
- 139. Mulder JT. New Syracuse opioid court aims to tackle epidemic, save lives. *Syracuse.com*. January 3, 2019. syracuse-opioid-court-aims-to-tackle-epidemic-save-lives.html. Accessed July 23, 2019.
- 140. Watson ST. Opioid courts expand in Erie, Niagara counties to tackle epidemic. *Buffalo News*. October 25, 2018. *buffalonews*. com/2018/10/25/opiate-courts-expand-in-erie-niagara-counties-to-tackle-epidemic/. Accessed July 23, 2019.
- 141. Binswanger IA, Blatchford PJ, Mueller SR, Stern MF. Mortality after prison release: opioid overdose and other causes of death, risk factors, and time trends from 1999 to 2009. *Ann Intern Med.* 2013;159(9):592-600. doi:10.7326/0003-4819-159-9-201311050-00005.
- 142. Binswanger IA, Stern MF, Deyo RA, et al. Release from prison a high risk of death for former inmates. *N Engl J Med*. 2007;356(2):157-165. doi:10.1056/NEJMsa064115.
- 143. Ranapurwala SI, Shanahan ME, Alexandridis AA, et al. Opioid overdose mortality among former North Carolina inmates: 2000-2015. Am J Public Health. 2018;108(9):1207-1213. doi:10.2105/ AJPH.2018.304514.
- 144. How is opioid use disorder treated in the criminal justice system? National Institute on Drug Abuse website: <u>drugabuse.gov/publications/medications-to-treat-opioid-addiction/how-opioid-use-disorder-treated-in-criminal-justice-system.</u> Accessed July 23, 2019.
- 145. Joint Public Correctional Policy Statement on the Treatment of Opioid Use Disorders for Justice Involved Individuals [joint policy statement release]. Rockville, MD: American Correctional Association & American Society of Addiction Medicine; 2018. adopted February 12, 2018. Accessed March 10, 2020.
- 146. Joint Public Correctional Policy Statement on the Treatment of Opioid Use Disorders for Justice Involved Individuals [joint policy statement release]. Rockville, MD: American Correctional Association & American Society of Addiction Medicine; 2018.
 Adopted February 12, 2018. Accessed March 10, 2020.
- 147. 45 C.F.R. § 164.512(a).
- 148. 45 C.F.R. § 164.512(b)(1).
- 149. 45 C.F.R. § 164.512(f).
- 150. 45 C.F.R. §§ 164.512(k)(5)(i)(A)-(F).
- 151. 45 C.F.R. § 164.512(k)(5)(iii).
- 152. Goldstein MM. Health Information Privacy in the Correctional Environment. Oakland, CA: Community Oriented Correctional Health Services; 2012. https://departments/healthpolicy/DHP_Publications/pub_uploads/dhpPublication_C199DFF7-5056-9D20-3D2099CBB55AC369.pdf. Accessed April 2, 2020.
- 153. Wishner JB, Mallik-Kane K. *Information Sharing Between Medicaid and Corrections Systems to Enroll the Justice-Involved Population: Arizona and Washington*. Washington, DC: Urban Institute; 2017. urban.org/sites/default/files/publication/88046/info_sharing_2.pdf. Accessed March 10, 2020.

- 154. Obama administration recognizes Pima County in its Data-Driven Justice Initiative [press release]. Tucson, AZ: Pima County Behavioral Health; August 10, 2016. azahcccs.gov/AHCCCS/Downloads/Initiatives/WhiteHouseRecognizedPimaCountyJail.pdf. Accessed March 10, 2020.
- 155. Opioid overdose: state information. Centers for Disease Control and Prevention website: cdc.gov/drugoverdose/states/index.html. Updated October 3, 2017. Accessed July 23, 2019.
- 156. Prescription Drug Abuse Policy System. PDMP implementation dates [database online]. Philadelphia, PA: Policy Surveillance Program, Center for Public Health Law Research, Temple University Beasley School of Law. <u>pdaps.org/datasets/pdmp-implementation-dates</u>. Updated June 1, 2017. Accessed July 23, 2019.
- 157. For additional information on the near universal use of PDMPs by the states, see also Opioid overdose: what states need to know about PDMPs. Centers for Disease Control and Prevention website: cdc.gov/drugoverdose/pdmp/states.html. Updated October 3, 2017. Accessed July 23, 2019.
- 158. Prescription Drug Abuse Policy System. PDMP reporting and authorized use [database online]. Philadelphia, PA: Policy Surveillance Program, Center for Public Health Law Research, Temple University Beasley School of Law. <u>pdaps.org/datasets/prescription-monitoring-program-laws-1408223416-1502818373</u>. Updated July 1, 2016. Accessed March 3, 2020.
- 159. State PDMP profiles and contacts. Prescription Drug Monitoring Program Training and Technical Assistance Center website: pdmpassist.org/content/state-profiles. Accessed March 19, 2020.
- 160. Opioid overdose: what states need to know about PDMPs. Centers for Disease Control and Prevention website: cdc.gov/drugoverdose/pdmp/states.html. Updated October 3, 2017. Accessed July 23, 2019.
- 161. Opioid overdose: what states need to know about PDMPs. Centers for Disease Control and Prevention website: cdc.gov/drugoverdose/pdmp/states.html. Updated October 3, 2017. Accessed July 23, 2019.
- 162. Opioid overdose: prevention for states. Centers for Disease Control and Prevention website: cdc.gov/drugoverdose/states/state_prevention.html. Updated October 3, 2017. Accessed July 23, 2019.
- 163. Opioid overdose: what states need to know about PDMPs. Centers for Disease Control and Prevention website: cdc.gov/drugoverdose/pdmp/states.html. Updated October 3, 2017. Accessed July 23, 2019.
- 164. Fink DS, Schleimer JP, Sarvet A, et al. Association between prescription drug monitoring programs and nonfatal and fatal drug overdoses: a systematic review. *Ann Intern Med.* 2018;168(11):783-790. doi:10.7326/M17-3074.
- 165. Lai AY, Smith KC, Vernick JS, Davis CS, Caleb Alexander G, Rutkow L. Perceived unintended consequences of prescription drug monitoring programs. Subst Use Misuse. 2019;54(2):345-349. doi:10.1080/ 10826084.2018.1491052.
- 166. See Exec. Order No. 13181, 65 Fed. Reg. 81321 (Dec. 20, 2000) ("HIPAA applies only to 'covered entities,' such as health care plans, providers, and clearinghouses. HIPAA regulations therefore do not apply to other organizations and individuals that gain access to protected health information, including Federal officials who gain access to health records during health oversight activities.").
- 167. Davis CS, Green TC, Zaller ND. Addressing the overdose epidemic requires timely access to data to guide interventions. *Drug Alcohol Rev.* 2015;35(4):383-386. doi:10.1111/dar.12321.
- 168. Guidance from the Substance Abuse and Mental Health Services Administration explains that "disclosures of patient-identifying information by federally-assisted programs (including OTPs and DATA-waived physicians) are permitted with written patient consent under 42 CFR part 2. However, redisclosures of such information is prohibited. Since 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. Therefore, OTPs and DATA-waived physicians should not disclose patient-identifying information to PDMPs." See Dear colleague letter. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2011. mailto:samhsa.gov/sites/default/files/programs.campaigns/medication_assisted/dear colleague-letters/2011-colleague-letter-state-prescription-drug-monitoring-programs.pdf. Accessed March 11, 2020.

- 169. See Connecting for impact: linking potential prescription drug monitoring programs (PDMPs) to patient care using health IT. Office of the National Coordinator for Health Information Technology, US Dept of Health and Human Services website: health-care-settings/connecting-impact-linking-potential-prescription-drug-0. Reviewed January 13, 2020. Accessed March 12, 2020.
- 170. Connecting Prescribers and Dispensers to PDMPs Through Health IT: Six Pilot Studies and Their Impact. Washington DC: Office of the National Coordinator for Health Information Technology, US Department of Health and Human Services; 2012. healthit.gov/sites/default/files/pdmp-pilot_studies_summary_0.pdf. Accessed March 12, 2020.
- 171. Shatterproof's report on prescription drug monitoring programs is now available. Shatterproof website: shatterproof.org/blog/shatterproofs-report-prescription-drug-monitoring-programs-now-available. Published March 28, 2016. Accessed July 23, 2019.
- 172. Baldridge S. New Pa. prescription monitoring program has cut doctor-shopping for opioids, officials say. Lancaster Online. May 14, 2017. lancasteronline.com/news/new-pa-prescription-monitoring-program-has-cut-doctor-shopping-for/article_5f2b2300-37ff-11e7-b46e-134ad23b62cf.html. Accessed July 23, 2019 (discussing early success metrics of the Pennsylvania PDMP program).
- 173. State drug utilization data [database online]. Baltimore, MD: Centers for Medicare and Medicaid Services; 2019. data.medicaid.gov/State-Drug-Utilization/Opioid-addiction-drugs-1/9ndp-gam7. Accessed March 13, 2020.
- 174. Opioid prescribing mapping tool improved with Medicaid and rural data [press release]. Baltimore, MD: Centers for Medicare and Medicaid Services; 2019. <u>cms.gov/newsroom/press-releases/opioid-prescribing-mapping-tool-improved-medicaid-and-rural-data</u>. Accessed July 25, 2019.
- 175. Medicare Part D opioid prescribing mapping tool. Centers for Medicare and Medicaid Services website: mailto:cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap_Medicare_PartD.html. Updated May 1, 2019. Accessed July 25, 2019.
- 176. See, e.g., Case study: northern Kentucky. New America website: newamerica.org/public-interest-technology/reports/mapping-opioidepidemic/case-study-northern-kentucky/. Accessed July 25, 2019.
- 177. Mental health data and resource web maps. Tri-County Health Department website: <u>mentalhealth-tchdgis.opendata.arcgis.com/</u>. Accessed July 25, 2019.
- 178. Mapping the opioid epidemic. Opioid Mapping Initiative website: opioidmappinginitiative-opioidepidemic.opendata.arcgis.com/. Accessed July 25, 2019.
- 179. Dasgupta N, Beletsky L, Ciccarone D. Opioid crisis: no easy fix to its social and economic determinants. *Am J Public Health*. 2018;108(2):182-186. doi:10.2105/AJPH.2017.304187.
- 180. See Volkow N. Addressing the opioid crisis means confronting socioeconomic disparities. National Institute on Drug Abuse website: drugabuse.gov/about-nida/noras-blog/2017/10/addressing-opioid-crisis-means-confronting-socioeconomic-disparities. Published October 25, 2017. Accessed July 25, 2019.
- 181. See, e.g., Chatterjee A, Yu EJ, Tishberg L. Exploring opioid use disorder, its impact, and treatment among individuals experiencing homelessness as part of a family. *Drug Alcohol Depend*. 2018;188:161-168. doi:10.1016/j.drugalcdep.2018.04.012.
- 182. Carter J, Zevin B, Lum PJ. Low barrier buprenorphine treatment for persons experiencing homelessness and injecting heroin in San Francisco. Addict Sci Clin Pract. 2019;14:20. <u>ascpjournal.biomedcentral.</u> <u>com/articles/10.1186/s13722-019-0149-1</u>. Accessed March 13, 2020.
- 183. Syed ST, Gerber BS, Sharp LK. Traveling towards disease: transportation barriers to health care access. *J Community Health*. 2013;38(5):976-993. doi:10.1007/s10900-013-9681-1.
- 184. Sigmon SC. Access to treatment for opioid dependence in rural America: challenges and future directions. *JAMA Psychiatry*. 2014;71(4):359-360. doi:10.1001/jamapsychiatry.2013.4450.
- 185. See 45 C.F.R. § 160.103.
- 186. 45 C.F.R. § 164.512(a).
- 187. 45 C.F.R. § 164.512(b)(1).

- 188. See 45 C.F.R. § 164.502(d).
- 189. See, e.g., Cherico-Hsii S, Bankoski A, Singal P, et al. Sharing overdose data across state agencies to inform public health strategies: a case study. *Public Health Rep.* 2016;131(2):258-263. doi:10.1177/003335491613100209.
- 190. Allegheny County Data Warehouse. Allegheny County Analytics, Allegheny County Department of Human Services website: <u>alleghenycountyanalytics.us/index.php/dhs-data-warehouse/</u>. Accessed July 25, 2019.
- 191. Hacker K, Jones LD, Brink L, et al. Linking opioid-overdose data to human services and criminal justice data: opportunities for intervention. *Public Health Rep.* 2018;133(6):658-666. doi:10.1177/0033354918803938.
- 192. NORC (National Opinion Research Center) at the University of Chicago. Drug overdose deaths in the United States [database online]. Chicago, IL: NORC at the University of Chicago & USDA Rural Development; 2017. opioidmisusetool.norc.org/. Accessed March 13, 2020.
- 193. Actionable Data Sharing: Opportunities to Leverage Public Health Data to Enhance Cross-Sector Partnerships. Arlington, VA: Association of State and Territorial Health Officials. astho.org/Integration/Integration-Forum-Actionable-Data-Sharing/. Accessed March 13, 2020.
- 194. Actionable Data Sharing: Opportunities to Leverage Public Health Data to Enhance Cross-Sector Partnerships. Arlington, VA: Association of State and Territorial Health Officials. astho.org/Integration/Integration-Forum-Actionable-Data-Sharing/. Accessed March 13, 2020.
- 195. Haas E, Truong C, Bartolomei-Hill L, Baier M, Bazron B, Rebbert-Franklin K. Local Overdose Fatality Review Team recommendations for overdose death prevention. *Health Promotion Pract.* 2018;20(4):553-564. doi:10.1177/1524839918797617.
- 196. Haas E, Truong C, Bartolomei-Hill L, Baier M, Bazron B, Rebbert-Franklin K. Local Overdose Fatality Review Team recommendations for overdose death prevention. *Health Promotion Pract.* 2018;20(4):553-564. doi:10.1177/1524839918797617.
- Maizlish N, Delaney T, Dowling H, et al. California Healthy Places Index: frames matter. *Public Health Rep.* 2019;134(4):354-362. doi:10.1177/0033354919849882.
- 198. 42 U.S.C. § 242t.
- 199. 45 C.F.R. § 164.501.
- 200. ODMAP. High Intensity Drug Trafficking Areas (HIDTA) Program website: hidta.org/ODMap/. Accessed January 20, 2020.
- 201. Opioid overdose: opioid basics commonly used terms. Centers for Disease Control and Prevention website: <u>cdc.gov/drugoverdose/opioids/terms.html</u>. Reviewed February 12, 2019. Accessed July 19, 2019.
- 202. Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain United States, 2016. MMWR Recomm Rep. 2016;65(No. RR-1):1-49. doi:10.15585/mmwr.rr6501e1.
- 203. Social determinants of health: know what affects health. Centers for Disease Control and Prevention website: <u>cdc.gov/socialdeterminants/index.htm</u>. Updated January 29, 2018. Accessed January 20, 2020.
- 204. Mental health and substance use disorders. Substance Abuse and Mental Health Services Administration website: <u>samhsa.gov/find-help/disorders</u>. Updated April 13, 2019. Accessed January 20, 2020.
- 205. 42 C.F.R. § 2.11.
- 206. 42 C.F.R. § 2.12(b)(1).
- 207. 42 C.F.R. § 2.12(b)(2).
- 208. 42 C.F.R. § 2.12(b)(3).
- 209. 42 C.F.R. § 2.12(b)(4).
- 210. Substance abuse confidentiality regulations. Substance Abuse and Mental Health Services Administration website: samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs. Updated April 18, 2019. Accessed January 20, 2020.
- 211. 42 C.F.R. § 2.11.
- 212. 42 C.F.R. § 2.11.
- 213. 42 C.F.R. § 2.11.