California Health Care Foundation

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Overcoming Data-Sharing Challenges in the Opioid Epidemic: Integrating Substance Use Disorder Treatment in Primary Care

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About the Authors

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Contents

Executive Summary

In response to the opioid epidemic, states and the federal government have sought to increase the availability of substance use disorder (SUD) treatment. Through medication-assisted treatment (MAT) programs and other efforts, primary care practices have taken a more prominent role in providing SUD care.[1] Primary care practices are stepping up to treat addiction due to many factors — recognition of the role of the medical system in driving opioid overuse and addiction, shifting of attitudes about addiction with acceptance of SUD as a chronic disease, and insufficient specialized treatment resources to address growing demands, especially in rural areas. However, common roadblocks for primary care practices are the inability to efficiently and effectively communicate with SUD providers and a lack of clear guidance about how to share SUD and primary care treatment information.

This paper summarizes the requirements of the federal SUD confidentiality rules set forth under 42 Code of Federal Regulations (CFR) Part 2, discusses the steps that primary care practices currently take to effectively coordinate SUD care without violating the rules, suggests additional compliance strategies that might enhance data sharing, and offers for consideration modest revisions to the rules that could promote the integration of care without undermining patient privacy. The key findings of the paper are as follows:

1. **42 CFR Part 2 typically does not allow a patient's information that is subject to the regulation to be disclosed without the patient's written consent.** This even applies for the purpose of providing treatment (except in a medical emergency).
2. **Part 2 applies to a federally assisted primary care practice if the practice "holds itself out" as providing SUD services.** A primary care practice meets this test if the practice maintains a license to provide SUD services or otherwise indicates that the practice has specialized SUD expertise through advertising, signage, personnel classifications, or other means. There is substantial ambiguity as to when a practice crosses the line into "holding itself out" when engaging in these types of activities.
3. **In interviews, primary care practices subject to Part 2 reported that a key challenge is developing record systems that segregate information subject to Part 2 from other medical information.** These practices must have a system under which personnel outside the Part 2 program cannot access a patient's SUD record unless the patient has consented.
4. **Avoiding Part 2 regulation simplifies data sharing among practitioners serving patients with SUDs.** Some primary care practices delivering SUD care may be able to avoid regulation under Part 2 by limiting the scope and active promotion of their SUD services.
5. **Primary care practices that operate Part 2 programs can best integrate care if they utilize a single electronic health record (EHR) system that segregates Part 2 records from other records.** This system could potentially rely on technical safeguards such as firewalls, or administrative safeguards such as access-control policies coupled with audits.
6. **The administrative burden of obtaining consent can be reduced by integrating consent requests into standard workflows.** Consents should be written as broadly as the law allows and the patient permits, and may be combined with other forms.
7. **Primary care practices also stated in interviews that specialized SUD providers generally do not share their records because they typically do not obtain a patient's written consent to share records with other providers.** In some cases, SUD providers may fear that their patients will be stigmatized if their data are shared with practitioners outside of the SUD program; in other cases, the process of consent may be viewed as an avoidable burden in an environment where resources are extremely limited.
8. **Primary care practices can gain greater access to SUD treatment information by working with specialized SUD programs in their communities to standardize consent forms and procedures for requesting consent.** Community-wide electronic health information exchanges can also improve access to Part 2 records.
9. **Modest changes to the Part 2 rules could improve access to SUD information.** These changes could include permitting consent forms to designate a class of recipients (rather than just individual providers), clarifying that the type of Part 2 records being disclosed can be described in general terms, and allowing care coordinators to be recognized as "qualified service organizations" so that such coordinators can access Part 2 records on behalf of Part 2 programs without patient consent.

Introduction

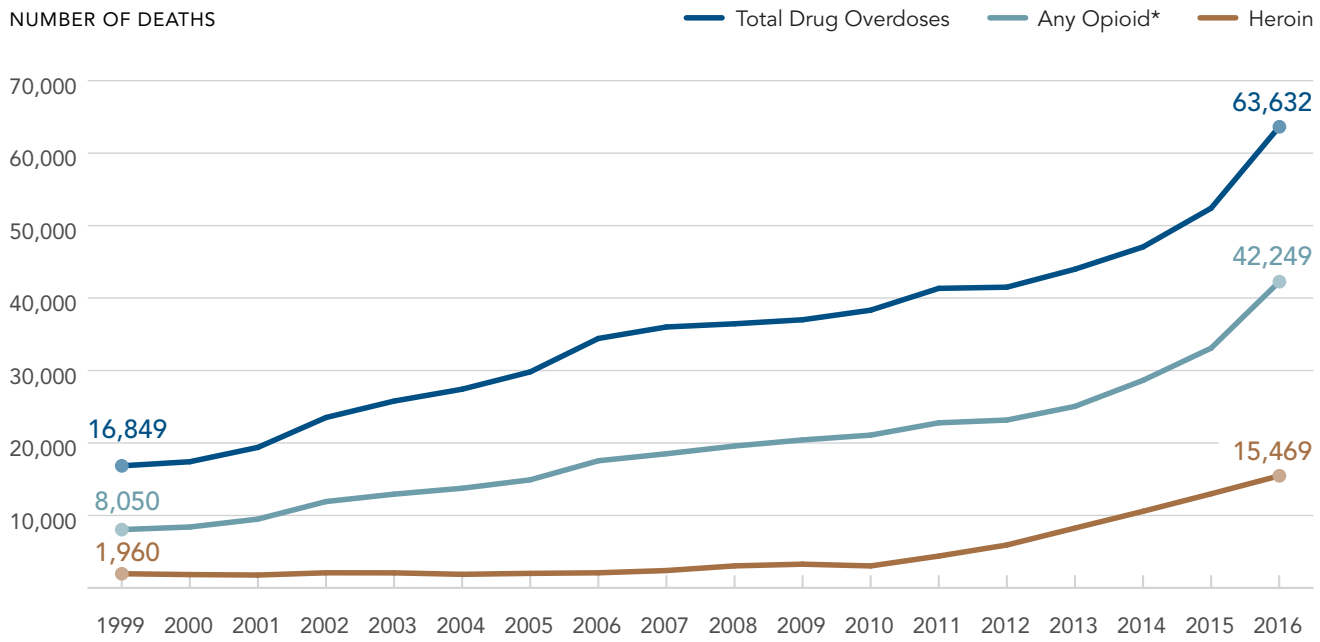
It is difficult to exaggerate the impact of the opioid epidemic on the health of this nation. In 2016, over 63,000 Americans died from drug overdoses, more than three times the rate in 1999 (see Figure 1). Approximately two-thirds of those overdose deaths were from use of opioids, with the death rate from heroin use alone climbing approximately 600% in this 17-year period.[2] These numbers represent not only lost lives, but destroyed families and communities.

Many analyses of the epidemic focus on its underlying causes, such as increased use of prescriptions of addictive painkillers like OxyContin and the loss of jobs in rural areas. Many have also called for increased funding for services, whether it be through improved access to health insurance or other forms of funding. The capacity of the existing delivery system to provide the necessary care has also been called into question. Less common are discussions about another critical aspect of the response to the opioid epidemic — the mechanisms for sharing information about opioid addiction and other SUDs among the providers charged with treating SUD patients.

The opioid epidemic comes at a time when the delivery system for SUD care is evolving, as states and providers aim to break down treatment siloes and encourage care to be coordinated among different providers and integrated with other forms of health care, including physical and mental health services. Yet better care coordination is only possible if traditional SUD providers can effectively exchange information with other parts of the health care system such as primary care physicians. This type of information sharing can be a significant challenge for providers, as they are required to balance the stringent privacy protections in federal and state laws with these new goals of coordinating care.

This paper examines the laws that regulate SUD information sharing and how providers responding to the opioid epidemic navigate those laws. This paper focuses on primary care practices that have taken on increased responsibility for SUD care as the opioid epidemic has stretched the capacity of specialized SUD treatment centers. Certain sections of this paper focus on California as a case study, but the issues discussed in this paper are applicable to primary care practices throughout the country.

Figure 1. Number of Drug Overdose Deaths in the United States, by Selected Drug Type, 1999 to 2016



*Includes heroin.

Source: *Drug Overdose Deaths in the United States, 1999–2016,* Centers for Disease Control and Prevention, December 2017, www.cdc.gov.

The following section of this paper provides an overview of the federal SUD confidentiality regulation, 42 Code of Federal Regulations (CFR) Part 2, which protects the privacy of certain information related to the treatment of opioid use and other SUDs. The paper goes on to examine how these federal rules compare to other state and federal privacy protections applicable to SUD information, to analyze these rules from the perspective of primary care practices who treat individuals for opioid use and other SUDs, and to suggest strategies that primary care practices can undertake to achieve compliance with these privacy protections while promoting information sharing that benefits patients needing opioid use treatment. Finally, modest changes to the Part 2 rules are identified that might simplify SUD data sharing without compromising patient privacy.

As part of this paper, interviews were conducted with primary care practices in California, Connecticut, and Oregon that provide treatment to opioid users; a specialized SUD provider that operates throughout the country; and an association that represents primary care practices. Also interviewed were representatives of the California Department of Health Care Services — the state agency that regulates SUD providers and operates Medi-Cal, the state's Medicaid program — as well as the New York State Department of Health, New York's Medicaid agency.

Overview of 42 CFR Part 2

Statutory Origins

Federal confidentiality protections for SUD date back to 1972, when Congress enacted the Drug Abuse Prevention, Treatment, and Rehabilitation Act (DAPTRA).[3] As amended, DAPTRA makes confidential "records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States."[4] DAPTRA generally requires patient consent for the disclosure of SUD information, but it does contain limited exceptions to the consent requirement. In particular, SUD information may be disclosed without consent in the following narrow cases:

- To medical personnel in the case of a "bona fide medical emergency."
- To "qualified personnel" conducting "scientific research, management audits, financial audits, or program evaluation."
- As authorized by a court order, including in cases to avert a substantial risk of death or serious bodily harm.[5]

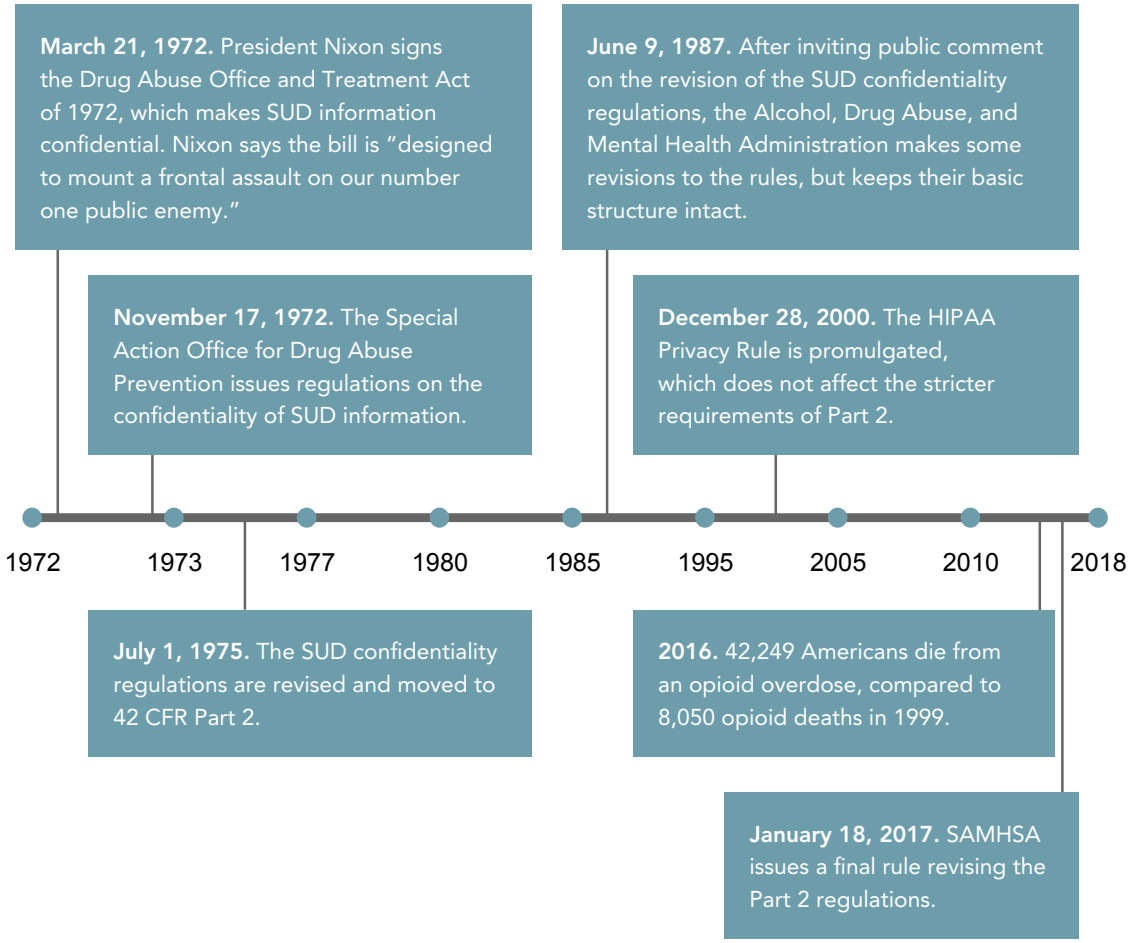
In addition, the statute does not apply to records shared with the military, the Department of Veteran Affairs, or the reporting of incidents of suspected child abuse to state and local authorities.[6]

Shortly after DAPTRA was enacted, the newly created Office for Drug Abuse Prevention adopted regulations interpreting the law. In issuing the regulations, the agency explained the rationale behind the law and the rules:

> *Drug abuse in our society, at least with heroin, inevitably involves unlawful possession of drugs as a minimum criminal complication, and the very high cost of the heroin required to maintain a full-blown habit leads in many instances to a pattern of crimes against property. Socially, there is no more crushing a stigma than to be known as a junkie. If society is to make significant progress in the struggle against drug abuse, it is imperative that all unnecessary impediments to voluntary treatment be removed. There is clear agreement among drug abuse treatment program operators that their ability to assure patients and prospective patients of anonymity is essential to the success of their programs. The identification of a person as a patient of a general practitioner or hospital clinic is not ordinarily of great significance, but the identification of a person as an enrollee in a narcotic treatment program can, in and of itself, have profoundly adverse consequences.*[7]

The regulations have been modified several times over the past 45 years (see Figure 2, page 6). But the underlying rationale for these rules — and the high level of protection for SUD information that they provide — has not materially changed. The analysis that follows is based on the most recent version of these regulations.

Figure 2. Timeline of Substance Use Disorder Confidentiality Laws



Applicability of Part 2

Given the brevity of DAPTRA and its lack of details, most providers turn to the regulations at 42 CFR Part 2, not the underlying statute, to determine the applicability of the federal SUD protections. The Part 2 regulations do not apply to every record maintained by any health care provider that shows that a patient has an SUD. Instead, in order for Part 2 to be applicable to an SUD record, three requirements must be met. First, the record must "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."[8] Second, the record must have been obtained by a "program." Third, that "program" must be "federally assisted."[9] The first requirement is fairly straightforward, but the remaining two require further explanation.

In order to meet the terms of the second requirement and qualify as a "program," an individual or entity must either "hold itself out" as providing SUD services, or have an identified unit that "holds itself out" as providing such services. In addition, a Part 2 program includes "medical personnel or other staff in a general medical facility" if such staff's "primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and is identified as such specialized medical personnel or other staff by the general medical facility."[10] General medical facilities may include hospitals, Federally Qualified Health Centers (FQHCs), and physician practices.[11] The Substance Abuse and Mental Health Services Administration (SAMHSA), the federal agency responsible for administering Part 2, has said that an individual or entity "holds itself out" as providing SUD services if it engages in:

> *Any activity that would lead one to reasonably conclude that the individual or entity provides substance use disorder diagnosis, treatment, or referral for treatment, including but not limited to: (1) Authorization by the state or federal government (e.g., licensed, certified, registered) to provide, and provides, such services, (2) Advertisements, notices, or statements relative to such services, or (3) Consultation activities relative to such services.*[12]

Even if an individual or entity is considered a "program," it still may not be subject to Part 2 if it does not meet the third requirement — that is, is not "federally assisted." The definition of "federal assistance" is quite broad: A program is federally assisted if, among other things, it participates in Medicare or Medicaid and is paid claims under those programs, receives any other type of federal funding, is tax-exempt, or maintains a Drug Enforcement Agency registration. Nevertheless, a small class of providers that hold themselves out as providing SUD services do not qualify as federally assisted. For example, a private, for-profit SUD treatment center that does not accept Medicare, Medicaid, or other federal funding may not be federally assisted and therefore may not be subject to regulation under Part 2. Thus, any clinic or practice seeing Medicaid or Medicare patients (therefore, receiving federal funding for their care) would be subject to regulation under Part 2 if they met the first requirement (identifying patients as having SUDs) and the second requirement (hold themselves out as an SUD provider).

Limited Exceptions to Part 2 Restrictions

As noted earlier, the circumstances under which a Part 2 program may disclose SUD information without patient consent are extremely limited under DAPTRA. The Part 2 regulations track the statute by allowing disclosures for purposes of child abuse reporting, responding to medical emergencies, conducting research, performing audit evaluations, and pursuant to court orders.[13] Like DAPTRA, the regulations do not apply to disclosures made within the armed forces or from the Department of Veterans Affairs.[14]

As is the case under the statute, there is no Part 2 exception that allows the sharing of SUD information for treatment unrelated to a medical emergency. However, this does not mean a practitioner in a Part 2 program may never share information regarding a patient being treated by said practitioner. The Part 2 disclosure prohibitions:

> *[D]o not apply to communications of information between or among personnel having 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 substance use disorders if the communications are: (i) Within a part 2 program; or (ii) Between a part 2 program and an entity that has direct administrative control over the program.*[15]

Thus, two practitioners working for the same Part 2 program may share SUD information for treatment purposes. The "administrative control" exception is discussed below.

In addition, a Part 2 program may disclose SUD information without patient consent to a "qualified service organization" that provides services to that program.[16] A qualified service organization (QSO) is an individual or entity that provides services to a Part 2 program "such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting, population health management, medical staffing, or other professional services" and which has entered into an agreement with the Part 2 program in which the QSO agrees, among other things, to abide by the Part 2 restrictions.[17] The QSO exception is an implicit acknowledgment of the reality that Part 2 programs cannot feasibly obtain patient consent to share SUD information with the range of contractors they must rely on to help administer their operations.

Consent Requirements

Assuming no exception applies, a Part 2 program must obtain a patient's consent before disclosing any of the patient's SUD records. DAPTRA requires consent but says little about the form or content of the consent, stating only that it needs to be written. In contrast, the Part 2 rules contain detailed specifications about what must be included in the consent form. Among other things, the form must include the patient's name, a description of how much and what kind of information may be disclosed, the purpose of the disclosure, and a date, event, or condition upon which the consent will expire.[18]

In addition, the consent form typically must include the name of the person or entity that is receiving the SUD information (an exception to this rule included in the 2017 revisions to the regulations is discussed below).[19] The Part 2 regulations do not define "entity" but the typical definition of this term is a distinct legal entity. Accordingly, the more conservative course for a Part 2 program is to name every legal entity that may receive information on the form. Thus, if a community health center has multiple sites that are all operated by the same legal entity then all of those sites can receive a patient's Part 2 information if the patient's consent names that legal entity. In contrast, if the different sites are operated by different affiliates of the same organization, then the consent form may need to list those affiliates in order for the patient's information to be disclosed to each of those sites. This does not mean, however, that the form must name every clinician employed by each legal entity; listing the name of the entity is sufficient.

The seemingly simple requirement to name the recipient of the information, in fact, has become a barrier to information exchange. This is because a patient's providers may change frequently. When a patient is initially admitted for treatment by a Part 2 program, the patient may sign a consent authorizing the disclosure of information to the person or organization serving as the patient's primary care physician. But the patient may switch primary care physicians or organizations while receiving treatment at the Part 2 program, or the patient may begin receiving services from a new psychologist or other specialist during that time. If the patient previously identified an FQHC on a consent form, for example, and the patient begins seeing a new practitioner who works for that FQHC, then the patient need not execute a new consent form. However, if the patient begins receiving care from a practitioner that is not employed or contracted by that FQHC, then the patient would need to sign a new form. In other words, patients need to sign a new consent form every time they begin a relationship with a new treating provider that is not an employee or contractor of a provider listed on a previously signed consent form.

While Part 2 requires significant specificity in the consent form, the rules do not mandate that the consent be a stand-alone document. Thus, a Part 2 consent form may be combined with a broader consent for the disclosure of other medical records or a general intake or registration form as long as all of the Part 2 elements are included in the document. This flexibility may provide opportunities for streamlining the process of obtaining a Part 2 consent.

While a record must originate in a Part 2 program in order to be subject to Part 2, that does not mean Part 2 applies only to records maintained by Part 2 programs. Instead, the rules apply to any recipient of Part 2 information that is made aware that the information being disclosed is subject to Part 2.[20] As a result, an individual or entity that receives Part 2 information under a written consent must also be informed of its Part 2 obligations, which arise under the Part 2 redisclosure restriction. To facilitate compliance with this requirement, the rules mandate that when Part 2 information is disclosed pursuant to the patient's consent, a written statement must be provided to the recipient together with the information. This written statement — sometimes referred to as a redisclosure warning — informs the recipient that the records being provided are subject to Part 2 and that the recipient cannot redisclose those records unless permitted by Part 2.[21]

Recent Revisions to Part 2

After years without any substantive changes to the Part 2 rules, SAMHSA modified the regulations in 2017 and again in early 2018. The revisions were intended to account for the growth in health information technology. In practice, however, the changes left the basic structure of the Part 2 rules largely intact.

The most significant change to the Part 2 regulations is that they no longer require the name of the specific information recipient, whether that recipient is an individual person or a legal entity, to be included on the consent form in certain circumstances. Instead, a general designation — which could state, for instance, "all of the providers that provide me with treatment" — can be included in the form in limited situations. The use of a general designation could minimize the type of problems associated with changes in a patient's treating providers that are discussed above. To take advantage of this provision, however, the SUD information typically must be exchanged through an intermediary, such as "an entity that facilitates the exchange of health information," rather than directly between individual providers.[22] If the recipient is a health information exchange, for example, the exchange may receive and maintain the information without patient consent as a QSO of the disclosing Part 2 program, and then redisclose the information in

accordance with the general designation set forth in the consent to the exchange's participants that have a treating provider relationship with the patient.[23] But the health information exchange cannot redisclose the information to an individual or entity that lacks a treating provider relationship. While the regulation does not define "an entity that facilitates the exchange of health information," the notion seems to be that the entity should be separate and apart from individual providers, and that an electronic health record system that is owned by a single provider organization would not fall within this definition.

The revised regulations arguably create an odd result. If a patient signs a consent form under which the patient agrees to allow a Part 2 program to disclose their information to "all of the providers that provide me with treatment," then the Part 2 program cannot disclose the patient's information directly to the patient's primary care practice because that primary care practice has not been specifically named on the form and the primary care practice is not an "entity that facilitates the exchange of health information." But the rules do allow disclosure to the primary care practice if the Part 2 program transmits the information through a health information exchange in which the primary care practice participates. The policy rationale for this distinction is not clear.

In allowing the use of a general designation of information recipients in limited circumstances, SAMHSA made it easier for entities to exchange SUD information through multistakeholder information exchanges and other intermediaries. But the revised regulations also took a step in the opposite direction, requiring *all* consent forms — whether using a specific or general designation of recipients — to meet a new requirement. While the previous version of the regulation mandated that the consent form describe "how much and what kind of information is to be disclosed," under the 2017 revision, the Part 2 regulations now require "an explicit description of the substance use disorder information that may be disclosed." It is possible that SAMHSA simply intends that the consent form must list different types of SUD information that must be disclosed, such as treatment histories, discharge summaries, and prescription drug records. But in the preamble to the regulation, SAMHSA discussed the possibility of consent forms including checkboxes next to categories of SUD information and allowing patients to select which categories may be disclosed, such as agreeing to the disclosure of SUD medications but not clinical notes.[24] Such a rule could pose a barrier to the electronic exchange of SUD records, since the disclosing party would need the technical ability to segregate its records according to the wishes of its patients, a capacity that many electronic health records systems currently lack. The regulation itself, however, makes no reference to this type of checkbox requirement, and in discussing the issue SAMHSA has been equivocal as to whether it believes a form with checkboxes is required.

The January 2018 revisions to Part 2 are comparatively minor. While they retain the requirement that a disclosing party provide a redisclosure warning to the information recipient, the text of that warning may now be significantly shorter, as it is sufficient to state that "42 CFR Part 2 prohibits unauthorized disclosure of these records."[25] In addition, the 2018 revisions allow recipients of Part 2 information to disclose that information to their "contractors, subcontractors, or legal representatives to carry out payment and/or health care operations" on their behalf. Thus, for example, if a patient signs a consent allowing a Part 2 program to disclose to the patient's health insurer, that insurer can now redisclose to a utilization management contractor for purposes of determining whether the insurer should pay the Part 2 program for services it provided, even if the consent form never identified such contractor. Although the definition of "health care operations" under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) includes "case management and care coordination," SAMHSA said in the preamble to the amended rule that the provision "is not intended to cover care coordination or case management."[26] This may reflect the belief that the new exception should not allow the sharing of Part 2 information for treatment purposes, as HIPAA also says that care coordination undertaken by a provider can be considered treatment.[27] Thus, if patients sign a consent allowing their information to be shared with a primary care practice, that primary care practice cannot, in turn, share that information with a contractor that assists the practice in coordinating the care of its patients.[28] Again, there is no clear explanation for the policy rationale behind this distinction.

Relationship of Part 2 to HIPAA

Part 2 is significantly stricter than HIPAA. HIPAA limits the use and disclosure of "protected health information" (PHI), which is defined as health information created or received by a provider, health plan, employer, or health care clearinghouse that can be used to identify an individual.[29] HIPAA restricts the sharing of PHI by covered entities such as providers and health plans.[30] Virtually all Part 2 programs are covered entities under HIPAA.

HIPAA, like Part 2, treats PHI as confidential and prohibits its disclosure absent patient authorization unless an exception applies. But HIPAA differs substantially from Part 2 in that the HIPAA exceptions are much broader than those under Part 2. HIPAA allows for disclosure without patient consent for purposes of providing treatment to a patient, determining the amount of payment that should be made to a provider, or for "health care operations," which include quality improvement and care coordination, among other activities.[31] There are some limitations to this general rule. For example, psychotherapy notes cannot be exchanged under these exceptions, and PHI can be exchanged to support the health care operations of the recipient only if both the disclosing party and the recipient have a relationship with the person subject to the PHI.[32] But, generally speaking, the treatment, payment, and health care operations exceptions are fairly broad.

In short, under HIPAA, providers that care for the same patient can share the patient's records with one another regardless of whether the patient has authorized such data sharing. Under Part 2, unless there is a medical emergency, such information exchange is typically prohibited without patient consent. The basic policy assumption underlying HIPAA is that physicians, nurses, social workers, and other types of licensed health care professionals can be trusted to share a patient's information with one another for health care–related purposes. In contrast, the basic policy assumption underlying Part 2 is that SUD information is simply too stigmatizing to allow for disclosure in the ordinary course of treatment without the patient's consent.

HIPAA also differs from Part 2 with respect to its authorization requirements. The HIPAA authorization requirements contain many of the same elements as the Part 2 consent requirements: Both require a description of the information to be disclosed, a description of the purpose of the disclosure, and the specification of an expiration date or expiration event, among other elements.[33] But HIPAA only requires the authorization form to identify the "class of persons" to whom disclosure may be made. In contrast, as discussed above, Part 2 typically requires the name of the specific recipients.

HIPAA and Part 2 are thus in significant tension. But HIPAA does not displace more stringent federal laws. In issuing the Privacy Rule in December 2000, the federal Department of Health and Human Services explained that there was no conflict between Part 2 and HIPAA "because these disclosures [under HIPAA] are permissive and not mandatory."[34] In other words, a provider can comply with both HIPAA and Part 2 by abiding by the rules of the stricter regulation, which for Part 2 programs will almost always be Part 2.

Table 1. 42 CFR Part 2 and HIPAA: A Comparison of Key Provisions

	PART 2	HIPAA
What types of providers does the law apply to?	Federally assisted providers that hold themselves out as providing SUD services	Virtually all health care providers
Can a provider disclose PHI to another provider without patient consent for purposes of treatment?	No, unless it's a medical emergency	Yes
Can a provider disclose PHI without patient consent to a contractor for administrative purposes such as assistance with billing?	Yes, if the provider and contractor have entered into a qualified service organization agreement	Yes, if the provider and contractor have entered into a business associate agreement
Does an authorization form need to list the name(s) of individuals and legal entities that may receive the patient's information?	Typically yes, although a general designation may be used when exchanging through certain intermediaries	No

California Privacy Laws

California's Confidentiality of Medical Information Act (CMIA) mirrors HIPAA in many respects. It applies to "medical information," defined as "any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment."[35] Similar to HIPAA, medical information is treated as confidential, but there are broad exceptions permitting disclosure. The CMIA allows providers and health plans to disclose medical information without patient consent for purposes of diagnosis or treatment.[36] Thus, like HIPAA, CMIA allows two providers to exchange a patient's records if the exchange is related to treating the patient.

However, under Part 2, "no state law may either authorize or compel any disclosure prohibited by the regulations in this part."[37] Thus, if both CMIA and Part 2 are applicable, a provider must comply with the stricter requirements of Part 2.

In addition to the CMIA, Section 11845.5 of the California Health and Safety Code regulates the confidentiality of SUD information in the state. Section 11845.5 closely follows DAPTRA in that it declares confidential all records "maintained in connection with the performance of any alcohol and other drug abuse treatment or prevention effort or function conducted, regulated, or directly or indirectly assisted by the department." There are limited exceptions to Section 11845.5 that track DAPTRA and Part 2: like the federal statute and regulation, Section 11845.5 allows for disclosures without consent for medical emergencies, research, audits, or program evaluation, and it also allows disclosure without consent for communications within the same program. In fact, some portions of Section 11845.5 mirror DAPTRA almost word for word.[38]

There are no California regulations that interpret Section 11845.5. Instead, the state's SUD regulation states that providers must abide by the privacy protections set forth at 42 CFR Part 2.[39] Thus, it appears that the state views state law as being coextensive with Part 2 and not imposing any restrictions that go beyond what is required under federal law.[40]

Challenges Faced by Primary Care Practices That Treat SUD Disorders

In many parts of the country, there are simply not enough providers specializing in SUD care to meet the treatment demand created by the opioid epidemic. As a result, primary care practices — including private physician practices and freestanding clinics such as FQHCs — are commonly providing care to people living with SUDs.

From the perspective of primary care practices, the state and federal SUD confidentiality regulations can be quite confusing. On the one hand, those regulations are written with licensed SUD facilities in mind, and therefore do not target primary care practices that include a modest scope of incidental SUD-related care within their service offerings. On the other hand, labeling oneself a "primary care practice" is not an automatic shield from Part 2 obligations. This section analyzes Part 2 from the perspective of primary care practices and addresses the practical challenges they face in obtaining medical information needed to treat patients with SUDs.

Applicability of Part 2 to Primary Care Practices

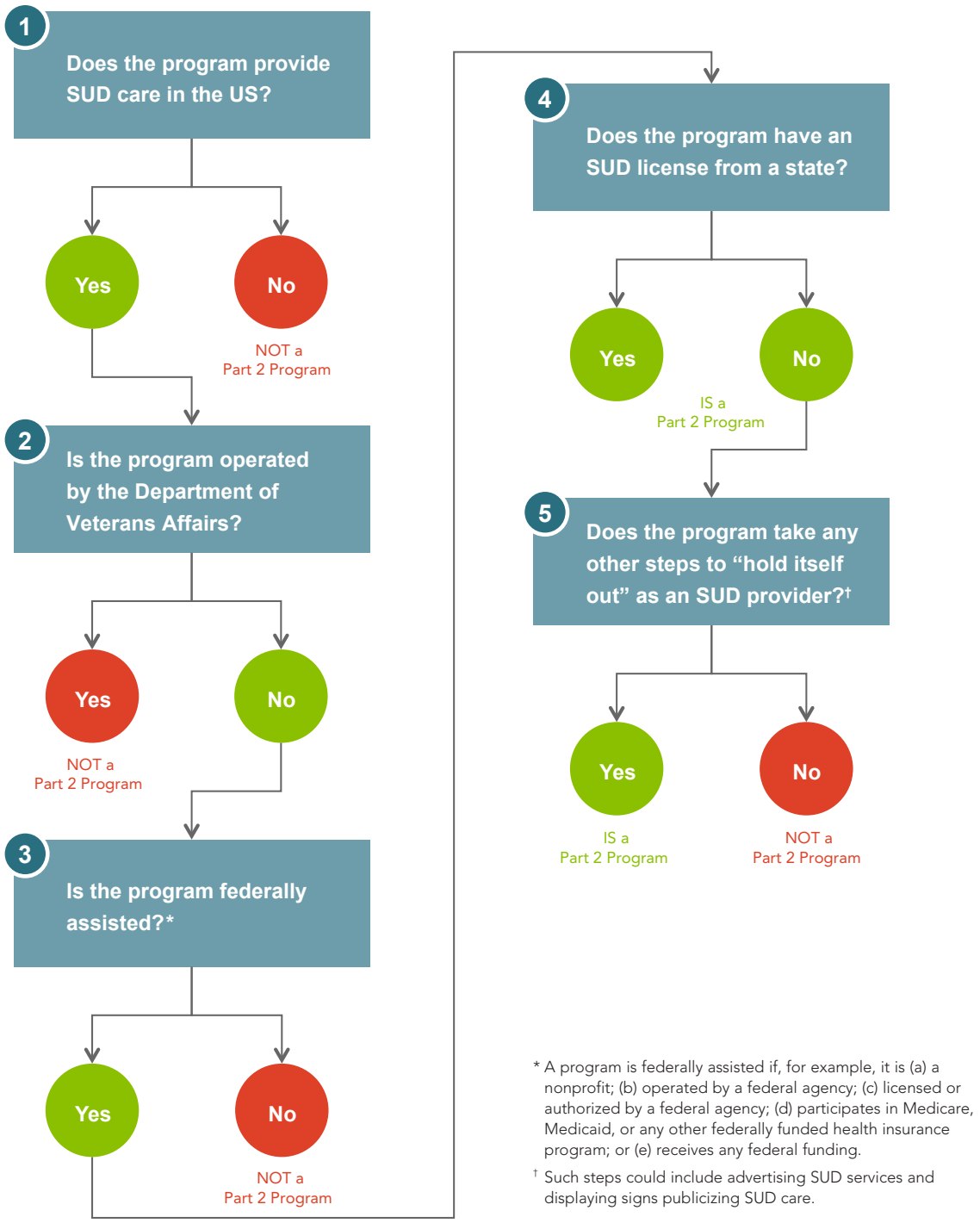
As noted above, SAMHSA characterizes primary care practices such as FQHCs as "general medical facilities." Assuming that such practices are "federally assisted" — for example, they are tax-exempt, participate in Medicare or Medicaid, or receive other federal funds — such practices are subject to Part 2 if the practice as a whole, or a unit within the practice, "holds itself out" as providing SUD services (see Figure 3, page 12). The same rule applies to individual clinicians: Assuming a clinician receives some form of federal assistance, that person will be subject to Part 2 if they hold themselves out as providing SUD services. The key question, then, is when a primary care practice crosses the line from incidental SUD-related care to holding itself out as treating SUDs.

SAMHSA has been clear that if a provider is licensed to provide SUD services, it is considered to "hold itself out" as providing SUD care. Thus, if a primary care practice is licensed by a state as a detoxification facility, an SUD outpatient program, or other specialized SUD provider, it will be subject to Part 2, except in the rare case when it is not "federally assisted." If a practice operates an SUD unit

with a specialized license and a separate primary care unit, then the SUD unit is subject to Part 2 but the primary care unit is not. This is the case regardless of whether the two units are located at the same or different sites.

Notably, SAMHSA has taken the position that individual clinicians with a waiver to prescribe or dispense buprenorphine and certain other controlled substances under the Drug Addiction Treatment Act of 2000 (DATA 2000) do

Figure 3. Is Your Program Subject to Part 2?



* A program is federally assisted if, for example, it is (a) a nonprofit; (b) operated by a federal agency; (c) licensed or authorized by a federal agency; (d) participates in Medicare, Medicaid, or any other federally funded health insurance program; or (e) receives any federal funding.

† Such steps could include advertising SUD services and displaying signs publicizing SUD care.

not necessarily hold themselves out as providing SUD care.[41] In other words, SAMHSA does not view a clinician with a DATA 2000 waiver as being licensed to provide SUD care. This does not mean that such clinicians are not subject to Part 2; instead, SAMHSA has said the analysis is "fact-specific."[42] Similarly, a primary care practice is not subject to Part 2 merely because it employs a clinician with a DATA 2000 waiver.

Part 2 regulations and SAMHSA guidance do not provide great clarity as to when a provider crosses the line of "holding itself out" as an SUD provider, and therefore primary care practices can make reasonable judgments as to what activities can be undertaken without implicating Part 2. Assuming a primary care practice does not maintain a specialty SUD license from the state, the application of Part 2 will largely depend on the practice's efforts to publicize the fact that it provides SUD services.[43] If a primary care practice includes references to SUD services in mass media advertising, displays brochures that describe the availability of SUD care from such practice, or posts signs on-site announcing the availability of SUD diagnosis or treatment, the practice arguably is "holding itself out" as providing SUD care. For example, in recent guidance SAMHSA said that a physician working at a mental health center who is identified as the facility's lead SUD physician and primarily treats patients with SUDs does hold herself out as an SUD provider.[44] On the other hand, it is unlikely that a practice will be deemed to be "holding itself out" as providing SUD services if the practice conducts routine screenings for SUD conditions and informs a patient of the availability of counseling after a screening shows the patient has an SUD. SAMHSA said in that same guidance that a physician who has a DATA 2000 waiver but "occasionally" treats patients with an opioid dependency is not subject to Part 2.

Segregating Part 2 Records

While in some cases primary care practices will not be subject to the restrictions of Part 2, in other cases they will be. Where Part 2 is applicable, Part 2 providers need to determine how to maintain their medical records in compliance.

The fact that a primary care practice is subject to Part 2 does not automatically mean that all of the practice's medical records are governed by Part 2. Part 2 only applies to records that identify a person as having, or having had, an SUD. Thus, any records that relate to treatment of any condition that is not an SUD — whether for treatment of schizophrenia or the common cold — would not be subject to Part 2 so long as the records themselves did not make any reference to the patient having an SUD.

Further, even some records that do reference a patient having an SUD may not be subject to Part 2. If a "general medical facility" has a unit that holds itself out as providing SUD care, but all other units of the facility do not provide such services, then only the SUD unit is subject to Part 2. For example, if a primary care practice owns three clinic locations, one of which is licensed by the state to provide SUD services and the others are not, only the location licensed to provide SUD services would be subject to Part 2. If a physician in one of the other locations dispensed buprenorphine to patients but the practice did not advertise the availability of SUD treatment, the records associated with that activity would not be subject to Part 2, even though another location owned by the same entity would be governed by the regulations.

From the primary care practice's perspective, there is, however, a downside to this rule. A practitioner working in a Part 2 program may share Part 2 information with other personnel in that program without the patient's consent, but generally cannot do so outside the program. To take the previous example, a counselor working at the site licensed as an SUD program could discuss a patient's case with another clinician at that same location if necessary to provide treatment. But absent patient consent, the counselor could *not* contact the patient's primary care physician working at a separate site to discuss the patient's SUD treatment, even though the counselor and primary care physician are employed by the same organization.

The Part 2 rules do allow for communications without consent between Part 2 programs and entities with "direct administrative control" over such programs. However, SAMHSA has stated in guidance that "patient information may not be exchanged among all of the programs and personnel that fall under the umbrella of the entity that has administrative control over the Part 2 program."[45] SAMHSA views this exception as only allowing for sharing of information for administrative purposes relating to the operation of the Part 2 program, such as submitting bills; the exception does not cover disclosures to clinicians outside the Part 2 program for treatment purposes.

Thus, in practice a primary care practice that has a unit that is subject to Part 2 and separate units that are not governed by the regulations must take steps to ensure that the Part 2 unit does not share SUD records with the other units without patient consent. SAMHSA has said:

> *In order for a program in a general medical care facility to share information with other parts or units within the general medical care facility, administrative controls must be in place to protect Part 2 information if it is shared.*[46]

SAMHSA has not provided detailed guidance on what these administrative controls should be. In the case of physical records, it may be sufficient to keep the SUD records in separately marked cabinets and inform non–Part 2 personnel that those records cannot be accessed without patient consent. In the case of electronic health records, a firewall can be used that prevents non–Part 2 personnel from accessing Part 2 records without consent. However, there may be alternatives to a firewall, such as other access controls set forth in policies and procedures under which staff are trained about the legal restrictions, and SUD records are audited on a regular basis to ensure that they have not been accessed inappropriately.

Experiences of Primary Care Practices with Part 2 Compliance

Preparing this paper involved speaking with primary care practices in California, Connecticut, and Oregon that provide SUD services to better understand how they seek to comply with Part 2 in practice. Also interviewed was a primary care trade association that has been working with its members on this issue, as well as a provider that operates specialized SUD facilities in states throughout the country and aims to coordinate care with primary care practices.

Primary care practices take different approaches to managing SUD data. A threshold issue for these practices is whether they conclude that Part 2 applies to their delivery of SUD services or instead deliver such services in a manner that keeps them outside the scope of Part 2 regulation. Since these practices are all "federally assisted," in order to avoid Part 2 compliance obligations, they cannot "hold themselves out" as providing SUD care.

The primary care association noted that some of its members have taken a variety of steps to prevent any component of their operations from being characterized as a Part 2 program. These steps include referring to certain staff members as "behavioral health counselors" rather than "substance use disorder counselors." One primary care practice indicated that its staff wanted to do more outreach to appropriate patients regarding the availability of SUD services, but they have not done so out of concern that this activity could cause the practice to become subject to Part 2. Instead, that practice said that discussions about SUD services occur only on a patient-by-patient basis, not through ads or brochures. If a practitioner has concerns about a patient's overuse of opioids, for example, then the practitioner will recommend a MAT program.[47]

In contrast, some primary care practices have accepted the fact that some of their facilities are subject to Part 2. These primary care practices therefore segregate Part 2 records from other health records. For example, one primary care practice operates a detoxification facility that is licensed by the state as an SUD provider. The practice noted that it had created an EHR system in which Part 2 records are segregated from other medical records. The Part 2 records can only be accessed if the individual seeking the record certifies that such individual is part of the patient's treatment team and has the right to review the record. Moreover, staff are instructed to check in the EHR system to make sure an authorization has been signed by the patient before seeking to access that record. Another primary care practice that operates a separate SUD facility uses a different EHR system for its primary care sites than for its SUD site.

Primary care practices that operate Part 2 programs seek to implement protocols to ensure that patient consents meet Part 2 requirements but sometimes face barriers in doing so. One primary care practice with multiple sites specifically lists all of its locations on its model consent form, so if the patient agrees to sign that consent, any practitioner who is providing care to the patient at any of those sites can view the patient's record. In contrast, one FQHC said the local county requires behavioral health providers to use a county-provided health form and does not allow revisions to that form. That FQHC said they were unsure if county rules allowed one consent form to be used to cover both its primary care sites and its behavioral health sites, so it operated under the assumption that separate consent forms were needed. This interpretation may create barriers to accessing SUD records in some cases.

Another primary care practice that is subject to Part 2 said it attempted to address the limitations of Part 2 by putting more data in the hands of its patients. The practice invested the resources to develop a patient portal that contains physical health, mental health, and SUD records. By giving patients direct access to their own health information, the practice found that they were helping promote sharing with other providers, since patients would sometimes print out their SUD records and share them with other treating providers.

Regardless of whether a primary care practice is subject to Part 2, such practices often seek to obtain information from unaffiliated Part 2 programs. The primary care practices interviewed noted that it was still fairly rare for specialized SUD practices that are not affiliated with the primary care practice to seek consent from patients to allow the specialized SUD provider to share information with the primary care practice. One primary care practice noted that a specialized SUD provider that was located across the street from its facility would sometimes ask patients if they would consent to share their records with the primary care practice, since there was a significant overlap in the patients who were treated by both providers. But this primary care practice noted that this level of cooperation was the exception, not the rule. Similarly, one FQHC indicated that some of its patients received care at a residential SUD program, and that the FQHC sometimes sought information from that program in order to coordinate the patient's care. But the residential program was underfunded, understaffed, and lacked an electronic health records system; moreover, it did not have a standing process for asking patients for consent to share information with other treating providers. As a result, the FQHC and the residential program spent substantial time faxing information back and forth in an attempt to obtain the patient's consent. The FQHC noted that this was a time-consuming process, and the staff at the residential center simply did not have the capacity to ask for patient consent on a routine basis.

One primary care practice observed that fear about noncompliance with Part 2 rules often leads practitioners to change their practices in ways that negatively affect patient care. That practice explained that even though the organization had determined that the provision of MAT at certain locations did not make those locations subject to Part 2, some social workers at those facilities were not sure, and were reluctant to share SUD screening results with colleagues. That practice also said that some if its primary care physicians had grown frustrated with their inability to obtain SUD medication records to determine which of their patients were struggling with addiction, and worried that if they prescribed benzodiazepines — anti-anxiety drugs such as Xanax that have addictive properties — that those drugs would be abused by their patients, and they would be labeled as "candyman" doctors. As a reaction, these physicians refused to prescribe benzodiazepines, telling patients they would have to obtain such prescriptions from behavioral health providers.

The primary care practices interviewed did not view the opioid epidemic as having caused a change in data-sharing practices. Instead, they see the opioid epidemic as heightening the importance of striking the right balance between sharing SUD information and protecting patient privacy. The primary care association noted that, in response to the epidemic, there has been an influx of new SUD treatment programs offered in the primary care setting, such as MAT programs.

The specialized SUD provider interviewed had a different perspective. That provider, which operates methadone clinics and outpatient detoxification programs throughout the country, acknowledged that primary care practices often express concerns about not having access to treatment records from the SUD provider's facilities. This provider noted that the concern was often raised in the context of benzodiazepines, since a primary care clinician would want to make sure that his or her patients were not taking a benzodiazepine and an opioid at the same time. However, in the SUD provider's view, the high stigma and potential criminal penalties that people with SUDs can face justify the need for more stringent SUD privacy rules. The provider noted that many of its patients do fear that their records may be wrongly shared with criminal justice agencies, an employer, or a family member, and that they appreciated the strict confidentiality requirements of the rules. The SUD provider said that it does not typically list a patient's other treatment providers on the consent form. The provider also noted that not all data-sharing problems stemmed from the privacy rules: Since SUD programs were excluded from meaningful use funding, they often lacked EHR infrastructure, making it more difficult for them to share records electronically even in cases where there is consent.

Information Exchange Under New SUD Funding Models in California

In the past several years, California has revised the funding model for SUD services for its low-income residents in two important respects. First, California's 1115 waiver — known as the California Medi-Cal 2020 waiver — is redesigning the delivery system for SUD services under Medicaid. Second, through the 21st Century Cures Act, California is receiving $90 million in federal funding to implement the Medication Assisted Treatment Expansion Project, which targets the uninsured, from 2017 to 2019. Both of these models assume increased coordination among different provider entities treating patients with SUDs, and therefore Part 2 poses a potential challenge to their implementation.

Under the California Medi-Cal 2020 waiver, the state has established the Drug Medi-Cal Organized Delivery System (DMC-ODS). In the DMC-ODS, counties have an option of implementing a pilot program under which the county is responsible for the delivery of Medi-Cal SUD services, that is, a system where the county plays the role as a managed care contractor responsible for SUD services. Under the waiver, the counties may provide certain SUD services not available under the Medi-Cal state plan. The waiver emphasizes increasing coordination between the SUD providers and primary care practices. Under the terms of the waiver, SUD providers "will regularly communicate with physicians of clients who are prescribed these medications unless the client refuses to consent to sign a 42 CFR Part 2 compliant release of information for this purpose."[48] The waiver requires counties to coordinate care to ensure that Medi-Cal beneficiaries successfully transition between different levels of SUD care and between specialized SUD care and physical health care.

One of the main components of the Medication Assisted Treatment Expansion Project is the California Hub & Spoke System. Under this system, "hubs" are narcotic treatment programs, which are providers that specialize in SUD services and dispense methadone. The "spokes" are typically primary care practices that employ physicians who have a waiver to prescribe buprenorphine; these physicians may practice independently, be part of a larger physician practice, or be part of an FQHC. Under the model, patients with more complex needs or severe addictions are treated by the hubs, while patients with milder addictions — or those who are treated and then stabilized by the hubs — can be managed in primary care spokes. The model creates formal relationships between hubs and spokes so that they make referrals to one another as appropriate.[49]

Both the DMC-ODS and the California Hub & Spoke System rely on models where Part 2 providers need to share Part 2 information with other entities. Under the DMC-ODS, it is the certified SUD providers that will share Part 2 information with the counties (which operate as managed care plans), which in turn may redisclose that information to other county-contracted providers who can provide SUD patients with additional services. Under the California Hub & Spoke System, the hubs — federally assisted, licensed opioid treatment providers — are expected to share information directly with the spokes, which, as primary care practices, often will not be subject to Part 2.

The underlying Part 2 compliance challenge for both models is the same. Information held by a Part 2 program is to be used in part as the basis for providing a suite of services to a patient. Since there is no exception to Part 2 that would allow for such data sharing, the Part 2 program must obtain a patient's consent, and such consent must specifically name the information recipients. It is therefore important for all providers to coordinate with the applicable Part 2 providers about the language in the consent form. In the case of DMC-ODS, this means that counties could provide to Part 2 programs the names of the primary care practices or clinics that typically treat those patients so that the Part 2 programs could include the names of those organizations on the consent form they provide to patients. In the case of the California Hub & Spoke System, this would mean that the hubs would need to include the names of their applicable spokes on their forms.

By proactively identifying which providers might need to receive a patient's information under these models, Part 2 programs, working with counties and the state, can facilitate information exchange that complies with Part 2. In conversation with the Department of Health Care Services, state officials said Part 2 programs were making efforts to use consent forms that named other providers. However, given that specialized SUD providers historically have not included the names of their patient's primary care practices on consent forms, it may be a challenge to change this practice in a short time period.

Strategies for Sharing Part 2 Information

As the opioid epidemic demands greater treatment resources from primary care practices, many of these practices view the requirements of 42 CFR Part 2 as a significant obstacle. Some practices wish to see a fundamental change to federal law that allows specialized SUD providers to share Part 2 information with primary care practices for treatment purposes without patient consent. But even if such legal changes are not forthcoming in the near future, there are still steps that primary care practices can take to improve clinical information exchange without running afoul of Part 2. Based on discussions with primary care practices and their representatives, several potential strategies are identified below.

Structuring Operations to Avoid Part 2 Applicability

For primary care practices that offer limited SUD services, such as addiction counseling or MAT that do not require a specialized SUD license, the applicability of Part 2 is likely to depend on the extent to which the practice publicizes the fact that it provides SUD services. Primary care practices must weigh the benefits and drawbacks of structuring their operations to keep them outside the scope of Part 2 regulation. On the one hand, by limiting efforts to publicize the provision of SUD services, a primary care practice may avoid the Part 2 requirements and may share all medical records for treatment purposes without patient consent. The burden of managing a patient consent process and segregating the records of different units is eliminated. On the other hand, limiting the range of and communication about SUD services may undermine optimal patient care, especially as a growing share of the population served by certain primary care practices struggles with opioid addiction, and an important public health purpose is served by aggressively informing the public about which providers are able to treat addiction.

The outcome of this cost-benefit analysis may depend on several factors:

- **The nature of the primary care practice's services.** The type of services offered by a primary care practice may influence the decision about whether the availability of SUD treatment should be openly promoted. For example, a clinic that offers mental health services may decide that SUDs are so commonly interrelated with mental health problems that the clinic must make it widely known that it treats both types of behavioral health conditions, even though this action will trigger the need for Part 2 compliance. In contrast, a primary care practice that has little or no mental health treatment capacity may conclude that SUD care is less integral to its practice, and therefore the cost of Part 2 compliance outweighs the benefit of promoting SUD services.
- **The composition of the primary care practice's patient population.** Primary care practices located in areas that have been hardest hit by the opioid epidemic may feel an obligation to make the availability of SUD treatment services widely known in the community. Practices that serve a large number of low-income patients, who tend to experience a higher rate of opioid addiction and other SUDs, may reach the same conclusion. In these cases, practices are more likely to determine that the percentage of their patients likely to need SUD treatment is too high to avoid the type of robust SUD service offering that will trigger Part 2 regulation.
- **The availability of other SUD resources in the community.** Primary care practices may feel compelled to aggressively advertise the availability of SUD services if there is limited or no specialized SUD treatment capacity in the local community. They may conclude that the community need is too great to ignore, even if such advertising results in Part 2 compliance obligations. In contrast, if there is an adequate specialized SUD treatment system in the area, primary care practices may decide that a more limited and subtle role in the provision of SUD-related services strikes the right balance.

Development of Flexible EHR Infrastructure

If a primary care practice is subject to Part 2, the practice can simplify Part 2 compliance by investing in an EHR infrastructure that facilitates the segregation of Part 2 records. If a program's Part 2 electronic health records are maintained separately from other medical records, there is a technical foundation for restricting practitioners working outside the Part 2 program from accessing SUD

information, even if the practitioner is employed by the same legal entity that operates the Part 2 program.

Once SUD records are segregated, there are different options for achieving Part 2 compliance, including the following:

- The EHR could be designed to block access to SUD records through access controls that permit login to the Part 2 program component of the system only by employees whose user IDs are associated with that program.
- The EHR could couple the type of access controls described above with a mechanism that allows a user to open up access to a patient's SUD records if the user certifies that patient consent has been obtained. Alternatively, access to Part 2 records could be facilitated by intake staff, who change consent values in the EHR when a patient provides consent as part of the registration process.
- In lieu of technical access controls, a primary care practice could develop policies and procedures prohibiting staff from accessing Part 2 records without patient consent. System users would be trained in compliance with these restrictions and warned about the consequences of improper access. The practice could conduct periodic system audits to verify that users accessing Part 2 records were either performing services for the Part 2 program or had obtained patient consent.

As an alternative to data segregation within a single EHR, practices can use an entirely separate EHR for their Part 2 program or maintain Part 2 records separately on paper. Indeed, these approaches are being utilized by several of the interviewed practices. But each of these options is likely to impede information sharing between primary care and SUD providers even when there is patient consent, and thereby undermine effective care coordination.

Effective Use of Consent Forms

If a primary care practice is subject to Part 2, it is important for that practice to develop a process for obtaining consent that not only complies with Part 2 but also minimizes the need to obtain multiple consents from the same patient. A primary care practice should carefully determine which entities are listed as information recipients on its model consent form. If the practice operates multiple primary care locations through different legal entities, the practice can list all of the locations on the consent form to ensure data exchange in the event of changes in a patient's site of care. Similarly, if the practice contracts with a separate organization to provide care management to its patients, the practice should include the name of that care management organization on the practice's consent forms. A Part 2 program may also find it useful to include the names of unaffiliated local provider organizations frequently treating its patients on the consent form. There is no legal obstacle to being overinclusive on the consent form.

In addition, as discussed above, a Part 2 consent form can be integrated into a more comprehensive document, such as an intake or registration form, or a consent for the disclosure of all medical records. The Part 2 rules do not mandate the use of a stand-alone consent. By integrating a Part 2 consent into a broader document that is part of the provider's existing workflow, the administrative burden of obtaining consent can be minimized.

Proper Training and Education

There are likely to be benefits in training staff on the key Part 2 requirements. Staff at non–Part 2 practices may mistakenly believe that their practice is subject to Part 2, or they may otherwise view Part 2 as applying more expansively than it actually does. Explaining to staff the limits of Part 2 may make practitioners more willing to share information in ways that could help improve treatment and care coordination without violating state and federal law. And where a primary care practice is subject to Part 2, such training will help reduce the likelihood that staff violate the law.

There may also be a need for primary care practices, trade associations, and state or local government agencies to facilitate community-wide education on Part 2 requirements. Misunderstandings about the scope of Part 2 and the required elements of a Part 2 consent may impede data sharing even when it is legally permissible. Establishing a common understanding in the community, especially about the validity of consent forms being used by various providers, may minimize the undue caution some stakeholders exercise when they contemplate sharing SUD information. Government agencies can be particularly important in creating a shared community-wide understanding of Part 2 rules.

Obtaining Information from Local Specialized SUD Programs

Even if a primary care practice does provide SUD services, it is likely that some of the practice's patients with opioid addictions will be receiving care from specialized SUD providers. In such cases, primary care practices will be relying on information from these specialized SUD providers. Specialized SUD providers may be reluctant to provide such information for multiple reasons. Doing so would require them to revise their consent forms, which would entail additional time and resources. Moreover, some SUD providers may not want to share information even if allowed under the law, as they may worry that primary care practices will not do enough to protect the privacy of their own patients.

There are, however, actions that primary care practices can take to increase the likelihood that information can be obtained from specialized SUD providers:

- **Build relationships.** There is no requirement that a Part 2 program include the name of another provider on its model consent form. But if SUD programs know the local primary care practices and understand how those practices may use Part 2 information, the SUD programs may develop more trust in their potential partners and therefore may be more willing to use consent forms that name these other providers.
- **Obtain consent on behalf of Part 2 programs.** The Part 2 rules do not dictate who must obtain consent from a patient, nor do they require the consent form to identify the source of the Part 2 information by name. Therefore, if a primary care practice knows that one of its patients was obtaining care from a specialized SUD program and if the practice believes information from that specialized SUD provider is relevant to the primary care practice's treatment, the primary care practice can contact the specialized SUD provider, provide a copy of the signed consent form, and ask for the patient's Part 2 information. To avoid disputes about the adequacy of the consent form, the primary care practice can share a copy with local SUD providers in advance to obtain their sign-off.
- **Use a health information exchange.** Due to a quirk in the latest version of the Part 2 rules, the Part 2 authorization form requirements are less strict if Part 2 information is shared through a health information exchange or other intermediary, rather than directly between providers. In particular, consent forms that list a class of information recipients (such as "all my treating providers") comply with Part 2 when SUD information is shared through an intermediary. Reliance on this type of consent eliminates the need to anticipate in advance which specific treating providers may later require access to SUD information. In addition, health information exchanges may already have a patient's consent on file that would allow a primary care practice to obtain a patient's Part 2 information. By joining such a health information exchange, the primary care practice may be able to access such information. If no such exchange exists, a primary care practice could work with other providers in the region to create one.

Many of the strategies discussed above require a certain level of cooperation among multiple organizations or even the entire community of stakeholders. As a result, trade associations and local and state government agencies have an especially critical role to play in supporting these solutions.

Putting Data in Patients' Hands

Developing a patient portal can be an expensive undertaking for small primary care practices without discretionary funds. But for practices with the resources to operate a patient portal, developing such a site may be worth the costs. Patients may be more likely to actively participate in their own care if they have access to their own health care records. Moreover, giving patients ready access to their own records may support information sharing with other providers. Even if a Part 2 program neglects to include the name of a specific provider as a potential information recipient on a consent form, patients receiving care from that provider can decide to share records on their own if the Part 2 program operates a patient portal and the patients have a computer or phone that allows access to the portal. There are no restrictions on how patients can choose to share their own information.

Further Amendments to Part 2

In its recent rulemakings, SAMHSA has signaled that it has little interest in fundamentally altering the Part 2 regulatory framework, and that any such overhaul of the regulation would require legislative change, which seems unlikely. But there are still modest revisions that SAMHSA could make to Part 2 that, without altering the rule's basic requirements, would ease the burden on providers seeking to share SUD records for treatment purposes. A few of these potential amendments to Part 2 include the following:

- **Broaden the right of providers to include a class of data recipients on the consent form.** As discussed above, a general designation of data recipients is sufficient under Part 2 only if information is shared through an intermediary such as an electronic data exchange. The rationale for this limitation is unclear. This flexibility could be extended to direct disclosures between providers for treatment purposes. By using consent forms that permit disclosure to a class such as "all of my treating providers," a Part 2 program can avoid the often insurmountable burden of obtaining a new consent whenever the patient commences a relationship with a new provider.
- **Extend the definition of a QSO to include care coordination and case management.** Some primary care organizations that operate Part 2 programs employ care coordinators and case managers who work with a variety of patients who have complex needs, including those with SUDs. Due to their broad responsibilities, these employees may be part of the primary care component of the organization rather than its Part 2 component. As a result, patient consent is required for the Part 2 unit to share information with these employees, even though they serve as a bridge between SUD treatment and primary care. By allowing care coordinators and case managers who facilitate SUD patients' access to, but do not directly deliver, primary medical care, the regulations could promote the integration of health care services.
- **Clarify that Part 2 consents are not required to include a series of checkboxes that allow patients to select which types of information may be disclosed.** SAMHSA has created confusion by suggesting in the preamble to a recent regulatory amendment that this type of "checkbox" approach is necessary, even though it is not mentioned in the regulations themselves. The checkbox is infeasible, especially when Part 2 records are transmitted electronically through multiprovider exchanges. SAMHSA could eliminate uncertainty that may be hampering data sharing by clarifying that the checkbox is not required.

Endnotes

1. Throughout this paper, the term "primary care practice" refers to organizations that provide primary care services — such as Federally Qualified Health Centers, clinics, and private physician practices — and their staff.
2. *Drug Overdose Deaths in the United States, 1999–2016*, Centers for Disease Control and Prevention, December 2017, www.cdc.gov.
3. The Drug Abuse Prevention, Treatment and Rehabilitation Act of 1979, Pub. L. No. 96–181, 93 Stat. 1309. The law was initially titled the "Drug Abuse Office and Treatment Act" but was renamed in 1980.
4. 42 United States Code (USC) § 290dd–2(a).
5. 42 USC § 290dd–2(b)(2).
6. 42 USC § 290dd–2(e). These are the only exceptions listed in DAPTRA. As discussed below, the Part 2 regulations include additional exceptions. Under certain circumstances, Part 2 also allows for disclosure without consent for communications within a Part 2 program or with an entity having direct administrative control over the program, to qualified service organizations, and to law enforcement to report crimes occurring on the premises of a program. 42 CFR § 2.12(c)(3), (4), (5).
7. 37 Fed. Reg. 24636, 24636 (November 17, 1972).
8. 42 CFR § 2.12(a)(1)(i).
9. 42 CFR § 2.12(a)(1)(ii).
10. 82 Fed. Reg. 6052, 6065 (January 18, 2017); *see also* 42 CFR § 2.11.
11. 82 Fed. Reg. 6052, 6066 (January 18, 2017).
12. Ibid.
13. 42 CFR §§ 2.12(c)(6), 2.51, 2.52, 2.53, and 2.61.
14. 42 CFR § 2.12(c)(1), (2). Department of Veteran Affairs (VA) facilities are treated somewhat differently than facilities operated by the military. VA records are exempted from Part 2 entirely. In contrast, SUD records maintained by the Armed Forces may be subject to Part 2, but disclosures within the Armed Forces or from the Armed Forces to a VA facility are not subject to Part 2. In effect, military health care facilities are Part 2 programs, but the facilities only need to comply with Part 2 to the extent they are disclosing Part 2 information outside the Armed Forces or VA.
15. 42 CFR § 2.12(c)(3).
16. 42 CFR § 2.12(c)(4).
17. 42 CFR § 2.11.
18. 42 CFR § 2.31(a).
19. 42 CFR § 2.31(a)(4).
20. 42 CFR § 2.12 (d)(2)(i)(C).
21. 42 CFR § 2.32.
22. 42 CFR § 2.31(a)(4)(iii)(B).
23. 42 CFR § 2.31(a)(4)(iii)(B)(3).
24. 82 Fed. Reg. 6052, 6086 (January 18, 2017).
25. 83 Fed. Reg. 239, 251 (January 3, 2018).
26. 45 CFR § 164.501; 83 Fed. Reg. 239, 243 (January 3, 2018).
27. 45 CFR § 164.501.
28. If the care managers were employees of a primary care practice, then the practice could disclose Part 2 information to these care managers, because the patient's consent allows the sharing of Part 2 information with employees of the entity named on the consent. Similarly, if the primary care practice contracted with individuals to provide care management services (i.e., issued those individuals IRS 1099 forms), then arguably the consent form would apply to those care managers as well. However, if the care managers instead were employed by a separate organization, then the care managers could not receive Part 2 information unless their employer was also named on the consent form.
29. 45 CFR § 160.103.
30. Ibid. Technically, HIPAA does not apply to all providers, but only those providers that engage in certain electronic transactions with health plans. A very small number of providers that accept patients only on a private pay basis and do not submit claims to health insurers, therefore, are not subject to HIPAA.
31. 45 CFR §§ 164.501, 164.506(c).
32. 45 CFR §§ 164.506(c)(4), 164.508(a)(2).
33. 45 CFR § 164.508(c).
34. 65 Fed. Reg. 82461, 82482 (December 28, 2000).
35. California Civil Code § 56.05(j).
36. California Civil Code § 56.10(c)(1).
37. 42 CFR § 2.20.
38. *Compare* California Health and Safety Code § 11845.5(b)(3) (allowing for disclosure without consent to "qualified personnel for the purpose of conducting scientific research, management audits, financial and compliance audits, or program evaluation, but the personnel may not identify, directly or indirectly, any individual client in any report of the research, audit, or evaluation, or otherwise disclose patient identities in any manner") with 42 USC § 290dd–2(b)(2)(B) (allowing for disclosure without consent to "qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner").

39. California Code of Regulations, Title 9, §§ 9866(c), 10155(a), 10568(c), 10569(a)(1), 11036.

40. Section 11845.5 regulates an "alcohol and other drug abuse treatment or prevention effort or function." While that term is not defined, a provision in the statute does define "an alcohol and other drug abuse program" to include "free clinics" — which include FQHCs — "that are established for the purpose, either in whole or in part, of providing any medical or dental care, social services, or treatment, or referral to these services for those persons recognized as having a problem of narcotics addiction or drug abuse." California Health and Safety Code § 11842.5(d). In other words, the state could claim that certain FQHCs are formed "in part" to provide SUD care and therefore are subject to Section 11845.5 even if such FQHCs do not hold themselves out as providing SUD care.

41. 82 Fed. Reg. 6052, 6066 (January 18, 2017). Although the Drug Addiction Treatment Act of 2000 allowed only physicians to prescribe and dispense buprenorphine, the Comprehensive Addiction and Recovery Act of 2016 allows nurse practitioners and physician assistants to prescribe or dispense buprenorphine from July 22, 2016, to October 1, 2021. 21 USC § 823(g)(2).

42. 82 Fed. Reg. 6052, 6066 (January 18, 2017).

43. Ibid.

44. *Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me?*, Substance Abuse and Mental Health Services Administration, www.samhsa.gov (PDF).

45. H. Westley Clark, *Applying the Substance Abuse Confidentiality Regulations to Behavioral Health Primary Care Providers*, Substance Abuse and Mental Health Services Administration, www.integration.samhsa.gov (download PPT).

46. "Applying the Substance Abuse Confidentiality Regulations," Substance Abuse and Mental Health Services Administration, last modified May 1, 2018, www.samhsa.gov.

47. Medication-assisted treatment is the combination of counseling and the prescription of a substance such as buprenorphine intended to help the patient reduce or cease the use of opioids.

48. "152. Coordination with DMC-ODS Providers," in *California Medi-Cal 2020 Demonstration*, Centers for Medicare & Medicaid Services, last modified April 5, 2018, www.medicaid.gov (PDF).

49. *CA Hub and Spoke System (CA H&SS) Overview*, California Department of Health Care Services (DHCS), www.dhcs.ca.gov (PDF); *CA Hub and Spoke Awards*, DHCS, July 19, 2017, www.dhcs.ca.gov (PDF).