

Chapter 2:

Substance Use Disorder Confidentiality Regulations and Care Integration in Medicaid and CHIP

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Recommendations

- 2.1** The Secretary of Health and Human Services should direct relevant agencies to issue joint subregulatory guidance that addresses Medicaid and CHIP provider and plan needs for clarification of key 42 CFR Part 2 provisions.
- 2.2** The Secretary should direct a coordinated effort by relevant agencies to provide education and technical assistance on 42 CFR Part 2. Such efforts should target state Medicaid and CHIP programs, health plans, primary care and specialty providers, patients and their families, and other relevant stakeholders.

Key Points

- Disclosure of medical information about substance use disorders (SUDs) can expose individuals to harm, such as criminal prosecution and loss of employment or child custody. Such disclosures risk discouraging individuals from seeking treatment for their SUDs.
- Federal regulations (42 CFR Part 2) protect the confidentiality of certain SUD-related information. Providers generally need patient consent to share protected information, both inside and outside the health care system.
- Requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA, P.L. 104-191) that govern privacy of most other patient health information are generally less stringent, permitting providers and plans to share information for payment, treatment, and health care operations purposes without patient consent.
- Part 2 can be a barrier to integrating physical and behavioral health services for Medicaid and CHIP enrollees with SUDs. Some stakeholders contend that the rules are too restrictive, confusing, and challenging to implement, and that they limit, sometimes inadvertently, sharing of important patient information among providers and plans. Such information gaps can affect the provision of high-quality care and hamper delivery system reforms.
- Some stakeholders call for closer alignment of Part 2 with HIPAA. Others suggest that more should be done to improve stakeholder understanding of Part 2 and to develop tools to facilitate consent and disclosure processes.
- It is the Commission's view that additional subregulatory guidance could address confusion about Part 2 and highlight existing opportunities to share information. This guidance should include clear and consistent definitions about which providers and what information is subject to Part 2 and how information can be shared in a Part 2-compliant manner. Targeted education and technical assistance efforts developed in consultation with stakeholder groups is also needed.
- At this time, the Commission does not recommend alignment of Part 2 and HIPAA, but it intends to explore this issue in the future.

CHAPTER 2: Substance Use Disorder Confidentiality Regulations and Care Integration in Medicaid and CHIP

As part of MACPAC's prior work on behavioral health disorders and Medicaid's response to the opioid epidemic, the Commission identified the need for improved integration of mental health, substance use disorder (SUD), and physical health services (MACPAC 2017, 2016). People with SUDs commonly have serious comorbidities, such as other behavioral health disorders, cardiovascular diseases, cancer, hepatitis C, and HIV (SAMHSA 2016, NIDA 2010). Fragmentation of care can affect access to care and result in inappropriate use of services, poor health status, and increased costs (MACPAC 2016).

The Commission has noted that the federal law on confidentiality of SUD-related patient records (42 USC § 290dd-2) and its implementing regulations (42 CFR Part 2)—together usually referred to as Part 2—act as a barrier to integrated care by hindering the exchange of information among the providers who treat individuals with SUDs and the payers who finance that care. Part 2 applies to information that identifies a person as having or having had an SUD and that is maintained by certain health care providers. Part 2 generally requires patients to provide explicit prior written consent to sharing of such SUD-related information, either within the health care system or outside of it. These rules are meant to minimize the risk that unauthorized disclosures of such information could expose patients to harmful consequences (SAMHSA 2017). Part 2 requirements are generally stricter than those imposed by the Health Insurance Portability and Accountability Act of 1996 (HIPAA, P.L. 104-191), a law that established privacy protections

and standards for lawful disclosures of most other health information. HIPAA generally allows information to be shared without patient consent among health care providers and payers for payment, treatment, and health care operations purposes.

Many clinicians, state Medicaid agencies, health plans, health information technology (health IT) companies, some patient advocates, and others have raised concerns in regulatory comment letters, journal articles, and other venues that the Part 2 regulations are confusing, restrictive, and challenging to implement (SAMHSA 2018a, Partnership 2017, McCarty et al. 2016, NAMD 2016). Information gaps between different providers treating the same patient or among multiple entities responsible for administering benefits can undermine the provision of whole-person care (MACPAC 2017, 2016).¹ Lack of comprehensive patient information may also hamper delivery system reforms, which aim to hold providers and health plans accountable for costs and health outcomes. Thus many stakeholders support relaxing consent standards to align them more closely with HIPAA standards for sharing of information among providers and payers inside the health care system (Partnership 2017, NAMD 2016). But other stakeholders, in particular certain patient advocates, warn that creating more avenues for sensitive health information to be disclosed without patient consent could harm patients and discourage individuals from seeking care for SUDs (Clark 2018, Reid 2018). Additional clarifying guidance on the existing regulations, however, would be a meaningful step to help providers, payers, and patients understand rights and obligations under the current law as well as existing opportunities for information sharing.

To better understand how Part 2 affects care delivery for beneficiaries of Medicaid and the State Children's Health Insurance Program (CHIP) who have SUDs and possible ways to promote information sharing, MACPAC conducted a review of publicly available information.² Although there is little research on this topic, comments

submitted in response to federal rulemaking and a Substance Abuse and Mental Health Services Administration (SAMHSA) public listening session on Part 2 provide many insights into the views of state Medicaid directors, SUD specialty providers, primary care providers, Medicaid managed care organizations (MCOs), and patient advocates (SAMHSA 2018a, 2018b, 2017).

In addition, in November 2017, MACPAC convened an expert roundtable of federal and state Medicaid and behavioral health officials, health care providers, legal experts, researchers, Medicaid MCOs, and patient advocates.³ Roundtable participants agreed that Part 2 generally protects individuals from harms that may occur due to unauthorized disclosure of SUD treatment information. They particularly noted the importance of protecting such information from disclosure to non-health care entities without explicit consent. There was, however, less agreement on the degree to which explicit patient consent should be required for the exchange of information within the health care system for purposes of treatment, payment, and health care operations, and whether Part 2 protections that go beyond HIPAA requirements in these settings are necessary.

A key theme from the roundtable was the significant confusion among many stakeholders about the scope and applicability of Part 2, which can lead to its inconsistent application and may hamper care coordination and care transitions. As this report went to print, SAMHSA and the Office of the National Coordinator for Health Information Technology (ONC) jointly issued two fact sheets with scenarios illustrating how Part 2 may apply to certain providers, patient information, and disclosures made using electronic health information exchange. Because the Commission has not had the opportunity to review this new guidance, any discussion in this chapter regarding stakeholder confusion about the regulations' provisions and the need for subregulatory guidance does not reflect the contents of these new fact sheets.

The Commission, therefore, recommends the following actions be taken by the Secretary of the U.S. Department of Health and Human Services (the Secretary) to ensure that federal regulations do not unnecessarily stifle information exchange among providers, payers, and patients::

- The Secretary of Health and Human Services should direct relevant agencies to issue joint subregulatory guidance that addresses Medicaid and CHIP provider and plan needs for clarification of key 42 CFR Part 2 provisions.
- The Secretary should direct a coordinated effort by relevant agencies to provide education and technical assistance on 42 CFR Part 2. Such efforts should target state Medicaid and CHIP programs, health plans, primary care and specialty providers, patients and their families, and other relevant stakeholders.

Adoption of the second recommendation is contingent on adoption of the first, because educational and technical assistance activities should focus on disseminating the contents of the clarifying guidance.

The Commission will monitor U.S. Department of Health and Human Services (HHS) guidance and activities to examine whether such actions promote stakeholder understanding and information sharing under Part 2 or have an unintended effect of identifying additional impediments to care delivery and integration under Part 2. The Commission will also continue to explore whether other steps, in particular, closer alignment of Part 2 with HIPAA, could facilitate information sharing and thus improve Medicaid and CHIP beneficiaries' access to coordinated, high-quality care.

This chapter begins by providing background on the need for confidentiality protections of SUD information. It summarizes current Part 2 regulations and compares key HIPAA and Part 2 regulatory provisions. The chapter goes on to discuss the types of challenges Part 2 may pose to effective and integrated care delivery for Medicaid

and CHIP enrollees with SUDs. It then presents the rationale for the Commission's recommendations for improving the understanding and implementation of the existing Part 2 regulations and the implications of these recommendations for the federal government, states, enrollees, plans, and providers. The chapter ends by briefly outlining the Commission's plans to explore other steps Medicaid and CHIP stakeholders have suggested for addressing concerns about Part 2's effect on the delivery of care.

The Need for Confidentiality of SUD-Related Health Information

Disclosure of SUD-related information can have serious consequences including criminal arrest, prosecution, and incarceration; loss of employment, housing, or child custody; discrimination by medical professionals; and denial of life or disability insurance. Unlike other chronic illnesses, SUDs are widely stigmatized and, depending on the substance being used, may involve criminalized behavior (AHLA 2017, Lopez and Reid 2017, SAMHSA 2017, NASEM 2016, Curtis et al. 2013). Patient advocates and providers have relayed experiences with local law enforcement officers who attempted to access SUD treatment facilities and patient records to gather information to bring criminal charges. Individuals who take methadone as part of medication-assisted treatment (MAT) for opioid use disorder have also reported being denied visitation with their children or threatened with eviction (Lopez and Reid 2017). Federal and state antidiscrimination laws that protect individuals with disabilities—such as those stemming from chronic diseases—only apply to some people with SUDs (FindLaw 2018, USCCR 2000).⁴ In light of these circumstances, patients, providers, plans, and government health officials generally support heightened protection from unauthorized disclosure of SUD-related information outside of the health

care system (ACHP et al. 2016, LAC 2016, NAMD 2016).

Discrimination against people with SUDs can also occur within the health care system. Health professionals may have inadequate education, training, and support working with patients with SUDs. Providers, even SUD specialty providers, may view such patients as violent, manipulative, and poorly motivated to participate in their own care (van Boekel et al. 2013). Patients have reported instances of being “fired” by their physicians when their SUD was disclosed or being disparaged for taking methadone as part of MAT (Lopez and Reid 2017). Such negative attitudes and lack of empathy can perpetuate stigma, undermining a patient's feelings of empowerment and leading to poor treatment outcomes (van Boekel et al. 2013). Moreover, concern about disclosure of such sensitive information is one reason individuals with SUDs do not seek care (CBHSQ 2017, Stone 2015).

Thus, some stakeholders oppose relaxing SUD confidentiality protections, even if the changes are limited to treatment contexts. These stakeholders assert that patients should retain control over when their SUD-related information is shared and with whom (Clark 2016, Reid 2018, DASPOP 2016, EPIC 2016, LAC 2016).

The Part 2 Regulations

The federal Confidentiality of Substance Use Disorder Patient Records regulations contained in 42 CFR Part 2 govern the confidentiality and disclosure of SUD treatment and prevention records for people receiving treatment from federally assisted programs. These regulations were first promulgated in 1975 and implement statutory requirements under the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (P.L. 91-616) and the Drug Abuse Prevention, Treatment, and Rehabilitation Act of 1972 (P.L. 92-255). These two laws were later consolidated in the 1992 Alcohol, Drug Abuse, and Mental Health Administration

Reorganization Act (P.L. 102-321). The law is intended to encourage individuals to seek treatment for SUDs by addressing the stigma of SUDs and concerns that individuals receiving treatment could be subject to negative consequences. Specifically, the statute (42 USC 290dd-2) includes provisions that:

- require written patient consent to disclose records of a patient’s identity, diagnosis, prognosis, or treatment information that are maintained in connection with SUD education, prevention, training, treatment, rehabilitation, or research activities or programs and that are conducted, regulated, or directly or indirectly assisted by any federal department or agency;⁵
- prevent, absent a court order for good cause, SUD treatment records from being acquired or used by law enforcement to investigate a patient or initiate or substantiate any criminal charges;⁶
- exempt from the prior written consent requirement disclosures made for the following reasons:
 - to medical personnel in case of a bona fide medical emergency, and
 - for purposes of scientific research, management and financial audits, or program evaluation, so long as any report of such activity does not directly or indirectly identify the individual patient;
- charge the Secretary with issuing regulations to carry out the law, including prescribing definitions, safeguards, and procedures, to facilitate compliance and prevent circumvention of the law.

The implementing regulations at 42 CFR Part 2 subsequently introduced several definitions and requirements, including spelling out the types of providers and information that are subject to the law, when patient consent is not required, and processes for securing and managing consent.

SAMHSA, the operating division of HHS that oversees Part 2, updated the regulations most recently in January 2017 and January 2018 (SAMHSA 2018b, 2017). SAMHSA has acknowledged that additional subregulatory guidance may be needed to clarify a number of issues, and stated in the preamble to the 2018 rule that it plans to explore additional alignment with HIPAA where possible (SAMHSA 2018b, 2017). Below we summarize key provisions of the Part 2 regulations and the preambles to the 2017 and 2018 final rules, focusing on those particularly relevant to delivery of services to Medicaid and CHIP beneficiaries.

When patient consent is required

Providers subject to Part 2 (referred to as Part 2 programs) are generally required to obtain a patient’s prior written consent to disclose information to another individual or entity that would identify the patient as having or having had an SUD, for example, records related to SUD diagnosis, treatment, or referral for treatment.

After a patient has provided written consent to share information with a third party, the disclosure must include a notice to the recipient that the information received is protected by Part 2 and that the recipient is prohibited from redisclosing it except in accordance with Part 2 provisions (42 CFR 2.32). Entities receiving protected information may not subsequently disclose it to anyone else—including other providers and payers involved in the patient’s care—without first obtaining another written consent from the patient, or unless one of the limited exceptions to the consent requirement applies. For example, a primary care provider who receives Part 2 protected information from an SUD treatment provider generally cannot redisclose that information to a specialist or to a managed care plan unless the primary care provider obtains a new separate consent from the patient specifically authorizing such disclosure.

The regulations, consistent with the underlying statute, also prevent, absent a court order meeting

specific requirements, SUD treatment records from being acquired and used by law enforcement to investigate or prosecute a patient (42 CFR 2.12, 42 CFR 2.61).

When patient consent is not required

There are limited circumstances under which the regulations permit information to be disclosed or redisclosed without patient consent. Protected patient information may be disclosed without consent for communications:

- among staff within a Part 2 program or between a Part 2 program and an entity with direct administrative control over the Part 2 program, so long as each staff person needs the information to carry out duties related to diagnosis, treatment, or referral for treatment of patients with SUDs (42 CFR 2.12); and
- between a Part 2 program and a qualified service organization (QSO).

QSOs are organizations that provide Part 2 programs with administrative and professional services, such as data processing; bill collecting; dosage preparation; laboratory analyses; legal, accounting, medical staffing, and other professional services; and services to prevent or treat child abuse or neglect, including training on child care and individual and group therapy. QSO services may include population management services. But the preamble to the 2017 rule specifically excludes care coordination activities from QSO services not subject to patient consent requirements because SAMHSA considers such services to have a treatment component (42 CFR 2.11–2.12).

Patient consent is also not required for certain other disclosures, including the following:

- to medical personnel in the case of bona fide medical emergencies where prior consent cannot be obtained (42 CFR 2.51);
- for research, but only if the recipient of the information is subject to and complies with rules related to HIPAA or the HHS Common

Rule for the protection of human subjects (45 CFR 46), and only if research reports exclude individually identifiable information (42 CFR 2.52);

- for Medicare, Medicaid, and CHIP audits and evaluations (42 CFR 2.53);
- to report suspected child abuse and neglect under state law (42 CFR 2.12); and
- in response to a special authorizing court order (42 CFR 2.61).

Redisclosure without patient consent is only permitted in limited circumstances, which include the following:

- recipients of protected information may redisclose the information to contractors, subcontractors, and legal representatives carrying out Medicare, Medicaid, and CHIP audits and evaluations (42 CFR 2.53); and
- an entity such as a Medicaid MCO that, pursuant to a patient’s consent, receives protected information for purposes of payment or health care operations activities, may redisclose that information to its contractors, subcontractors, and legal representatives without obtaining a separate patient consent—but only if the redisclosure is necessary for carrying out the activities for which the initial consent was granted (42 CFR 2.33).⁷

All of these disclosures and redisclosures must include the notice that the received information is protected by Part 2 and that further disclosure is prohibited except in accordance with Part 2 provisions.

Providers and information subject to Part 2

Information identifying individuals as having or having had an SUD becomes subject to Part 2 when it originates with providers who are “federally assisted” and meet the definition of a “program” (42 CFR 2.12). The term “federally assisted,” in

accordance with the statute, is defined broadly and includes, but is not limited to:

- entities that receive any federal funding, even if not for SUD services;
- entities that are registered with the U.S. Drug Enforcement Administration (DEA) to dispense controlled substances for treatment of SUDs; and
- entities that hold federal tax-exempt status (42 CFR 2.12).

A “program” is defined as:

- an individual 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
- medical personnel or other staff in a general medical care facility whose primary function is the provision of SUD diagnosis, treatment, or referral for treatment and who are identified as such providers (42 CFR 2.11).

In the preamble to the 2017 final rule, SAMHSA notes that hospitals, federally qualified health centers (FQHCs), or trauma centers would generally be considered “general medical care facilities.” The preamble also states that “holds itself out” means any activity that would lead one to reasonably conclude that the individual or entity provides SUD diagnosis, treatment, or referral for treatment, including but not limited to state or federal government authorization to provide such services (e.g., being licensed, certified, or registered), advertising the provision of such services, and providing consultation activities related to such services.

Part 2 protections do not necessarily apply to records of all patients receiving SUD treatment

because some providers, such as certain primary care providers or FQHCs, may not fall under the definition of a Part 2 program. In these cases, HIPAA governs disclosure practices. A Part 2 program generally must also comply with HIPAA regulations to the extent that there is no applicable Part 2 provision for a patient’s SUD-related information, and for any non-SUD related health information held by the provider.

Notice to patients about Part 2

A Part 2 program must, at the time of a patient’s admission, provide the patient with a written notice that includes a summary of the Part 2 confidentiality protections, the limited circumstances under which information may be disclosed without patient consent, a statement that violation of Part 2 is a crime, and contact information for reporting suspected violations (42 CFR 2.22).

Elements of patient consent

Required elements of the patient consent to disclose information include:

- the purpose of the disclosure;
- how much and what kind of information is to be disclosed;
- the date or condition upon which consent expires; and
- the individual or entity to whom the patient allows disclosure of the protected information (42 CFR 2.31).

For the amount and kind of information to disclose, the consent form must allow patients to describe in detail which SUD-related information they want to share. The preamble to the 2017 rule suggests that this can be accomplished by providing blank spaces for patients to fill in or by providing a list of choices based on fields commonly used in medical records, including in electronic health records (EHRs).⁸ The form may also include fields allowing patients to select to share “all my SUD information” or “none

of my SUD information,” as long as more granular options are available.

In the consent form, patients must specify who may receive the information by identifying one of the following:

- the name of an individual;
- the name of an entity, as long it has a treating provider relationship with the patient;
- the name of a third-party payer; or
- the name of an intermediary entity without a treating provider relationship that shares information with participants in that entity.

The preamble to the 2017 rule provides examples of intermediary entities that could be named on the consent form, including health information exchanges (HIEs) and entities that coordinate care, such as accountable care organizations (ACOs). If the patient names such an intermediary entity, then the patient must also name the recipient to whom the entity is ultimately sending the information, for example, a physician who participates in the HIE or ACO. The intended end recipient must be a participant in the intermediary entity. The patient can name an individual, name an entity with a treating provider relationship, or make a “general designation” of individuals or organizations, provided that they have a treating provider relationship with the patient (42 CFR 2.31). For example, as discussed in the preamble to the 2017 rule, the patient could permit the HIE to disclose information to “all my treating providers,” or to “all my current and future treating providers.”⁹ A treating provider relationship exists, regardless of whether there has been an actual in-person encounter, when two conditions are met: (1) the patient agrees to or is legally required to be diagnosed, evaluated, or treated, or agrees to receive a consultation; and (2) an individual or entity agrees to provide or actually does provide such services to the patient (42 CFR 2.11).

Comparison of Part 2 and HIPAA privacy provisions

While Part 2 rules dictate disclosures of SUD-related information, HIPAA regulations govern the use and disclosure of most other individually identifiable health information—that is, any information related to physical or mental health conditions, health care services, or payment for such care.¹⁰ Most notably, HIPAA permits sharing without patient consent for purposes of payment, treatment, and health care operations. Part 2’s allowances for disclosure without consent are far more limited, and generally do not include disclosure for treatment purposes (Table 2-1).

Challenges Associated with Part 2

Despite stakeholder agreement about the importance of Part 2 in protecting patients from harm that may occur from unauthorized disclosure of SUD information, and despite the recent update to Part 2, many stakeholders in public comments and at the MACPAC roundtable continue to report challenges in complying with the regulations and concerns about restrictions on information sharing (SAMHSA 2018a).

Limits on the sharing of SUD-related health information can cause harm

Despite widespread agreement about the importance of integrating SUD treatment with other medical care, stakeholders disagree about the extent to which SUD treatment information should be shared for this purpose without patient consent. In many comment letters to SAMHSA, organizations representing Medicaid officials, providers, and plans, as well as some patient advocates, noted that the possible harms associated with withholding SUD-related information from health care providers, which can result in uncoordinated care, outweigh the risks that increased sharing of sensitive

TABLE 2-1. Components of HIPAA and Part 2 Regulations **T 2-1**

Component	HIPAA regulations	Part 2 regulations
Who must comply?	<p>Covered entity. Any health plan, health care provider, or health care clearinghouse that electronically transmits health information in connection with transactions subject to HIPAA.</p>	<p>Part 2 program. Any federally assisted:</p> <ul style="list-style-type: none"> • individual or entity (other than a general medical facility), or identified unit in a general medical facility that holds itself out as providing, and provides, SUD diagnosis, treatment, or referral for treatment; or • provider in a general medical facility who is identified as and whose primary function is SUD diagnosis, treatment, or referral for treatment.
What information is protected?	<p>Protected health information. Any individually identifiable health information about past, present, or future physical or mental health or condition, care provision, or payment.</p>	<p>Patient identifying information. Any information identifying a patient as having or having had an SUD, such as records related to SUD diagnosis, treatment, or referral for treatment.</p>
When can information be disclosed without patient consent?	<p>Circumstances include, but are not limited to:</p> <p>Inside health care system</p> <ul style="list-style-type: none"> • with the exception of psychotherapy notes,¹ information for purposes of: <ul style="list-style-type: none"> – treatment – payment – health operations (includes care coordination and case management) • communications between covered entities and business associates who provide administrative and professional services to the covered entity • audits <p>Outside health care system</p> <ul style="list-style-type: none"> • law enforcement and judicial and administrative proceedings pursuant to a court order, court-ordered warrant, subpoena, and certain other situations • child abuse and neglect reporting 	<p>Circumstances include, but are not limited to:</p> <p>Inside health care system</p> <ul style="list-style-type: none"> • communications: <ul style="list-style-type: none"> – among Part 2 program staff involved in patient care – with QSOs providing administrative and professional services to the Part 2 program • to medical personnel in medical emergencies • audits and evaluations • to prevent multiple enrollments in maintenance treatment or withdrawal management programs <p>Outside health care system</p> <ul style="list-style-type: none"> • law enforcement and judicial and administrative proceedings pursuant only to a special court order • child abuse and neglect reporting
Are recipients of information subject to the same requirements, and can recipients share information further?	<ul style="list-style-type: none"> • If recipient is a HIPAA-covered entity or business associate, then HIPAA requirements continue to apply and redisclosure is permitted under the same conditions as initial disclosures. • If recipient is not a HIPAA-covered entity or business associate, then HIPAA protections no longer apply and redisclosure is permitted. 	<ul style="list-style-type: none"> • Recipients of protected information are bound by Part 2 and generally prohibited from redisclosing information without patient consent. • Limited exceptions include allowing redisclosure without patient consent to contractors, subcontractors, or legal representatives for: <ul style="list-style-type: none"> – carrying out Medicaid and CHIP audits and evaluations; and – payment or health care operations.

Notes: HIPAA is the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191). Part 2 is 42 CFR Part 2. QSO is qualified service organization. SUD is substance use disorder. Some sensitive health data (e.g., data related to HIV/AIDS, mental health, and reproductive health) may also be subject to state laws providing additional disclosure protections. Part 2 does not apply to records exchanged within and between the U.S. Department of Veterans Affairs and the uniformed services.

¹ Psychotherapy notes are a mental health care provider’s notes documenting or analyzing the conversations during counseling sessions. These notes do not include summaries of diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

Sources: 42 CFR Part 2, 45 CFR Part 164.

information could lead to disclosures that cause harm (ABHW 2016, APA 2016, MHA 2016, NAMD 2016, WHCA 2016).

Providers generally assert that effective care necessitates access to a patient's entire treatment history and current medications. When patients are unable or unwilling to accurately report on current or past medications, drug use, treatments, or health care providers, restrictions on access to such information could result in inadequate or even dangerous care, such as prescribing medications with potentially dangerous or even deadly interactions with other medications (SAMHSA 2018a, Wakeman and Friedman 2017, APA 2016, MHA 2016, ACP 2016). For example, a provider unaware of a patient's opioid use disorder history could prescribe opioids to someone in recovery, potentially contributing to a relapse (Clement and Keeton 2018). Even when a health care record reflects care that has been delivered elsewhere, if SUD treatment information has been withheld, providers may not know that the record is incomplete.

Requirements for obtaining specific consent can make it difficult to coordinate care, manage care transitions, and follow up on patient referrals,

discouraging use of integrated care models (Box 2-1). For example, an individual newly entering treatment may receive multiple SUD treatment services from different Part 2 providers (e.g., inpatient detoxification followed by residential treatment and subsequent outpatient counseling), as well as other medical care from non-Part 2 providers for hepatitis C. In order for an MCO care manager assigned to this patient to develop a comprehensive transition plan and coordinate services, each individual Part 2 program must first secure the patient's consent for a disclosure to the care manager. The care manager in turn must secure consent from the patient to then share information with the providers that make up the patient's care team (AHCCCS 2016, Anthem 2016, Beacon 2016, IN FSSA 2016, NAMD 2016). However, it may be possible for the care manager to secure a patient's consent that uses a general designation to share information with all of the patient's future treating providers. In that case, no new consents would be required to share information with a solo practice physician who is a new addition to the care team. Still, providers and payers attending MACPAC's roundtable stated that even when patients consent, the consent and disclosure process creates unnecessary delays in the sharing of essential information.

BOX 2-1. Examples of Part 2 Restrictions on Information Sharing in the Health Care System

Part 2 requirement. A Part 2 program generally cannot share information with an outside health care provider without prior written patient consent. A provider not subject to Part 2, however, can generally provide the Part 2 program with information about a mutual patient without the patient's consent.

Example. Mary is a Medicaid enrollee being treated with buprenorphine for an opioid use disorder in a stand-alone SUD clinic, which is subject to Part 2. She is also getting care for hypertension from a family physician who is in private practice and is not a Part 2 program. Mary has told her family physician that she is getting treatment for her SUD. HIPAA permits the physician to give the SUD clinic updates about any changes to Mary's antihypertensive medication, without first requiring her consent. The SUD clinic, however, has not secured Mary's prior written consent to share information with her family physician, and therefore cannot provide information about her buprenorphine dosage and frequency of drug counseling sessions.

BOX 2-1. (continued)

Part 2 requirement. Patients generally must consent for a Part 2 program to share SUD information with payers when filing insurance claims. Payers in most cases cannot share this information with a patient's other treating providers or use it for care coordination without a patient's consent. Payers, however, do not need consent to redisclose the protected information to contractors, subcontractors, or legal agents for payment and health care operations purposes.

Example. John is an enrollee in a Medicaid MCO. He uses drugs and is hospitalized following a car accident. During his stay, he meets with the hospital's addiction specialist who diagnoses his SUD and develops a treatment plan. The hospital's legal counsel previously determined that the addiction specialist is a Part 2 provider.

The hospital may submit claims to John's MCO for the physical health care portion of his stay without John's consent. However, Part 2 requires the hospital first to secure John's consent to share information with the MCO for the addiction specialist service claims. Upon receipt, the MCO is able to redisclose both the physical and SUD-related information to its third-party administrator for claims processing without John's consent.

John agrees to enter an intensive outpatient program at a local SUD clinic after discharge from the hospital. Part 2 restricts the MCO from disclosing the SUD diagnosis and treatment plan to John's primary care provider without John's consent.

The MCO would also like to have one of its in-house care managers follow up with John after he is discharged, to encourage compliance with the intensive outpatient program and discuss available services to support long-term recovery. Before sharing his information with the care manager, however, the MCO must first get John's consent.

Part 2 requirement. Part 2-protected information must be segregated from the rest of a patient's medical record, including any electronic health record, and generally may only be made available with patient consent—even when a Part 2 program shares medical records with a non-Part 2 program in the same practice or health system.

Example. Beth is prescribed buprenorphine for her opioid use disorder by a psychiatrist in a large multispecialty practice. The practice's legal counsel has determined that the psychiatrist is a Part 2 provider. Beth relapses and develops a serious skin infection likely related to her intravenous drug use. She seeks care from the practice's dermatologist but does not disclose that she has been in SUD treatment with the practice's psychiatrist, and the dermatologist does not ask about any SUD history. Despite being part of the same practice, the dermatologist is unable to see the SUD information in Beth's medical record because she has previously chosen not to share that information with all providers in the practice. Her dermatologist cannot consider any potential antibiotic drug interactions were she to resume SUD treatment and take buprenorphine. The dermatologist also does not know to alert her psychiatrist about the infection.

Notes: Part 2 is 42 USC 290dd-2 and its implementing regulations 42 CFR Part 2. SUD is substance use disorder. HIPAA is the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) and its implementing regulations 45 CFR Part 164. MCO is managed care organization. These examples illustrate requirements related to disclosures under HIPAA and Part 2 only and do not include consideration of other laws, such as state laws related to HIV/AIDS, mental health, reproductive health, and domestic violence, which may also place restrictions and conditions on disclosure of sensitive health information.

Sources: 42 CFR Part 2. 45 CFR Part 164.

Some stakeholders also expressed concern at the roundtable and in regulatory comments to SAMHSA that separate medical records, consent requirements and forms, and privacy regimes for SUD-related information perpetuate stigma by treating such patients and their health information differently from other patients. They argued that the separate requirements imply that SUD patients should be ashamed of their condition and that they must hide it to be treated fairly and non-prejudicially by the health care system (MHA 2016).

Confusion over when Part 2 applies

Discussion at the MACPAC roundtable in particular and the regulatory comment letters highlighted the tremendous uncertainty among many stakeholders about when Part 2 applies and to whom. Specifically, there is confusion about:

- who is considered a treatment provider subject to Part 2;
- what parts of patient health records are covered by Part 2;
- when SUD information can be shared among staff within a Part 2 program; and
- the level of detail required in certain parts of the written patient consent to make Part 2-compliant disclosures.

Lacking more definitive guidance, providers may interpret the regulations narrowly and opt not to share Part 2 records, unnecessarily limiting other providers' access to important patient information. Concerns that offering certain services will subject them to confusing Part 2 requirements may also discourage some providers from offering SUD care. Conversely, confusion may also lead some providers to mistakenly conclude that they are not subject to Part 2.

Defining providers subject to Part 2. The setting in which an SUD service is provided determines in part whether a patient's SUD-related health information is protected by Part 2. SAMHSA, however, has not

published definitive subregulatory guidance that clearly enumerates which providers and settings are subject to the rule, leaving key concepts such as "holding oneself out as providing SUD care" and "general medical facility" largely open to interpretation. As a result, it is unclear whether certain providers meet the definition of a Part 2 program. Absent more definitive guidance, provider behavior can be arbitrary or inconsistent.

For example, consider the situations of a multispecialty practice that provides integrated care by employing an SUD specialist who prescribes buprenorphine for opioid use disorder as part of MAT, or a primary care provider in solo practice offering MAT. Providers with a DATA-2000 waiver from SAMHSA and the DEA to prescribe buprenorphine for MAT meet the definition of being federally assisted (42 CFR 2.12).¹¹ But in the preamble to the 2017 final rule, SAMHSA states that holding a DATA-2000 waiver does not necessarily by itself make the provider a "program" subject to Part 2. Because of this ambiguity, providers must use their own judgment to determine whether part or all of their practices' medical records fall under Part 2 limitations and protections.

At the roundtable, a clinician described the experience of an internist with addiction specialty certification who provided SUD consultations at a liver transplant clinic and an HIV clinic within the same health system. The system's attorneys recommended that the internist cease providing consultations because they concluded that this would make both clinics Part 2-covered entities. Under this interpretation, both clinics would have been required to maintain medical records systems that segregated SUD information from other medical information.

Providers also report that different attorneys, even within the same hospital or health system, may disagree on Part 2's application. SAMHSA has indicated that additional subregulatory guidance to further define the phrase "holds itself out" as providing SUD diagnosis, treatment, or referral for treatment is forthcoming but has not made any

commitments with regard to timing (SAMHSA 2017).

Parts of patient health records affected by

Part 2. It is not necessarily clear how Part 2 applies to records for unrelated medical care delivered to patients in conjunction with SUD treatment, medical care for illnesses resulting from or associated with an SUD, or medications used to treat SUDs that may also be used in the treatment of other illnesses (APCD Council 2016, CO SIM 2016). Part 2 restrictions apply to information that would identify a patient as having or having had an SUD. Providers, however, may be unsure about what information triggers this determination. For example, a patient in an SUD treatment program may have liver disease, pancreatitis, or hypertension that is directly attributable to an SUD. According to roundtable participants and some regulatory comment letters, it can be unclear which of the diagnoses and related treatments for these illnesses are protected by Part 2, because some are more often associated with having an SUD than others. Ultimately, roundtable participants said, providers are being asked to make judgment calls that exacerbate their confusion and concerns about complying with Part 2.

SAMHSA puts the onus on the Part 2 program to provide patients with a written notice about Part 2's confidentiality protections and to explain the consent process to them (SAMHSA 2017). However, due to confusion about when the regulations apply, some providers might mistakenly think they are not subject to Part 2. In such cases, patients would not be made aware that their information should be protected. Some stakeholders at the MACPAC roundtable indicated that even when providers subject to Part 2 are aware of their obligations, they may not adequately explain the protections and the consent process to patients. This may leave patients unsure about how and what parts of their medical records are protected and how to permit the sharing of such information with other providers. To address these concerns, stakeholders have called on SAMHSA to develop a national education campaign or additional patient education requirements for Part 2 providers, including plain

language interpretations of patients' rights under Part 2 and the implications of providing consent (Northwell Health 2016, LACSAPC 2016).

Sharing information within a Part 2 program. The degree to which information can be shared within a Part 2 program is unclear. The regulations permit communication about protected information among staff within a Part 2 program or between Part 2 program staff and staff at an entity with direct administrative control over the Part 2 program when it is in connection with the staffs' duties to provide diagnosis, treatment, or referral for treatment for the patients with SUDs. However, SAMHSA does not further define or give examples of what it considers "direct administrative control," and in the preamble to the 2017 rule advises stakeholders to consult with legal counsel to ensure compliance. Providers that commented during the rulemaking process requested that this concept be further defined, and some even requested that communications between a Part 2 program and another entity under common ownership or control be exempt from the consent requirement (SAMHSA 2017).

Requirements for consenting to a disclosure. There is also confusion about the individuals and entities to whom information can be disclosed and how patients may specify what kind of information can be disclosed.

To provide greater flexibility in sharing information, including through intermediaries such as HIEs and ACOs, the 2017 Part 2 update now allows patients to make a "general designation" of an individual or entity to whom information can be disclosed, so long as that person or entity has a "treating provider relationship" with the patient. Regulatory comments by organizations representing providers and payers, however, asserted that the terms are ambiguous. For example, it is not clear whether care coordinators can be considered to have a treating provider relationship with the patient for purposes of the general designation option (SAMHSA 2017). Some stakeholders requested the general designation be expanded to include situations and relationships beyond treating providers (Rosecrance

Health Network 2017). There is also confusion about whether the general designation option is available only when coupled with disclosure through an intermediary entity, or if Part 2 programs can share information directly with providers based on a general designation in the consent form.

When providing consent, a patient must specify how much and what type of information can be shared. The preamble to the 2017 rule states that the consent form may include an option to share all of a patient's SUD information, but it must also provide the patient with specific, so-called granular, options that allow the patient to select only certain information to share. SAMHSA suggests that one way to present these options is to use information fields that generally appear in patient records. This could include diagnostic information, medications and dosages, lab tests, allergies, substance use history summary, trauma history summary, clinical notes and discharge summary, employment information, living situation and social supports, and claims and encounter data.

Stakeholders have requested that SAMHSA provide sample consent forms that comply with Part 2's granular field requirements (Reid 2018, CCC 2016, Cerner Corporation 2016). SAMHSA has stated that it is developing subregulatory guidance that might include a sample consent form, but nothing has been issued to date (SAMHSA 2017).

Effect on Medicaid and CHIP delivery systems

In 2014, Medicaid was the largest source of insurance payment for SUD treatment, financing 21 percent of all such treatment (MACPAC 2017). Because of Medicaid's sizeable role and the fact that enrollees with SUDs often have serious comorbidities, state Medicaid agencies and MCOs are pursuing strategies to proactively manage the complex health care needs of their beneficiaries (MACPAC 2016). These initiatives seek to break down the historical silos between behavioral health care—often delivered outside of medical settings—and physical health care. The goal of integration

is to improve care coordination and transitions, and ultimately patient outcomes (MACPAC 2017, 2016; McCarty et al. 2016). But if Part 2 restrictions contribute to missing or inconsistent information in patient medical records and claims data, the success of efforts to integrate behavioral and physical health care may be affected.

Lack of information also makes it difficult to predict financial risk (as is needed under capitated payment arrangements) and to track care for high-risk, high-cost patients. For example, in states where SUD services are carved out of Medicaid managed care, MCOs may be unaware that an enrollee is being treated for SUDs. While some state agencies have developed a consent process to facilitate the flow of information between SUD treatment providers and MCOs, plans are still prohibited from further sharing information with the patient's other providers without a separate consent (DHMH 2015). This can also affect value-based payment initiatives, which hold providers accountable for patient outcomes, because providers may not have complete information about their patients or be fully aware of their medical history. A roundtable participant described a Medicaid patient-centered medical home (PCMH) program, in which the PCMH providers use claims information to help manage the care of patients attributed to their practice. Unless the patient has signed a consent form, however, SUD-related claims are suppressed. For new patients, providers have also expressed frustration about the time needed to secure consent and access to the SUD-related claims.

The 2018 rule made changes to permit Medicaid and CHIP agencies and MCOs to redisclose information without additional patient consent to contractors and subcontractors for payment and health care operations activities—but not for treatment purposes. SAMHSA explicitly excluded care coordination and case management functions from its list of permissible activities because, as discussed in the preambles to the 2017 and 2018 rules, SAMHSA deems those functions to include a treatment component. Plans and state officials argue that the benefits of including care

coordination and case management as permitted activities outweigh the risks of disclosure. They further contend that such activities contribute to patient safety, an activity that SAMHSA lists as falling under health care operations. Classifying care coordination and case management as patient safety activities rather than as treatment would allow payers to redisclose this information to contractors and subcontractors (ACAP 2016, NAMD 2016).

Barriers to information sharing

Even when patient consent to disclose SUD treatment information within the health care system has been obtained, there are other barriers to sharing treatment information.

First, many community-based SUD treatment providers have not adopted EHRs at the same pace as the rest of the health care system (SAMHSA 2017, Williams 2013). Historically, SUD providers did not use electronic records, in part because most SUD care was largely funded through grants, so providers did not bill for individual services. Despite increased insurance participation by these providers and the increasing number of patients receiving SUD treatment who are covered by Medicaid, CHIP, or private insurance, many of these providers continue to share information only by paper, phone, or fax. Slow adoption of EHRs is also due to lack of financial incentives. Most SUD treatment providers were not eligible for the incentives available under the meaningful use program created by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 (Title XIII of P.L. 111-5) (SAMHSA 2017). Those ineligible included psychologists, clinical social workers, community mental health centers, psychiatric hospitals, and residential treatment centers (Dougherty et al. 2013).

Second, even when providers are using EHRs, there are several challenges with the electronic transmission of Part 2-protected data, which must be segmented from other, HIPAA-protected, health information. There are currently no

federal requirements for EHRs to include the functionality to comply with Part 2 and there is disagreement as to whether and to what degree widespread Part 2-compliant interoperability is even technically feasible. For example, ONC and SAMHSA have developed the Data Segmentation for Privacy (DS4P) standard and the Consent2Share software application to manage patient consent preferences and share Part 2-protected information electronically through EHRs and HIEs. But the Health Information Technology Standards Committee advising ONC called into question the maturity of the DS4P standard, suggesting that additional testing and refinements are needed (HITSC 2015).

Additionally, designing and maintaining systems that comply with Part 2 requirements (including incorporating updates such as those made by the 2017 and 2018 Part 2 regulatory changes) can be costly (Netsmart 2017, SAMHSA 2017, CIHS 2014, Williams 2013). As a result, many EHRs and HIEs simply omit SUD treatment information from the rest of a patient's medical record and SUD treatment providers are often excluded from participation in HIEs (RTI 2014).

Some stakeholders, particularly patient advocates who are supportive of the current Part 2 rules, hold a different view of the capability of EHRs to handle Part 2 information. They argue that state laws already require heightened protections for sharing of other sensitive health data, such as for HIV/AIDS, mental health, reproductive health, and domestic violence, so existing EHR systems must be capable of segmentation for these purposes. Similarly, under federal HIPAA regulations, psychotherapy notes maintained in an EHR must also be segregated from the rest of a patient's record. These stakeholders contend that tools such as DS4P and Consent2Share allow for the necessary segmentation of such data (Reid 2018).

Finally, prescription drug monitoring programs (PDMPs), which are meant to help providers avoid potentially fatal drug interactions, help clinicians identify patients who may be at risk for

prescription drug misuse, and identify providers with inappropriate prescribing patterns, often lack information on pharmacotherapies used to treat SUDs (ASAM 2018, State Attorneys General 2016, PDMP COE 2014). Part 2 permits opioid treatment programs that dispense methadone or buprenorphine and Part 2 providers with DATA-2000 waivers to prescribe buprenorphine to report to PDMPs, if the patient gives consent. However, SAMHSA advises these providers to not share information with PDMPs because it is SAMHSA's view that it is not feasible for PDMPs to protect such information from redisclosures prohibited by Part 2 (SAMHSA 2011). Because PDMPs often originated as a criminal justice tool, there is particular concern that law enforcement may have access to protected information (Knopf 2016).

Commission Recommendations

In this report, the Commission makes two recommendations to address the widespread confusion among health care providers and payers of care for Medicaid and CHIP enrollees with SUDs about the ability to exchange health information for treatment purposes. Adoption of the second recommendation is contingent on adoption of the first, because educational and technical assistance activities should focus on disseminating the contents of clarifying guidance.

As this report went to print, SAMHSA and ONC jointly issued two fact sheets with scenarios illustrating how Part 2 may apply to certain providers, patient information, and disclosures made using electronic health information exchange. The Commission has not had the opportunity to review this new guidance and evaluate the extent to which it addresses our recommendations. We appreciate SAMHSA and ONC's effort and look forward to analyzing the impact of this guidance as we continue our work in this area.

Recommendation 2.1

The Secretary of Health and Human Services should direct relevant agencies to issue joint subregulatory guidance that addresses Medicaid and CHIP provider and plan needs for clarification of key 42 CFR Part 2 provisions.

Rationale

This recommendation calls for subregulatory guidance from HHS to further clarify several key aspects of the Part 2 regulations that Medicaid and CHIP stakeholders have identified as ambiguous and confusing. HHS should ensure that such guidance does not add any additional complexity that would further exacerbate confusion and provider reluctance to share information. At a minimum, guidance should provide clear and consistent definitions and explanations of the following:

- which providers are covered by Part 2, including whether providers prescribing buprenorphine or SUD specialists practicing in multispecialty settings are covered;
- the meaning of the phrase “holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment”;
- which information must be protected, including that related to non-SUD medical care delivered to patients in SUD treatment settings, medical care for illnesses associated with SUD, and medications used to treat SUD;
- which entities or individuals within a Part 2 program can share SUD information with each other without patient consent and whether SUD information must be segregated in EHRs accessible to other providers within the Part 2 program; and
- when a patient can use a general designation to identify recipients to whom information is to be disclosed, and when a treating provider

relationship exists (e.g., whether a care coordinator falls into this category).

Guidance should also include sample consent forms that specify the granularity required by Part 2 and how to opt in or out of data sharing and redisclosures.

Comments submitted in response to Part 2 rulemaking and discussions during MACPAC's expert roundtable suggest that providers and payers may be misinterpreting the regulations because of their ambiguity and complexity. This may lead to unnecessary self-imposed restrictions on information sharing, affecting delivery of whole-person care to Medicaid and CHIP enrollees with SUDs.

Clarifying Part 2 may help promote more information sharing, as currently permitted, without requiring further regulatory changes. SAMHSA has already noted that additional subregulatory guidance might be helpful in some of these areas, and Medicaid directors, MCOs, providers, and others have also requested additional clarification. Such guidance should also lead to more consistent and appropriate application of Part 2.

In developing new guidance, the Secretary should solicit input from affected stakeholders and provide opportunities for the review of draft content. The Secretary should also involve all relevant agencies and staff with a role in implementing Part 2 as well as those whose work with HIPAA, Medicaid, and CHIP intersects with Part 2. This would include, but not be limited to, SAMHSA, the Centers for Medicare & Medicaid Services (CMS), ONC, and the HHS Office for Civil Rights (OCR).

Because providers and plans are generally also subject to HIPAA privacy and disclosure requirements, guidance should discuss the interaction between HIPAA and Part 2 requirements and provide assistance in determining which rules apply in a given scenario. SAMHSA last provided such information in 2004, but has not issued an update reflecting the 2017 and 2018 changes to Part 2 (SAMHSA 2004). For compliance purposes,

HHS should give affected stakeholders sufficient time to make any necessary adjustments to their practice following issuance of subregulatory guidance.

The Commission recognizes that some stakeholders are seeking more fundamental changes that would permit sharing of most SUD-related information inside the health care system without requiring patient consent. At this time, the Commission is not prepared to make such recommendations and intends to further study and analyze issues related to the alignment of Part 2 and HIPAA requirements.

Implications

Federal spending. This recommendation would not have a direct effect on federal Medicaid and CHIP spending.

States. Any improved information sharing as the result of clearer guidance has the potential to improve the coordination of SUD treatment and physical health care, and to support related Medicaid- and CHIP-led delivery system and payment reform initiatives. Additional guidance can help states better understand the regulations and improve their ability to exchange enrollee information with plans and providers.

Enrollees. For enrollees with SUDs, additional guidance that helps patients and providers better understand requirements for patient consent may improve care coordination and allay patient concerns that the sharing of their SUD treatment information may cause harm.

Plans and providers. This recommendation would have a direct effect on Medicaid and CHIP MCOs and providers. More definitive guidance on Part 2 would reduce confusion about which providers are subject to Part 2. Similar to the potential effects on states, better plan and provider understanding may foster more consistent and increased data sharing. This, in turn, could improve patient care and consideration of SUDs in delivery system and payment reforms promoting whole-person care.

Recommendation 2.2

The Secretary should direct a coordinated effort by relevant agencies to provide education and technical assistance on 42 CFR Part 2. Such efforts should target state Medicaid and CHIP programs, health plans, primary care and specialty providers, patients and their families, and other relevant stakeholders.

Rationale

Additional subregulatory guidance is necessary but not sufficient to address requests for clarification about confusing and ambiguous Part 2 provisions. In federal rulemaking, SAMHSA has recognized that education and training of staff and patients on Part 2 regulations is needed, but has yet to provide these opportunities. Given Medicaid's significant role in financing SUD treatment, it is the Commission's view that education and technical assistance is needed to ensure that: (1) providers and plans are fully aware of how and when information can be shared; and (2) beneficiaries understand under what circumstances information is protected and when and how they can provide consent to share that protected information with others. Education for patients and their families should also explain the importance of coordinated care and why the disclosure of SUD treatment information to other providers may improve care coordination and health outcomes. Such efforts could also ensure that providers, patients, Medicaid and CHIP managed care plans, state agencies, and other stakeholders understand the more recent changes to Part 2. As with the first recommendation, the Secretary should work with relevant agencies, including but not limited to SAMHSA, CMS, ONC, and OCR.

To maximize the utility of education and technical assistance efforts and further increase their reach, HHS should partner with relevant national and state stakeholder organizations to develop and disseminate information tailored to each constituency. Jointly developed efforts could create multiple channels through which to communicate information to a broader audience. For example, CMS uses informational bulletins to communicate

changes in policy; SAMHSA's Treatment Improvement Protocols are widely recognized among community-based SUD providers; and OCR has experience leading HIPAA-related education and has developed frequently asked questions documents, continuing medical education modules, and training materials for state attorneys general. Patient advocacy organizations and health care provider and health lawyer associations regularly communicate with their members through various avenues.

Implications

Federal spending. This recommendation would not have a direct effect on federal Medicaid and CHIP spending.

States. Providing education and technical assistance to state Medicaid and CHIP officials and other related state agencies can help them better understand what patient information, such as claims data or quality metrics, can be shared with plans and providers. It may also help improve care coordination, leading to improved health outcomes for Medicaid and CHIP beneficiaries.

Enrollees. For enrollees with SUDs, additional education could lead to improved understanding of privacy rights. Education would also inform enrollees of the benefits to them of allowing their protected SUD health information to be shared with their other treating providers.

Plans and providers. This recommendation will benefit Medicaid and CHIP managed care plans and providers to the extent that it reduces confusion about what information is protected by Part 2 and the Part 2 consent requirements. With additional education and technical assistance, plans and providers may be able to develop additional Part 2-compliant processes that increase the sharing of SUD information.

Looking Ahead

Adoption of the Commission's recommendations would be an important step to help alleviate confusion and improve existing opportunities for information sharing and care coordination. Going forward, the Commission is interested in studying additional ways to address concerns about Part 2's effects on care delivery for Medicaid and CHIP enrollees.

First, the Commission remains concerned about barriers to information sharing that negatively affect patients and intends to explore further how Part 2 could be aligned with HIPAA to allow greater sharing of information without patient consent for treatment, payment, and health care operations. The Commission recognizes that there is substantial disagreement about such changes and will therefore want to consider the potential advantages and drawbacks. This will include understanding in greater detail:

- how HIPAA protections differ from Part 2, such as provisions related to disclosures to the criminal justice system and other entities that may discriminate against individuals with SUDs;
- how HIPAA provisions support coordinated care and care integration practices;
- whether less patient control over information disclosures could affect individuals' willingness to seek SUD treatment; and
- the extent to which alignment can be achieved through regulatory changes versus requiring a statutory change.

Second, the Commission notes that the existing Part 2 regulatory framework does not address the limited functionality of most EHR systems to segment data or the low rate of EHR adoption among SUD providers. The current framework also does not adequately address the limitations on the sharing of information by most SUD treatment providers with PDMPs. The Commission

is interested in better understanding these challenges as well as proposals to address them, such as providing financial incentives for EHR adoption to behavioral health providers in Medicaid and establishing national EHR interoperability requirements.

Endnotes

¹ The organization and financing of Medicaid mental health and SUD treatment services varies across states. In some states, managed care plans provide both physical and behavioral health services. In other states, some or all behavioral health services are carved out, either under a capitated arrangement to a plan with specialized expertise or under fee for service. Some states may also limit carve in or carve out arrangements to certain defined populations (MACPAC 2016). Because of the variability in Medicaid benefits and certain federal restrictions on what Medicaid can pay for, other state programs may fund some SUD treatment and recovery support services for Medicaid beneficiaries—most often through a state's substance abuse agency. These services may include residential treatment, case management, peer support, housing supports, and other recovery support services (Pew and MacArthur 2015, Woodward 2015, NASADAD 2010).

² A discussion of 42 CFR Part 2's provisions that are specific to minors and parental involvement in consent to treatment and disclosure of Part 2-protected information is beyond the scope of this chapter.

³ The goal of the roundtable was not to develop recommendations, but to gain insight from a broad array of stakeholders on how to protect SUD treatment information while supporting appropriate information sharing among providers and payers. Specifically, we sought to learn more about the following: (1) why Part 2 protections are needed; (2) how Part 2 affects care delivery, information exchange, care coordination, and new delivery and payment models in Medicaid; and (3) what operational, regulatory, or statutory changes could support the integration of SUD treatment with other medical care while protecting Medicaid enrollees with SUDs from discrimination.

⁴ For example, the Americans with Disabilities Act (P.L.

101-336) and the Fair Housing Act (Title VIII of P.L. 90-284) explicitly exclude individuals engaged in current illegal drug use; individuals entering treatment for substance use disorder would not be protected from potentially losing their jobs were this information disclosed to their employer.

⁵ The statute explicitly excludes application to records exchanged within or between the U.S. Department of Veterans Affairs (VA) and the uniformed services. Disclosure of VA-related information is governed by 38 USC 7332.

⁶ Good cause includes the need to avert a substantial risk of death or serious bodily harm. The statute says that in assessing good cause, the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services (42 USC 290dd-2(b)(2)(C)).

⁷ To redisclose Part 2-protected information to its contractors, subcontractors, or legal representatives, a contract or comparable legal instrument must be in place, which includes language stating that the recipient is fully bound by Part 2's provisions upon receipt of the protected information (42 CFR 2.33). The preamble to the 2018 rule includes a list of illustrative examples of permissible payment and health care operations activities. Examples include the following:

- billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing and related health care data processing;
- clinical professional support services (e.g., quality assessment and improvement initiatives; utilization review and management services);
- patient safety activities;
- accreditation, certification, licensing, or credentialing activities;
- underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care;
- activities related to addressing fraud, waste and abuse;
- conducting or arranging for medical review, legal services, and auditing functions;

- determinations of eligibility or coverage (e.g. coordination of benefit services or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;
- risk adjusting amounts due based on enrollee health status and demographic characteristics; and
- review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges (SAMHSA 2018b).

⁸ In the preamble to the 2017 final rule, SAMHSA suggests that consent form field options can be taken from a generally accepted architecture, such as the Consolidated-Clinical Document Architecture (C-CDA), or document, such as the Summary of Care Record as defined by CMS for the EHR Incentive Programs.

⁹ If the patient makes a “general designation,” the patient can request a “list of disclosures,” that is, a list of parties who received the disclosed information in the previous two years. This request must be in writing. The entity facilitating the information sharing has 30 days following receipt of the patient’s written request to provide the list, which must also include a brief description of the patient identifying information that was disclosed to each party (42 CFR 2.13).

¹⁰ In addition to being subject to HIPAA, certain other sensitive health data—for example, patient data related to HIV/AIDS, mental health, reproductive health, and domestic violence—may also be subject to state laws mandating heightened disclosure protections.

¹¹ The Drug Addiction Treatment Act of 2000 (DATA 2000, P.L. 106-310) requires physicians to take a special eight-hour training course to receive a DATA-2000 waiver which authorizes them to prescribe buprenorphine as part of MAT or for withdrawal management. Depending on the waiver, a physician is limited to prescribing the drug to up to 30, 100, or 275 patients. As part of the Comprehensive Addiction and Recovery Act of 2016 (CARA, P.L. 114-198), advanced practice nurses and physician assistants can also qualify for a waiver for up to 30 patients from 2016 through 2021, but only if their state license includes prescribing authority for Schedule III, IV, or V medications for the treatment of pain (SAMHSA 2018c).

References

- Alliance of Community Health Plans (ACHP), American Association on Health and Disability (AAHD), American Dance Therapy Association (ADTA), et al. 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 12, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0325>.
- All-Payer Claims Database Council (APCD Council). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 11, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0229>.
- American Health Lawyers Association (AHLA). 2017. *42 CFR Part 2 in retrospective: The 20-year journey of the alcohol and drug abuse treatment confidentiality regulations*. Member briefing, May 17. Washington, DC: AHLA. https://www.healthlawyers.org/Members/PracticeGroups/TaskForces/BH/briefings/Documents/42_CFR_Part2_MB.pdf.
- American Psychiatric Association (APA). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 11, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0241>.
- Anthem Inc. (Anthem). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 11, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0244>.
- Arizona Health Care Cost Containment System (AHCCCS). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 12, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0332>.
- Association for Behavioral Health and Wellness (ABHW). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 12, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0261>.
- Association for Community Affiliated Health Plans (ACAP). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 12, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0293>.
- American Society of Addiction Medicine (ASAM). 2018. *Public policy statement on prescription drug monitoring programs (PDMPs)*. Rockville, MD: ASAM. https://www.asam.org/docs/default-source/public-policy-statements/2018-statement-on-pdmpsf406229472bc604ca5b7ff000030b21a.pdf?sfvrsn=63ba42c2_0.
- Beacon Health Options (Beacon). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 12, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0292>.
- Center for Behavioral Health Statistics and Quality (CBHSQ), Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services. 2017. Results from the 2016 National Survey on Drug Use and Health: Detailed tables. Rockville, MD: SAMHSA. <https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2016/NSDUH-DetTabs-2016.htm>.
- Central City Concern (CCC). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 9, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0177>.
- Cerner Corporation. 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 1, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0110>.
- Clark, H.W. 2018. Testimony before the U.S. Senate Committee on Health, Education, Labor and Pensions, February 27, 2018, Washington, DC. <https://www.help.senate.gov/imo/media/doc/Clark6.pdf>.
- Clark, H.W. 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 12, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0324>.
- Clement, T., and T.M. Keeton. 2018. Policy pulse: We must change outdated patient health record privacy regulations. *Kennedy Forum Blog*. February 6. <https://thekennedyforum.org/policy-pulse-we-must-change-outdated-patient-health-record-privacy-regulations/>.
- Colorado State Innovation Model Office (CO SIM). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 12, 2016).

<https://www.regulations.gov/document?D=HHS-OS-2016-0005-0299>.

Curtis, M.A., S. Garlington, and L.S. Schottenfeld. 2013. Alcohol, drug, and criminal history restrictions in public housing. *Cityscape: A Journal of Policy Development and Research* 15, no. 3: 37–52. <https://www.huduser.gov/portal/periodicals/cityscpe/vol15num3/ch2.pdf>.

Department of Health and Mental Hygiene (DHMH), State of Maryland. 2015. *Joint chairmen's report on specialty behavioral health information sharing: Improving the exchange and coordination of care for Medicaid-eligible individuals accessing specialty behavioral health services*. November 2015. Baltimore MD: DHMH. <https://mmcp.health.maryland.gov/Documents/JCRs/datasharingJCRfinal11-15.pdf>.

Dougherty, M., M. Williams, M. Millenson, and J. Harvell. 2013. *EHR payment incentives for providers ineligible for payment incentives and other funding study*. Washington, DC: Office of Disability, Aging and Long-Term Care Policy, Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. <https://aspe.hhs.gov/system/files/pdf/76706/EHRPI.pdf>.

Drug & Alcohol Service Providers Organization of Pennsylvania (DASPOP). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (March 22, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0060>.

Electronic Privacy Information Center (EPIC). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 12, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0265>.

FindLaw. 2018. The Americans with Disabilities Act and “current” illegal drug use. New York, NY: Thomson Reuters. <http://corporate.findlaw.com/litigation-disputes/the-americans-with-disabilities-act-and-current-illegal-drug.html>.

Health IT Standards Committee (HITSC). 2015. Letter from Jon White and John Halamka to the National Coordinator for Health Information Technology regarding review of “ONC’s 2015 edition health information technology certification criteria, 2015 edition base electronic health record definition, and ONC health IT certification program modifications (Certification NPRM).” May 29, 2015. https://www.healthit.gov/sites/default/files/facas/HITSC_Cert_NPRM_Transmittal.

[Letter_2015_05_29.pdf](#).

Indiana Family and Social Services Administration (IN FSSA). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 11, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0236>.

Knopf, A. 2016. OTPs should not report patient information to PDMPs, but should use PDMPs for patient care. *Addiction Treatment Forum*, August 11. <http://atforum.com/2016/08/otps-report-patient-information-pdmps-patient-care/>.

Legal Action Center (LAC). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 12, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0310>.

Lopez, K., and D. Reid. 2017. Discrimination against patients with substance use disorders remains prevalent and harmful: The case for 42 CFR Part 2. *Health Affairs Blog*, April 13. <https://www.healthaffairs.org/doi/10.1377/hblog20170413.059618/full/>.

Los Angeles County Substance Abuse Prevention and Control (LACSAPC). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 12, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0331>.

McCarty, D., T. Rieckmann, R.L. Baker, and K.J. McConnell. 2016. The perceived impact of 42 CFR Part 2 on coordination and integration of care: A qualitative analysis. *Psychiatric Services* 68, no. 3: 245–249. <https://ps.psychiatryonline.org/doi/ref/10.1176/appi.ps.201600138>.

Medicaid and CHIP Payment and Access Commission (MACPAC). 2017. Chapter 2: Medicaid and the opioid epidemic. In *Report to Congress on Medicaid and CHIP*. June 2017. Washington DC: MACPAC. <https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf>.

Medicaid and CHIP Payment and Access Commission (MACPAC). 2016. Chapter 4: Integration of behavioral and physical health services in Medicaid. In *Report to Congress on Medicaid and CHIP*. March 2016. Washington DC: MACPAC. <https://www.macpac.gov/publication/integration-of-behavioral-and-physical-health-services-in-medicaid/>.

Mental Health America (MHA). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 12, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0273>.

National Academies of Sciences, Engineering, and Medicine (NAEM). 2016. *Ending discrimination against people with mental and substance use disorders: The evidence for stigma change*. Washington, DC: The National Academies. <https://www.nap.edu/catalog/23442/ending-discrimination-against-people-with-mental-and-substance-use-disorders>.

National Association of Medicaid Directors (NAMD). 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 12, 2017). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0285>.

National Association of State Alcohol and Drug Abuse Directors (NASADAD). 2010. *The effects of health care reform on access to, and funding of, substance abuse services in Maine, Massachusetts, and Vermont*. Washington, DC: NASADAD.

National Institute on Drug Abuse (NIDA), National Institutes of Health, U.S. Department of Health and Human Services. 2010. *Comorbidity: Addiction and other mental illnesses*. Rockville, MD: NIDA. <https://www.drugabuse.gov/sites/default/files/rcomorbidity.pdf>.

Netsmart. 2017. SAMHSA makes progress with 42 CFR Part 2 final rule; more still needed. *Netsmart CareThreads Blog*, January 17. <https://carethreads.ntst.com/2017/01/17/netsmart-samhsa-makes-progress-with-42-cfr-part-2-final-rule-more-still-needed/>.

Northwell Health. 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 12, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0336>.

Partnership to Amend 42 CFR Part 2 (Partnership). 2017. Letter from Rebecca Murow Klein to Chris Christie, Chair of the White House Commission on Combatting Drug Addiction and the Opioid Crisis, regarding “Changes to federal regulations governing the confidentiality of drug and alcohol treatment and prevention records.” May 3, 2017. <http://www.helpendopiodcrisis.org/wp-content/uploads/2017/08/Partnership-to-Amend-42-CFR-Part-2-Letter-to-Opioid-Commission.pdf>.

Pew Charitable Trusts and MacArthur Foundation (Pew and MacArthur). 2015. *Substance use disorders and the role of the states*. Washington, DC: Pew. <http://www.pewtrusts.org/~media/assets/2015/03/substanceusedisordersandtheroleofthestates.pdf>.

Prescription Drug Monitoring Program Center of Excellence (PDMP COE). 2014. *Briefing on PDMP effectiveness*. Boston, MA: Heller School of Social Policy and Management at Brandeis University. http://www.pdmpassist.org/pdf/COE_documents/Add_to_TTAC/Briefing%20on%20PDMP%20Effectiveness%203rd%20revision.pdf.

Reid, D., Legal Action Center. 2018. Public comment before the Medicaid and CHIP Payment and Access Commission, January 25, 2018, Washington, DC. <https://www.macpac.gov/wp-content/uploads/2017/07/January-2018-MACPAC-Meeting-Transcript.pdf>.

RTI International (RTI). 2014. *Behavioral health data exchange consortium: ONC state health policy consortium project final report*. Report to the Office of the National Coordinator for Health Information Technology (ONC), contract no. HHSP23320095651WC. June 2014. Research Triangle Park, NC: RTI. https://www.healthit.gov/sites/default/files/bhdeconsortiumfinalreport_06182014_508_compliant.pdf.

Rosecrance Health Network. 2017. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (February 19, 2017). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0429>.

Stone, R. 2015. Pregnant women and substance use: Fear, stigma, and barriers to care. *Health and Justice* 3, no. 2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5151516/>.

SAMHSA-HRSA Center for Integrated Health Solutions (CIHS). 2014. *The current state of sharing behavioral health information in health information exchanges*. Washington, DC: CIHS. https://www.integration.samhsa.gov/operations-administration/HIE_paper_FINAL.pdf.

State attorneys general. 2016. Comment letter on proposed rule: Confidentiality of substance use disorder patient records (April 12, 2016). <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0333>.

Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services.

2018a. *January 31, 2018 SAMHSA 42 CFR part 2 listening session transcript*. Rockville, MD: SAMHSA. <https://www.samhsa.gov/sites/default/files/42cfrpart2listening-session-securitylist.pdf>.

Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services. 2018b. Confidentiality of substance use disorder patient records. Final Rule. *Federal Register* 83, no. 2 (January 3): 239–252. <https://www.federalregister.gov/documents/2018/01/03/2017-28400/confidentiality-of-substance-use-disorder-patient-records>.

Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services. 2018c. *Buprenorphine waiver management*. Rockville, MD: SAMHSA. <https://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/buprenorphine-waiver>.

Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services. 2017. Confidentiality of substance use disorder patient records. Final Rule. *Federal Register* 82, no. 11 (January 18): 6052–6127. <https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records>.

Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services. 2016. *Co-occurring disorders*. Rockville, MD: SAMHSA. <https://www.samhsa.gov/disorders/co-occurring>.

Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services. 2011. Letter from H. Westley Clark to staff in opioid treatment programs (OTPs) regarding “Encouragement to utilize state prescription drug monitoring programs (PDMPs) as an additional resource to maximize safety of patient care pursuant to applicable state guidelines.” September 27, 2011. https://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/dear_colleague_letters/2011-colleague-letter-state-prescription-drug-monitoring-programs.pdf.

Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services. 2004. *The confidentiality of alcohol and drug abuse patient*

records regulation and the HIPAA privacy rule: Implications for alcohol and substance abuse programs. Rockville, MD: SAMHSA. <https://www.samhsa.gov/sites/default/files/part2-hipaa-comparison2004.pdf>.

U.S. Commission on Civil Rights (USCCR). 2000. Chapter 4: Substance abuse under the ADA. In *Sharing the dream: Is the ADA accommodating all?* Washington, DC: USCCR. <http://www.usccr.gov/pubs/ada/ch4.htm>.

van Boekel, L.C., E.P.M. Brouwers, J. van Weeghel, and H.F.L. Garretsen. 2013. Stigma among health professionals towards patients with substance use disorders and its consequences for healthcare delivery: Systematic review. *Drug and Alcohol Dependence* 131, no. 1–2: 23–35. [http://www.drugandalcoholdependence.com/article/S0376-8716\(13\)00067-7/fulltext](http://www.drugandalcoholdependence.com/article/S0376-8716(13)00067-7/fulltext).

Wakeman, S., and P. Friedman. 2017. Outdated privacy law limits effective substance use disorder treatment: The case against 42 CFR Part 2. *Health Affairs Blog*, March 1. <https://www.healthaffairs.org/doi/10.1377/hblog20170301.058969/full/>.

Williams, A.B. 2013. *Issue brief: Behavioral health and health IT*. Washington, DC: The Office of the National Coordinator for Health Information Technology. https://www.healthit.gov/sites/default/files/bhandhit_issue_brief.pdf.

Woodward, A. 2015. *The CBHSQ report: The substance abuse prevention and treatment block grant is still important even with the expansion of Medicaid*. Rockville, MD: Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/data/sites/default/files/report_2080/ShortReport-2080.html.

Commission Vote on Recommendations

In its authorizing language in the Social Security Act (42 USC 1396), Congress requires MACPAC to review Medicaid and CHIP program policies and make recommendations related to those policies to Congress, the Secretary of the U.S. Department of Health and Human Services, and the states in its reports to Congress, which are due by March 15 and June 15 of each year. The Commission is also directed to examine issues affecting Medicaid and CHIP, including the implications of changes in health care delivery in the United States and in the market for health care services on such programs. Each Commissioner must vote on each recommendation, and the votes for each recommendation must be published in the reports. The recommendations included in this report, and the corresponding voting record below, fulfill this mandate.

Per the Commission’s policies regarding conflicts of interest, the Commission’s conflict of interest committee convened prior to the vote to review and discuss whether any conflicts existed relevant to the recommendations to clarify regulations governing the exchange of health information that would identify Medicaid and CHIP enrollees as having or having had a substance use disorder. It determined that, under the particularly, directly, predictably, and significantly standard that governs its deliberations, no Commissioner has an interest that presents a potential or actual conflict of interest.

The Commission voted on Recommendation 2.1 and Recommendation 2.2 on March 1, 2018.

Clarification of Key Provisions Governing Health Information Privacy under 42 CFR Part 2

<p>2.1 The Secretary of Health and Human Services should direct relevant agencies to issue joint subregulatory guidance that addresses Medicaid and CHIP provider and plan needs for clarification of key 42 CFR Part 2 provisions.</p> <p>Yes: Burwell, Carter, Cerise, Cruz, Davis, Douglas, George, Gold, Gorton, Lampkin, Milligan, Retchin, Scanlon, Szilagyi, Thompson</p> <p>Not Present: Gordon, Weil</p>	<table border="1" style="background-color: #f2f2f2; border-collapse: collapse;"> <tr> <td style="padding: 5px;">15</td> <td style="padding: 5px;">Yes</td> </tr> <tr> <td style="padding: 5px;">2</td> <td style="padding: 5px;">Not Present</td> </tr> </table>	15	Yes	2	Not Present
15	Yes				
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<p>2.2 The Secretary should direct a coordinated effort by relevant agencies to provide education and technical assistance on 42 CFR Part 2. Such efforts should target state Medicaid and CHIP programs, health plans, primary care and specialty providers, patients and their families, and other relevant stakeholders.</p> <p>Yes: Burwell, Carter, Cerise, Cruz, Davis, Douglas, George, Gold, Gorton, Lampkin, Milligan, Retchin, Scanlon, Szilagyi, Thompson</p> <p>Not Present: Gordon, Weil</p>	<table border="1" style="background-color: #f2f2f2; border-collapse: collapse;"> <tr> <td style="padding: 5px;">15</td> <td style="padding: 5px;">Yes</td> </tr> <tr> <td style="padding: 5px;">2</td> <td style="padding: 5px;">Not Present</td> </tr> </table>	15	Yes	2	Not Present
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