April 11, 2016

Ms. Kana Enomoto
Acting Administrator
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockville, MD 20852

RE: Comments on Confidentiality of Substance Use Disorder Patient Records Proposed Rule (SAMHSA-4162-20)

Dear Ms. Enomoto:

On behalf of the nation’s Medicaid Directors, we appreciate the opportunity to comment on the proposed rule titled, “Confidentiality of Substance Use Disorder Patient Records” (SAMHSA-4162-20).

The National Association of Medicaid Directors (NAMD) is a bi-partisan, non-profit association representing Medicaid Directors in all 50 states, the District of Columbia, and the territories. Medicaid programs are the largest payer of behavioral health services in the nation and are increasingly responsible for the health coverage for beneficiaries affected by substance use disorders (SUDs). In 2009, Medicaid provided 1 out of every 5 dollars spent on SUD treatment, and the program is expected to account for 28 percent of spending on SUD services by 2020.1

NAMD welcomes SAMHSA’s acknowledgement that the current Confidentiality of Alcohol and Drug Abuse Patient Records regulations are outdated and present a significant barrier to high-quality services for those with SUDs. We share SAMHSA’s goal – and more broadly that of the U.S. Department of Health and Human Services – to ensure individuals with SUDs can benefit from new and emerging integrated care models and appropriate management and exchange of health information. We appreciate the proposed changes that seek to do this, specifically the new general “to whom” designation.

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We also share SAMHSA’s concern that privacy must be safeguarded to ensure individuals are not deterred from seeking treatment. We take seriously the need to protect SUD information records from being used to support law enforcement activities. We appreciate the difficult task SAMHSA faced in trying to balance the goals of privacy and allowing those with SUD to benefit from improvements in care delivery.

We are, however, concerned these proposed changes do not sufficiently accommodate the movement to collaborative care and more rapid and comprehensive communication between providers. We also believe some aspects of the proposed regulation may reverse or undermine steps SAMHSA has already taken to advance our shared goals around care coordination for those with SUD. Therefore, we respectfully request that SAMHSA reconsider available policy options – including working with the Congress to articulate any statutory barriers. We call on SAMHSA and its partners throughout the Administration to revisit the Part 2 restrictions and advance policies which enhance alignment and support integrated care models for Medicaid eligible individuals with a SUD. Our overarching recommendations are listed below, and enclosed we provide more detailed comments on the provisions of the proposed rule.

We request that SAMHSA revise the proposed rule to better support the care coordination and information exchange which ensures patient safety and positive outcomes. Given the dominant role of Medicaid as a payer of SUD screening, prevention and treatment services, NAMD’s members are working to address historical bifurcation in service delivery for affected enrollees. State Medicaid agencies are doing this through an array of person-centered models and approaches, including but not limited to health homes, coordinated care entities, and accountable care organizations. According to NAMD’s 2015 Medicaid Operations Survey, 92 percent of respondents were implementing or exploring a behavioral healthcare innovation in their program.² These models of person-centered care require engagement from ALL of an individuals’ providers in order to ensure care is seamlessly coordinated across the delivery system, including medical/surgical, SUD and social services. However, 42 CFR Part 2 denies individuals with SUD the benefits of tools that are available to all other individuals with chronic diseases. Medicaid Directors initially raised these concerns in a June 2014 letter on Part 2 and SAMHSA’s interpretation of the underlying statute.

We ask SAMHSA to align the regulations for substance use disorder data with the privacy requirements that govern all other health information, where possible. We believe doing so would result in a more appropriate balance of the social harms related to disclosure of information and the medical harm and overdose deaths related to poor coordination of care. The preamble states that SAMHSA is seeking to ensure individuals are not made more vulnerable by seeking SUD treatment. But it is possible that individuals receiving treatment in a Part 2 program could be more vulnerable by reason of the non-availability of their patient record than an individual with an SUD who does not seek treatment. This is particularly true for persons receiving medication-assisted treatment (MAT) and utilizing methadone or buprenorphine in a Part 2

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program. Because of the barriers to information sharing that are perpetuated under the proposed rule, it will be unknown to other providers if the person is receiving a prescription opiate from specialty SUD providers. This can lead to overdose and death. Further, NAMD believes the rule discourages the very models of integrated care Medicaid and other public payers are working to offer to vulnerable and complex populations, including individuals with SUDs. SAMHSA must seek a more appropriate balance between privacy, patient safety, and high-quality, coordinated care.

We recognize that 42 U.S.C § 290dd-2 is more prescriptive than the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and may require that SUD information be subject to more stringent limitations on use and disclosure under Part 2 than it is under the HIPAA privacy rule. Nevertheless, SAMHSA has significant latitude under 42 U.S.C § 290dd-2 to align certain elements of Part 2’s requirements with corresponding requirements of the HIPAA privacy rule. In particular, SAMHSA should address the consent in a way that better aligns them with HIPAA. In doing so, SUD information would remain subject to the same stringent limitations required under the statute – including the important prohibition against use of covered information for criminal charges or criminal investigation. But consent would be handled in a manner that minimizes the complexity and administrative burden involved in complying with both Part 2 and the HIPAA rules.

Further, by aligning Part 2 with the HIPAA rules where possible, SAMHSA would not treat SUD treatment data differently than other types of health care data in circumstances where the underlying statute has not required different treatment. This is significant at a time when we are focused on ensuring parity in access to services. The inequity in the treatment of SUD information has widespread implications on care delivery and outcomes for Medicaid eligible patients and conflicts with SAMHSA’s stated goals for the proposed rule. While complete alignment with HIPAA may not be possible, SAMHSA can take more significant action than that which is currently proposed to bring the treatment of SUD data and the treatment of the patients with a SUD in line with all other types of health care data and patients receiving such care.

SAMHSA should apply the proposed exception under Qualified Service Organizations (QSOs) to third party payers and other holders of Part 2 information. This change would permit state Medicaid agencies, or other third party payers, to fulfill core functions and comply with efficiency requirements under the Medicaid statute. As you know, Medicaid programs must carry out a range of administrative functions as a third party payer of SUD to ensure the quality of services and safeguard against fraud, waste and abuse. Much like SUD providers, third party payers, including Medicaid, outsource functions (e.g., data analytics, clinical support and program integrity activities, etc.) or utilize services from contractors and third party vendors to serve beneficiaries (e.g., managed care entities, organizations providing clinical expertise, entities providing data analytic support, etc.). To the extent these functions involve access to claims data or other SUD information maintained by Medicaid, the agency must be able to provide access to this information to the contractor or service provider. NAMD believes the proposed changes to Part 2 fail to permit Medicaid agencies or other third party payers to fulfill these core functions and needs.
SAMHSA must revise the rule to clarify that state Medicaid agencies are permitted to share data to audit and oversight entities, consistent with their responsibility to respond to lawful audit or evaluation requests. Medicaid programs are jointly administered by the states and federal government; therefore, they are subject to state and federal oversight. It is not uncommon for Medicaid agencies to provide access to claims data in the course of audits and evaluations for oversight entities, including to the HHS Office of the Inspector General and the Government Accountability Office, its state program integrity unit, among others.

Finally, we encourage SAMHSA to add education initiatives to the national agenda. These should be designed to help consumers understand how their SUD and other health information is protected, shared, used and disclosed.

Again, we appreciate SAMHSA’s willingness to tackle the complex and important issue of 42 CFR Part 2. Further, we wish to emphasize that NAMD and our members are committed to working with SAMHSA and your colleagues in other parts of the Department of Health and Human Services to address our concern with 42 CFR Part 2 and ensure high-quality, coordinated care for those with SUD. We look forward to an ongoing engagement on this issue.

Sincerely,

Thomas J. Betlach
Arizona Health Care Cost Containment System Director
State of Arizona
President, NAMD

John B. McCarthy
Director
Ohio Department of Medicaid
State of Ohio
Vice-President, NAMD
NAMD Recommendations on SAMHSA Proposed Rule: Confidentiality of Substance Use Disorder Patient Records

In addition to the regulation’s impact on Medicaid’s ability to function as a payer, Medicaid Directors have four main concerns with SAMHSA’s interpretation of Part 2 as it relates to patient care and health outcomes. The recommendations we offer in the sections that follows emerge from these four concerns, which include:

- **Part 2 prevents individuals with SUD from fully benefiting from advancements in health information exchange (HIE).** The rule aptly points out that current regulations do not reflect the evolving role of health information technology in care delivery. Though the rule tweaks the consent requirements, it maintains the need for a separate consent that must name the care coordination entity or HIE. This will continue to decrease the chance that individuals with SUD will receive the benefits of health information technology. Separate and time-limited consent will still require HIEs to have separate IT solutions and “segmented consent,” which have not proven effective due to the complexity for IT vendors and cost to providers. For instance, SAMHSA has invested significant resources in this area but state Medicaid Directors are aware of only extremely limited uptake among providers. As HIEs often do under the current rules, separate consent will encourage them to exclude SUD treatment from coordinated care models and approaches. Innovative delivery models that rely on HIE may also not fully benefit those with SUD. For example, an electronic care coordination tool accessible to all health home providers may have limited impact if providers have to check multiple sources for waivers and disclosures.

The Centers for Medicare and Medicaid Services (CMS) is attempting to tackle the limited participation of SUD providers in HIE. States welcome the recent CMS guidance which permits them to claim 90 percent federal matching funds for the costs of connecting providers in the EHR Incentive Program to others, such as SUD treatment providers. While this may start to offset the cost burden, states and providers will continue to face the complex requirements of operationalizing Part 2 in HIE, which we expect will continue to inhibit uptake. Therefore, CMS’ new funding for HIE could be maximized through more substantial revisions to Part 2.

- **It disadvantages patients with SUD and puts them at safety risk.** The rule appears to keep individuals from receiving integrated care delivery or participating in person-centered models that are built on the foundation of integration (i.e., ACOs or health homes). SAMHSA would discourage this integration by requiring general medical practices to comply with the costly and burdensome Part 2 requirements if they choose to house a specialty SUD treatment provider. This is a step backwards in the movement towards high quality, person-centered care. Further, the consent requirements – even with the general “to

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whom” designation – still requires patients to anticipate what care they will need from whom in the future. They must regularly update consents and identify the name of any care coordination entity, or they will not receive appropriate level of attention and supports that providers would otherwise give to any patient with a known chronic disorder. Perhaps most troubling, the proposed rule will continue to put patients at risk for overdose and death by segmenting certain controlled substances off from the rest of health care.

- **It limits the number and capacity of SUD treatment providers.** The proposed regulations generally retain the administrative requirements of Part 2 that place a significant cost burden on providers. As a result, the SUD treatment system is likely to remain small and isolated from general health care providers. For example, the separate consent requirements of 42 CFR Part 2 require SUD providers to bear the expense of constantly updating and re-doing consents. Likewise, in order to have electronic health records, these providers have to bear the expense of systems that can track and manage the complicated 42 CFR Part 2 consent requirements. Such costs, and others resulting from the rule, keep Part 2 providers from deducting resources to new staff, services or other practice redesign initiatives that would improve access to care.

- **Part 2 prevents integration of physical and behavioral health services and collaboration between providers.** As previously mentioned, the current interpretation of Part 2 places a significant administrative burden and cost on providers and creates liability concerns for general health care organizations. This discourages integration of substance use disorder services into general health care settings. More importantly, the new language SAMHSA proposed appears to expand the information that is considered to be covered under Part 2 to certain providers within general medical practices. This creates another major disincentive for general medical practices and mental health providers to add staff with specialized expertise in substance abuse treatment. For example, in order to have a SUD expert on staff, general medical practices would have to modify their electronic health record system, create a separate consent process, and likely hire additional administrative staff. This could have negative consequences for patients and providers who are seeking to serve them by promoting bifurcation, discouraging integration of services, and reducing access to care. For example, a state may not be able to recruit practices to serve as health homes, if the staffing model requires the health home to include a SUD professional. This runs counter to the push to improve care delivery and outcomes through physical and behavioral health integration.

NAMD believes these concerns can largely be remedied through the recommendations in the sections that follow. Further, we also welcome an ongoing dialogue with SAMHSA on the application of these recommendations and any further refinements that are necessary to improve patient care and safeguard privacy under the statute.
CONSENT

1. The most appropriate way to safeguard the privacy of SUD information without hindering high-quality, coordinated care is to align Part 2 requirements for confidentiality with requirements applicable to other health information, where alignment is possible. Medicaid Directors believe SAMHSA should use its significant latitude under 42 U.S.C § 290dd-2 to better align these regulations with the privacy regulations issued under Health Insurance Portability and Accountability Act of 1996 (HIPAA). The privacy protections issued under HIPAA have broad applicability in terms of both the information and the parties subject to the rule. Although many actors in the health care industry were already subject to privacy requirements under state and federal law (including Part 2 and, in the case of state Medicaid agencies, privacy regulations issued under the Social Security Act), the introduction of the HIPAA privacy standards brought much needed attention to the issue of how health information could and should be used and disclosed. It also, for the first time, brought an appreciable level of uniformity around certain issues, such as what a valid consent to use or disclose health information should look like.

While we understand that total alignment with HIPAA’s privacy requirements is not possible, we believe the statute could permit greater consistency with such requirements. Specifically, 42 U.S.C § 290dd-2 provides that SUD information may be disclosed with the patient’s prior written consent, as further prescribed by regulation. Nothing in 42 U.S.C § 290dd-2, however, dictates the particular form or content of such consent. While we understand the rationale behind setting standards in this area, the vast majority of programs and third party payers are already subject to, and comply with, form and content standards under the privacy rule that are similar, but not identical, to those currently set forth in Part 2.

Given the strides made in this area towards consistency, it is disappointing that SAMHSA has not chosen to align the requirements for a written consent under Part 2 with the requirements for a valid authorization under the HIPAA privacy rule. In fact, the proposed rule would add even more complexity in this area, increasing the burden on programs and payers alike. The misaligned consent requirements also perpetuate a paternalistic view of individuals with a SUD as somehow less able to make decisions related to their own care than individuals who do not have a SUD. The misaligned consent requirements also threaten patient safety by preventing coordination of SUD treatment and physical healthcare. For example, a patient receiving methadone as medication-assisted treatment may be prescribed opiates for pain – including methadone – by a physical health provider, creating the risk of overdose. For these reasons, we respectfully ask that SAMHSA use this opportunity to support meaningful alignment between Part 2 and HIPAA in the area of consent.

Finally, if SAMHSA does not believe it is permissible to align the consent requirements with
HIPAA, we request that the agency’s response to comments include a description and justification of why such alignment is not feasible under the statute.

2. If alignment with HIPAA is not possible, patients should, at a minimum, have the option to give a global consent for all treating providers and care coordination entities (§2.31(a) and §2.31(b)). Medicaid Directors appreciate the change the rule makes to consent, which would allow for consent to name an entity and “all my treating providers.” This is a small step toward allowing health care information to flow between treating providers. However, it is likely to have limited utility and continues to place an undue burden on patients. It would require that a patient name a specific intermediary organization on their consent if they are using the general “to whom” option, which would assume patients know if there is a relevant care coordination entity and the name of it. Adding further confusion for patients, many states may have multiple HIEs. As an example, a state may have 10 or more HIEs and the patient and provider would need to know which ones to list that are associated with each treating provider. This places a significant burden on patients in order to receive coordinated care. Further, patients would also have to anticipate their future care needs, including care coordination models in which they may not currently participate and HIEs in which their providers may participate in the future. This burden does not exist for individuals with physical health conditions.

This “to whom” approach also places a burden on SUD providers to name the correct intermediaries – for example, the appropriate HIEs for a given patient, if there are multiple HIEs in a state. In this example, and others like it, SUD providers may revert to paper exchange of information because of this burden. This not only would silo patients and deny them the benefits of HIEs, it will also make it extremely difficult for providers to track disclosures, as proposed under §2.13(d). If providers must use a manual tracking process, this will create significant administrative burdens. We also believe this will discourage many providers from disclosing information, even paper form.

Similarly, the alternative approach to consent, in which SAMHSA proposes to define “organization,” is helpful, but also runs into similar concerns in its ability to promote coordinated care. We also read this approach to require that individuals know the name of the intermediary organization and anticipate their future needs if they enroll in such an organization in the future. Once again, this places a major burden on the patient and a burden on the provider, which will limit SUD provider engagement in HIEs and other care coordination tools and models.

Offering patients the option to give a global consent of indefinite duration is more effective than the proposed revision or alternative approach. The option of a global consent empowers patients and permits them to elect to have information shared with all their treating providers and all entities coordinating their care. For example, there could be check boxes indicating whether the patient elects to have their information shared with all treating providers and all care coordination entities/HIEs. It gives patients a choice that they do not
currently have without placing a burden on them, such as naming their current care coordination entity or anticipating future needs. Patients may want to elect this type of consent when it could improve the quality or the coordination of their care.

3. If alignment with HIPAA is not possible, SAMHSA should permit consumers to designate the Medicaid agency or its contracted entities as an intermediary for purposes of consent (§§2.31(a)(4)(iv) and 2.11). As discussed above, the general “to whom” designation or the approach of defining “organization,” would be a helpful first step. We request that SAMHSA maximize the utility of either change by permitting third party payers and managed care entities to serve as intermediaries under the definition of organization in §2.11 or under §§2.31(a)(4)(iv), allowing them to share information with all of the patient’s treating providers. Managed care organizations, by their intent and design, serve as the center of care coordination and are responsible for promoting quality care and patient safety. Similarly, in fee-for-service delivery systems, the state assumes this role or contracts with other entities (i.e., an administrative service organization) to carry out such functions. Allowing the state or its contracted entity to serve as an intermediary and connect with the patients’ physical health providers would maximize their ability to coordinate care for beneficiaries and address major safety concerns, such as drug-drug interactions or risk of overdose.

4. If the patient lists the third-party payer or a payer’s contracted entity (i.e., a MCO) on the consent it should permit both the third party payer and its contracted entities to receive the Part 2 information (§§2.31(a) and §2.31(b)). If SAMHSA does not align consent requirements with HIPAA, but rather finalizes the general “to whom” designation or the definition of “organization,” the regulation should accommodate the operational realities of Medicaid. Medicaid programs are increasingly contracting with managed care organizations for the delivery of services, with nearly 72 percent of Medicaid beneficiaries enrolled in some form of managed care.4 Consumers may not be aware of the differences between the two entities, and may not name both “Medicaid” and the managed care plan on the consent. However, for purposes of payment, the individual’s data must be available to both the MCO and the Medicaid agency. MCOs rely on this health information in order to make appropriate payment to the provider. At the same time, state Medicaid agencies rely on encounter data to carry out its mandatory oversight functions and set appropriate capitation payments to the health plans. Therefore, at a minimum, the final rule must explicitly permit consent to Medicaid or the MCO to apply to both entities as the third party payer.

Further, Medicaid programs and MCOs, much like providers, rely on a range of contracted entities and supports to carry out their duties. These entities, in essence, are an extension of the Medicaid agency or MCO as they support the mandatory functions of the program. Examples of contracted supports to Medicaid may include data analytics, rate setting, program integrity functions, and contracted clinical support. In order to ensure that

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Medicaid programs can carry out its operational requirements, consent that names the Medicaid agency or the MCO should permit disclosure to the entity’s contractors, when necessary. As we discuss below, SAMHSA can further address this concern by applying the qualified service organization exemption to third party payers.

5. SAMHSA should remove the requirement to include in the consent “an explicit description of the substance use disorder information that may be disclosed” (§2.31(a)(3)). We are troubled that the rule would require patients to complete these descriptions in order to receive coordination of care. No similar federal requirement exists for individuals accessing other types of health care services. This new requirement creates an unnecessary burden for patients who wish to have any and all of their substance use disorder information disclosed to their providers. It also necessitates that patients anticipate what future care they will get from the substance use provider. For example, a patient may be receiving cognitive behavioral therapy for an SUD. Three months later, the patient may begin receiving medication-assisted treatment (MAT). The patient would not be able to anticipate this future need, which impede the sharing of this vital information with their physical health providers. In this particular example, and many others like it, the patient is put at risk of drug-drug interactions as a result, and will not receive appropriately coordinated care.

Requiring a description of information in the consent is also problematic because it presumes that the patient and a requesting new health care provider know the format, titling, and nomenclature used for substance use disorder information in the Part 2 program that they are requesting information from. As a result, the Part 2 program is likely to respond, asking the requesting provider to restate the request using the Part 2 program’s nomenclature for formatting substance use disorder information. This will obstruct and delay timely prompt quality treatment and coordinated care.

QUALIFIED SERVICE ORGANIZATIONS

6. The QSO exception to the restrictions on disclosure should include communications between a third party payer or other holder of Part 2 information and a QSO. The QSO definition should also be revised accordingly (§§2.11 “Qualified Service Organization” and 2.12(c)(4)). As we emphasized in our June 2014 letter to SAMHSA, state Medicaid agencies receive and deal with data that might be characterized as falling within Part 2 on a routine basis. Such information is primarily received from Part 2 programs and managed care entities in the form of claims and encounter data. As with all claims and encounter data, such information is integral to the agency’s core function as a government-funded health insurer and to supporting and administrative activities (e.g., third-party liability, outcome evaluation, cost containment, data processing activities, and prescription drug monitoring). Allowing a third party payer to disclose Part 2 data to their contractors and vendors (or their “QSOs” in Part 2 parlance), ensures Medicaid programs can outsource necessary functions and obtain services from outside vendors when the function or service involves the use of Part 2 data.
This position is consistent with the terms of 42 U.S.C § 290dd-2, a point recognized by HHS in 1975 when the concept of a QSO was first introduced. (See Public Health Service, HHS, Confidentiality of Alcohol and Drug Abuse Patient Records, 40 Fed. Reg. 27802, 27806 [July 1, 1975]: Part 2’s “authorizing legislation was not intended to prohibit programs from carrying on accepted practices in terms of obtaining specialized services from outside organizations”). In fact, amending Part 2 to apply the exception under QSOs to third party payers and other holders of Part 2 information would better reflect the intent of Part’s authorizing legislation. The legislation is cast in terms of the information which is to be treated as confidential, and not in terms of the holder of such information on which the duty of confidentiality is imposed. See id.

7. We support the revision of the definition of a qualified service organization (QSO) to include population health management and encourage the inclusion of other functions to support improved care delivery (§2.11 “Qualified Service Organization”). Medicaid Directors share SAMHSA’s intent of promoting population health management, including for those with SUD. Therefore, while it does not address all of Medicaid Directors’ concerns, we agree that other allowable uses of Part 2 data by QSOs, such as population health management, is a positive step toward improving coordination and care delivery. This addition would be maximized by coupling it with the recommendation above (see Recommendation 6). This would ensure that the Medicaid agency or managed care plan is able to carry out its responsibilities and contract with appropriate entities to conduct population health management across all Medicaid beneficiaries with a SUD. In addition, other allowable uses by QSOs would further maximize the utility of the QSO exemption and ensure states’ ability to deliver quality care. Additional functions should include: case management; clinical professional support services (e.g., quality improvement initiatives, utilization review and management services); third party liability and coordination of benefit support services; activities related to preventing fraud, waste and abuse; and other activities and functions typically performed by contractors for or on behalf of third party payers.

APPLICABILITY

8. SAMHSA should not expand the definition of “program” to individuals within a general medical practice whose primary function is the provision of SUD services (§2.11 “Program”). This provision extends Part 2 covered entity status to a large number of general medical practices who do not “hold themselves out” to the public as providing SUD treatment. Specifically, it appears to require general healthcare organizations that hire an individual employee with specialty substance abuse treatment expertise to be considered a covered entity. Given the administrative burden and cost of compliance with Part 2, this discourages general healthcare organizations, such as primary care providers, from integrating SUD treatment services into their predominant treatment operations. For instance, general healthcare organizations may find it advantageous to not deliver
screening, brief intervention, and referral for treatment (SBIRT) or any incidental SUD treatment utilizing staff with specialized training. Ultimately, this only harms care for those with SUD by limiting integration of behavioral health and physical health services and access to care. It will also prevent individuals with an SUD from benefiting from innovations, such as accountable care organizations, health homes, and episode-based payment approaches that are premised on integration of general medical services and behavioral health care.

We believe the most appropriate approach is to retain the existing regulation language rather than finalize the proposed language that would apply Part 2 to individual providers within general medical practices. This will encourage providers to offer specialty substance use disorder treatment internally without compromising the quality of clinical care for their patients and assuming the increased administrative costs and burdens of 42 CFR Part 2.

9. SAMHSA should clarify that 42 CFR Part 2 only applies to emergency department personnel with SUD expertise if the hospital advertises such services to the general public (§2.12(e)(1)). Without clarification, the current regulatory language – specifically the example in §2.12(e)(1) – will continue to discourage emergency departments from hiring staff with specialized expertise in substance use disorders. The current language appears to apply 42 CFR Part 2 to these specialized staff if their primary function “….is provision of a substance use disorder diagnosis, treatment, referral for treatment and they are identified as providing such services.” To encourage the availability of these staff in emergency departments, the rule should not apply if the person staffing the emergency room does not publicly advertise SUD treatment services.

10. The definition of “treatment” should be limited to care for the SUD and not include care of other medical conditions secondary to or that arose because of the SUD (§2.11). Medicaid Directors are concerned the proposed rule will require diagnoses and treatments done in general medical practices, which happen to also house a SUD treatment unit, to fall under 42 CFR Part 2 if the medical care delivered is related to a SUD. For example, liver cirrhosis and hepatitis C are frequently caused by alcoholism and intravenous drug abuse, but the care is typically provided by distinct provider types from the SUD treatment professionals. This broad application of Part 2 will adversely impact these multi-unit health care organizations where most treatment units are of a general medical nature but contains a specialty substance use disorder unit. They would have to apply the burdensome requirements of 42 CFR Part 2 to physical health care that happens to be related to SUDs, such as hepatitis C diagnosis and treatment information. This discourages integration of SUD services into multi-unit practices and creates disparities between providers. Medical providers in a setting without a SUD treatment provider, but treating the same physical health conditions resulting from an SUD, would not have to meet the requirements of Part 2. Whereas a multi-unit practice with a SUD treatment provider would have to ensure these services comply with the requirements of Part 2.
11. SAMHSA should clarify that 42 CFR Part 2 does not apply to community mental health centers that hold themselves out as providing general behavioral health crisis services (§2.12(e)(1)). The current definition is silent on how the application of Part 2 applies to certain behavioral health programs, including community mental health centers. SAMHSA should clarify that Part 2 does not apply to providers who deliver community behavioral health crisis services in general but that make no specific mention of SUD diagnosis, treatment, or referral.

REDISCLOSURE

12. SAMHSA should remove the expansive language in the prohibition on redisclosure (§2.32). While we appreciate the proposed rule’s clarification on the prohibition on redisclosure, we are troubled that it could inappropriately expand this prohibition to health care data that may not be related to an SUD. According to the preamble, any prescription medication that may be used for substance abuse treatment could not be redisclosed by any entity covered under Part 2, unless it is accompanied by further clarification. This is problematic given certain medications are frequently related to a SUD or for another distinct physical health or mental health condition. Consider the following examples:

- Benzodiazepines are routinely used for generalized anxiety disorder, but can also be used to treat alcohol withdrawal. If a Part 2 program is delivering integrated physical and substance use disorder services, this prescription information for benzodiazepines would have to be removed from all HIEs and PDMPs unless it is paired with a non-SUD diagnosis. The same would be true of carbamazepine (an anticonvulsant) and clonidine (a blood pressure medication) since they are routinely used to treat the symptoms of withdrawal states.

- Methadone is most frequently used for withdrawal and maintenance programs, but also used for the treatment of pain. Once again, this information would likely be excluded from redisclosure under the proposal, unless it is accompanied by a diagnosis. This is extremely problematic, given that overdose deaths are disproportionately result from methadone. If the team of treating providers is not aware of a methadone prescription, care could not be appropriately managed by the treating providers. This would exacerbate a very real life threatening medical harms of this drug, and others like it.

SAMHSA must prioritize the safety of patients who are taking these medications (often for physical health conditions) and not add additional barriers to the sharing of this information to the health care treatment team.

13. The final rule should give patients the option to consent to have their information redisclosed to treating providers and care coordination entities (§2.32). The current prohibition on redisclosure imposes an unnecessary burden on patients receiving SUD treatment who wish to have the same level of quality care and coordinated care as persons
in the rest of the health care system. Many patients would choose to want their information shared through redisclosure when they believe it would improve the quality of their care or the coordination of their care. At a minimum, Medicaid Directors believe that patients should have the option to consent to redisclosure of their health information, which would achieve greater alignment with HIPAA. Further, this redisclosure should continue to prohibit information from being shared with law enforcement or for criminal prosecution purposes. Finally, this patient choice could be supported through educational materials and information on this option.

**DISCLOSURES TO PREVENT MULTIPLE ENROLLMENTS**

14. SAMHSA should explicitly allow registries in the form of HIEs and PMDPs to collect and share information about prescription drugs that present safety concerns (§2.34). We recognize that there are unique privacy concerns associated by PDMPs and strongly agree with the need to protect privacy so individuals are not discouraged from seeking treatment. But in order to achieve an appropriate balance between privacy and patient safety, SAMHSA should work with states on a path forward for permitting prescription drug reporting to PDMPs while creating the necessary safeguards.

The rule maintains that registries may continue to be used to prevent multiple enrollments in withdrawal management or maintenance treatment programs. This recognizes the need to prevent multiple enrollments in these programs due to the nature of the substances they prescribe and the potential safety risks to patients. However, the rule does not explicitly allow for similar reporting of medication-assisted treatment prescriptions to HIEs or PDMPs to address the same patient safety concern.

Opiates and other prescription drugs with the potential for abuse have the same physiological and behavioral effects whether they are prescribed by withdrawal management or maintenance treatment program or any other prescribers. Allowing registries in the form of HIEs or PDMPs to disclose these controlled substance prescriptions would prevent multiple prescribing of prescription drugs. This will have a significant impact on prescription drug abuse and overdose, which is a growing concern for Medicaid Directors. In particular, methadone is reported by the Centers for Disease Control and Prevention (CDC) to be involved in 30 percent of prescription overdose deaths. CDC also reports that the death rate from methadone overdoses was nearly 6 times higher in 2009 than in 1999. While buprenorphine abuse and overdose deaths are much rarer, they are rapidly increasing in number. SAMHSA has an opportunity to address this concern and actively fight the epidemic of opiate overdoses by allowing all controlled substances used for substance abuse treatment to be shared on HIEs and PDMPs.

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AUDITS AND EVALUATIONS

15. SAMHSA should explicitly allow a program or a third party payer – i.e., a Medicaid program – to disclose Part 2 information to an auditor or evaluator (§2.53). Part 2 recognizes that the records of a Part 2 program may be the subject of an audit or evaluation by a third party, thus requiring disclosure of Part 2 information by the program to the auditor or evaluator. However, it fails to recognize that a state Medicaid agency is just as often (if not more often) the entity that is the subject of an audit or evaluation, including from the Centers for Medicare & Medicaid Services, the HHS Office of the Inspector General, the state fraud control unit, etc. Part 2’s permission to disclose such information to auditors and evaluators should likewise extend to third party payers. By amending Part 2 to reflect this reality, SAMHSA will better recognize the landscape in which state Medicaid agencies operate and allow them to comply with legally authorized requests for Part 2 information from their auditors and evaluators. Further, these requests would still be subject to the same safeguards imposed on audit and evaluation requests of Part 2 programs and ensure the continued confidentiality of such information. Finally, this change would be consistent with 42 U.S.C § 290dd-2, which identifies an audit or evaluation as a permissible disclosure of SUD information, without regard to the holder of information.

RESEARCH

16. Medicaid programs should explicitly be permitted to contract with entities to conduct data analytics using Part 2 information (§2.52). Under current regulations, Medicaid agencies have faced challenges in carrying out data analytics activities around SUD services through contracted entities. Medicaid programs often rely on contracted entities, such as universities, to provide the specialized capacity it cannot house. Allowing entities covered by HIPAA and subject to the HHS Common Rule to conduct research using Part 2 data is a helpful first step toward addressing this concern. However, a more advisable approach, which we discuss above, is to clarify Medicaid’s ability to allow contracted entities to receive Part 2 information under the QSO exemption. Data analytic services are only one of many essential functions that Medicaid agencies contract to other entities. Applying the QSO exemption to third party payers, therefore, would permit Medicaid to partner with contracted entities for a range of functions, which are essential to program operations.

17. Medicaid agencies and their contractors should be permitted to link Part 2 information to state data sets for purposes of research (§2.52). As currently proposed, the rule prohibits entities from linking Part 2 data with state data sets, even if both data sets are housed within the entity permitted to conduct Part 2 research. Prohibiting these linkages limits Medicaid agencies and their contracted entities’ ability to identify and remedy concerns in the delivery system, such as safety risks, and make data-driven policy decisions. This would prevent Medicaid or its contractor from linking Part 2 information with state public health data, which may, for example, provide critical information on emergency department visits for overdose.
18. SAMHSA should permit Part 2 information that is de-identified and presented in the aggregate to be more readily used in research (§2.52). We believe this is another area where SAMHSA can promote greater alignment with HIPAA, which provides allowances for covered information that is de-identified and presented in the aggregate. Such alignment with the Part 2 provisions would enhance the ability to conduct research that improves care for those with SUDs without putting their safety or treatment information at risk.