

June 24, 2014

Ms. Pamela Hyde
Administrator
Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road
Rockville, MD 20857

RE: Comments on SAMHSA Public Listening Session on Confidentiality of Alcohol and Drug Abuse Patient Records

Dear Ms. Hyde:

On behalf of the states' Medicaid Directors and Mental Health Program Directors, we appreciate the opportunity to comment on the privacy requirements for substance use disorder health information (42 CFR Part 2). This is a critically important issue that has cross-cutting impacts on the programs financed and administered by our respective members.

As background, NAMD is a bipartisan organization which represents Medicaid Directors in the fifty states, the District of Columbia and the territories. This rule is of particular interest to our members because state Medicaid programs are increasingly responsible for the financing, delivery and oversight of services that are implicated by the privacy regulations. Specifically, Medicaid provided \$3.4 billion in medical expenditures to treat the substance use disorders of 1.1 million beneficiaries in 2008.¹

NASMHPD is the member organization representing the state executives responsible for the \$37 billion public mental health service delivery system serving 7.2 million people annually in all 50 states, 4 territories, and the District of Columbia. For NASMHPD's member officials, the rule has proven over time to be a troubling and continuing barrier to holistically addressing the mental health and chronic condition co-morbidities that so often co-occur with a patient's substance use disorders.

Across the country, state Medicaid agencies and providers are rapidly embracing approaches to deliver integrated care through models such as health homes, coordinated care entities, and accountable care organizations. These efforts, which rely on information sharing and team-based care, are primarily focused on improving the delivery of services for Medicaid beneficiaries. However, the fundamental tenets of these models have proved infinitely more challenging and in some case impossible to apply with respect to populations with substance use disorders.

¹ Bouchery, Ellen, Rick Harwood, Rosalie Malsberger, et al., "Medicaid Substance Abuse Treatment Spending: Findings Report," Mathematica Policy Research, Department of Health and Human Services, Sept. 28, 2012, <http://aspe.hhs.gov/daltcp/reports/2012/MSAspend.shtml#execsum>.

Research studies suggest that integrated care may improve health outcomes and reduce mortality for individuals with substance use disorders and comorbid medical problems.² Meanwhile, our members' experiences indicate that the bulk of the regulations at 42 CFR Part 2 are a major barrier to providing high quality, coordinated care for those with substance use disorders covered by Medicaid or receiving care through the public mental health delivery system. While other Medicaid beneficiaries reap the benefit of advances in care delivery, the stringent language of 42 CFR Part 2 limits the flow of vital health information and impedes team-based care for those with substance use disorders. Permitting the transfer of this information for the purposes of treatment, care coordination, and case management would improve the quality of care for those with substance use disorders and allow these individuals to benefit from advances in care delivery.

Development and adoption of electronic health records (EHRs) and health information exchange (HIE) mechanisms have provided new, more efficient and effective tools for coordinating care and realizing our shared goals around improved patient health and outcomes. However, 42 CFR Part 2 has been a barrier that has kept these tools from benefiting individuals with substance use disorders. We appreciate that the Office of the National Coordinator for the Department of Health and Human Services (ONC) plans to work to improve standards, technology, and workflow that enable the electronic collection and management of consent as well as the electronic exchange of related information within existing legal requirements. While we support these goals and the ONC's work, more immediate steps are needed to support coordination of care across providers and government programs.

Our members believe that the underlying policy problems can best be remedied by repealing 42 CFR Part 2 in its entirety, retaining only the existing statutory prohibition against the use of covered drug or alcohol abuse treatment records to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient. We recognize that this would require a statutory change and call on Congress to advance legislative language to repeal the provisions of 42 U.S.C §§ 290dd-3 and 290ee-3 not aligned with the privacy provisions of HIPAA or its underlying regulations, with the exception of the existing statutory prohibition against the use of covered drug or alcohol abuse treatment records to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

In the absence of congressional action, we appreciate the Substance Abuse and Mental Health Administration's (SAMHSA) interim work to mitigate the impediments to improving care for impacted populations. We respectfully request that SAMHSA align federal substance use disorder privacy regulations, to the greatest extent possible, with those federal requirements, primarily found under the Health Insurance Portability and Accountability Act (HIPAA), that govern the privacy of all other types of health information.

In calling for this change, we recognize there are concerns about the disclosure and use of the sensitive information contained in the electronic records of patients with substance use disorders.

² Druss, BG and SA von Esenwein, "Improving General Medical Care for Persons with Mental and Addictive Disorders: Systematic Review," *General Hospital Psychiatry*, 2006 Mar-Apr, 28(2), 145-53, <http://www.ncbi.nlm.nih.gov/pubmed/16516065>.

States take these concerns very seriously and place a high priority on protecting the privacy of Medicaid enrollees and patients of our public mental health system, including information pertaining to substance use disorder treatment.

However, as policymakers have done in all other areas of personal health information, including for those with mental health conditions, they must balance privacy protections with the health, safety and welfare of patients, their families and their communities. We also recommend that education initiatives be added to the national agenda for consumers to help consumers understand how their health information is protected, shared, used and disclosed. We believe the promise of improvements in care and safety stemming from this regulatory change far outweigh concerns about the potential release of sensitive information. Federal and state partners and other stakeholders must do more to help promote this change of culture and public sentiment.

We also want to be clear that we are *not* calling for changes to the penalties for individuals or entities that would violate the modernized privacy regulations nor to other law that protects these individuals. As these individuals receive higher quality care – and ultimately achieve a higher quality of life – patient privacy would continue to be robustly protected through the use of the existing financial penalties already in place to deter inappropriate use of information. Further, patients would also continue to be protected by the Americans with Disabilities Act, which prohibits employment termination based on substance abuse treatment and recovery.

The enclosed document contains our responses to questions in the *Federal Register's* Notice of Public Listening Session on 42 CFR Part 2. We appreciate your consideration of the state experiences reflected in this document.

Our associations are committed to working with SAMHSA and your colleagues in other parts of the Department of Health and Human Services and we look forward to an ongoing, engaging dialogue with you regarding the confidentiality of alcohol and drug abuse records.

Sincerely,

Matt Salo
Executive Director
National Association of Medicaid Directors

Robert W. Glover, PhD.
Executive Director
National Association of State Mental Health
Program Directors

RESPONSE TO QUESTIONS

A. APPLICABILITY OF 42 CFR PART 2

How would redefining the applicability of 42 CFR Part 2 impact patients, health care provider organizations, HIEs, CCOs, HIT vendors, etc.?

Ideally, the Medicaid Directors and Mental Health Program Directors believe the requirements of 42 CFR Part 2 should be repealed in their entirety or alternatively defined in a way that it is operationally identical to the requirements of HIPAA. Any health information privacy requirements related to substance use disorder treatment that differ from the privacy requirements related to general medical care and mental health treatment will always be a barrier to:

- Increasing access to substance use disorder services;
- Integrating substance use disorder services with the rest of health care;
- Ensuring patient safety;
- Providing high-quality medical care to people receiving substance use disorder treatment services; and
- Reducing the stigma of substance use disorders that acts as a disincentive for individuals to seek treatment.

Separate health information privacy requirements for substance use disorder treatment makes it significantly less likely that people with substance use disorders, including Medicaid beneficiaries, will receive the attention and time to support continuing remission. It also makes it less likely that these individuals will have early recurrence identified, which is routinely provided to those with other chronic medical conditions. For example, when providers know a person has had a chronic condition, they inquire about it and look more closely for signs that the person remains healthy in that area. For a patient with a substance use disorder, keeping the condition secret deprives the individual of the additional care and treatment they would receive if they had any other chronic condition.

In addition, the risk of an adverse drug event (ADE) increases if access to medication history is restricted, threatening patient safety and increasing Medicaid costs.³ The health care system spends an amount equal to the cost of the medications themselves due to the associated ADEs.⁴ If access to information about certain prescribed medications is restricted, patients face increased likelihood of ADEs because providers cannot fully assess the risk of prescribing a new medication.

³ Zwicker D, Fulmer T, "Reducing Adverse Drug Events," In: Boltz M, Capezuti E, Fulmer T, Zwicker D, eds. *Evidence-Based Geriatric Nursing Protocols for Best Practice*; 2012. (4): 324-62, <http://www.guideline.gov/content.aspx?id=43938>; FitzGerald RJ, "Medication Errors: the Importance of an Accurate Drug History," *Br J Clin Pharmacol*. June 2009; 67(6): 671-75, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2723207/pdf/bcp0067-0671.pdf>.

⁴ Centers for Disease Control and Prevention, "Medication Safety Basics," Aug. 14, 2012, <http://www.cdc.gov/medicationsafety/basics.html#ref>; New England Healthcare Institute, "A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease," Aug. 2009, http://adhereforhealth.org/wp-content/uploads/pdf/ThinkingOutsidethePillbox_Report.pdf.

ADEs have also been found to increase linearly with the increase in the number of unique medications in the patient's drug regimen.⁵ Further, studies also show that one of the largest drivers of hospital readmissions is inappropriate or unreconciled drug regimens.⁶

Another consequence of the special requirements of 42 CFR Part 2 is that it imposes significant administrative burdens and costs on the providers least able to bear them. Specialty substance use disorder individual treatment providers and organizations are arguably the most underfunded and undercapitalized providers in the health care system.

In addition, 42 CFR Part 2 was implemented well before health information and related technologies were even contemplated, and has not been meaningfully updated to reflect modern technology. As a result, 42 CFR Part 2 adds a financial burden and enormous complexity to health IT initiatives. The added complexity and cost make it likely that substance use disorder information will be omitted altogether from HIEs. Further, the requirements associated with 42 CFR Part 2 necessitate expensive customization of EHRs and requires service providers to commit additional funds and resources to manage EHR integration into their practice workflow. Finally, attempting to segregate substance use disorder information from the EHR is also exceptionally costly and may result in changes that threaten federal certification status for an EHR.

Our members also continue to believe that having separate health information privacy requirements for substance use disorder treatment is discriminatory and perpetuates stigma. The requirements keep persons with substance use disorders and the providers who treat them marginalized and disadvantaged compared to other patients and providers in the health care system. Addressing substance use disorder information in the same manner as other health information would help to break down the barriers of stigma and normalize substance use disorders. It would also help to acknowledge that these disorders are chronic diseases, making patients more likely to have conversations with their providers about their concerns and seek treatment.

We would retain only the provisions of 42 U.S.C §§290dd-3(c) and 290ee-3(c) which prohibit the use of covered drug or alcohol abuse treatment records to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient. The perception that substance use records of an individual in treatment can be used to launch or substantiate a criminal investigation—whether legally justified or not—often does, in fact, serve to discourage individuals needing treatment from seeking that treatment, while the sharing of the information with criminal justice agencies would not further the desired goal of increasing the integration of care for those individuals.

⁵ Silva DCB, Araujo OR, Arduini RG, et al., "Adverse Drug Events in a Paediatric Intensive Care Unit: a Prospective Cohort," *BMJ Open*. 2013, 3:e001868, <http://bmjopen.bmj.com/content/3/2/e001868.full.pdf+html>.

⁶ Institute for Safe Medication Practices and Maryland Patient Safety Center, "Taking Charge of Your Medication Safety Challenges," Nov. 3, 2011, <http://www.marylandpatientsafety.org/html/education/medsafe/2011/documents/SCarson.pdf>; New England Healthcare Institute, "Improving Medication Adherence and Reducing Readmissions," October 2012, <http://www.nacds.org/pdfs/pr/2012/nehi-readmissions.pdf>.

If SAMHSA determines it does *not* have the authority to amend regulations in a way that generally aligns the use of substance use treatment information with the use of all other health information under HIPAA privacy protections as described above, at a minimum, Medicaid Directors and Mental Health Program Directors believe the following regulatory changes would be a positive step forward:

- **The regulation should be limited to substance use disorder specialty treatment services.** The regulation should not cover screening, diagnosis, or referral to specialty treatment. Including screening, diagnosis and referral discourages providers who are not specialty substance use disorder treatment providers from inquiring about substance use concerns and discourages organizations from implementing substance use screening. Further, including health information derived from screening, diagnosis, and referrals under these special rules adds significant analytic complications and costs for integration with health information exchanges.
- **With respect to providers, the regulation should only apply to substance use disorder specialty treatment programs and providers specifically licensed, credentialed, or accredited by generally recognized state and national bodies.** We believe it should not apply to programs and individual treatment providers who have no specialty license, credential, or accreditation specific to specialty substance use disorder treatment. This would more clearly define which providers can be considered covered entities and assure that protected status is only attached to programs and providers that have met a minimum quality standard.

Further, designating substance use disorder specialty providers would also make it easier to connect these providers to the covered health information they generate. This information could be tracked with their provider billing and NPI numbers.

If a credentialing requirement is not applied, at a minimum, the regulation should continue to limit covered entity status only to organizations and individuals that hold themselves out to the public as being substance use disorder specialty treatment providers (as discussed in the previous bullet). This provision gives providers and organizations some control over whether they are considered a covered entity. It also allows them to offer specialty substance use disorder treatment internally to their patients without having to bear the decreased quality of clinical care and increased administrative costs and burdens of 42 CFR Part 2.

In addition, it is important to consider whether and how new rules should apply to specialty substance use disorder treatment providers' information on a retroactive basis. We encourage SAMHSA to work with our associations to dialogue with Medicaid Directors and Mental Health Program Directors on the best timing and approach to implementation.

- **The regulation should not apply to individually certified or licensed specialty substance use disorder treatment providers practicing within a larger organization unless the larger organization is also accredited, certified, or licensed as a specialty treatment provider.** Requiring any health care organization that hires an employee with specialty substance use disorder treatment credentials to be considered a covered entity would be a substantial disincentive for general health care organizations to integrate substance use disorder treatment services into their predominant treatment operations. It would significantly restrict integration of substance use disorder treatment with general health care, which Medicaid Directors and Mental Health Program Directors believe is foundational to improving care.
- **State Medicaid agencies and other third party payers/health care entities including public behavioral health programs, should be permitted to disclose substance use disorder data in the course of an audit or evaluation of the state’s Medicaid program or of the payers/entities’ activities.** State Medicaid programs, as federal and state-funded health insurers, are subject to extensive audit and evaluation requirements at both the state and federal level. Explicitly including third party payers within 42 CFR §2.53 would help state Medicaid agencies comply with the legal requirements applicable to Medicaid programs. This change would be consistent with the rationale for amending Part 2 to explicitly allow third party payers to disclose Part 2 data to qualified service organizations (QSOs) and qualified researchers/research organizations.

B. CONSENT REQUIREMENTS

Specifically, we [SAMHSA] are analyzing the current requirements and considering the impact of adapting them to: 1. Allow the consent to include a more general description of the individual, organization, or health care entity to which disclosure is to be made.

Our members believe that consent requirements should be streamlined and standardized to support consumers in making informed decisions about the sharing of their health information. The difference in physical health, mental health and substance use disorder treatment consent requirements adds to the complexity of this process for consumers and providers.

As a result, Medicaid Directors and Mental Health Program Directors agree that SAMHSA’s proposed change would be helpful, particularly if the patient could consent to a template statement that he or she is consenting to the health care information covered by the regulation being handled in a manner consistent with the privacy protections of HIPAA. This approach should help to ensure that treatment, payment, and operations as defined by HIPAA are covered by the consent, or at a minimum, treatment, case management, and coordination of care should be covered.

In addition, SAMHSA should consider the benefits of allowing the statewide HIE to be identified as the organization to which disclosure is made rather than individual HIE participants. Such a

policy may be beneficial in some states; however we note that other challenges would still exist. For example, HIEs would still be required to place a redisclosure statement on the shared record for subsequent times that it is shared, which some states do not have an existing mechanism to do.

2. Require the patient be provided with a list of providers or organizations that may access their information, and be notified regularly of changes to the list.

We do not believe this recommendation reflects current HIT capabilities. However, even if it becomes feasible, there are still concerns that this would be unworkable and would assure that substance use disorder treatment information covered by the regulation would almost never be shared on HIEs, shared in urban regions where there are many providers, or shared when persons have multiple medical conditions and see multiple providers. Lists of specified providers would be lengthy and change frequently, so the lists would require ongoing updates and notification of changes provided.

One possible approach SAMHSA may wish to consider to improve the feasibility of such a policy, is that patients could be referred to websites that are regularly updated with the list of HIE participants and providers. In this scenario, an oversight entity may be appropriate and this entity would need resources to maintain these updated lists.

3. Require the consent to name the individual or health care entity permitted to make the disclosure.

This would not be workable for an HIE, and as a result would not address Medicaid Directors' and Mental Health Program Directors' concern about the ability to provide integrated care. The consent would be captured by the entity currently providing treatment, but that entity would need to request substance use disorder and treatment data from other HIE participants that have treated the patient in the past. Those other entities could only disclose information if they had previously captured consent from the patient with their entity named to make the disclosure.

Even outside of an HIE, this change would result in substance use disorder treatment information being shared significantly less often than it is now. If an individual provider must be named in the disclosure, the medical records department of an organization would constantly have to crosscheck whether that provider is still employed by the organization. If the consent names the organization, any merger or acquisition of that organization would void all prior consent.

4. Require that if the health care entity permitted to make the disclosure is made up of multiple independent units or organizations that the unit, organization, or provider releasing substance abuse related information be specifically named.

We do not believe this recommendation reflects current technological capabilities or the realities of how organizations function. Imposing such a requirement would ensure that information about specialized substance use disorder treatment is never shared in organizations with multiple independent units.

The reality is that such organizations often use the same EHR and most, if not all, EHRs lack the functionality to segregate information that can and cannot be shared within the EHR. Where organizations with multiple units have separate EHRs, they still extensively exchange and aggregate data for purposes of treatment, payment, and operations.

This requirement would create a substantial disincentive for those organizations to offer specialized substance use disorder treatment, which would threaten access to these services for Medicaid and public mental health program beneficiaries. Any change to the regulation that creates additional standards that differ from HIPPA simply creates more obstacles that disadvantage specialized substance use disorder treatment patients and providers. This would add complexities in the HIE systems if the consent forms used by various health care entities do not include the same substance use disorder treatment data. It would also create confusion for users of data obtained through the HIE when the included information varies by health care entity.

In addition, the development of standards for the exchange of substance use disorder or behavioral health information should be designed to facilitate the exchange of all health information. These standards should allow all substance use disorder and behavioral health facilities and clinics to use one common continuity of care document (CCD) standard that meets their unique needs.

5. Require that the consent form explicitly describe the substance abuse treatment information that may be disclosed.

We believe this requirement would ensure the information about specialized substance use disorder treatment is shared much less often than it already is. Since many patients continue to receive treatment over time, the consent would have to be continuously updated to reflect the treatment received. There would be confusion about how detailed and specific the descriptions of treatment would have to be. Further, the technical capacity does not currently exist to segment the data that may or may not be disclosed.

Would these changes maintain the privacy protections for patients?

Our members recognize and stand behind the importance of patient privacy. We believe privacy will continue to be protected through the alignment of general health information privacy requirements with substance use disorder information privacy requirements. Specifically, penalties and consequences for breaches of information will remain in place, deterring those with malicious intent from misusing information.

Further, we recommend that the national agenda around substance use disorder issues include a consumer education component to address how health information is protected, shared, used, and disclosed. This will help to ensure consumers understand the legal protections that govern all of their health information, including information related to substance use disorders.

Would these changes address the concerns of HIEs, health homes, ACOs, and CCOs?

Aligning the privacy regulations for alcohol and drug abuse records with privacy requirements for medical and mental health information would allow entities to provide all Medicaid beneficiaries

and public mental health program patients with the same IT and data analytic supports and benefits. If alignment is not possible, our recommendations in response to Part A would be a positive step forward to address the concerns of HIEs, health homes, ACOs, and CCOs, and ensure those entities can deliver quality care to Medicaid beneficiaries and public mental health program patients with substance use disorders.

Further, to ensure secure and safe sharing of all health information in these innovative models of care, we believe standards should be established for information sharing within health homes, ACOs, and CCOs. SAMHSA and its sister federal agencies should work with states and other expert and stakeholders to evaluate the feasibility of using the behavioral health and substance use disorder CCD or consolidated CDA as the foundational document for the development of these standards for information sharing.

Would these changes raise any new concerns?

Revising the current regulation so that it is operationally identical to the privacy provisions of HIPAA would require provider education and clarifications.

C. REDISCLOSURE

Would this type of change facilitate technical solutions for complying with 42 CFR Part 2 in an EHR or HIE environment?

We believe this change would have very limited benefit due to the significant resource demands involved in the technology required to manage redisclosure of selected portions of each patient's private health information. EHRs would only be able to filter out the substance use disorder treatment information that falls within defined data elements and does not include free text. Providers having free text fields in their EHRs, such as progress notes, could still run the risk of releasing a progress note containing information that would identify a patient as a recipient of substance use disorder treatment.

D. MEDICAL EMERGENCY

What factors should providers take into consideration in determining whether a medical emergency exists?

Our members agree that the current regulation should be amended to allow the release of specialized substance use disorder treatment information in an emergency using the same methods and standards applied under the privacy provisions of HIPAA. In addition, a consistent definition of a "medical emergency" should be developed to facilitate the appropriate sharing of substance use treatment information in a medical emergency. Specifically, a "medical emergency" should be defined as any treatment provided in an emergency department. The exigencies of a medical emergency permit no time or opportunity to apply specialized, complicated requirements for handling information or to consider nuanced descriptions of what does and does not constitute an emergency. Creating different versions of the "break the glass" functionality would also create additional complexity within HIE systems with additional costs to create and maintain this functionality. It would also add steps in the workflow for

emergency departments to determine which version of “break the glass” is warranted and to make the proper request of the system.

E. QUALIFIED SERVICE ORGANIZATION (QSO)

[...] One potential solution includes expanding the definition of a qualified service organization (QSO; § 2.11) to explicitly include care coordination services and to allow a QSO Agreement (QSOA) to be executed between an entity that stores Part 2 information, such as a payer or an ACO that is not itself a Part 2 program, and a service provider.

If 42 CFR Part 2 cannot be aligned with the requirements of HIPAA, this would be a helpful change. 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 and data processing activities).

If a third party payer is not able to disclose Part 2 data to a QSO under Part 2, state Medicaid programs could effectively be prohibited from contracting any functions, or obtaining any services from outside vendors, if the function or service involved the use of Part 2 data. This could undermine the operational efficiency of state Medicaid programs, which also serve as a major source of funding for substance abuse treatment services provided by Part 2 programs.

Are there other use cases we should be taking into consideration?

The expansion of QSO agreements should also include subcontractors that health care entities employ, contract with, or otherwise engage to perform the same services. We encourage SAMHSA to consider other allowable uses of Part 2 data by QSOs including: 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 and other health care entities.

F. RESEARCH

SAMHSA is considering expanding the authority for releasing data to qualified researchers/research organizations to health care entities that receive and store Part 2 data, including third-party payers, health management organizations, HIEs, and care coordination organizations.

If 42 CFR Part 2 cannot be aligned with the requirements of HIPAA, this would be a helpful change.

Are there specific privacy concerns associated with expanding the authority or releasing data to qualified researchers/research organizations in this way?

No.

G. ADDRESSING POTENTIAL ISSUES WITH ELECTRONIC PRESCRIBING AND PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs)

How do pharmacy information system vendors anticipate addressing this issue? Are there specific technology barriers SAMHSA should take into consideration?

We do not believe there is a technically, financially, or administratively feasible way to bring PDMPs into compliance with the current regulation. Older PDMPs aggregate the data from weekly or monthly disk dumps from the pharmacy systems. As a result, maintaining the drug list and the patient list would be daunting. In addition, it would be difficult and in some situations impossible in context of date of service and original prescriptions versus refills for the pharmacy to maintain and segregate the opt-ins versus opt-outs for patients who want to withhold access but later choose to allow access. Pharmacy data systems simply do not have mechanisms for managing patient consent and lack the ability to identify which providers are subject to Part 2 in order to prevent the data from reaching the PDMP.

In order to selectively screen out prescriptions received from covered entities under 42 CFR Part 2, either the individual pharmacies or the switch companies would need to have a digital list uniquely identifying all covered entities, cross-walked to their NPI numbers. It is unlikely they would be able or willing to compile such a list. It is also unlikely they would be willing to accept such a list from an outside entity unless the entity accepted liability for any errors on the list. Any entity compiling and maintaining this list would have to update it, on almost a daily basis, to account for provider changes. It is unclear who would bear the extensive costs involved in such frequent updates.

The other alternative would be to mandate that switch companies screen out all medications deemed indicative of specialty substance use disorder treatment from data they transmit to PDMPs. However, this too would create additional administrative costs. The list of drugs they would screen out as indicative of specialty substance use disorder treatment would need to be nationally standardized, government endorsed, and continuously updated as new manufacturers enter and leave the market and as new formulations are marketed or dropped. This would require a substantial ongoing regulatory assessment and updating of the drugs to be screened out.

We are also concerned that the provisions of 42 CFR Part 2 restrict the effectiveness of PDMPs and present a major threat to patient safety by limiting the reporting of certain controlled substances to PDMPs. Many drug overdoses occurring today could otherwise be prevented by addressing some of the restrictive language in 42 CFR Part 2 which applies to PDMPs. For example, at least two medications used in specialized substance use disorder treatment are commonly abused controlled substances: methadone and buprenorphine. 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 1999.⁷ While buprenorphine abuse and overdose deaths are much rarer, they are

rapidly increasing in number. Methadone and buprenorphine dispensed by opioid treatment programs (OTPs) should also be reported to PDMPs.

In addition, not applying 42 CFR Part 2 to PDMPs could improve the quality of care for those receiving naltrexone or similar opiate antagonists. This prescription, which is increasingly used in specialty substance use disorder treatment, renders all opiate pain medication completely ineffective. Injectable naltrexone is very long-acting, with its effects lasting up to 40 days. When a person on naltrexone undergoes surgery or another medical procedure requiring anesthesia or analgesia, the anesthesiologist must know to use medications other than the usual opiates. If the anesthesiologist is not informed of the presence of naltrexone in the patient's system, the patient will experience extreme pain. Not applying 42 CFR Part 2 to PDMPs would help to prevent such tragedies.

Finally, we recognize that PDMPs in some states are accessible by law enforcement. To ensure those with substance use disorders receive the safety benefit of PDMPs and are not discouraged from seeking treatment, SAMHSA should prohibit health care information in the PDMP from being used in initiating or substantiating any criminal charges against a patient or to conduct a criminal investigation of a patient.

Are there other concerns regarding 42 CFR Part 2 and PDMPs? Please describe relevant use cases and provide recommendations on how to address the concerns.

To fully address concerns with this regulation and PDMPs, we strongly believe the regulations at 42 CFR Part 2 should be repealed in their entirety, with the exception of the statutory prohibition against release of health care information for use in initiating or substantiating any criminal charges against a patient or to conduct a criminal investigation of a patient. Recognizing this would require a statutory change, we urge SAMHSA to not apply 42 CFR Part 2 to the transmission of pharmacy data to PDMPs, or at the very least not apply the requirements to the transmission of pharmacy data about the prescription opiates methadone and buprenorphine or opiate antagonists such as naltrexone to PDMPs.

Attempting to apply 42 CFR Part 2 generally to PDMPs would further complicate the transfer, use, and interpretation of data by PDMPs, which ultimately affects the ability of Medicaid programs to ensure beneficiaries receive quality care. In the unfortunate event that the regulations are applied to PDMPs, we recommend the requirements only apply to medications used solely for specialized substance use disorder treatment.