



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
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Commissioner

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June 23, 2014

PrivacyRegulations@SAMHSA.hhs.gov

Re: Substance Abuse and Mental Health Services Administration's (SAMHSA) information solicitation concerning the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2

The New York City Department of Health and Mental Hygiene (the "Department") writes in response to SAMHSA's request for public input concerning potential changes to 42 CFR Part 2.

Introduction:

Since the last update to Title 42 of the Code of Federal Regulations Part 2 (42 CFR Part 2) in 1987, the settings in which substance abuse treatment services are delivered have changed dramatically. At the moment, 42 CFR Part 2 works both to protect against the effects of, and also paradoxically to perpetuate, the stigma of substance use disorder and substance use disorder treatment within the mainstream healthcare landscape. We support the Substance Abuse and Mental Health Services Administration's decision to explore potential updates and modifications to 42 CFR Part 2 to address these changes in the healthcare setting and better support delivery of high quality and truly coordinated care.

The increasing focus on coordinated care, with growing emphasis on holistic approaches to health that incorporate social determinants of health and behavioral health (including substance use disorders) along with physical health care, is supported by the growth of health information technology (HIT) and health information exchange (HIE). Relevant changes in the care delivery landscape include:

- Transition towards team-based models of care, including increasing engagement of non-physician care providers, and coordination across the entire patient care continuum (hospital, ambulatory, long term care, mental health).
 - More individuals and more organizations need access to patient health information.
 - As team-based models develop and increasing numbers of care providers and organizations seek access to patient information, patients seek assurance that their data are protected and secure. The original goal of increasing patient participation in substance abuse and mental health treatment by ensuring privacy protections must be balanced against the growing understanding of the value offered, for patients and providers, by care coordination.
- Transition towards HIT. Data are stored in electronic formats that can be quickly recalled, updated, and shared, giving providers access to comprehensive data for decision-making.

- Regulations surrounding privacy and security of sensitive health information must take into account changes in the HIT landscape as well as changes in patient perceptions of privacy and care coordination. Changes in patient perspective on sharing of substance use treatment data indicate growing interest in integrated care and concomitantly in data sharing.
- Innovations in payment models are increasingly addressing coordination across the care continuum, creating an environment in which providers and organizations need to share information in order to successfully meet new standards. Relevant models and programs include: Electronic Health Record (EHR) Incentive Program, Centers for Medicare and Medicaid Services (CMS) Pioneer and Shared Savings Accountable Care Organizations, State Medicaid Accountable Care Organizations (ACOs), other state programs (demonstration programs, New York State’s Delivery System Reform Incentive Payment Program), Patient Centered Medical Home, and commercial payer pay-for-performance programs.
 - The ability to routinely, consistently, and safely exchange health information between organizations is increasingly vital to health care delivery providers and organizations.

Challenges in managing and sharing substance use treatment data, including information regarding substance abuse, will hold back efforts to better integrate behavioral health into care coordination processes and must be addressed. As of 2014, most health information technology currently available does not adequately address substance abuse treatment information management requirements as delineated in 42 CFR Part 2. Challenges include: documentation and management of consent is not a standard EHR functionality; specific subsets of data within the EHR cannot be segmented; and providers cannot choose to share eligible portions in the record and instead must refrain from sharing the entire record. The same holds true for behavioral health-specific care management software; while technically possible, data segmentation creates substantial complexity for provider workflows and is not typically available. Finally, lack of clarity in existing regulations surrounding health information exchange has created a scenario in which neither vendors nor Health Information Exchanges (HIEs) are clearly responsible for segmentation or screening.

The Department therefore supports SAMHSA’s efforts to review and revise 42 CFR Part 2, and suggest SAMHSA strongly consider aligning these regulations with existing health information management regulations in order to streamline these processes and facilitate integration with other care settings. Factors to keep in mind include:

- Wherever possible, integrate processes into existing workflows. By avoiding creation of separate workflows, processes will be less burdensome for organizations and providers and support increased compliance.
- Existing EHR and HIE technologies are not constructed to support separation of data on various aspects of medical care. Furthermore, separation of substance abuse treatment information from other medical data may currently interfere with the coordination and engagement of different aspects of a person’s health.
- Similarly, consent management models are complex and can be challenging to implement, particularly when layered over the existing, widely varying, consent landscape. Better integration of consent models across all types of health data can support

improved coordination of care and integration of behavioral health, including substance use disorder, care into other treatment settings.

- We understand that the applicability of HIPAA protections does not match that of 42 CFR Part 2, particularly around limitations based upon federal assistance (for Part 2) and electronic transfer of data (for HIPAA). We encourage SAMHSA, however, to learn from existing medical record models for data and consent management. Congruence between protections through HIPAA and Part 2, particularly around applicability, scope of protections and a public health exemption, would seem to be advantageous for future efforts to align data collection, management and sharing as health care becomes increasingly integrated. Documentation, sharing, and use of protected health information is covered by existing regulations; behavioral health and physical health share similar issues of patient privacy and protection, and SAMHSA may be able to adapt existing structures and requirements to suit its needs.

We would also like to highlight the need for SAMHSA to consider the regulations' impact on incarcerated populations. The Department's Bureau of Correctional Health Services provides health care, including two federally-funded substance abuse treatment programs, as well as discharge planning services directly, and through its contracts, to inmates in the New York City jail system. The City's jail population has significant rates of patients with substance abuse and therefore these regulations dramatically impact the methods by which we coordinate care for inmates.

a. Applicability of 42 CFR Part 2

The Department welcomes additional clarity regarding the applicability of the 42 CFR Part 2. We believe that narrowly defining the applicability of the regulations would prove beneficial for patients, healthcare provider organizations and Regional Health Information Organizations (RHIOs). SAMHSA is proposing to define covered information according to type of treatment rather than according to type of facility. We support SAMHSA's proposal to more clearly define the types of information that are covered, but wish to highlight several concerns or considerations.

First, our assessment indicates that this option would not be feasible in the absence of health information technology capable of managing patient consent and segmenting patient records. In systems such as our own where specialty substance abuse treatment is integrated with other general healthcare services, an overbroad application of the definition of Part 2 records needlessly hinders care coordination. As SAMHSA recognizes in the discussion on redisclosure, most current electronic health records (EHRs) do not permit data segmentation. This absence of capability has created scenarios under the current regulations in which an entire patient record, including records of care unrelated to substance abuse treatment, is classified as a 42 CFR Part 2 record.

Given the current state of the technology, the proposed change to the regulations would not lead to a substantive change in CHS's ability to participate in health information exchange. However, once the technology is available, the proposed option would indeed facilitate sharing of data and care coordination by enabling us to more effectively manage covered data. On the other hand, while such segmentation would allow for some immediate data accessibility and sharing, segmentation also cuts against efforts to integrate care more fully. Therefore, we both recommend that SAMHSA explore opportunities to incentivize or require the development of the capacity to manage patient consent and segment patient records within the EHR, and that

SAMHSA work to align more general protections with those applicable through other regulations, such as HIPAA.

Second, we support SAMHSA's proposal to more clearly define the types of information that are covered. We encourage SAMHSA to clearly delineate screening, brief intervention, and referrals as information that is not subject to 42 CFR Part 2, and clarify the types of specialty substance abuse treatment services that would indeed be covered. For example, for a small practice provider who does not consider themselves a specialty substance abuse treatment provider, concern could arise regarding where to draw a line between brief intervention or pre-treatment substance abuse services and treatment when the provider prescribes a supportive medication aimed at reducing certain mental health and/or substance abuse symptoms. Alongside such a policy change, we suggest clarifying the types of organizations and providers who would be covered by 42 CFR Part 2.

b. Consent Requirements

Our comments focus on two aspects of the consent requirement: (1) its application to participants in RHIOs and (2) the notice of consent provision discussed on p. 5 of the Notice of Public Listening Document. Further, we advocate for a public health exception to the consent requirements so that drug and alcohol records may be shared with public health authorities or other entities who are legally authorized to receive such information for the purpose of preventing or controlling disease, injury or disability.

RHIO Participation

RHIOs facilitate health information exchange (HIE) among care providers with EHRs. A consent form that specifically names the RHIO (as the releasing organization) and the health care organization/entity (as the receiving organization) is sufficient for the purposes of making the patient aware to whom they are authorizing the release of their health information. Therefore, we agree with the proposed change to allow for a more general description of the healthcare organization or entity (as referenced in b1 on page 5). While there is significant variation in consent requirements across states, in New York State, consent is not required to upload a patient's health information to a RHIO, but rather is required to be obtained at the point of care when a provider would like to 'pull down' or look up the patient's records.

Obtaining Consent and Notice in a Correctional Health Facility

Regarding the proposal to maintain a list of providers or organizations that may access information (as suggested by (b)(2) on page 5), we would like clarity about which party – the healthcare provider or the HIE/RHIO – would be required to provide the patient with a list of providers or organizations that may access their information and regular notifications of changes to this list. This requirement has the potential to be very burdensome for the provider, as the provider may not be regularly notified of changes to the RHIO participant list. Currently, many of the RHIOs provide a periodically updated list of their members on their website and we believe that should be sufficient should the patient be interested in learning more. Furthermore, including this level of detail within the consent may require regular updates to the authorization form itself which would be administratively burdensome to the provider. We believe that the patient will have adequate notice of the use of his or her information if the consent form listed a general description of the organization to which disclosure will be made.

We agree that consent forms should list the name of the entity permitted to make the initial disclosure, listed as (b)(3) on page 5. We would like clarification as to how this proposed change is different from the current regulation.

Public Health Exception

Similar to the Health Insurance Portability and Accountability Act of 1996's Privacy Rule exception for public health entities,ⁱ we encourage SAMHSA to incorporate a public health exception into 42 CFR Part 2 that permits drug and alcohol records to be shared for specified public health purposes.

Public health authorities – which include federal public health agencies, tribal health agencies, state public health agencies, local public health agencies and anyone performing public health functions under a grant from such agencies – frequently acquire, use and exchange protected health information to perform mandated public health activities such as surveillance, program evaluation, and research. As noted by the Centers for Disease Control and Prevention, state and federal law have acknowledged this need for health information and condoned the use and collection of identifiable information by public health authorities.ⁱⁱ

A 42 CFR Part 2 public health exception like the Privacy Rule's would permit organizations covered by 42 CFR Part 2 to disclose drug and alcohol information, without authorization, to public health authorities for the purpose of preventing or controlling disease, injury, or disability, including reporting of disease or injury, reporting vital events, conducting public health surveillance, investigations, or interventions, reporting child abuse and neglect, and monitoring adverse outcomes related to food, drugs, biological products, and medical devices. This exception would acknowledge the importance of public health activities and acknowledge public health authorities' need for comprehensive record access to conduct their missions. We urge SAMHSA to consider this exception.

c. Redis closure:

Given the current functionality of most EHRs, data segmentation, or 'tagging' of certain pieces of information within a patient's medical record, as discussed on page 6 of the advisory document, is not technically feasible. Therefore, we disagree that applying the disclosure prohibition only to identifiable substance abuse information will facilitate any technical solutions for complying with 42 CFR Part 2 in an EHR or HIE environment in the near future. Most EHRs currently have the ability to contribute patient data to an HIE/RHIO at the patient level, not at the services rendered level— essentially an "all or nothing" approach. While this proposed change would act to maintain patient privacy, it is not consistent with the current technical capabilities of most EHRs, and therefore is not a viable solution. We acknowledge that there are currently efforts to move towards data segmentation, such as the Data Segmentation for Privacy pilot sponsored by the ONCⁱⁱⁱ, however these efforts are still nascent.^{iv}

We would further like to request clarification on the applicability of the consent and redis closure provision within the same organization versus across distinct legal organizations. We are unclear how this would apply to new care models and organization such as ACOs and health homes and request further clarification.

d. Medical Emergency

We support SAMHSA's efforts to facilitate use of covered information to prevent emergencies in addition to when a bona fide emergency already exists. We suggest SAMHSA explore the analogous decisions being made by HIEs across the country and leverage existing 'break the glass' (e.g. the policies being implemented in the State Health Information Network of New York)^v policies in order to minimize confusion among providers and organizations as to the circumstances under which access would be valid.

c. Qualified Service Organization (QSO)

The Department supports the proposal of expanding the definition of a QSO to explicitly include care coordination services and allowing healthcare entities to exchange data via a QSOA. According to SAMHSA’s “Frequently Asked Questions: Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange”^{vi}, HIEs and providers may already share Part 2 records without patient consent so long as QSOA is in effect. Per this guidance, DOHMH entered into a QSOA with a local RHIO. Other RHIO participants are expected to sign QSOAs as well. We support the formalization of the FAQ guidance in the regulations. We request that HIEs be named specifically in addition to ACOs and CCOs.

f. Research

We support the expansion of authority for releasing data to qualified researchers and research organizations to include entities that receive and store Part 2 data, including HIEs.

The Department appreciates the opportunity to comment on potential changes to the regulations. Thank you for your consideration.

Sincerely,

Thomas Merrill
General Counsel

ⁱ 45 CFR § 164.512(b)

ⁱⁱ <http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm>

ⁱⁱⁱ <http://wiki.siframework.org/Data+Segmentation+for+Privacy+Homepage>

^{iv} <http://healthitsecurity.com/2013/10/31/oncs-data-segmentation-for-privacy-completes-pilot-phase/>

^v http://nyhealth.org/wp-content/uploads/2012/07/Privacy-and-Security-Policies-for-RHIOS_v2.2.pdf

^{vi} <http://www.samhsa.gov/healthprivacy/docs/ehr-faqs.pdf>

Public Comment
Confidentiality of Alcohol and Drug Abuse Patient Records
Document Number 2014-10913 Document Citation 79 FR 26929

Department of Health and Human Services
Substance Abuse and Mental Health Services Administration

I am writing to respond to the Request for Public Comment on the Confidentiality of Alcohol and Drug Abuse Patient Records Document Number 2014-10913 Document Citation 79 FR 26929.

By way of background I am a licensed social worker with over thirty years of experience in the field providing mental health and substance use services. I have had a private clinical practice as well as having been administrator in inpatient and outpatient settings having run the largest single site behavioral health (mental health and substance use) organization in NYC.

I am also well versed in the technology aspects of care integration, Meaningful Use, Data Segmentation for Privacy and the workings of health information exchange. While Vice President Health Information Technology & Strategic Development at the National Council for Behavioral Health I was the project lead for a SAMHSA-HRSA funded project working with five state health information exchanges (HIEs) to try to work out the barriers of sharing substance use information through a HIE. I have recently taken a new position at one of the largest health systems in the nation, the North Shore-LIJ Health System where I will be focusing on the use of technology to assist in integrated care efforts.

I am also a consumer/family member of someone suffering from a substance use disorder.

My comments are drawn from my many years of experience in clinical settings as well as personal experience and knowledge of current and future capabilities of information technology.

a) Applicability

SAMHSA asks if changing the applicability of Part 2 to include any federally assisted health care provider that provides a patient with specialty substance abuse services would change stakeholder concerns or raise new concerns. Changing the Applicability of 42 CFR Part 2 (Part 2) to include what "services are provided" would not in my opinion improve the ability to share substance use information.

Applying Part 2 to a wider range of providers, many of whom would not be covered by Part 2 currently would not address the problem. In fact, it would extend the problem to a far wider number of organizations. SAMHSA identifies that providers conducting Screening Brief Intervention and Referral to Treatment (SBIRT) would not be covered. I do not believe that SAMHSA is recognizing the vastly changing landscape in healthcare integration. Many physical health care providers are in fact providing specialty substance use services over and above

SBIRT. These services are provided as adjunct services to medical care to treat comorbid chronic physical health and substance use disorders. Many Federally Qualified Health Centers (FQHCs) and medical providers that have become Health Homes provide these services. At the present time and based on current SAMHSA guidance these entities would not be covered under Part 2 as their "primary function" is not substance use treatment but medical care.

In integrated environments it is also difficult to separate physical health care treatment vs. substance use treatment in the electronic health record. If the entire record is tagged as "a substance use record" then the entire record would need to be treated against the more stringent Part 2 requirements. This will not, in my opinion, make sharing of information easier and lead to better coordinated and quality care.

We need to also consider the significant financial and administrative burden to the industry to develop software in EHRs, HIEs and other platforms to address this new requirement. The development of this capability would be a significant hardship on vendors who are already experiencing significant difficulty responding to other HITECH and Meaningful Use (MU) requirements. In fact ONC has just extended MU Stage 2 for an additional year for this very reason.

I would recommend that the Part 2 regulations be clarified as being Applicable to substance use programs that are federally assisted and hold some form of license or certification in their state to provide substance use services as separate and distinct services. This would help greatly to clarify which programs are and are not covered. EHRs would also be able to then flag the entire record from that provider as being covered by Part 2. As we move to data segmentation (3 - 5 years from now) this tag could then be applied to all data from a licensed Part 2 Program and would allow for far greater specificity than is provided now or would be provided if SAMHSA's recommendation were followed.

b) Consent Requirements

1) Allowing the consent to include a more general description of the individual, organization or health care entity to which disclosure is to be made would have an immediate and positive impact on EHRs, HIEs, HIOs, ACOs and others to share information.

Responses from patients from focus groups conducted at state level HIEs for the SAMHSA PBHCI Grantee HIE Supplement indicated that patients were acceptable to their information being shared with "providers involved in their care". Patients are not concerned that a provider joined the HIE or ACO prior to their signing a consent or after. What is important and has been voiced repeatedly is that they want to share information only with those providers involved in their care. Patients are aware of providers that are involved in their care or to whom they have received a referral. They do not, however, want anyone associated with the ACO, HIE etc. to be reviewing their record without a requirement to do so. This sentiment continues to be voiced by

many patients in their search to receive the same quality care that individuals without substance use disorders receive. This would bring Part 2 more in line with HIPAA. Patients could then at any time request a Report of Disclosures which the HIE or ACO etc. should be able to provide based on their audit trails which all MU EHRs must have and most HIEs already have embedded in their systems.

"Involved in my Care" would in fact be auditable using several auditable parameters.

- having a prior treatment relationship with the patient,
- having been named specifically on a release form,
- having a scheduled appointment with a provider or
- the provider having received a referral to treat the patient from another provider

would all fit under the description of "Involved in my Care". These parameters are all auditable in an electronic world as well as in a paper world.

2) Requiring the patient to be provided a list of providers or organizations that may access their information and being provided a list of these providers is important. This notice, however, should be allowed to be via a web site of the HIE, ACO or other entity or be provided via paper at any time at the provider's office where the Part 2 consent was originated. If these were licensed or certified substance use programs as recommended in number 1) above knowing which entity needs to have a paper listing available for patient review is indeed manageable.

3) Requiring the name of the individual or organization permitted to make the disclosure is not a burden. If Part 2 is Applicable as recommended in 1) above and allows for a more flexible description of the provider then this requirement will be very helpful in gaining informed consent from the patient at the Part 2 provider location where the consent originates. Informed consent is necessary and there should be national efforts targeted to educate substance use patients about informed consent and its implications.

4) If Part 2 is Applicable to only licensed or certified substance use entities then the patient would have identified what organization is allowed to disclose the information. This would include specified detox units in hospitals as they would have a specific license or certification. A detox occurring on a medical floor that is not a designated detox unit would not be covered.

5) Requiring the consent to explicitly describe the substance use treatment information that may be disclosed is not workable in today's electronic environment nor will it be in the near future. Few if any HIEs across the country can currently process parts of a record. This level of granularity cannot occur until there is full data segmentation nationally in all EHRs and HIEs. Given the state of technology today and recognizing the difficulties that vendors have with

meeting MU requirements and the MU cycle this cannot occur for another three to five years. When patients agree to join a HIE they agree to share all of their information or not join the HIE. This limitation of technology will not disappear until full data segmentation is ubiquitous.

c) Redisdisclosure

Although I agree with SAMHSA's reference to maintaining the data provenance (this is in line with the recommendation in Section a) Applicability, we do not agree that current or near future technology can support this activity. Maintaining "data provenance" will require data segmentation of substance use vs. non substance use fields in EHRs which will then pass the identified and segmented data to other systems. Current systems cannot perform this function. Current systems can only apply a tag to a document with a Part 2 Disclaimer, however, this tag only applies to the document as a whole and integrating the data as structured and useable data is not occurring due to current data segmentation limitations.

In integrated environments where substance use services are provided as an adjunct to medical services separating substance use from non substance use information is not easily accomplished and few EHRs can do this today.

My and others' recommendation to resolve the Redisdisclosure issue is to allow the consent to include a more general description of the individual, organization or health care entity to whom the disclosure is to be made. Allowing the description of "Providers Involved in my Care" would resolve this issue.

A patient who was provided the opportunity to provide Informed Consent at the Part 2 covered organization would be educated to the benefits and risks of redisdisclosure by the Part 2 program. If the patient is not agreeable to information being redisdisclosed then activating the switch in the Part 2 EHR or other electronic system that restricts any information from being released is easily implemented at the EHR level technologically at the Part 2 provider and would restrict the patient's information from being released from the Part 2 organization.

d) Medical Emergency

I agree with SAMHSA's recommendation to amend the medical emergency provision to prevent emergencies or to share information with a detox center when a patient arrives and is unable to provide informed consent due to their level of intoxication.

Currently Part 2 is sufficiently flexible to allow any provider to determine an "emergency" based on their judgment. Organizations, however, may need some guidance as to what level of staff may make the "emergency" determination. In many organizations front line administrative staff take the referral information and collect other information for the provider prior to the patient

actually arriving at a facility. Would receiving information from the referring provider or while en route in an ambulance that the patient is incoherent and unable to provide consent be enough for that front desk/administrative person to reach out to the HIE to "break the glass" and obtain information. If they did so then do they or the provider with a clinical credential note the "emergency" in the record. I have heard that organizations may need some guidance on this.

e) Qualified Service Organization (QSO)

We agree with SAMHSA that a potential solution is to expand the definition of a QSO to explicitly include care coordination and population management services and to allow a QSO Agreement to be executed between an entity that stores Part 2 information, such as a payor or an ACO that is not itself a Part 2 program or a service provider.

The care coordination and population management issues are also resolved with allowing the more general description of the individual, organization or health care entity that information can be released to. "Providers Involved in my Care" would include care coordination and population management activities.

f) Research

I agree with SAMHSA that allowing organizations that have Part 2 data such as third party payers, HIEs, ACOs and other care coordination entities the ability to conduct research either using their own staff or contracted staff. If using outside entities to conduct the audit/research there should be an agreement with the outside entity that they agree to conform to Part 2 redisclosure restrictions. Deidentified data should be utilized wherever possible and should follow the current and future HIPAA construct for deidentified data.

The current demands of our changing health care system and the focus on the Triple Aim of Better Care, Better Health and Lower Costs requires that health systems with oversight of Part 2 program services analyze their services to determine quality, cost and also monitor if they are improving the health of their population. Further restricting their ability to do this does not allow the country to meet its goals.

g) Addressing Potential Issues with Electronic Prescribing and Prescription Drug Monitoring Programs (PDMPs)

The issue of how to keep Part 2 information from being shared via ePrescribing and PDMPs raises the general issue of what happens if Part 2 information is obtained from other than a consent and how it might then be used to discriminate against a patient in substance use treatment.

In a recent Thompson's Health Care Compliance Expert White Paper, April 2014, Renee Popovits et al recommend that a new section be added to Part 2 Establishing the Mandatory Exclusion from Evidence of Information Obtained in Violation of 42 CFR Part 2 and a section addressing the Use of Program Records in Civil Proceedings. The paper cites specific regulatory language and processes within Part 2 which would allow these revisions.

Adding these provisions and ensuring that law enforcement could not use the data if it did not obtain it using the current subpoena process in Part 2 would protect substance users in treatment from law enforcement discovering where they are and being able to incarcerate them. Similarly the Civil Proceedings provision, also identified in the aforementioned White Paper, would ensure that Part 2 data not obtained via consent or the current subpoena process in Part 2 would not be able to be used against a substance user for civil proceedings.

These two changes would strengthen Part 2 protections for patients. Patients would have the knowledge that if their information was obtained outside of Part 2 requirements or otherwise obtained inadvertently it would not be available to be used against them to incarcerate them or for instance to take a child away from a mother who is in substance use treatment. These are two very important issues for patients.

I agree with adding these sections and providing additional protections for patients within Part 2.

I also agree with the recommendation to add Anti-Discrimination Protections as identified in this White Paper.

I agree that a Duty to Warn provision be added to Part 2. Many providers have experienced a bind between Part 2 requirements and notifying law enforcement or others in the case of a patient being considered a threat to others. Adding this wording would provide clear guidance to providers and allow for them to share Part 2 information without consent in the case of a Duty to Warn situation.

Part 2 should also be amended to specifically allow for electronic signatures.

I also strongly recommend that SAMHSA, HHS, ONC, CDC and other federal agencies engage in a varied and highly visible public education campaign regarding informed consent for patients and providers including the benefits and risks of sharing information so that patients can make decisions based on informed consent and their preferences.

I thank you for the opportunity to comment on this most important issue. Resolving these issues will allow substance use patients to receive the same quality coordinated care that medical patients have the opportunity to receive.

-----Original Message-----

From: Nguyen, tuan [<mailto:tuan.nguyen@mhmraharris.org>]

Sent: Wednesday, June 25, 2014 3:25 PM

To: Privacy Regulations (SAMHSA)

Subject: privacy -- 42CFR-chapter 2

I wholeheartedly support the full respect of an individual's rights to privacy, particularly when disclosure is not accompanied by informed consent for treatment.

Economic, programmatic, and social concerns cannot override such protection. The rights to refuse treatment has been upheld by various case laws, up to the ruling by the Supreme Court. Thus disclosing illness conditions, particularly in situations and environments (such as jail, prisons, or restrictive care places, homeless centers, etc.) where the coercive pressure is likely, should not be allowed without the person's prior consent for disclosure; or by court order on a case by case basis.

Tuan D.Nguyen, Ph.D.

713-970-7161

Director, Executive Decision Support

MHMRA of Harris County

To whom it may concern with the Substance Abuse & Mental Health Services Administration (SAMHSA) of the U.S. Department of Health and Human Services:

I am a patient of an opioid treatment program living in long term, sustained recovery from opiate use disorder. I am extremely concerned about the possibility my confidentiality and privacy under 42 CFR Part 2 might be relaxed or even eliminated as it is currently known. Despite being one of the most evidence based and proven effective treatments in all of medicine, methadone maintenance treatment (MMT) remains misunderstood and stigmatized - even by medical and healthcare professionals who SHOULD know better and be educated on the research, studies and facts.

It has been my experience dealing with primary care physicians and other medical professionals that discovering I am a methadone patient, despite my productive life and my contributions to my community and society at large, greatly changes their perceptions of who I am and what my intentions may be. Simply put, I have often been discriminated against and treated differently by medical providers to whom I have disclosed my status as a patient of an opioid treatment program up front. I have learned, often the hard way, that it is far better for the quality of my care to first establish a relationship with doctors, nurses, psychologists, etc. and THEN, when they know ME and I have decided I am READY, inform them I am living in long term medication assisted recovery. This right has been afforded to me because of 42 CFR Part 2, and it would be a GREAT disservice and injustice to the more than 300,000 of us MMT patients in the country to change or relax confidentiality regulations in even the slightest way. Relaxing or changing our precious confidentiality as currently guaranteed under 42 CFR Part 2 could further discourage individuals in active opioid addiction from seeking what the CDC has deemed the "most effective treatment" currently available and/or influencing those currently enrolled as patients of opioid treatment programs to drop out, most always guaranteeing disastrous results... We shouldn't even CONSIDER any changes that could have these outcomes, even if the potential is only slight, at a time we are facing an opioid addiction and overdose epidemic of historic proportions.

As a certified MAT advocate I am prepared to mobilize the patient AND provider community in anyway necessary to preserve these rights notwithstanding pressure from outside groups.

Please stand firm against outside influences and do what SAMHSA has long been trusted to do: Those things that are in the best interest of substance use and mental health patients and their recoveries from the illnesses by which we are afflicted.



June 25, 2014

Cathy J. Friedman

SAMHSA Public Health Analyst

Substance Abuse and Mental Health Services Administration

1 Choke Cherry Road

Room 5-1011

Rockville, MD 20857

Re: FR Document 2014-10913. Applicability of 42 CFR Part 2, Confidentiality and Drug Abuse Patient Records

PrivacyRegulations@SAMHSA.hhs.gov
<http://www.samhsa.gov/healthprivacy/>

Dear Ms. Friedman:

The American Health Information Management Association (AHIMA) is pleased to submit the following comments on Substance Abuse and Mental Health Services Administration: Applicability of 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records. AHIMA represents more than 71,000 educated health information management and health informatics professionals in the United States and around the world. AHIMA is committed to promoting and advocating for high quality research, best practices and effective standards in health information and to actively contributing to the development and advancement of health information professionals worldwide. AHIMA's enduring goal is quality healthcare through quality information (www.ahima.org). The discussion below provides AHIMA's responses to several of SAMSHA's questions.

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.?*

The current regulations apply to 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records. The proposed information gathering seeks to obtain direct input from stakeholders on updating the regulations. As noted by SAMSHA listening session participants, AHIMA agrees that more substance abuse treatment occurs in general healthcare settings and integrated care settings, which are typically not covered under the current regulations. For example, in *Behavioral Consultation and Primary Care: A Guide to Integrating Services* (2006), Robinson and Reiter estimate that more than two-thirds of primary care visits are related to psychosocial issues. Evidence also points to the sizeable presence in various mainstream general healthcare settings of persons with substance use conditions—both unidentified and identified. More than 1.5 million visits for treatment at hospital emergency departments in 2008 were found to be associated with some form of substance misuse or abuse (Drug Abuse Warning Network, 2008). Drug or alcohol disorders in 2006 were associated with about 3 percent of hospital stays in the United States, accounting for an estimated \$12 billion in costs (Russo and Elixhauser, 2006; Kassed, Levit, and Hambrick, 2007). Significant increases have also been noted recently in the number of mental health and substance abuse visits to federally qualified health centers (FQHCs)—increasing almost 45 percent between 2001 and 2007 (Bureau of Primary Care, n.d.). FQHC staff

deal with important health issues with their patients, sometimes including discussions related to the use of alcohol and tobacco (Carlson et al., 2001).

Redefining the applicability of 42 CFR Part 2 would bring a greater consistency to the access, use, and disclosure of alcohol and drug abuse patient records. A greater consistency in managing this patient information would address multiple challenges faced by healthcare professionals managing data regardless of media, including increased administrative expenses that are the result of complying with current disparate regulations. AHIMA believes that SAMHSA should consider limiting the changes to information related to current medications, medication history, diagnosis, patient encounters, and allergies. Without this limitation, AHIMA believes that the proposed definition based on services could negatively impact providers, as it would expand the current definition to providers and facilities that provide services but do not meet current facility definitions. There are two primary concerns with basing the definition on “service”:

1. If the definition is too broad or vague, it could have the unintended effects of including providers and entities that were not meant to be covered, and
2. If the definition is too defined or specific, it could quickly become outdated by not keeping up with changes in the marketplace.

- *Would this change address stakeholder concerns?*

AHIMA believes that the proposed changes would provide more consistent guidance to healthcare organizations and reduce inconsistent interpretations of the regulations. AHIMA believes that these changes would foster better care coordination because of greater consistencies in how the information is managed. However, considering the long history and established culture surrounding the current regulations, many stakeholders will react with concerns regarding confidentiality, security, and privacy. The changes will likely result in the need for the training and education of an array of stakeholders, including clinicians, health information management, patients, and others. Therefore, time and resources will be needed to clarify the new consent process. AHIMA believes that SAMSHA should work with public partners (such as the Office of Civil Rights (OCR) and the Centers for Medicare and Medicaid Services (CMS) to provide such stakeholder education and training. Additionally, AHIMA believes that it will be critical for consumers and patients to understand the new consent requirements and urges SAMSHA to help assure that consumers, patients and their caregivers are appropriately informed. Furthermore, AHIMA urges the Department of Health and Human Services to harmonize terms, definitions, and requirements relating to confidentiality, security and privacy of health information across Federal agencies and programs, including HIPAA.

- *How would this change raise any new concerns?*

Redefining the applicability of 42 CFR Part 2 may not result in the desired outcome of making these types of records easier to access. The change could result in unintended outcomes such as diminished information workflow or new barriers to health information exchange, because of the potential impact on providers not currently defined under 42 CFR Part 2. This could create complications with electronic health record (EHR) design, development, and configuration as currently substance abuse records are typically partitioned from the rest of EHR data.

Consent Requirements

- *Would these changes maintain the privacy protections for patients?*

AHIMA believes that the privacy protections for patients would be maintained. The proposed changes would likely streamline provider communications with their patients while the information itself will remain protected health information and will be protected as such under 42 CFR Part 2. AHIMA recommends that SAMSHA work with its federal partners to further explore and study encryption for this type of data.

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

AHIMA believes that these changes would address some concerns expressed by stakeholders such as of HIEs, health homes, ACOs, and CCOs. The proposed changes may not provide the level of relief sought by these entities, but they will encourage patients and providers to work together to share health data electronically and in real time.

- *Would these changes raise any new concerns?*

Alcohol and drug abuse patient records have received elevated levels of protection. AHIMA believes that the proposal to modify the current requirements will raise confidentiality, privacy, and security concerns from healthcare industry stakeholders. Moving forward with facilitating the flow of information in this context does raise some concerns and questions, such as:

- How difficult would it be to manage the consent and revocation process?
- Could patients provide a general consent to release information to others in a specific institution or would the consent require a list of specific individuals to whom the information could be released?
- Would the consent form require a description of the specific information to be disclosed? If so, how would this happen with patient-level data such as problem lists and medications?

It is difficult to address the refusal or revocation of consent in cases of the EHR for an entire health system. If the primary care physician, as a member of a health system, has access to that health system's EHR, then it becomes difficult and even impossible to prevent complete access to patient's record. This could hold true for health information exchanges in the 1:1 denial of access. The 42 CFR Part 2 changes will need to be implemented with transparency and education. In addition, all patient consent requests must be made in advance of the planned health information exchange and the information used will be commensurate with the circumstances for why health data is exchanged. Patients should be made aware that their consent to share health information is revocable at any time and that any access, use, or disclosure of patient information will not be used for discriminatory purposes or as a condition for receiving medical treatment.

Redisclosure

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

AHIMA believes that efforts are under way to facilitate technical solutions, although uncertainty exists about widespread availability and implementation of specific functionality of solutions, such as the ability of a system to segregate specific types of data.

- *Would these changes maintain the privacy protections for patients?*

AHIMA believes that the effectiveness of the security protections depends upon the industry's ability to come to consensus on effective standards, policies, processes, and workflows. In addition, overall success is dependent upon the stakeholders' ability to consistently implement privacy safeguards. If there are not consistent implementation of standards, policies, processes, and workflows, PHI likely will be at a greater risk of exposure.

Additionally, AHIMA believes that application of this law to only information that identifies an individual as substance abuser, needs further definition to exclude (at the very least) medications. Using SAMSHA's proposed definition, medication used to treat substance abuse would be an identifier by its very nature. AHIMA is concerned that excluding this data from redisclosure would be a patient safety issue preventing the sharing of drug-to-drug interaction and related information.

Medical Emergency

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

AHIMA believes that the current law/regulation should be revisited. To parse out certain data based upon a service is unwieldy and unmanageable. It creates patient safety issues, such as the lack of access to a patient's complete data, and can be technically difficult to accomplish. AHIMA believes that consideration should be given to make applicability, consent, redisclosure, and emergency access to be consistent with current psychiatric record protections. AHIMA recommends applying the appropriate (industry recognized) clinical and legal criteria and definitions for a medical emergency, which includes life/death situations, medical allergies, mental status and other situations that require immediate medical attention.

- *Are there specific use cases SAMHSA should take into consideration?*
- *Are there patient concerns about the impact of this change on their privacy?*

AHIMA believes that this is currently a contentious and complex issue and will remain one in the future. Deciding what information to make available for a medical emergency is a delicate question, as emergencies may be viewed differently by different people and what may be viewed as an emergency in "real time" may not be viewed as an emergency after some time elapses. This may result in additional risk for unintentional disclosures of information that may not be medically necessary, but when considering the situation in real time, it is more beneficial to have more information than not enough so that the appropriate quality care can be provided. For example, providing access to substance abuse medications is intended to address patient safety issues. However, access, use and disclosure to knowledge of the patient's substance abuse medications could have other unintended consequences and negative outcomes with regard to privacy, confidentiality, and security. Safeguards must be in place to ensure that access is limited to the "minimum necessary" and "need to know" guidelines.

Research

- *Are there factors that should be considered related to how current health care entities are organized, how they function or how legal duties and responsibilities attach to entities that make up an umbrella organization?*

AHIMA believes that issues with regard to responsibility for the process would need to be addressed. Any solution would need, at a minimum, to mirror the current process with regard to safeguards, controls, responsibility, and authority to take action.

- *Would this change address concerns related to research?*

AHIMA believes that if properly designed and implemented, these changes would facilitate research opportunities.

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

AHIMA believes that data under 42 CFR part 2 is still considered to have “extra” protections. Since this is considered “sensitive” information and is afforded extra protections by law, it appears that any research conducted will still require authorization from the patient prior to release. Expanding authority and allowing for greater distribution of data would most likely introduce new privacy challenges. AHIMA suggests that SAMSHA work with public and private sectors partners to fully explore the potential

Conclusion

Thank you for providing AHIMA the opportunity to comment on these important questions. AHIMA has developed several publicly available resources^{1, 2, 3, 4, 5} about privacy, confidentiality and security of health records and health information and would be pleased to provide additional information to SAMSHA and its Federal partners on these critical topics. We look forward to continuing our work with you to advance our nation’s healthcare system. If you have any comments or questions, please do not hesitate to contact me or Meryl Bloomrosen, AHIMA’s Vice President of Public Policy and Government Relations at Meryl.Bloomrosen@ahima.org or at 202-659-9440.

Sincerely,

Lynne Thomas Gordon, MBA, RHIA, CAE, FACHE, FAHIMA
CEO

¹ Laws and Regulations Governing the Disclosure of Health Information (Updated)

http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050565.hcsp?dDocName=bok1_050565

² Authorization Requirements for the Disclosure of Protected Health Information (Updated)

http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050486.hcsp?dDocName=bok1_050486

³ Redisdisclosure of Patient Health Information (Updated)

http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050541.hcsp?dDocName=bok1_050541

⁴ Patient Access and Amendment to Health Records (Updated)

http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050401.hcsp?dDocName=bok1_050401

⁵ Gorton, Elisa R. "A New Age for Mental and Substance Abuse Health Records: Considerations for Protecting Highly Sensitive Records in Electronic Systems." *Journal of AHIMA* 83, no.4 (April 2012): 42-43.



Health Share of Oregon
208 SW 5th Ave, Ste 400
Portland, OR 97204
503-416-1460

June 25, 2014

Cathy Friedman
Public Health Analyst
The Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road
Rockville, MD 20857

Delivered via email

Re: Confidentiality of Alcohol and Drug Abuse Patient Records (42 CFR Part 2), FR Doc. 2014-10913

Dear Ms. Friedman:

Health Share of Oregon is our state's largest coordinated care organization (CCO), serving more than 225,000 Oregon Health Plan (OHP) members (Medicaid enrollees). Our organization was founded and continues to be governed by eleven of Portland's leading health care organizations, including county mental health authorities, hospital and health systems, and health plans. Our goal is to improve health care to achieve better health outcomes for our members at a lower cost to the State.

Thank you for the opportunity to comment on 42 CFR Part 2. While we appreciate the intent of the law—to ensure that there are no disincentives to accessing treatment for substance use disorders—its current implementation impedes nationwide efforts to reduce silos and break down barriers to care coordination.

There are three county-based behavioral health systems that collaborate under Health Share's umbrella to create a regional behavioral health system for Medicaid enrollees. The way that 42 CFR Part 2 has been interpreted in our community prevents providers from the three systems from coordinating care for patients who might see one provider in one county at one time and a provider in another county at another time. In addition to the three county systems, we also coordinate care for complex patients across private health care systems. Without more flexibility to coordinate care for members who require treatment for substance use disorders across these systems, their quality of care will suffer.

The most basic example of a barrier to care coordination presented by this rule is the difficulty that CCOs have in integrating behavioral health with primary care when providers are unable to share information about a fundamental diagnosis underlying other comorbidities. In our membership, there is a 20% prevalence rate of substance use disorders among adults. Hampering our ability to coordinate care for 20% of our adult population undermines our ability to achieve the triple aim, thereby undermining the State's ability to achieve the health transformation in which our state and federal governments have invested so heavily.

Health Share respectfully requests that SAMHSA re-open the rule to consider modifications that would align the rule with the Health Insurance Portability and Accountability Act (HIPAA) requirements. Health care entities are deeply familiar with HIPAA compliance and the protection of personal information. Health care professionals, including care coordination staff, should be able to share information about substance use disorder diagnoses for the purposes of treatment, planning, and operations without first obtaining a release from patients. HIPAA includes protections for patients whose information is compromised that would work well for the purposes of this rule, as well.

Thank you for the opportunity to comment on these proposed rules. We are committed to serving as an example of how Medicaid systems can achieve better health outcomes through improved health care delivery at lower costs, and the current version of 42 CFR Part 2 impedes our ability to achieve the Triple Aim for a substantial part of our membership. We hope that you will consider revising the proposed rules per our recommendations. Please do not hesitate to contact us with any questions or concerns.

Sincerely,

Janet L. Meyer
Chief Executive Officer
Health Share of Oregon

Contact for further correspondence:
Ashlen Strong
Government & Regulatory Affairs Manager
503-416-4982
ashlen@healthshareoregon.org

Transforming
health
together.

June 25, 2014

The Substance Abuse and Mental Health Services Administration (SAMHSA)
1 Choke Cherry Road, Room 5-1011
Rockville, MD 20857

RE: FR Doc. 2014-10913 – 42 CFR Part 2

Dear To Whom It May Concern:

I am writing on behalf of Chestnut Health Systems (“Chestnut”). Chestnut is a private, not-for-profit organization provider of addiction treatment services for adolescents and adults in Illinois. Chestnut has drug and alcohol treatment centers in Belleville, Bloomington-Normal, Granite City, Joliet and Maryville, Illinois. Chestnut offers a comprehensive scope of behavioral health and human services. Our professional and experienced staff is committed to providing high quality care and services to the communities we serve. From drug and alcohol addiction inpatient facilities, to work-life and employee assistance programs, to a research institute, Chestnut continuously works to achieve its mission to make a difference and improve quality of life through excellence in service.

As a provider of substance abuse treatment services, Chestnut is intimately familiar with the considerable difficulties surrounding compliance with the federal confidentiality regulations at 42 CFR Part 2 (“Part 2”). Moreover, these confidentiality issues have become even more complicated in the context of our rapidly changing health care delivery system as a result of health care reform. Providers are increasingly moving to an electronic health record, and while some health care providers are being incentivized by the federal government to adopt electronic health records through meaningful use regulations, most behavioral health providers are currently ineligible for such incentives. Nonetheless, paper records and written consents are becoming impractical and obsolete. Further, there is a very significant national interest in promoting the coordination of health services delivered by multiple providers through new integrated care models including health information exchanges (“HIEs”), health homes, accountable care organizations (“ACOs”) and other care coordination entities (“CCEs”). Unfortunately, the current statutory and regulatory framework for the Federal Confidentiality of Alcohol and Drug Abuse Patient Records law (“SUD Confidentiality Law”) provide no guidance on electronic health records because many of the concepts did not exist forty years ago. Likewise, such providers cannot effectively participate in HIEs, health homes, ACOs, or CCEs. The unfortunate and unintended result is that the important benefits of electronic health records, HIEs, health homes, ACOs and CCEs as mechanisms to coordinate the continuum of care are significantly diminished by the SUD Confidentiality Law and the attendant regulations at Part 2. Further, since the SUD Confidentiality Law was implemented, the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the Health Information Technology for Economic and Clinical Health (“HITECH”) Act have been enacted. It is imperative to address

these laws in Part 2 to ensure that records covered by Part 2 are subject to its broader protections in all cases. This is especially true given the advent of electronic health records and the limited data segmentation capabilities that exist at this time.

Cognizant of the arduous task of revising and updating the regulations at Part 2, Chestnut is pleased to provide SAMHSA with our response to the Notice of Public Listening Session published in the Federal Register on May 12, 2014. Thank you for your commitment to advancing the confidentiality conversation as it relates to substance abuse treatment information protected by Part 2. We offer the below comments and recommendations in response to SAMHSA's proposed concepts and questions on the seven specific topics discussed in the proposed rule and at the public listening session on June 11, 2014. Our consideration of these issues is informed by our firsthand experience of the unique challenges Part 2 poses for meaningful exchange of substance abuse treatment information for the purpose of coordinating and integrating care to improve patient outcomes.

a. Applicability of 42 CFR Part 2

SAMHSA has proposed that covered information under Part 2 could be defined based on what substance abuse treatment services are provided instead of being defined by the type of facility providing the services. SAMHSA has posed the following questions related to this potential change.

- *How would redefining the applicability of Part 2 impact patients, health care provider organizations, HIEs, CCOs, HIT vendors, etc.?*
- *Would this change address stakeholder concerns?*
- *Would this change raise any new concerns?*

We oppose broadening the applicability of Part 2 to include entities other than Part 2 programs because doing so would detrimentally impact patients, health care provider organizations, health information exchanges ("HIEs"), care coordination organizations ("CCOs") and health IT vendors by further restricting the sharing of health information for care coordination purposes. Such a change would further hinder the meaningful exchange of patient health information for the benefit of treatment.

Sitting prominently on SAMHSA's website is a slogan: "*Behavioral Health is Essential to Health*". Stated another way, "*Health is Essential to Behavioral Health.*" With this in mind, the following two principles should guide any changes to the applicability section of the regulations at Part 2. First, changes to this section must focus on what is best for the patient. We strongly support confidentiality protections for patients, however, having separate health information privacy requirements for substance abuse treatment patients does more harm to the patient, harm to their families and harm to their communities by necessitating a separate and unequal health data sharing environment that prevents the full inclusion of substance abuse treatment patients into integrated health settings and systems. Second, any changes to this section should also consider what is necessary for providers to deliver optimal care and what barriers must be addressed in order to ensure providers can deliver optimal care. Broadening the applicability of this section would make it more difficult for providers to share medical

information through the ILHIE and other HIEs, which makes it more difficult to deliver timely, optimal care.

Specifically, we recommend the following with regard to the applicability section of Part 2:

1. We support the harmonization of Part 2 wherever possible with the Health Insurance Portability and Accountability Act (“HIPAA”) and its implementing regulations. It is our strong belief that efforts to harmonize Part 2 with HIPAA would ensure increased care coordination among treating providers and other entities which share health information for care coordination and integration purposes, improve patient care and enhance privacy protections by making confidentiality restrictions more uniform across health care settings. This allows for the achievement of improved health outcomes through increased coordination of care for patients. We also support preserving certain patient protections afforded under Part 2, such as the criminal penalties for violations of Part 2 at Section 2.4 and the stringent court order requirements at Sections 2.61-2.66.
2. We support clarifying that the regulations at Part 2 apply only to substance abuse specialty treatment programs and providers who are specifically licensed, credentialed, or accredited as substance abuse treatment providers. Further, the regulations should not apply to individual certified or licensed specialty substance abuse treatment providers who are practicing within a larger organization unless the larger organization is also specifically licensed, credentialed or accredited as a substance abuse treatment provider.
3. We are also opposed to any attempts to further define “covered information” based on what substance abuse treatment services are provided. Any changes to this section of the regulations should consider simplification as well as how patient protections can be retained and enhanced as described in the White Paper entitled “*Part 2 Evolution: A Vision for Integrated Care and Enhanced Rights*” by Renée Popovits, et al.
4. We oppose extending Part 2 applicability to health care providers who provide only screening, brief intervention and referral to treatment (“SBIRT”) services. We do not believe it was ever the intent of the regulations to cover treatment information of this limited nature. Providers of SBIRT services provide brief screenings of individuals who may require substance abuse treatment and referrals to appropriate and specialized treatment. Providers of SBIRT services are not themselves providing specialized substance abuse treatment services.

b. Consent Requirements

SAMHSA is 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.*
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.*
3. *Require the consent to name the individual or health care entity permitted to make the disclosure.*
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.*
5. *Require that the consent form explicitly describe the substance abuse treatment information that may be disclosed*

SAMHSA has asked for comments on patient privacy concerns as well as the anticipated impact of the consent requirements on integration of substance abuse treatment data into HIEs, health homes, ACOs, and CCOs. Specifically, SAMHSA has posed the following questions:

Would these changes maintain the privacy protections for patients?

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

Would these changes raise any new concerns?

Providers, patients and HIEs in the State of Illinois know first-hand the challenges associated with consent issues. However, both real and perceived consent barriers continue to block successful coordination of care efforts for Illinois patients. Illinois patients deserve the option and the choice of deciding whether they want their substance abuse treatment information shared through HIEs. If the consent roadblocks are not addressed, patients will continue to be deprived of their right to participate. Providers must be able to treat a whole person in an integrated delivery system in a coordinated way to yield better outcomes. Patients deserve it. A patient should not be excluded from HIE participation unless the patient decides to be excluded. It is the patient's choice.

Requiring the consent to name the specific individual or health care entity permitted to receive the disclosure prevents programs covered by Part 2 from participating in HIEs, health homes, accountable care organizations ("ACOs") and care coordination entities ("CCEs") because it is impossible to specify every organization and/or individual who might possibly receive information via an HIE, health home, ACO or CCE. Thus, even when a patient seeks to affirmatively consent to include his or her information in an HIE, health home, ACO or CCE, he or she cannot effectively provide such consent under current Part 2 regulations. Moreover, requiring patients to be provided with a list of providers or organizations that may access their information and be notified regularly of changes to the list would be impossible in the context of HIEs, where providers join HIE networks on a daily basis.

This requirement that a single individual or organization be named on a Part 2 consent is wholly inconsistent with the important federal and Illinois goals of achieving care coordination and integration. This requirement functions to discriminate against Part 2 program patients in two ways. First, general medical/surgical patients have the ability to provide a broader consent, but substance abuse treatment patients are restricted from doing so. Second, substance abuse treatment patients are effectively excluded from participation in HIEs due to the rigidity of the consent regulations and the technological inability to uniformly segregate substance abuse data in accordance with the stringent requirements contained in Part 2. As a result, a digital divide exists between general medical/surgical patients and substance abuse treatment patients as substance abuse treatment patients are not given an equal opportunity to participate or decide who should have access to their information. This not only perpetuates discrimination against substance abuse treatment patients (the very stigma that the SUD Confidentiality Law and Part 2 was intended to address) but it also interferes with the important objectives of the Affordable Care Act.

Given this, we urge SAMHSA to revise Part 2 consent requirements. Specifically, SAMHSA should:

1. Address the “To Whom” problem by revising the regulations to permit disclosures of substance abuse treatment information in a manner consistent with HIPAA by permitting patients to generally consent to disclosures of their substance abuse treatment information for the purposes of treatment, payment or health care operations. SAMHSA should additionally adopt the HIPAA definitions of “treatment,” “payment” and “health care operations”. Among other goals, this revision allows patient substance abuse treatment information to be disclosed to one or more HIEs, health homes, ACOs or CCEs, including any individual or institutional provider participating in such organizations with a direct treatment relationship with the patient, as treatment under HIPAA includes the coordination or management of health care and related services by one or more health care providers.
2. Harmonize the consent elements in Section 2.31 with the authorization requirements in HIPAA.
3. Assuming there is initial consent to disclosure to the HIE, health home, ACO or CCE, permit the redisclosure of information among such data recipients in a manner consistent with HIPAA, including redisclosure for the purposes of treatment, payment and health care operations without additional patient consent.
4. Adopt appropriate safeguards such as requiring data custodians to maintain audit trails and conduct routine audits.
5. Afford meaningful protections to address patient discrimination concerns as a result of relaxing the consent provisions, such as a mandatory exclusion from evidence provision for information obtained in violation of Part 2.

To the extent patient consent is required for a disclosure, we offer the following comments:

1. We support allowing the consent to include a more general description of the individual, organization, or other health care entity to which disclosure is to be made in order to enable the exchange of health information.
2. We oppose requiring the patient to be provided with a list of providers or organizations that may access their information and be notified regularly of changes to the list as such requirements are unduly burdensome and would be impossible in the context of HIEs and coordination of care. To clarify, we are not opposed to providing such a list to a patient if specifically requested, but we do not believe this should be a mandatory requirement.
3. We oppose any requirement that multiple independent units or organizations that make up a health care entity that may make a disclosure must be specifically named.
4. We agree that the consent form should continue to include how much and what kind of substance abuse treatment information is to be disclosed, as is currently required under Section 2.31. We do not support requiring consents to include more information than is already required under the current regulations as doing so would prevent the meaningful exchange of health information and coordination of care.

c. Redisclosure

SAMHSA is considering revising the redisclosure provision to clarify that the prohibition on redisclosure only applies to information that would identify an individual as a substance abuser,

and allows other health-related information shared by the Part 2 program to be redisclosed, if legally permissible. SAMHSA has posed the following questions regarding this potential change:

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

Would these changes maintain the privacy protections for patients?

The prohibition on redisclosure in Section 2.32 effectively prevents providers participating in an HIE, health home, ACO, or CCE from disclosing substance abuse treatment information among each other for treatment and care coordination purposes. Therefore, in addition to revising Part 2 to allow patients to consent to the disclosure of their substance abuse treatment information to an HIE, health home, ACO or CCE and its provider-members that are providing treatment to a patient (as recommended in Section (b) above), we also recommend revising the regulations to allow for the redisclosure of substance abuse treatment information by and among provider-members of an HIE, health home, ACO or CCE with a direct treatment relationship for the purposes of treatment, payment or health care operations. Further, we recommend that the regulations be revised to establish that the prohibition on redisclosure does not apply to outside HIEs or provider-members of such exchanges who have a direct treatment relationship with the patient and who need access to records to treat the patient on an emergent basis.

To be clear, we are recommending that for purposes of treatment, payment and health care operations, substance abuse treatment information should be able to be disclosed and redisclosed by and among provider-members of an HIE, health home, ACO or CCE with a direct treatment relationship with the patient. However, this change would not allow for information to be further disclosed or redisclosed by an HIE, health home, ACO or CCE or its provider-members without a patient's consent for any purposes other than for treatment, payment and health care operations, or as permitted under applicable exceptions under Part 2. Moreover, Part 2 information would not be accessible to anyone outside of the HIE, health home, ACO or CCE unless a specific exception applies or the stringent court order requirements under Part 2 are met. In other words, Part 2 information would not be able to be disclosed for non-treatment purposes to law enforcement, employers, insurance companies, divorce attorneys or others seeking to use the information against the patient. Furthermore, we urge SAMHSA to go one step further in order to protect patients against unlawful disclosure of their substance abuse treatment information by adding a mandatory exclusion from evidence provision to Part 2.

d. Medical Emergency

SAMHSA has posed the following questions regarding the medical emergency exception under Part 2:

- *What factors should providers take into consideration in determining whether a medical emergency exists?*
- *Are there specific use cases SAMHSA should take into consideration?*
- *Are there patient concerns about the impact of this change on their privacy?*

We support expanding the medical emergency exception to give providers more discretion to determine when a bona fide medical emergency exists. Further, we support amending the

standard to allow providers to use the medical emergency provision to *prevent* emergencies or to share information with a detoxification center when a patient is unable to provide informed consent due to their level of intoxication. If a medical emergency of any kind can be prevented, we believe providers should be able to disclose Part 2 information as necessary in an effort to prevent such an emergency from occurring. Patient safety and quality of care should be of primary importance.

Additionally, we believe the requirement under Section 2.51 that a Part 2 program immediately document a disclosure pursuant to a medical emergency should be removed from the regulations. Under Section 2.51, information covered by Part 2 may be disclosed to treat the patient for a condition which poses an immediate threat to the patient's health and which requires immediate medical intervention. Currently, disclosures in these urgent scenarios must be "immediately" documented in writing setting forth the name of the personnel to whom the disclosure was made and their affiliation with any health care facility, the name of the individual making the disclosure, the date and time of the disclosure and the nature of the emergency. This documentation requirement is unduly burdensome in a crisis situation. Thus, if a hospital "breaks the glass" in this scenario, the Part 2 program may not know whose record was accessed except through an audit trail and would have difficulty documenting timely or accurately. It is also important to note that when Part 2 information is disclosed pursuant to a medical emergency, that information loses its Part 2 protections and can therefore be further disclosed by the entity in receipt of the information. We recommend revisions to the regulations governing redisclosure consistent with Section (c) herein.

e. Qualified Service Organization (QSO)

SAMHSA is considering expanding the definition of a qualified service organization 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. SAMHSA has posed the following questions regarding expanding the QSOA concept:

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

Are there specific patient concerns about the impact of this change on their privacy?

Generally, we support expanding the QSO concept to enable increased sharing of health information for care coordination purposes. However, we are concerned that expanding the QSOA exception as contemplated would not address the issue of redisclosure of such information by the HIE, health home, ACO or CCE to which the Part 2 provider is originally disclosing information. Accordingly, true bi-directional health information exchange would not be permitted under Part 2 even if the QSO concept is broadened as SAMHSA proposes. Given this, as suggested in Section (b) above, we recommend that SAMHSA revise Part 2 to enable the disclosure of substance abuse treatment information to HIEs, health homes, ACOs, CCEs and other entities and providers involved in the patient's treatment, consistent with HIPAA. Furthermore, we recommend SAMHSA make clear that the prohibition on redisclosure does not apply to an HIE, health home, ACO, CCE or an affiliated provider if a patient consents to their information being disclosed to such HIE, health home, ACO, CCE, or other care coordination entity involved in the patient's treatment. We believe that these changes to the regulations would

enable greater patient choice and help ensure that treatment is appropriately coordinated for behavioral health patients.

Furthermore, we strongly believe that it should be the patient's choice and decision as to whether they want their substance abuse treatment information shared among providers for the benefit of their treatment. For this reason, we advocate for revisions to the regulations in order to permit patients to consent to their substance abuse treatment information being shared with HIEs, health homes, ACOs and CCEs in the same manner as HIPAA. We believe that permitting patients to consent to such disclosures of their information is the better mechanism for achieving increased coordination of care as opposed to using the QSO mechanism to achieve this aim.

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. SAMHSA has posed the following questions related to this potential change.

- *Are there factors that should be considered related to how current health care entities are organized, how they function or how legal duties and responsibilities attach to entities that make up an umbrella organization?*
- *Would this change address concerns related to research?*
- *Are there specific privacy concerns associated with expanding the authority or releasing data to qualified researchers/research organizations in this way?*
- *Are there additional use cases that should be considered in the research context?*

As a preliminary matter, the proposed rule states that health care entities that receive and store Part 2 data would be able to disclose patient identifying information to researchers for the purpose of research, audit and evaluation. We believe that audit and evaluation functions are addressed separately in Section 2.53 and should not be comingled in this research provision unless these terms will be further defined. Our comments below focus on disclosure for the purpose of research only.

Under HIPAA, a health care entity may disclose protected health information ("PHI") for the purpose of research if: (1) the recipient researcher has obtained approval by its institutional review board; (2) the patient consented to the release of his or her information; (3) the PHI is part of a limited data set; or (4) the data is first de-identified. SAMHSA's proposed expansion of the research exception would align the research exception under Part 2 more closely with the requirements under HIPAA, which we support. Specifically, a health care entity that receives and stores Part 2 data would be able to disclose patient identifying information for the purpose of research, provided that the researcher first obtains approval by its institutional review board. We support this change in Part 2 and are generally supportive of other changes to Part 2 which make the regulations consistent with the rules under HIPAA.

However, under this expanded exception, the researcher would only be permitted to disclose patient identifying information back to the health care entity that supplied the information. When the health care entity is a health information organization ("HIO") that oversees and

governs the exchange of health-related information among its participating organizations or is a CCO comprised of several program participants, a unique situation arises. The information disclosed back to an HIO or a CCO would represent a combination of the information belonging to individual HIO participants or the individual CCO program participants. When the information is disclosed back to the health care entity after the conclusion of the research study, then the question arises as to whether each participant of the HIO or each program participant of the CCO is entitled to the research report. The research report would represent an amalgamation of individual participants' patient health information and would provide each participant with information about other participants' patients, something they would not have access to before.

In an HIO context, the HIO is a business associate of each of its covered entity-participants. As such, it may not disclose patient identifying information of one participant back to other participants. Alternatively, in a CCO context, each program participant is a partial owner of the CCO. As such, the CCO would be able to disclose patient identifying information received through a research study back to all participants. These issues must be carefully considered in revising the research exception under Part 2.

We believe expanding the authority for releasing data to qualified researchers/research organizations to health care entities that receive and store Part 2 data would address concerns related to research. Effective management of our population's health is critical. We need statistics about what ails the population and information about where our resources should be directed based on those statistics. It is imperative that substance abuse data be included in these statistics so that we can identify underlying health problems affecting our population and the most effective interventions. Expanding the authority to release patient identifying information from health care entities that receive and store Part 2 information to researchers will allow for this. It will create a larger pool of information that will more accurately reflect our population's health and can serve as a basis for the development and implementation of appropriate healthcare measures.

g. Addressing Potential Issues with Electronic Prescribing and Prescription Drug Monitoring Programs

SAMHSA has posed the following questions regarding 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?*
- *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.*
- *Are there patient concerns about the impact of e-prescribing and PDMPs on their privacy?*

Of particular concern to some is that PDMP programs are state run and each PDMP follows certain prescription drugs and not others, has particular access requirements and tracking methods, and has different procedures for sharing information with law enforcement and other entities. These programs are not consistent across state lines and because each state employs different rules and procedures, establishing a federal standard under Part 2 may result in further

complications and prevent necessary collection and utilization of information about prescription drug abuse and unlawful drug-seeking behaviors for the benefit of the general public.

There is also a lack of common technical standards, vocabularies, and system-level access controls to allow PDMPs to share computable information with electronic health records and pharmacy systems that prescribers and dispensers use to support automated queries and reporting. No formal standards or specifications exist for sharing a PDMP report electronically with a prescriber or dispenser. This will continue to pose a problem even if the regulations are revised to address issues with PDMP data sharing.

Patients want to know that information regarding prescription drugs they have been prescribed for substance abuse treatment is protected just like all other Part 2 information. Accordingly, patients should be informed that if e-prescribing is used to prescribe them prescription drugs for substance abuse treatment, such information may not be protected by Part 2 and therefore may be redisclosed, including to PDMPs.

The goals of PDMPs are important, being to address unlawful drug-seeking behaviors and reduce overdoses, deaths and health care costs associated with abuse of prescription drugs. However, Part 2 requires consent to disclosures absent other limited exceptions applying. Patients, persons in recovery and other interested stakeholders have legitimate concerns about substance abuse treatment information, including prescription drug information, being accessible by law enforcement and leading to investigation, arrest or other forms of discrimination. For this reason and others, we recommend adding the following specific provisions to the regulations in order to protect against wrongful use of Part 2 information and discrimination against persons who are receiving/have received substance abuse treatment:

1. Add new section establishing the mandatory exclusion from evidence of information obtained in violation of Part 2.
2. Add new section limiting the use of Part 2 information in civil proceedings (in addition to criminal proceedings).
3. Add anti-discrimination provisions prohibiting health plans, providers and employers from discrimination against persons who are the subject of records covered by Part 2.

Disclosures for Public Health Reporting and Public Health Activity Purposes

We believe Part 2 should be revised to allow for the disclosure of Part 2 information for required public health reporting purposes or other public health activities in accordance with HIPAA and applicable State law. Specifically, we believe SAMHSA should make clear that Part 2 information may be disclosed for public health reporting or other public health activities purposes under the audit and evaluation exception at Section 2.53. Like other health care programs, Part 2 programs regularly encounter public health issues, such as patients with communicable diseases. However, Part 2 does not allow for reporting to public health authorities in these serious situations without specific patient consent. Often times, State law mandates public health reporting, yet providers find themselves unable to report in compliance with Part 2. This poses significant risks to the public and serves as an obstacle to improved health and wellness of populations. In order to better manage population health and improve the overall effectiveness of our health care delivery system, public health reporting must be

permitted by law and promoted as a critical component of care. Therefore, we urge SAMHSA to revise Part 2 to specifically allow disclosures for public health reporting purposes and other public health activities under the audit and evaluation exception at Section 2.53.

Duty to Warn

In the interest of public safety and the welfare of substance abuse treatment clients, we also urge SAMHSA to add a “duty to warn” exception to the regulations at Part 2 which allows disclosures of patient information without patient consent when such disclosures are necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. Section 164.512(j) of HIPAA and most state laws expressly permit a health care provider to disclose patient information without consent, including information from mental health records, if the provider in good faith believes the disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. However, the regulations at Part 2 do not contain an exception which allows substance abuse treatment providers to make disclosures of patient information in such situations. Ironically, many treatment providers erroneously believe a “duty to warn” exception exists now under the regulations. The Newtown, Connecticut tragedy that occurred in December of 2012 shocked and pained the entire nation. In search of answers and recognition of the unacceptability of the status quo, national experts gathered to address gun violence, our mental health system’s treatment, funding needs and prevention strategies to reduce the potential for reoccurrence of such horrific events. As part of that process, the “duty to warn” laws were front and center of that discussion. On January 15, 2013 HHS issued confusing guidance to health care providers indicating that no federal law prohibited them from reporting threats of violence to law enforcement authorities. While this was intended to reassure providers who were uncertain about exercising their “duty to warn” under federal statutes, it was inaccurate. While HIPAA is by far the best known and most widely used federal privacy protection, Part 2 governs many behavioral health providers. This guidance caused some treatment providers to wonder whether Part 2 was now preempted by the Executive Orders issued by the President and requires clarification.

Section 164.512(j) of HIPAA permits disclosures in a “duty to warn” situation to any of the following: law enforcement officials, family members of the patient or others who may reasonably be able to prevent or lessen the threat. In contrast, the only exceptions under Part 2 which allow for disclosure of patient information without consent in situations in which a threat to the health or safety of a person or the public exists are the following: (i) disclosures pursuant to a valid court order (42 C.F.R. § 2.61-2.66); (ii) disclosures to law enforcement if an immediate threat to the health or safety of an individual exists due to a crime on program premises or against program personnel (42 C.F.R. § 2.12(c)(5)); (iii) reports to health care personnel under the medical emergency exception for purposes of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention (42 C.F.R. § 2.51); and (iv) anonymous disclosures made without divulging patient identifying information. Due to the lack of a “duty to warn” exception under Part 2, substance abuse treatment providers regularly face ethical dilemmas of patient rights versus public safety.

With the increased number of patients with co-morbid mental health conditions, the substance abuse treatment community is a critical intervention source that must understand its role in

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assisting complex patients with their recovery while appropriately identifying potential threats and communicating with law enforcement if greater public safety interests exist. Adding a “duty to warn” exception to Part 2 is a crucial and necessary change that will give providers the flexibility they need to mitigate serious danger to their patients and others. This “duty to warn” concept is a fixture of not just HIPAA, but also state common and licensure laws. It is taken very seriously by providers and does not, we believe, pose a potential area for abuse. Therefore, we urge SAMHSA to add a “duty to warn” exception to the regulations which permits disclosures of patient information without patient consent when such disclosures are necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public, thereby harmonizing Part 2 with HIPAA in this regard.

Conclusion

We appreciate the opportunity to comment on SAMHSA’s proposals to update Part 2. We encourage SAMHSA to work with its sister agencies, CMS and ONC, in revising the regulations and issuing subregulatory guidance of any kind. While we support SAMHSA pursuing specific revisions to Part 2 to enable increased exchange of health information for care coordination purposes, we recognize that the regulatory process takes considerable time. Given the confusion that currently exists and the significant challenges that providers continue to face as a result of the regulations at Part 2, we urge SAMHSA along with ONC and CMS to issue immediate joint subregulatory guidance which provides clarity on these issues and affords Part 2 providers appropriate guidance so that they are protected in relying on SAMHSA’s interpretations of the regulations and compliance with the same.

We respectfully request SAMHSA’s urgency in addressing these various issues under Part 2 in order to ensure increased care coordination and improved health outcomes for the benefit of patients in Illinois and nationally, and the behavioral health field.

Sincerely,

Russell J. Hagen, CEO
Chestnut Health Systems, Inc.
Chestnut Global Partners, LLC

Attached: *Part 2 Evolution: A Vision for Integrated Care and Enhanced Rights*



June 25, 2014

The Substance Abuse and Mental Health Services Administration (SAMHSA)
1 Choke Cherry Road, Room 5-1011
Rockville, MD 20857

RE: FR Doc. 2014-10913 – 42 CFR Part 2

Dear To Whom It May Concern:

I am writing on behalf of Gateway Foundation (“Gateway”). Gateway is the largest non-profit organization provider of drug rehab and alcohol treatment in Illinois, with drug treatment centers in Aurora, Chicago, Carbondale, Lake Villa, and Springfield, Illinois as well as St. Louis, Missouri. We are dedicated to making a real difference in the lives of the people we treat. Since 1968, we have been an industry leader in providing the answers individuals and their families need related to drug and alcohol treatment. Our substance abuse treatment programs treat both adults and teens and include Outpatient, Residential, Day Treatment and Aftercare. We also provide treatment to those who are challenged with a Co-Occurring/Dual-Diagnosed mental health problem. Gateway's drug and alcohol treatment programs are innovative, effective and cost-efficient. The work we have done has earned us numerous awards in the industry as well as accreditation by The Joint Commission, the leading accrediting organization for hospitals and other healthcare organizations. We also strive to educate individuals, businesses, policy makers and the public about major issues related to substance abuse, alcohol and drug addiction and treatment. We act as advocates in urging adoption of comprehensive drug rehab and alcohol treatment programs.

As a provider of substance abuse treatment services, Gateway is intimately familiar with the considerable difficulties surrounding compliance with the federal confidentiality regulations at 42 CFR Part 2 (“Part 2”). Moreover, these confidentiality issues have become even more complicated in the context of our rapidly changing health care delivery system as a result of health care reform. Providers are increasingly moving to an electronic health record, and while some health care providers are being incentivized by the federal government to adopt electronic health records through meaningful use regulations, most behavioral health providers are currently ineligible for such incentives. Nonetheless, paper records and written consents are becoming impractical and obsolete. Further, there is a very significant national interest in promoting the coordination of health services delivered by multiple providers through new integrated care models including health information exchanges (“HIEs”), health homes, accountable care organizations (“ACOs”) and other care coordination entities (“CCEs”). Unfortunately, the current statutory and regulatory framework for the Federal Confidentiality of Alcohol and Drug Abuse Patient Records law (“SUD Confidentiality Law”) provide no guidance on electronic health records because many of the concepts did not exist forty years ago. Likewise, such providers cannot effectively participate in HIEs, health homes, ACOs, or CCEs. The unfortunate and unintended result is that the important benefits of electronic health records,

HIEs, health homes, ACOs and CCEs as mechanisms to coordinate the continuum of care are significantly diminished by the SUD Confidentiality Law and the attendant regulations at Part 2. Further, since the SUD Confidentiality Law was implemented, the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the Health Information Technology for Economic and Clinical Health (“HITECH”) Act have been enacted. It is imperative to address these laws in Part 2 to ensure that records covered by Part 2 are subject to its broader protections in all cases. This is especially true given the advent of electronic health records and the limited data segmentation capabilities that exist at this time.

Cognizant of the arduous task of revising and updating the regulations at Part 2, Gateway is pleased to provide SAMHSA with our response to the Notice of Public Listening Session published in the Federal Register on May 12, 2014. Thank you for your commitment to advancing the confidentiality conversation as it relates to substance abuse treatment information protected by Part 2. We offer the below comments and recommendations in response to SAMHSA’s proposed concepts and questions on the seven specific topics discussed in the proposed rule and at the public listening session on June 11, 2014. Our consideration of these issues is informed by our firsthand experience of the unique challenges Part 2 poses for meaningful exchange of substance abuse treatment information for the purpose of coordinating and integrating care to improve patient outcomes.

a. Applicability of 42 CFR Part 2

SAMHSA has proposed that covered information under Part 2 could be defined based on what substance abuse treatment services are provided instead of being defined by the type of facility providing the services. SAMHSA has posed the following questions related to this potential change:

- *How would redefining the applicability of Part 2 impact patients, health care provider organizations, HIEs, CCOs, HIT vendors, etc.?*
- *Would this change address stakeholder concerns?*
- *Would this change raise any new concerns?*

We oppose broadening the applicability of Part 2 to include entities other than Part 2 programs because doing so would detrimentally impact patients, health care provider organizations, health information exchanges (“HIEs”), care coordination organizations (“CCOs”) and health IT vendors by further restricting the sharing of health information for care coordination purposes. Such a change would further hinder the meaningful exchange of patient health information for the benefit of treatment.

Sitting prominently on SAMHSA’s website is a slogan: “*Behavioral Health is Essential to Health*”. Stated another way, “*Health is Essential to Behavioral Health.*” With this in mind, the following two principles should guide any changes to the applicability section of the regulations at Part 2. First, changes to this section must focus on what is best for the patient. We strongly support confidentiality protections for patients, however, having separate health information privacy requirements for substance abuse treatment patients does more harm to the patient, harm to their families and harm to their communities by necessitating a separate and unequal health data sharing environment that prevents the full inclusion of substance abuse

treatment patients into integrated health settings and systems. Second, any changes to this section should also consider what is necessary for providers to deliver optimal care and what barriers must be addressed in order to ensure providers can deliver optimal care. Broadening the applicability of this section would make it more difficult for providers to share medical information through the ILHIE and other HIEs, which makes it more difficult to deliver timely, optimal care.

Specifically, we recommend the following with regard to the applicability section of Part 2:

1. We support the harmonization of Part 2 wherever possible with the Health Insurance Portability and Accountability Act (“HIPAA”) and its implementing regulations. It is our strong belief that efforts to harmonize Part 2 with HIPAA would ensure increased care coordination among treating providers and other entities which share health information for care coordination and integration purposes, improve patient care and enhance privacy protections by making confidentiality restrictions more uniform across health care settings. This allows for the achievement of improved health outcomes through increased coordination of care for patients. We also support preserving certain patient protections afforded under Part 2, such as the criminal penalties for violations of Part 2 at Section 2.4 and the stringent court order requirements at Sections 2.61-2.66.
2. We support clarifying that the regulations at Part 2 apply only to substance abuse specialty treatment programs and providers who are specifically licensed, credentialed, or accredited as substance abuse treatment providers. Further, the regulations should not apply to individual certified or licensed specialty substance abuse treatment providers who are practicing within a larger organization unless the larger organization is also specifically licensed, credentialed or accredited as a substance abuse treatment provider.
3. We are also opposed to any attempts to further define “covered information” based on what substance abuse treatment services are provided. Any changes to this section of the regulations should consider simplification as well as how patient protections can be retained and enhanced as described in the White Paper entitled “*Part 2 Evolution: A Vision for Integrated Care and Enhanced Rights*” by Renée Popovits, et al.
4. We oppose extending Part 2 applicability to health care providers who provide only screening, brief intervention and referral to treatment (“SBIRT”) services. We do not believe it was ever the intent of the regulations to cover treatment information of this limited nature. Providers of SBIRT services provide brief screenings of individuals who may require substance abuse treatment and referrals to appropriate and specialized treatment. Providers of SBIRT services are not themselves providing specialized substance abuse treatment services.

b. Consent Requirements

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

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

SAMHSA has asked for comments on patient privacy concerns as well as the anticipated impact of the consent requirements on integration of substance abuse treatment data into HIEs, health homes, ACOs, and CCOs. Specifically, SAMHSA has posed the following questions:

- *Would these changes maintain the privacy protections for patients?*
- *Would these changes address the concerns of HIEs, health homes, ACOs, and CCOs?*
- *Would these changes raise any new concerns?*

Providers, patients and HIEs in the State of Illinois know first-hand the challenges associated with consent issues. However, both real and perceived consent barriers continue to block successful coordination of care efforts for Illinois patients. Illinois patients deserve the option and the choice of deciding whether they want their substance abuse treatment information shared through HIEs. If the consent roadblocks are not addressed, patients will continue to be deprived of their right to participate. Providers must be able to treat a whole person in an integrated delivery system in a coordinated way to yield better outcomes. Patients deserve it. A patient should not be excluded from HIE participation unless the patient decides to be excluded. It is the patient's choice.

Requiring the consent to name the specific individual or health care entity permitted to receive the disclosure prevents programs covered by Part 2 from participating in HIEs, health homes, accountable care organizations ("ACOs") and care coordination entities ("CCEs") because it is impossible to specify every organization and/or individual who might possibly receive information via an HIE, health home, ACO or CCE. Thus, even when a patient seeks to affirmatively consent to include his or her information in an HIE, health home, ACO or CCE, he or she cannot effectively provide such consent under current Part 2 regulations. Moreover, requiring patients to be provided with a list of providers or organizations that may access their information and be notified regularly of changes to the list would be impossible in the context of HIEs, where providers join HIE networks on a daily basis.

This requirement that a single individual or organization be named on a Part 2 consent is wholly inconsistent with the important federal and Illinois goals of achieving care coordination and integration. This requirement functions to discriminate against Part 2 program patients in two ways. First, general medical/surgical patients have the ability to provide a broader consent, but substance abuse treatment patients are restricted from doing so. Second, substance abuse treatment patients are effectively excluded from participation in HIEs due to the rigidity of the consent regulations and the technological inability to uniformly segregate substance abuse data in accordance with the stringent requirements contained in Part 2. As a result, a digital divide exists between general medical/surgical patients and substance abuse treatment patients as substance abuse treatment patients are not given an equal opportunity to participate or decide who should have access to their information. This not only perpetuates discrimination against substance abuse treatment patients (the very stigma that the SUD Confidentiality Law and Part 2

was intended to address) but it also interferes with the important objectives of the Affordable Care Act.

Given this, we urge SAMHSA to revise Part 2 consent requirements. Specifically, SAMHSA should:

1. Address the “To Whom” problem by revising the regulations to permit disclosures of substance abuse treatment information in a manner consistent with HIPAA by permitting patients to generally consent to disclosures of their substance abuse treatment information for the purposes of treatment, payment or health care operations. SAMHSA should additionally adopt the HIPAA definitions of “treatment,” “payment” and “health care operations”. Among other goals, this revision allows patient substance abuse treatment information to be disclosed to one or more HIEs, health homes, ACOs or CCEs, including any individual or institutional provider participating in such organizations with a direct treatment relationship with the patient, as treatment under HIPAA includes the coordination or management of health care and related services by one or more health care providers.
2. Harmonize the consent elements in Section 2.31 with the authorization requirements in HIPAA.
3. Assuming there is initial consent to disclosure to the HIE, health home, ACO or CCE, permit the redisclosure of information among such data recipients in a manner consistent with HIPAA, including redisclosure for the purposes of treatment, payment and health care operations without additional patient consent.
4. Adopt appropriate safeguards such as requiring data custodians to maintain audit trails and conduct routine audits.
5. Afford meaningful protections to address patient discrimination concerns as a result of relaxing the consent provisions, such as a mandatory exclusion from evidence provision for information obtained in violation of Part 2.

To the extent patient consent is required for a disclosure, we offer the following comments:

1. We support allowing the consent to include a more general description of the individual, organization, or other health care entity to which disclosure is to be made in order to enable the exchange of health information.
2. We oppose requiring the patient to be provided with a list of providers or organizations that may access their information and be notified regularly of changes to the list as such requirements are unduly burdensome and would be impossible in the context of HIEs and coordination of care. To clarify, we are not opposed to providing such a list to a patient if specifically requested, but we do not believe this should be a mandatory requirement.
3. We oppose any requirement that multiple independent units or organizations that make up a health care entity that may make a disclosure must be specifically named.
4. We agree that the consent form should continue to include how much and what kind of substance abuse treatment information is to be disclosed, as is currently required under Section 2.31. We do not support requiring consents to include more information than is already required under the current regulations as doing so would prevent the meaningful exchange of health information and coordination of care.

c. Redisclosure

SAMHSA is considering revising the redisclosure provision to clarify that the prohibition on redisclosure only applies to information that would identify an individual as a substance abuser, and allows other health-related information shared by the Part 2 program to be redisclosed, if legally permissible. SAMHSA has posed the following questions regarding this potential change:

- *Would this type of change facilitate technical solutions for complying with 42 CFR Part 2 in an EHR or HIE environment?*
- *Would these changes maintain the privacy protections for patients?*

The prohibition on redisclosure in Section 2.32 effectively prevents providers participating in an HIE, health home, ACO, or CCE from disclosing substance abuse treatment information among each other for treatment and care coordination purposes. Therefore, in addition to revising Part 2 to allow patients to consent to the disclosure of their substance abuse treatment information to an HIE, health home, ACO or CCE and its provider-members that are providing treatment to a patient (as recommended in Section (b) above), we also recommend revising the regulations to allow for the redisclosure of substance abuse treatment information by and among provider-members of an HIE, health home, ACO or CCE with a direct treatment relationship for the purposes of treatment, payment or health care operations. Further, we recommend that the regulations be revised to establish that the prohibition on redisclosure does not apply to outside HIEs or provider-members of such exchanges who have a direct treatment relationship with the patient and who need access to records to treat the patient on an emergent basis.

To be clear, we are recommending that for purposes of treatment, payment and health care operations, substance abuse treatment information should be able to be disclosed and redisclosed by and among provider-members of an HIE, health home, ACO or CCE with a direct treatment relationship with the patient. However, this change would not allow for information to be further disclosed or redisclosed by an HIE, health home, ACO or CCE or its provider-members without a patient's consent for any purposes other than for treatment, payment and health care operations, or as permitted under applicable exceptions under Part 2. Moreover, Part 2 information would not be accessible to anyone outside of the HIE, health home, ACO or CCE unless a specific exception applies or the stringent court order requirements under Part 2 are met. In other words, Part 2 information would not be able to be disclosed for non-treatment purposes to law enforcement, employers, insurance companies, divorce attorneys or others seeking to use the information against the patient. Furthermore, we urge SAMHSA to go one step further in order to protect patients against unlawful disclosure of their substance abuse treatment information by adding a mandatory exclusion from evidence provision to Part 2.

d. Medical Emergency

SAMHSA has posed the following questions regarding the medical emergency exception under Part 2:

- *What factors should providers take into consideration in determining whether a medical emergency exists?*
- *Are there specific use cases SAMHSA should take into consideration?*

- *Are there patient concerns about the impact of this change on their privacy?*

We support expanding the medical emergency exception to give providers more discretion to determine when a bona fide medical emergency exists. Further, we support amending the standard to allow providers to use the medical emergency provision to *prevent* emergencies or to share information with a detoxification center when a patient is unable to provide informed consent due to their level of intoxication. If a medical emergency of any kind can be prevented, we believe providers should be able to disclose Part 2 information as necessary in an effort to prevent such an emergency from occurring. Patient safety and quality of care should be of primary importance.

Additionally, we believe the requirement under Section 2.51 that a Part 2 program immediately document a disclosure pursuant to a medical emergency should be removed from the regulations. Under Section 2.51, information covered by Part 2 may be disclosed to treat the patient for a condition which poses an immediate threat to the patient's health and which requires immediate medical intervention. Currently, disclosures in these urgent scenarios must be "immediately" documented in writing setting forth the name of the personnel to whom the disclosure was made and their affiliation with any health care facility, the name of the individual making the disclosure, the date and time of the disclosure and the nature of the emergency. This documentation requirement is unduly burdensome in a crisis situation. Thus, if a hospital "breaks the glass" in this scenario, the Part 2 program may not know whose record was accessed except through an audit trail and would have difficulty documenting timely or accurately. It is also important to note that when Part 2 information is disclosed pursuant to a medical emergency, that information loses its Part 2 protections and can therefore be further disclosed by the entity in receipt of the information. We recommend revisions to the regulations governing redisclosure consistent with Section (c) herein.

e. Qualified Service Organization (QSO)

SAMHSA is considering expanding the definition of a qualified service organization 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. SAMHSA has posed the following questions regarding expanding the QSOA concept:

- *Are there other use cases we should be taking into consideration?*
- *Are there specific patient concerns about the impact of this change on their privacy?*

Generally, we support expanding the QSO concept to enable increased sharing of health information for care coordination purposes. However, we are concerned that expanding the QSOA exception as contemplated would not address the issue of redisclosure of such information by the HIE, health home, ACO or CCE to which the Part 2 provider is originally disclosing information. Accordingly, true bi-directional health information exchange would not be permitted under Part 2 even if the QSO concept is broadened as SAMHSA proposes. Given this, as suggested in Section (b) above, we recommend that SAMHSA revise Part 2 to enable the disclosure of substance abuse treatment information to HIEs, health homes, ACOs, CCEs and other entities and providers involved in the patient's treatment, consistent with HIPAA.

Furthermore, we recommend SAMHSA make clear that the prohibition on redisclosure does not apply to an HIE, health home, ACO, CCE or an affiliated provider if a patient consents to their information being disclosed to such HIE, health home, ACO, CCE, or other care coordination entity involved in the patient's treatment. We believe that these changes to the regulations would enable greater patient choice and help ensure that treatment is appropriately coordinated for behavioral health patients.

Furthermore, we strongly believe that it should be the patient's choice and decision as to whether they want their substance abuse treatment information shared among providers for the benefit of their treatment. For this reason, we advocate for revisions to the regulations in order to permit patients to consent to their substance abuse treatment information being shared with HIEs, health homes, ACOs and CCEs in the same manner as HIPAA. We believe that permitting patients to consent to such disclosures of their information is the better mechanism for achieving increased coordination of care as opposed to using the QSO mechanism to achieve this aim.

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. SAMHSA has posed the following questions related to this potential change:

- *Are there factors that should be considered related to how current health care entities are organized, how they function or how legal duties and responsibilities attach to entities that make up an umbrella organization?*
- *Would this change address concerns related to research?*
- *Are there specific privacy concerns associated with expanding the authority or releasing data to qualified researchers/research organizations in this way?*
- *Are there additional use cases that should be considered in the research context?*

As a preliminary matter, the proposed rule states that health care entities that receive and store Part 2 data would be able to disclose patient identifying information to researchers for the purpose of research, audit and evaluation. We believe that audit and evaluation functions are addressed separately in Section 2.53 and should not be comingled in this research provision unless these terms will be further defined. Our comments below focus on disclosure for the purpose of research only.

Under HIPAA, a health care entity may disclose protected health information ("PHI") for the purpose of research if: (1) the recipient researcher has obtained approval by its institutional review board; (2) the patient consented to the release of his or her information; (3) the PHI is part of a limited data set; or (4) the data is first de-identified. SAMHSA's proposed expansion of the research exception would align the research exception under Part 2 more closely with the requirements under HIPAA, which we support. Specifically, a health care entity that receives and stores Part 2 data would be able to disclose patient identifying information for the purpose of research, provided that the researcher first obtains approval by its institutional review board. We support this change in Part 2 and are generally supportive of other changes to Part 2 which make the regulations consistent with the rules under HIPAA.

However, under this expanded exception, the researcher would only be permitted to disclose patient identifying information back to the health care entity that supplied the information. When the health care entity is a health information organization (“HIO”) that oversees and governs the exchange of health-related information among its participating organizations or is a CCO comprised of several program participants, a unique situation arises. The information disclosed back to an HIO or a CCO would represent a combination of the information belonging to individual HIO participants or the individual CCO program participants. When the information is disclosed back to the health care entity after the conclusion of the research study, then the question arises as to whether each participant of the HIO or each program participant of the CCO is entitled to the research report. The research report would represent an amalgamation of individual participants’ patient health information and would provide each participant with information about other participants’ patients, something they would not have access to before.

In an HIO context, the HIO is a business associate of each of its covered entity-participants. As such, it may not disclose patient identifying information of one participant back to other participants. Alternatively, in a CCO context, each program participant is a partial owner of the CCO. As such, the CCO would be able to disclose patient identifying information received through a research study back to all participants. These issues must be carefully considered in revising the research exception under Part 2.

We believe expanding the authority for releasing data to qualified researchers/research organizations to health care entities that receive and store Part 2 data would address concerns related to research. Effective management of our population’s health is critical. We need statistics about what ails the population and information about where our resources should be directed based on those statistics. It is imperative that substance abuse data be included in these statistics so that we can identify underlying health problems affecting our population and the most effective interventions. Expanding the authority to release patient identifying information from health care entities that receive and store Part 2 information to researchers will allow for this. It will create a larger pool of information that will more accurately reflect our population’s health and can serve as a basis for the development and implementation of appropriate healthcare measures.

g. Addressing Potential Issues with Electronic Prescribing and Prescription Drug Monitoring Programs

SAMHSA has posed the following questions regarding 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?*
- *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.*
- *Are there patient concerns about the impact of e-prescribing and PDMPs on their privacy?*

Of particular concern to some is that PDMP programs are state run and each PDMP follows certain prescription drugs and not others, has particular access requirements and tracking

methods, and has different procedures for sharing information with law enforcement and other entities. These programs are not consistent across state lines and because each state employs different rules and procedures, establishing a federal standard under Part 2 may result in further complications and prevent necessary collection and utilization of information about prescription drug abuse and unlawful drug-seeking behaviors for the benefit of the general public.

There is also a lack of common technical standards, vocabularies, and system-level access controls to allow PDMPs to share computable information with electronic health records and pharmacy systems that prescribers and dispensers use to support automated queries and reporting. No formal standards or specifications exist for sharing a PDMP report electronically with a prescriber or dispenser. This will continue to pose a problem even if the regulations are revised to address issues with PDMP data sharing.

Patients want to know that information regarding prescription drugs they have been prescribed for substance abuse treatment is protected just like all other Part 2 information. Accordingly, patients should be informed that if e-prescribing is used to prescribe them prescription drugs for substance abuse treatment, such information may not be protected by Part 2 and therefore may be redisclosed, including to PDMPs.

The goals of PDMPs are important, being to address unlawful drug-seeking behaviors and reduce overdoses, deaths and health care costs associated with abuse of prescription drugs. However, Part 2 requires consent to disclosures absent other limited exceptions applying. Patients, persons in recovery and other interested stakeholders have legitimate concerns about substance abuse treatment information, including prescription drug information, being accessible by law enforcement and leading to investigation, arrest or other forms of discrimination. For this reason and others, we recommend adding the following specific provisions to the regulations in order to protect against wrongful use of Part 2 information and discrimination against persons who are receiving/have received substance abuse treatment:

1. Add new section establishing the mandatory exclusion from evidence of information obtained in violation of Part 2.
2. Add new section limiting the use of Part 2 information in civil proceedings (in addition to criminal proceedings).
3. Add anti-discrimination provisions prohibiting health plans, providers and employers from discrimination against persons who are the subject of records covered by Part 2.

Disclosures for Public Health Reporting and Public Health Activity Purposes

We believe Part 2 should be revised to allow for the disclosure of Part 2 information for required public health reporting purposes or other public health activities in accordance with HIPAA and applicable State law. Specifically, we believe SAMHSA should make clear that Part 2 information may be disclosed for public health reporting or other public health activities purposes under the audit and evaluation exception at Section 2.53. Like other health care programs, Part 2 programs regularly encounter public health issues, such as patients with communicable diseases. However, Part 2 does not allow for reporting to public health authorities in these serious situations without specific patient consent. Often times, State law mandates public health reporting, yet providers find themselves unable to report in compliance

with Part 2. This poses significant risks to the public and serves as an obstacle to improved health and wellness of populations. In order to better manage population health and improve the overall effectiveness of our health care delivery system, public health reporting must be permitted by law and promoted as a critical component of care. Therefore, we urge SAMHSA to revise Part 2 to specifically allow disclosures for public health reporting purposes and other public health activities under the audit and evaluation exception at Section 2.53.

Duty to Warn

In the interest of public safety and the welfare of substance abuse treatment clients, we also urge SAMHSA to add a “duty to warn” exception to the regulations at Part 2 which allows disclosures of patient information without patient consent when such disclosures are necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. Section 164.512(j) of HIPAA and most state laws expressly permit a health care provider to disclose patient information without consent, including information from mental health records, if the provider in good faith believes the disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. However, the regulations at Part 2 do not contain an exception which allows substance abuse treatment providers to make disclosures of patient information in such situations. Ironically, many treatment providers erroneously believe a “duty to warn” exception exists now under the regulations. The Newtown, Connecticut tragedy that occurred in December of 2012 shocked and pained the entire nation. In search of answers and recognition of the unacceptability of the status quo, national experts gathered to address gun violence, our mental health system’s treatment, funding needs and prevention strategies to reduce the potential for reoccurrence of such horrific events. As part of that process, the “duty to warn” laws were front and center of that discussion. On January 15, 2013 HHS issued confusing guidance to health care providers indicating that no federal law prohibited them from reporting threats of violence to law enforcement authorities. While this was intended to reassure providers who were uncertain about exercising their “duty to warn” under federal statutes, it was inaccurate. While HIPAA is by far the best known and most widely used federal privacy protection, Part 2 governs many behavioral health providers. This guidance caused some treatment providers to wonder whether Part 2 was now preempted by the Executive Orders issued by the President and requires clarification.

Section 164.512(j) of HIPAA permits disclosures in a “duty to warn” situation to any of the following: law enforcement officials, family members of the patient or others who may reasonably be able to prevent or lessen the threat. In contrast, the only exceptions under Part 2 which allow for disclosure of patient information without consent in situations in which a threat to the health or safety of a person or the public exists are the following: (i) disclosures pursuant to a valid court order (42 C.F.R. § 2.61-2.66); (ii) disclosures to law enforcement if an immediate threat to the health or safety of an individual exists due to a crime on program premises or against program personnel (42 C.F.R. § 2.12(c)(5)); (iii) reports to health care personnel under the medical emergency exception for purposes of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention (42 C.F.R. § 2.51); and (iv) anonymous disclosures made without divulging patient identifying information. Due to the lack of a “duty to warn” exception under Part 2, substance abuse treatment providers regularly face ethical dilemmas of patient rights versus public safety.

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With the increased number of patients with co-morbid mental health conditions, the substance abuse treatment community is a critical intervention source that must understand its role in assisting complex patients with their recovery while appropriately identifying potential threats and communicating with law enforcement if greater public safety interests exist. Adding a “duty to warn” exception to Part 2 is a crucial and necessary change that will give providers the flexibility they need to mitigate serious danger to their patients and others. This “duty to warn” concept is a fixture of not just HIPAA, but also state common and licensure laws. It is taken very seriously by providers and does not, we believe, pose a potential area for abuse. Therefore, we urge SAMHSA to add a “duty to warn” exception to the regulations which permits disclosures of patient information without patient consent when such disclosures are necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public, thereby harmonizing Part 2 with HIPAA in this regard.

Conclusion

We appreciate the opportunity to comment on SAMHSA’s proposals to update Part 2. We encourage SAMHSA to work with its sister agencies, CMS and ONC, in revising the regulations and issuing subregulatory guidance of any kind. While we support SAMHSA pursuing specific revisions to Part 2 to enable increased exchange of health information for care coordination purposes, we recognize that the regulatory process takes considerable time. Given the confusion that currently exists and the significant challenges that providers continue to face as a result of the regulations at Part 2, we urge SAMHSA along with ONC and CMS to issue immediate joint subregulatory guidance which provides clarity on these issues and affords Part 2 providers appropriate guidance so that they are protected in relying on SAMHSA’s interpretations of the regulations and compliance with the same.

We respectfully request SAMHSA’s urgency in addressing these various issues under Part 2 in order to ensure increased care coordination and improved health outcomes for the benefit of patients in Illinois and nationally, and the behavioral health field.

Sincerely,

Michael J. Darcy
President and CEO
Gateway Foundation

Attached: *Part 2 Evolution: A Vision for Integrated Care and Enhanced Rights*

June 25, 2014

The Substance Abuse and Mental Health Services Administration (SAMHSA)
1 Choke Cherry Road, Room 5-1011
Rockville, MD 20857

RE: FR Doc. 2014-10913 – 42 CFR Part 2

Dear To Whom It May Concern:

We are writing on behalf of the law firm of Popovits & Robinson, P.C. located in Frankfort, Illinois. Popovits & Robinson, P.C. serves as general counsel to numerous community-based behavioral health providers and represents specialty hospitals, physician practice clients, research organizations, trade associations and governmental entities in corporate transactions, insurance and parity issues, contracting, behavioral health integration projects, corporate compliance, confidentiality, licensure, reimbursement, data sharing, electronic health records, health information exchange and public policy matters.

Popovits & Robinson, P.C. has had the longstanding privilege of representing a number of the most well-respected behavioral health providers in the State of Illinois and in the nation, including Chestnut Health Systems, Rosecrance Health Network and Gateway Foundation. Serving as General Counsel and Special Counsel to these providers for almost two decades, we know firsthand the various challenges that substance abuse treatment providers face as a result of the regulations at 42 CFR Part 2 (“Part 2”) and have considerable experience advising our clients on the complexities of Part 2 compliance.

In addition to serving as legal counsel for substance abuse treatment providers, I am also Co-Chair of the Substance Abuse Subcommittee of the Legal Task Force of the Illinois Health Information Exchange (“ILHIE”) Authority. In this capacity I have served as a subject-matter expert on Part 2 and have worked directly with the State of Illinois to develop solutions to the issues that providers, health information exchanges, and care coordination entities experience as a result of the restrictions on sharing of substance abuse treatment information under Part 2. Our comments below are also informed by our firm’s involvement in Illinois’ Behavioral Health Integration Project (“BHIP”). Illinois’ BHIP was a joint effort of the State of Illinois and dozens of behavioral health and medical care organizations throughout the State. The goal of the BHIP was to promote the exchange of health information among behavioral health and medical care providers to improve care by helping licensed substance abuse and mental health practitioners to better coordinate patient care with their clients’ primary care providers. One of the realized BHIP deliverables was to amend the state’s mental health confidentiality law to enable the secure electronic exchange of patients’ mental health information. Illinois was one of five states that received federal funding to support the BHIP. The BHIP’s efforts also supported Illinois’ Care Innovations Program which seeks to coordinate care for Illinois’ Medicaid recipients, focusing on improved preventive care and follow-up treatment. Ensuring appropriate access to relevant patient information, such as current medications and medication history, holds great promise for improving the overall health of patients.

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Finally, I am also one of the founding members of the Patient Protection Coalition, a multidisciplinary group devoted to analyzing and improving the regulations at Part 2 in the era of electronic health records.

Over the years, Popovits & Robinson, P.C. has been actively involved in efforts to reexamine Part 2 in the context our rapidly changing health care delivery system. Providers are increasingly moving to an electronic health record, and while some health care providers are being incentivized by the federal government to adopt electronic health records through meaningful use regulations, most behavioral health providers are currently ineligible for such incentives. Nonetheless, paper records and written consents are becoming impractical and obsolete. Further, there is a very significant national interest in promoting the coordination of health services delivered by multiple providers through new integrated care models including health information exchanges (“HIEs”), health homes, accountable care organizations (“ACOs”) and other care coordination entities (“CCEs”). Unfortunately, the current statutory and regulatory framework for the Federal Confidentiality of Alcohol and Drug Abuse Patient Records law (“SUD Confidentiality Law”) provide no guidance on electronic health records because many of the concepts did not exist forty years ago. Likewise, such providers cannot effectively participate in HIEs, health homes, ACOs, or CCEs. The unfortunate and unintended result is that the important benefits of electronic health records, HIEs, health homes, ACOs and CCEs as mechanisms to coordinate the continuum of care are significantly diminished by the SUD Confidentiality Law and the attendant regulations at Part 2.

Moreover, since the SUD Confidentiality Law was implemented, the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the Health Information Technology for Economic and Clinical Health (“HITECH”) Act have been enacted. It is imperative to address these laws in Part 2 to ensure that records covered by Part 2 are subject to its broader protections in all cases. This is especially true given the advent of electronic health records and the limited data segmentation capabilities that exist at this time.

Given these challenges under the regulations and in an effort to further advance this important confidentiality conversation, we conducted randomized polling of interested stakeholders across the country regarding the impact Part 2 has on patient choice, electronic health records and health information exchange, sharing of health information contemplated by the Affordable Care Act (“ACA”), and stigma and discrimination. With the input of leaders in the behavioral health field we developed 10 polling questions on these critical topics and posed them to behavioral health providers, the recovery community, and other interested stakeholders during the following sessions and conferences: CiMH’s 14th Annual Behavioral Health Information Management Conference and Exposition on April 24, 2014, ASAM’s 45th Medical-Scientific Conference on April 12, 2014, and the National Council for Behavioral Health Conference in Washington, D.C. on May 5, 2014. The results from these important polls are attached to these comments for your reference. Of the 259 stakeholders questioned about revising Part 2, 49% are in favor of easing the consent requirements to facilitate sharing of substance abuse treatment information among providers and 39% of those 259 are in favor of making Part 2 more consistent with HIPAA.

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As evidenced by these polling results and other stakeholder opinion, it is time we address these critical information sharing and patient protection issues through appropriate revisions to Part 2. Accordingly, we drafted the attached White Paper published by Thompson Publishing entitled “*Part 2 Evolution: A Vision for Integrated Care and Enhanced Rights*” which recommends seven specific updates to the regulations at Part 2 that are reflective of the changes that have taken place and lessons learned since the SUD Confidentiality Law and Part 2 were enacted over 40 years ago. We have also attached the White Paper to these comments for your reference.

Cognizant of the arduous task of revising and updating the regulations at Part 2, Popovits & Robinson, P.C. is pleased to provide SAMHSA with our response to the Notice of Public Listening Session published in the Federal Register on May 12, 2014. Thank you for your commitment to advancing the confidentiality conversation as it relates to substance abuse treatment information protected by Part 2. We offer the below comments and recommendations in response to SAMHSA’s proposed concepts and questions on the seven specific topics discussed in the proposed rule and at the public listening session on June 11, 2014. Our consideration of these issues is informed by our nuanced understanding, based on firsthand experience, of the unique challenges Part 2 poses for meaningful exchange of substance abuse treatment information for the purpose of coordinating and integrating care to improve patient outcomes.

a. Applicability of 42 CFR Part 2

SAMHSA has proposed that covered information under Part 2 could be defined based on what substance abuse treatment services are provided instead of being defined by the type of facility providing the services. SAMHSA has posed the following questions related to this potential change:

- *How would redefining the applicability of Part 2 impact patients, health care provider organizations, HIEs, CCOs, HIT vendors, etc.?*
- *Would this change address stakeholder concerns?*
- *Would this change raise any new concerns?*

We oppose broadening the applicability of Part 2 to include entities other than Part 2 programs because doing so would detrimentally impact patients, health care provider organizations, health information exchanges (“HIEs”), care coordination organizations (“CCOs”) and health IT vendors by further restricting the sharing of health information for care coordination purposes. Such a change would further hinder the meaningful exchange of patient health information for the benefit of treatment.

Sitting prominently on SAMHSA’s website is a slogan: “*Behavioral Health is Essential to Health*”. Stated another way, “*Health is Essential to Behavioral Health.*” With this in mind, the following two principles should guide any changes to the applicability section of the regulations at Part 2. First, changes to this section must focus on what is best for the patient. We strongly support confidentiality protections for patients, however, having separate health information privacy requirements for substance abuse treatment patients does more harm to the patient, harm to their families and harm to their communities by necessitating a separate and unequal health data sharing

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environment that prevents the full inclusion of substance abuse treatment patients into integrated health settings and systems. Second, any changes to this section should also consider what is necessary for providers to deliver optimal care and what barriers must be addressed in order to ensure providers can deliver optimal care. Broadening the applicability of this section would make it more difficult for providers to share medical information through the ILHIE and other HIEs, which makes it more difficult to deliver timely, optimal care.

Specifically, we recommend the following with regard to the applicability section of Part 2:

1. We support the harmonization of Part 2 wherever possible with the Health Insurance Portability and Accountability Act (“HIPAA”) and its implementing regulations. It is our strong belief that efforts to harmonize Part 2 with HIPAA would ensure increased care coordination among treating providers and other entities which share health information for care coordination and integration purposes, improve patient care and enhance privacy protections by making confidentiality restrictions more uniform across health care settings. This allows for the achievement of improved health outcomes through increased coordination of care for patients. We also support preserving certain patient protections afforded under Part 2, such as the criminal penalties for violations of Part 2 at Section 2.4 and the stringent court order requirements at Sections 2.61-2.66.
2. We support clarifying that the regulations at Part 2 apply only to substance abuse specialty treatment programs and providers who are specifically licensed, credentialed, or accredited as substance abuse treatment providers. Further, the regulations should not apply to individual certified or licensed specialty substance abuse treatment providers who are practicing within a larger organization unless the larger organization is also specifically licensed, credentialed or accredited as a substance abuse treatment provider.
3. We are also opposed to any attempts to further define “covered information” based on what substance abuse treatment services are provided. Any changes to this section of the regulations should consider simplification as well as how patient protections can be retained and enhanced as described in our attached White Paper entitled “*Part 2 Evolution: A Vision for Integrated Care and Enhanced Rights*”.
4. We oppose extending Part 2 applicability to health care providers who provide only screening, brief intervention and referral to treatment (“SBIRT”) services. We do not believe it was ever the intent of the regulations to cover treatment information of this limited nature. Providers of SBIRT services provide brief screenings of individuals who may require substance abuse treatment and referrals to appropriate and specialized treatment. Providers of SBIRT services are not themselves providing specialized substance abuse treatment services.

b. Consent Requirements

SAMHSA is 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.*
2. *Require the patient be provided with a list of providers or organizations that may access*

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- their information, and be notified regularly of changes to the list.*
- 3. Require the consent to name the individual or health care entity permitted to make the disclosure.*
 - 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.*
 - 5. Require that the consent form explicitly describe the substance abuse treatment information that may be disclosed.*

SAMHSA has asked for comments on patient privacy concerns as well as the anticipated impact of the consent requirements on integration of substance abuse treatment data into HIEs, health homes, ACOs, and CCOs. Specifically, SAMHSA has posed the following questions:

- Would these changes maintain the privacy protections for patients?*
- Would these changes address the concerns of HIEs, health homes, ACOs, and CCOs?*
- Would these changes raise any new concerns?*

Providers, patients and HIEs in the State of Illinois know first-hand the challenges associated with consent issues. However, both real and perceived consent barriers continue to block successful coordination of care efforts for Illinois patients. Illinois patients deserve the option and the choice of deciding whether they want their substance abuse treatment information shared through HIEs. If the consent roadblocks are not addressed, patients will continue to be deprived of their right to participate. Providers must be able to treat a whole person in an integrated delivery system in a coordinated way to yield better outcomes. Patients deserve it. A patient should not be excluded from HIE participation unless the patient decides to be excluded. It is the patient's choice.

Requiring the consent to name the specific individual or health care entity permitted to receive the disclosure prevents programs covered by Part 2 from participating in HIEs, health homes, accountable care organizations ("ACOs") and care coordination entities ("CCEs") because it is impossible to specify every organization and/or individual who might possibly receive information via an HIE, health home, ACO or CCE. Thus, even when a patient seeks to affirmatively consent to include his or her information in an HIE, health home, ACO or CCE, he or she cannot effectively provide such consent under current Part 2 regulations. Moreover, requiring patients to be provided with a list of providers or organizations that may access their information and be notified regularly of changes to the list would be impossible in the context of HIEs, where providers join HIE networks on a daily basis.

This requirement that a single individual or organization be named on a Part 2 consent is wholly inconsistent with the important federal and Illinois goals of achieving care coordination and integration. This requirement functions to discriminate against Part 2 program patients in two ways. First, general medical/surgical patients have the ability to provide a broader consent, but substance abuse treatment patients are restricted from doing so. Second, substance abuse treatment patients are effectively excluded from participation in HIEs due to the rigidity of the consent regulations and the technological inability to uniformly segregate substance abuse data in accordance with the

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stringent requirements contained in Part 2. As a result, a digital divide exists between general medical/surgical patients and substance abuse treatment patients as substance abuse treatment patients are not given an equal opportunity to participate or decide who should have access to their information. This not only perpetuates discrimination against substance abuse treatment patients (the very stigma that the SUD Confidentiality Law and Part 2 was intended to address) but it also interferes with the important objectives of the Affordable Care Act.

Given this, we urge SAMHSA to revise Part 2 consent requirements. Specifically, SAMHSA should:

1. Address the “To Whom” problem by revising the regulations to permit disclosures of substance abuse treatment information in a manner consistent with HIPAA by permitting patients to generally consent to disclosures of their substance abuse treatment information for the purposes of treatment, payment or health care operations. SAMHSA should additionally adopt the HIPAA definitions of “treatment,” “payment” and “health care operations”. Among other goals, this revision allows patient substance abuse treatment information to be disclosed to one or more HIEs, health homes, ACOs or CCEs, including any individual or institutional provider participating in such organizations with a direct treatment relationship with the patient, as treatment under HIPAA includes the coordination or management of health care and related services by one or more health care providers.
2. Harmonize the consent elements in Section 2.31 with the authorization requirements in HIPAA.
3. Assuming there is initial consent to disclosure to the HIE, health home, ACO or CCE, permit the redisclosure of information among such data recipients in a manner consistent with HIPAA, including redisclosure for the purposes of treatment, payment and health care operations without additional patient consent.
4. Adopt appropriate safeguards such as requiring data custodians to maintain audit trails and conduct routine audits.
5. Afford meaningful protections to address patient discrimination concerns as a result of relaxing the consent provisions, such as a mandatory exclusion from evidence provision for information obtained in violation of Part 2.

To the extent patient consent is required for a disclosure, we offer the following comments:

1. We support allowing the consent to include a more general description of the individual, organization, or other health care entity to which disclosure is to be made in order to enable the exchange of health information.
2. We oppose requiring the patient to be provided with a list of providers or organizations that may access their information and be notified regularly of changes to the list as such requirements are unduly burdensome and would be impossible in the context of HIEs and coordination of care. To clarify, we are not opposed to providing such a list to a patient if specifically requested, but we do not believe this should be a mandatory requirement.
3. We oppose any requirement that multiple independent units or organizations that make up a health care entity that may make a disclosure must be specifically named.

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4. We agree that the consent form should continue to include how much and what kind of substance abuse treatment information is to be disclosed, as is currently required under Section 2.31. We do not support requiring consents to include more information than is already required under the current regulations as doing so would prevent the meaningful exchange of health information and coordination of care.

c. Redisdisclosure

SAMHSA is considering revising the redisdisclosure provision to clarify that the prohibition on redisdisclosure only applies to information that would identify an individual as a substance abuser, and allows other health-related information shared by the Part 2 program to be redisdisclosed, if legally permissible. SAMHSA has posed the following questions regarding this potential change:

- *Would this type of change facilitate technical solutions for complying with 42 CFR Part 2 in an EHR or HIE environment?*
- *Would these changes maintain the privacy protections for patients?*

The prohibition on redisdisclosure in Section 2.32 effectively prevents providers participating in an HIE, health home, ACO, or CCE from disclosing substance abuse treatment information among each other for treatment and care coordination purposes. Therefore, in addition to revising Part 2 to allow patients to consent to the disclosure of their substance abuse treatment information to an HIE, health home, ACO or CCE and its provider-members that are providing treatment to a patient (as recommended in Section (b) above), we also recommend revising the regulations to allow for the redisdisclosure of substance abuse treatment information by and among provider-members of an HIE, health home, ACO or CCE with a direct treatment relationship for the purposes of treatment, payment or health care operations. Further, we recommend that the regulations be revised to establish that the prohibition on redisdisclosure does not apply to outside HIEs or provider-members of such exchanges who have a direct treatment relationship with the patient and who need access to records to treat the patient on an emergent basis.

To be clear, we are recommending that for purposes of treatment, payment and health care operations, substance abuse treatment information should be able to be disclosed and redisdisclosed by and among provider-members of an HIE, health home, ACO or CCE with a direct treatment relationship with the patient. However, this change would not allow for information to be further disclosed or redisdisclosed by an HIE, health home, ACO or CCE or its provider-members without a patient's consent for any purposes other than for treatment, payment and health care operations, or as permitted under applicable exceptions under Part 2. Moreover, Part 2 information would not be accessible to anyone outside of the HIE, health home, ACO or CCE unless a specific exception applies or the stringent court order requirements under Part 2 are met. In other words, Part 2 information would not be able to be disclosed for non-treatment purposes to law enforcement, employers, insurance companies, divorce attorneys or others seeking to use the information against the patient. Furthermore, we urge SAMHSA to go one step further in order to protect patients against unlawful disclosure of their substance abuse treatment information by adding a mandatory exclusion from evidence provision to Part 2.

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d. Medical Emergency

SAMHSA has posed the following questions regarding the medical emergency exception under Part 2:

- *What factors should providers take into consideration in determining whether a medical emergency exists?*
- *Are there specific use cases SAMHSA should take into consideration?*
- *Are there patient concerns about the impact of this change on their privacy?*

We support expanding the medical emergency exception to give providers more discretion to determine when a bona fide medical emergency exists. Further, we support amending the standard to allow providers to use the medical emergency provision to *prevent* emergencies or to share information with a detoxification center when a patient is unable to provide informed consent due to their level of intoxication. If a medical emergency of any kind can be prevented, we believe providers should be able to disclose Part 2 information as necessary in an effort to prevent such an emergency from occurring. Patient safety and quality of care should be of primary importance.

Additionally, we believe the requirement under Section 2.51 that a Part 2 program immediately document a disclosure pursuant to a medical emergency should be removed from the regulations. Under Section 2.51, information covered by Part 2 may be disclosed to treat the patient for a condition which poses an immediate threat to the patient's health and which requires immediate medical intervention. Currently, disclosures in these urgent scenarios must be "immediately" documented in writing setting forth the name of the personnel to whom the disclosure was made and their affiliation with any health care facility, the name of the individual making the disclosure, the date and time of the disclosure and the nature of the emergency. This documentation requirement is unduly burdensome in a crisis situation. Thus, if a hospital "breaks the glass" in this scenario, the Part 2 program may not know whose record was accessed except through an audit trail and would have difficulty documenting timely or accurately. It is also important to note that when Part 2 information is disclosed pursuant to a medical emergency, that information loses its Part 2 protections and can therefore be further disclosed by the entity in receipt of the information. We recommend revisions to the regulations governing redisclosure consistent with Section (c) herein.

e. Qualified Service Organization (QSO)

SAMHSA is considering expanding the definition of a qualified service organization 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. SAMHSA has posed the following questions regarding expanding the QSOA concept:

- *Are there other use cases we should be taking into consideration?*
- *Are there specific patient concerns about the impact of this change on their privacy?*

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Generally, we support expanding the QSO concept to enable increased sharing of health information for care coordination purposes. However, we are concerned that expanding the QSOA exception as contemplated would not address the issue of redisclosure of such information by the HIE, health home, ACO or CCE to which the Part 2 provider is originally disclosing information. Accordingly, true bi-directional health information exchange would not be permitted under Part 2 even if the QSO concept is broadened as SAMHSA proposes. Given this, as suggested in Section (b) above, we recommend that SAMHSA revise Part 2 to enable the disclosure of substance abuse treatment information to HIEs, health homes, ACOs, CCEs and other entities and providers involved in the patient's treatment, consistent with HIPAA. Furthermore, we recommend SAMHSA make clear that the prohibition on redisclosure does not apply to an HIE, health home, ACO, CCE or an affiliated provider if a patient consents to their information being disclosed to such HIE, health home, ACO, CCE, or other care coordination entity involved in the patient's treatment. We believe that these changes to the regulations would enable greater patient choice and help ensure that treatment is appropriately coordinated for behavioral health patients.

Furthermore, we strongly believe that it should be the patient's choice and decision as to whether they want their substance abuse treatment information shared among providers for the benefit of their treatment. For this reason, we advocate for revisions to the regulations in order to permit patients to consent to their substance abuse treatment information being shared with HIEs, health homes, ACOs and CCEs in the same manner as HIPAA. We believe that permitting patients to consent to such disclosures of their information is the better mechanism for achieving increased coordination of care as opposed to using the QSO mechanism to achieve this aim.

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. SAMHSA has posed the following questions related to this potential change:

- *Are there factors that should be considered related to how current health care entities are organized, how they function or how legal duties and responsibilities attach to entities that make up an umbrella organization?*
- *Would this change address concerns related to research?*
- *Are there specific privacy concerns associated with expanding the authority or releasing data to qualified researchers/research organizations in this way?*
- *Are there additional use cases that should be considered in the research context?*

As a preliminary matter, the proposed rule states that health care entities that receive and store Part 2 data would be able to disclose patient identifying information to researchers for the purpose of research, audit and evaluation. We believe that audit and evaluation functions are addressed separately in Section 2.53 and should not be comingled in this research provision unless these terms will be further defined. Our comments below focus on disclosure for the purpose of research only.

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Under HIPAA, a health care entity may disclose protected health information (“PHI”) for the purpose of research if: (1) the recipient researcher has obtained approval by its institutional review board; (2) the patient consented to the release of his or her information; (3) the PHI is part of a limited data set; or (4) the data is first de-identified. SAMHSA’s proposed expansion of the research exception would align the research exception under Part 2 more closely with the requirements under HIPAA, which we support. Specifically, a health care entity that receives and stores Part 2 data would be able to disclose patient identifying information for the purpose of research, provided that the researcher first obtains approval by its institutional review board. We support this change in Part 2 and are generally supportive of other changes to Part 2 which make the regulations consistent with the rules under HIPAA.

However, under this expanded exception, the researcher would only be permitted to disclose patient identifying information back to the health care entity that supplied the information. When the health care entity is a health information organization (“HIO”) that oversees and governs the exchange of health-related information among its participating organizations or is a CCO comprised of several program participants, a unique situation arises. The information disclosed back to an HIO or a CCO would represent a combination of the information belonging to individual HIO participants or the individual CCO program participants. When the information is disclosed back to the health care entity after the conclusion of the research study, then the question arises as to whether each participant of the HIO or each program participant of the CCO is entitled to the research report. The research report would represent an amalgamation of individual participants’ patient health information and would provide each participant with information about other participants’ patients, something they would not have access to before.

In an HIO context, the HIO is a business associate of each of its covered entity-participants. As such, it may not disclose patient identifying information of one participant back to other participants. Alternatively, in a CCO context, each program participant is a partial owner of the CCO. As such, the CCO would be able to disclose patient identifying information received through a research study back to all participants. These issues must be carefully considered in revising the research exception under Part 2.

We believe expanding the authority for releasing data to qualified researchers/research organizations to health care entities that receive and store Part 2 data would address concerns related to research. Effective management of our population’s health is critical. We need statistics about what ails the population and information about where our resources should be directed based on those statistics. It is imperative that substance abuse data be included in these statistics so that we can identify underlying health problems affecting our population and the most effective interventions. Expanding the authority to release patient identifying information from health care entities that receive and store Part 2 information to researchers will allow for this. It will create a larger pool of information that will more accurately reflect our population’s health and can serve as a basis for the development and implementation of appropriate healthcare measures.

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g. Addressing Potential Issues with Electronic Prescribing and Prescription Drug Monitoring Programs

SAMHSA has posed the following questions regarding 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?*
- *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.*
- *Are there patient concerns about the impact of e-prescribing and PDMPs on their privacy?*

We recognize how important the transmission of prescription drug information is in an integrated delivery system. We do not want to pose any barriers to the sharing of critical medication information for safety reasons. Of paramount importance in an integrated delivery system is patient safety and PDMPs are a critical component of that. Health care providers need to be able to identify people who may be receiving duplicative or inappropriate treatment, coordinate care of persons who may be at significant risk, identify medications or other treatments that may be contraindicated, and diagnose and treat underlying health conditions or avoid treatments that exacerbate such conditions.

Based on previous information we received from Randy Malan, Director of the Illinois Department of Human Services Bureau of Pharmacy and Clinical Services, we provide the following comments on the usage of PDMPs.

Prescription drug misuse and overdose is one of the fastest growing health epidemics in the United States. To address prescription drug abuse, many states have established PDMPs. PDMPs are statewide databases designed to be used as a tool by health care providers to identify and intervene in cases of potential prescription drug abuse. The databases collect, monitor, and analyze electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing practitioners. PDMPs collect a considerable amount of useful information that can help providers identify patients with prescription drug abuse problems; however, many states do not use these databases adequately. Providing health care providers with real-time access to the information contained in the PDMPs will facilitate the use of this information at the point of care.

There exist a number of important issues related to efforts to ensure EHRs support access to PDMPs. Practically, it is important that medication reconciliation be the focus of providing health care providers with access to information contained in PDMPs. To that end, it would be particularly helpful for behavioral health care providers to have access to external medication fill history for medication adherence monitoring purposes. Similarly, data indicating if a patient is not taking a drug prescribed or is taking two kinds of the same drug or drugs with contraindications would aid behavioral health care providers in detecting abuse and other health risks related to consumption of prescription drugs. Such capabilities would be quite beneficial for providers attempting to treat and effectively monitor patients with substance use disorders.

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In Illinois, the PDMP is utilized to support the role of the clinician in the detection and intervention of an addiction to prescription drugs. Clinicians require an aggregated record of medication for each patient that can be reviewed at the time of appointment. Similarly, the PDMP requires physician and script information for implementation purposes.

Prescription information can be made available to the HIE via query capabilities. In addition, a system of universal controlled substance pre-authorization will capture e-prescriptions when they arrive at the pharmacist and at the time that prescriptions are processed in real-time claims. This provides the appropriate information for surveillance and enforcement of the Illinois PDMP.

It is critically important that PDMP access be limited to clinicians and public health authorities for clinical interventions. Many states have enacted or considered enacting prohibitions on prescription shopping and other controlled substances prescription limitations in an effort to curb overdose. However, the criminalization of these activities and involvement of law enforcement will likely have a chilling effect on any persons seeking treatment. The altruistic objectives may otherwise have negative unintended consequences.

However, it is important to note that PDMPs differ significantly across states. Although the Illinois PDMP does not involve law enforcement agencies, some state-operated PDMPs are even run by law enforcement agencies. We believe that providing law enforcement agencies access to PDMP data will have a chilling effect on persons seeking treatment and therefore strongly disagree with giving law enforcement agencies such access. Furthermore, we advocate for the development of a national policy that effectively limits PDMP access to clinicians for clinical intervention purposes only.

There is also a lack of common technical standards, vocabularies, and system-level access controls to allow PDMPs to share computable information with electronic health records and pharmacy systems that prescribers and dispensers use to support automated queries and reporting. No formal standards or specifications exist for sharing a PDMP report electronically with a prescriber or dispenser. This will continue to pose a problem even if the regulations are revised to address issues with PDMP data sharing.

The goals of PDMPs are important, being to address unlawful drug-seeking behaviors and reduce overdoses, deaths and health care costs associated with abuse of prescription drugs. However, Part 2 requires consent to disclosures absent other limited exceptions applying. Patients, persons in recovery and other interested stakeholders have legitimate concerns about substance abuse treatment information, including prescription drug information, being accessible by law enforcement and leading to investigation, arrest or other forms of discrimination. For this reason and others, we recommend adding the following specific provisions to the regulations in order to protect against wrongful use of Part 2 information and discrimination against persons who are receiving/have received substance abuse treatment:

1. Add new section establishing the mandatory exclusion from evidence of information obtained in violation of Part 2.

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2. Add new section limiting the use of Part 2 information in civil proceedings (in addition to criminal proceedings).

Disclosures for Public Health Reporting and Public Health Activity Purposes

We believe Part 2 should be revised to allow for the disclosure of Part 2 information for required public health reporting purposes or other public health activities in accordance with HIPAA and applicable State law. Specifically, we believe SAMHSA should make clear that Part 2 information may be disclosed for public health reporting or other public health activities purposes under the audit and evaluation exception at Section 2.53. Like other health care programs, Part 2 programs regularly encounter public health issues, such as patients with communicable diseases. However, Part 2 does not allow for reporting to public health authorities in these serious situations without specific patient consent. Often times, State law mandates public health reporting, yet providers find themselves unable to report in compliance with Part 2. This poses significant risks to the public and serves as an obstacle to improved health and wellness of populations. In order to better manage population health and improve the overall effectiveness of our health care delivery system, public health reporting must be permitted by law and promoted as a critical component of care. Therefore, we urge SAMHSA to revise Part 2 to specifically allow disclosures for public health reporting purposes and other public health activities under the audit and evaluation exception at Section 2.53.

Duty to Warn

In the interest of public safety and the welfare of substance abuse treatment clients, we also urge SAMHSA to add a “duty to warn” exception to the regulations at Part 2 which allows disclosures of patient information without patient consent when such disclosures are necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. Section 164.512(j) of HIPAA and most state laws expressly permit a health care provider to disclose patient information without consent, including information from mental health records, if the provider in good faith believes the disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. However, the regulations at Part 2 do not contain an exception which allows substance abuse treatment providers to make disclosures of patient information in such situations. Ironically, many treatment providers erroneously believe a “duty to warn” exception exists now under the regulations. The Newtown, Connecticut tragedy that occurred in December of 2012 shocked and pained the entire nation. In search of answers and recognition of the unacceptability of the status quo, national experts gathered to address gun violence, our mental health system’s treatment, funding needs and prevention strategies to reduce the potential for reoccurrence of such horrific events. As part of that process, the “duty to warn” laws were front and center of that discussion. On January 15, 2013 HHS issued confusing guidance to health care providers indicating that no federal law prohibited them from reporting threats of violence to law enforcement authorities. While this was intended to reassure providers who were uncertain about exercising their “duty to warn” under federal statutes, it was inaccurate. While HIPAA is by far the best known and most widely used federal privacy protection, Part 2 governs many behavioral health

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providers. This guidance caused some treatment providers to wonder whether Part 2 was now preempted by the Executive Orders issued by the President and requires clarification.

Section 164.512(j) of HIPAA permits disclosures in a “duty to warn” situation to any of the following: law enforcement officials, family members of the patient or others who may reasonably be able to prevent or lessen the threat. In contrast, the only exceptions under Part 2 which allow for disclosure of patient information without consent in situations in which a threat to the health or safety of a person or the public exists are the following: (i) disclosures pursuant to a valid court order (42 C.F.R. § 2.61-2.66); (ii) disclosures to law enforcement if an immediate threat to the health or safety of an individual exists due to a crime on program premises or against program personnel (42 C.F.R. § 2.12(c)(5)); (iii) reports to health care personnel under the medical emergency exception for purposes of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention (42 C.F.R. § 2.51); and (iv) anonymous disclosures made without divulging patient identifying information. Due to the lack of a “duty to warn” exception under Part 2, substance abuse treatment providers regularly face ethical dilemmas of patient rights versus public safety.

With the increased number of patients with co-morbid mental health conditions, the substance abuse treatment community is a critical intervention source that must understand its role in assisting complex patients with their recovery while appropriately identifying potential threats and communicating with law enforcement if greater public safety interests exist. Adding a “duty to warn” exception to Part 2 is a crucial and necessary change that will give providers the flexibility they need to mitigate serious danger to their patients and others. This “duty to warn” concept is a fixture of not just HIPAA, but also state common and licensure laws. It is taken very seriously by providers and does not, we believe, pose a potential area for abuse. Therefore, we urge SAMHSA to add a “duty to warn” exception to the regulations which permits disclosures of patient information without patient consent when such disclosures are necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public, thereby harmonizing Part 2 with HIPAA in this regard.

Enforcement of Part 2

We also believe the regulations at Part 2 should specify a procedure for patients and Part 2 programs to file complaints regarding violations of Part 2. We further recommend that such procedures be consistent with HIPAA complaint procedures.

Conclusion

We appreciate the opportunity to comment on SAMHSA’s proposals to update Part 2. We encourage SAMHSA to work with its sister agencies, CMS and ONC, in revising the regulations and issuing subregulatory guidance of any kind. While we support SAMHSA pursuing specific revisions to Part 2 to enable increased exchange of health information for care coordination purposes, we recognize that the regulatory process takes considerable time. Given the confusion

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that currently exists and the significant challenges that providers continue to face as a result of the regulations at Part 2, we urge SAMHSA along with ONC and CMS to issue immediate joint subregulatory guidance which provides clarity on these issues and affords Part 2 providers appropriate guidance so that they are protected in relying on SAMHSA's interpretations of the regulations and compliance with the same.

We respectfully request SAMHSA's urgency in addressing these various issues under Part 2 in order to ensure increased care coordination and improved health outcomes for the benefit of patients in Illinois and nationally, and the behavioral health field.

Sincerely,

Renée Popovits
Founder and Principal Attorney
Popovits & Robinson, P.C.

Attached: *42 CFR Part 2 Polling Results*
Part 2 Evolution: A Vision for Integrated Care and Enhanced Rights



June 25, 2014

Submitted VIA E-Mail

The Substance Abuse and Mental Health
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Rockville, MD 20857
PrivacyRegulations@SAMHSA.hhs.gov

RE: FR Doc. 2014-10913 – 42 CFR Part 2

Dear To Whom It May Concern:

We are writing on behalf of the Illinois Governor's Office of Health Innovation and Transformation ("GOHIT"), the Illinois Health Information Exchange ("ILHIE") Authority, the Behavioral Health Work Group of the ILHIE Authority, co-chaired by Marvin Lindsey, M.S.W., C.A.D.C., of the Community Behavioral Healthcare Association, and the Substance Abuse Subcommittee of the Legal Task Force of the ILHIE Authority, co-chaired by Renée Popovits, Esq., founder and principal attorney of Popovits & Robinson, P.C.

GOHIT, into which the Illinois Governor's Office of Health Information Technology ("OHIT") was merged, was created by Executive Order #14-01 signed by Governor Pat Quinn and is responsible for implementing the State's Alliance for Health Innovation Plan. The Alliance for Health developed out of a six-month planning grant awarded by the Center for Medicare and Medicaid Innovation. The Alliance for Health brought together the State's health insurance plans, large provider organizations, public health practitioners and more than 80 business, consumer, provider and association stakeholders, to identify the innovations needed to achieve the triple aim: achieving better health for Illinois' residents, improving the effectiveness of the delivery system and lowering costs so that health care and insurance is affordable for everyone in the State. GOHIT leads Illinois' participation in the Center for Medicare and Medicaid Innovation's State Innovation Model Program including the transformation principles in the Innovation Plan, supporting stakeholder engagement, and creating and operating an Innovation and Transformation Resource Center.

The ILHIE Authority was established to oversee the Statewide ILHIE. The ILHIE enables health care providers to exchange electronic health information in a secure environment, provide authorized access to medical records, help prevent duplicate tests and procedures, and facilitate the accuracy of prescriptions and other medical orders. The ILHIE Authority and OHIT established Work Groups and subject matter subcommittees charged with focusing on key issues relating to health information exchange. The Work Groups and subcommittees advised and presented recommendations to OHIT and the ILHIE Authority. The Behavioral Health Work Group and Substance Abuse Subcommittee are composed of community behavioral health



providers and their representatives, State employees and other subject matter experts. GOHIT and the ILHIE Authority, including its Behavioral Health Work Group and the Substance Abuse Subcommittee, are committed to ensuring the exchange of health information, including substance abuse and mental health information, for the benefit of patient care, while ensuring the appropriate security and privacy of such information.

The below comments of GOHIT, the ILHIE Authority, Renée Popovits and Marvin Lindsey are also informed by the Illinois' Behavioral Health Integration Project ("BHIP"). Illinois' BHIP was a joint effort of the State of Illinois and dozens of behavioral health and medical care organizations throughout the State. The goal of the BHIP was to promote the exchange of health information among behavioral health and medical care providers to improve care by helping licensed substance abuse and mental health practitioners to better coordinate patient care with their clients' primary care providers. One of the realized BHIP deliverables was to amend the State's mental health confidentiality law to enable the secure electronic exchange of patients' mental health information. Illinois was one of five states that received federal funding to support the BHIP. The BHIP's efforts also supported Illinois' Care Innovations Program which seeks to coordinate care for Illinois' Medicaid recipients, focusing on improved preventive care and follow-up treatment. Ensuring appropriate access to relevant patient information, such as current medications and medication history, holds great promise for improving the overall health of patients.

Cognizant of the arduous task of revising and updating the regulations at 42 CFR Part 2 ("Part 2"), the undersigned are pleased to provide SAMHSA with our response to the Notice of Public Listening Session published in the Federal Register on May 12, 2014. Thank you for your commitment to advancing the confidentiality conversation as it relates to substance abuse treatment information protected by Part 2. We offer the below comments and recommendations in response to SAMHSA's proposed concepts and questions on the specific topics discussed in the proposed rule and at the public listening session on June 11, 2014. Our consideration of these issues is informed by our nuanced understanding of the unique challenges Part 2 poses for meaningful exchange of substance abuse treatment information for the purpose of coordinating and integrating care to improve patient outcomes. As SAMHSA considers regulatory changes, we encourage the immediate issuance of interim subregulatory guidance in accordance with the following comments.

a. Applicability of 42 CFR Part 2

SAMHSA has proposed that covered information under Part 2 could be defined based on what substance abuse treatment services are provided instead of being defined by the type of facility providing the services. SAMHSA has posed the following questions related to this potential change:

- *How would redefining the applicability of Part 2 impact patients, health care provider organizations, HIEs, CCOs, HIT vendors, etc.?*
- *Would this change address stakeholder concerns?*



- *Would this change raise any new concerns?*

We oppose broadening the applicability of Part 2 to include entities other than Part 2 programs because doing so would detrimentally impact patients, health care provider organizations, health information exchanges (“HIEs”), care coordination organizations (“CCOs”) and health information technology vendors by further restricting the sharing of health information for care coordination purposes. Such a change would further hinder the meaningful exchange of patient health information for the benefit of treatment.

Sitting prominently on SAMHSA’s website is a slogan: “*Behavioral Health is Essential to Health*”. Stated another way, “*Health is Essential to Behavioral Health.*” With this in mind, the following two principles should guide any changes to the applicability section of the regulations at Part 2. First, changes to this section must focus on what is best for the patient. We strongly support confidentiality protections for patients, however, having separate health information privacy requirements for substance abuse treatment patients does more harm to the patient, harm to their families and harm to their communities by necessitating a separate and unequal health data sharing environment that prevents the full inclusion of substance abuse treatment patients into integrated health settings and systems. Second, any changes to this section should also consider what is necessary for providers to deliver optimal care and what barriers must be addressed in order to ensure providers can deliver optimal care. Broadening the applicability of Part 2 would make it more difficult for providers to share medical information through the ILHIE and other HIEs, which makes it more difficult to deliver timely, optimal care.

Specifically, we recommend the following with regard to the applicability section of Part 2:

1. We support the harmonization of Part 2 wherever possible with the Health Insurance Portability and Accountability Act (“HIPAA”) and its implementing regulations. It is our strong belief that efforts to harmonize Part 2 with HIPAA would ensure increased care coordination among treating providers and other entities which share health information for care coordination and integration purposes, improve patient care and enhance privacy protections by making confidentiality restrictions more uniform across health care settings. This allows for the achievement of improved health outcomes through increased coordination of care for patients. We also support preserving certain patient protections afforded under Part 2, such as the criminal penalties for violations of Part 2 at Section 2.4 and the stringent court order requirements at Sections 2.61-2.66.
2. We support clarifying that the regulations at Part 2 apply only to substance abuse specialty treatment programs and providers who are specifically licensed, credentialed, or accredited as substance abuse treatment providers. Further, the regulations should not apply to individual certified or licensed specialty substance abuse treatment providers who are practicing within a larger organization unless the larger organization is also specifically licensed, credentialed or accredited as a substance abuse treatment provider.
3. We are also opposed to any attempts to further define “covered information” based on what substance abuse treatment services are provided. Any changes to this section of the regulations should consider simplification as well as how patient protections can be



retained and enhanced as described in the White Paper entitled “*Part 2 Evolution: A Vision for Integrated Care and Enhanced Rights*” by Renée Popovits, et al.

4. We oppose extending Part 2 applicability to health care providers who provide only screening, brief intervention and referral to treatment (“SBIRT”) services. We do not believe that it was ever the intent of the regulations to cover treatment information of this limited nature. Providers of SBIRT services provide brief screenings of individuals who may require substance abuse treatment and referrals to appropriate and specialized treatment. Providers of SBIRT services are not themselves providing specialized substance abuse treatment services.

b. Consent Requirements

SAMHSA is 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.*
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.*
3. *Require the consent to name the individual or health care entity permitted to make the disclosure.*
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.*
5. *Require that the consent form explicitly describe the substance abuse treatment information that may be disclosed.*

SAMHSA has asked for comments on patient privacy concerns as well as the anticipated impact of the consent requirements on integration of substance abuse treatment data into HIEs, health homes, ACOs, and CCOs. Specifically, SAMHSA has posed the following questions:

- *Would these changes maintain the privacy protections for patients?*
- *Would these changes address the concerns of HIEs, health homes, ACOs, and CCOs?*
- *Would these changes raise any new concerns?*

Providers, patients and HIEs in the State of Illinois know first-hand the challenges associated with consent issues. However, both real and perceived consent barriers continue to block successful coordination of care efforts for Illinois patients. Illinois patients deserve the option and the choice of deciding whether they want their substance abuse treatment information shared through HIEs. If the consent roadblocks are not addressed, patients will continue to be deprived of their right to participate. Providers must be able to treat a whole person in an integrated delivery system in a coordinated way to yield better outcomes. Patients deserve it. A patient should not be excluded from HIE participation unless the patient decides to be excluded. It is the patient’s choice.

Requiring the consent to name the specific individual or health care entity permitted to receive



the disclosure prevents programs covered by Part 2 from participating in HIEs, health homes, accountable care organizations (“ACOs”) and care coordination entities (“CCEs”) because it is impossible to specify every organization and/or individual who might possibly receive information via an HIE, health home, ACO or CCE. Thus, even when a patient seeks to affirmatively consent to include his or her information in an HIE, health home, ACO or CCE, he or she cannot effectively provide such consent under current Part 2 regulations. Moreover, requiring patients to be provided with a list of providers or organizations that may access their information and be notified regularly of changes to the list would be impossible in the context of HIEs, where providers join HIE networks on a daily basis.

This requirement that a single individual or organization be named on a Part 2 consent is wholly inconsistent with the important federal and Illinois goals of achieving care coordination and integration. This requirement functions to discriminate against Part 2 program patients in two ways. First, general medical/surgical patients have the ability to provide a broader consent, but substance abuse treatment patients are restricted from doing so. Second, substance abuse treatment patients are effectively excluded from participation in HIEs due to the rigidity of the consent regulations and the technological inability to uniformly segregate substance abuse data in accordance with the stringent requirements contained in Part 2. As a result, a digital divide exists between general medical/surgical patients and substance abuse treatment patients as substance abuse treatment patients are not given an equal opportunity to participate or decide who should have access to their information. This not only perpetuates discrimination against substance abuse treatment patients (the very stigma that the SUD Confidentiality Law and Part 2 was intended to address) but it also interferes with the important objectives of the Affordable Care Act.

Given this, we urge SAMHSA to revise Part 2 consent requirements. Specifically, SAMHSA should:

1. Address the “To Whom” problem by revising the regulations to permit disclosures of substance abuse treatment information in a manner consistent with HIPAA by permitting patients to generally consent to disclosures of their substance abuse treatment information for the purposes of treatment, payment or health care operations. SAMHSA should additionally adopt the HIPAA definitions of “treatment,” “payment” and “health care operations.” Among other goals, this revision allows patient substance abuse treatment information to be disclosed to one or more HIEs, health homes, ACOs or CCEs, including any individual or institutional provider participating in such organizations with a direct treatment relationship with the patient, as treatment under HIPAA is defined to include the coordination or management of health care and related services by one or more health care providers.
2. Harmonize the consent elements in Section 2.31 with the authorization requirements in HIPAA.
3. Assuming there is initial consent to disclosure to a HIE, health home, ACO or CCE, permit the redisclosure of information among such data recipients in a manner consistent



with HIPAA, including redisclosure for the purposes of treatment, payment and health care operations without additional patient consent.

4. Adopt appropriate safeguards such as requiring data custodians to maintain audit trails and conduct routine audits.
5. Afford meaningful protections to address patient discrimination concerns as a result of relaxing the consent provisions, such as a mandatory exclusion from evidence provision for information obtained in violation of Part 2.

To the extent patient consent is required for a disclosure, we offer the following comments:

1. We support allowing the consent to include a more general description of the individual, organization, or other health care entity to which disclosure is to be made in order to enable the exchange of health information.
2. We oppose requiring a patient be provided with a list of providers or organizations that may access their information and to be notified regularly of changes to the list as such requirements are unduly burdensome and would be impossible in the context of HIEs and coordination of care. To clarify, we are not opposed to providing such a list to a patient if specifically requested, but we do not believe this should be a mandatory requirement.
3. We oppose any requirement that multiple independent units or organizations that make up a health care entity that may make a disclosure must be specifically named.
4. We agree that the consent form should continue to include how much and what kind of substance abuse treatment information is to be disclosed, as is currently required under Section 2.31. We do not support requiring consents to include more information than is already required under the current regulations as doing so would prevent the meaningful exchange of health information and coordination of care.

c. Redisclosure

SAMHSA is considering revising the redisclosure provision to clarify that the prohibition on redisclosure only applies to information that would identify an individual as a substance abuser, and allows other health-related information shared by the Part 2 program to be redisclosed, if legally permissible. SAMHSA has posed the following questions regarding this potential change:

- *Would this type of change facilitate technical solutions for complying with 42 CFR Part 2 in an EHR or HIE environment?*
- *Would these changes maintain the privacy protections for patients?*

The prohibition on redisclosure in Section 2.32 effectively prevents providers participating in an HIE, health home, ACO, or CCE from disclosing substance abuse treatment information among each other for treatment and care coordination purposes. Therefore, in addition to revising Part 2 to allow patients to consent to the disclosure of their substance abuse treatment information to an HIE, health home, ACO or CCE and its provider-members that are providing treatment to a patient (as recommended in Section (b) above), we also recommend revising the regulations to allow for the redisclosure of substance abuse treatment information by and among provider-



members of an HIE, health home, ACO or CCE with a direct treatment relationship for the purposes of treatment, payment or health care operations. Further, we recommend that the regulations be revised to establish that the prohibition on redisclosure does not apply to outside HIEs or provider-members of such exchanges who have a direct treatment relationship with the patient and who need access to records to treat the patient on an emergent basis.

To be clear, we are recommending that for purposes of treatment, payment and health care operations, substance abuse treatment information should be able to be disclosed and redisclosed by and among provider-members of an HIE, health home, ACO or CCE with a direct treatment relationship with the patient. However, this change would not allow for information to be further disclosed or redisclosed by an HIE, health home, ACO or CCE or its provider-members without a patient's consent for any purposes other than for treatment, payment and health care operations, or as permitted under applicable exceptions under Part 2. Moreover, Part 2 information would not be accessible to anyone outside of the HIE, health home, ACO or CCE unless a specific exception applies or the stringent court order requirements under Part 2 are met. In other words, Part 2 information would not be able to be disclosed for non-treatment purposes to law enforcement, employers, insurance companies, divorce attorneys or others seeking to use the information against the patient. Furthermore, we urge SAMHSA to go one step further in order to protect patients against unlawful disclosure of their substance abuse treatment information by adding a mandatory exclusion from evidence provision to Part 2.

d. Medical Emergency

SAMHSA has posed the following questions regarding the medical emergency exception under Part 2:

- *What factors should providers take into consideration in determining whether a medical emergency exists?*
- *Are there specific use cases SAMHSA should take into consideration?*
- *Are there patient concerns about the impact of this change on their privacy?*

We support expanding the medical emergency exception to give providers more discretion to determine when a bona fide medical emergency exists. Further, we support amending the standard to allow providers to use the medical emergency provision to *prevent* emergencies or to share information with a detoxification center when a patient is unable to provide informed consent due to their level of intoxication. If a medical emergency of any kind can be prevented, we believe providers should be able to disclose Part 2 information as necessary in an effort to prevent such an emergency from occurring. Patient safety and quality of care should be of primary importance.

Additionally, we believe that the requirement under Section 2.51 that a Part 2 program immediately document a disclosure pursuant to a medical emergency should be removed from the regulations. Under Section 2.51, information covered by Part 2 may be disclosed to treat the patient for a condition which poses an immediate threat to the patient's health and which requires



immediate medical intervention. Currently, disclosures in these urgent scenarios must be “immediately” documented in writing setting forth the name of the personnel to whom the disclosure was made and their affiliation with any health care facility, the name of the individual making the disclosure, the date and time of the disclosure and the nature of the emergency. This documentation requirement is unduly burdensome in a crisis situation. Thus, if a hospital “breaks the glass” in this scenario, the Part 2 program may not know whose record was accessed except through an audit trail and would have difficulty documenting timely or accurately. It is also important to note that when Part 2 information is disclosed pursuant to a medical emergency, that information loses its Part 2 protections and can therefore be further disclosed by the entity in receipt of the information. We recommend revisions to the regulations governing redisclosure consistent with Section (c) herein.

e. Qualified Service Organization (QSO)

SAMHSA is considering expanding the definition of a qualified service organization 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. SAMHSA has posed the following questions regarding expanding the QSOA concept:

- *Are there other use cases we should be taking into consideration?*
- *Are there specific patient concerns about the impact of this change on their privacy?*

Generally, we support expanding the QSO concept to enable increased sharing of health information for care coordination purposes. However, we are concerned that expanding the QSOA exception as contemplated would not address the issue of redisclosure of such information by the HIE, health home, ACO or CCE to which the Part 2 provider is originally disclosing information. Accordingly, true bi-directional health information exchange would not be permitted under Part 2 even if the QSO concept is broadened as SAMHSA proposes. Given this, as suggested in Section (b) above, we recommend that SAMHSA revise Part 2 to enable the disclosure of substance abuse treatment information to HIEs, health homes, ACOs, CCEs and other entities and providers involved in the patient’s treatment, consistent with HIPAA. Furthermore, we recommend SAMHSA make clear that the prohibition on redisclosure does not apply to an HIE, health home, ACO, CCE or an affiliated provider if a patient consents to their information being disclosed to such HIE, health home, ACO, CCE, or other care coordination entity involved in the patient’s treatment. We believe that these changes to the regulations would enable greater patient choice and help ensure that treatment is appropriately coordinated for behavioral health patients.

Furthermore, we strongly believe that it should be the patient’s choice and decision as to whether they want their substance abuse treatment information shared among providers for the benefit of their treatment. For this reason, we advocate for revisions to the regulations in order to permit patients to consent to their substance abuse treatment information being shared with HIEs, health homes, ACOs and CCEs in the same manner as HIPAA. We believe that permitting patients to



consent to such disclosures of their information is the better mechanism for achieving increased coordination of care as opposed to using the QSO mechanism to achieve this aim.

Disclosures for Public Health Reporting and Public Health Activity Purposes

We believe Part 2 should be revised to allow for the disclosure of Part 2 information for required public health reporting purposes or other public health activities in accordance with HIPAA and applicable State law. Specifically, we believe SAMHSA should make clear that Part 2 information may be disclosed for public health reporting or other public health activities purposes under the audit and evaluation exception at Section 2.53. Like other health care programs, Part 2 programs regularly encounter public health issues, such as patients with communicable diseases. However, Part 2 does not allow for reporting to public health authorities in these serious situations without specific patient consent. Often times, State law mandates public health reporting, yet providers find themselves unable to report in compliance with Part 2. This poses significant risks to the public and serves as an obstacle to improved health and wellness of populations. In order to better manage population health and improve the overall effectiveness of our health care delivery system, public health reporting must be permitted by law and promoted as a critical component of care. Therefore, we urge SAMHSA to revise Part 2 to specifically allow disclosures for public health reporting purposes and other public health activities under the audit and evaluation exception at Section 2.53.

Conclusion

We appreciate the opportunity to comment on SAMHSA's proposals to update Part 2. We encourage SAMHSA to work with its sister agencies, CMS and ONC, in revising the regulations and issuing subregulatory guidance. While we support SAMHSA pursuing specific revisions to Part 2 to enable increased exchange of health information for care coordination purposes, we recognize that the regulatory process takes considerable time. Given the confusion that currently exists and the significant challenges that providers continue to face as a result of the regulations at Part 2, we urge SAMHSA along with ONC and CMS to issue immediate joint subregulatory guidance which provides clarity on these issues and affords Part 2 providers appropriate guidance so that they are protected in relying on SAMHSA's interpretations of the regulations and compliance with the same.



Governor's Office of
Health Innovation and
Transformation



We respectfully request SAMHSA's urgency in addressing these various issues under Part 2 in order to ensure increased care coordination and improved health outcomes for the benefit of patients in Illinois and nationally, and the behavioral health field.

Sincerely,

Laura Zaremba
Health Data and Technology Director
Governor's Office of Health Innovation and Transformation

Raul Recarey
Executive Director
Illinois Health Information Exchange Authority

Marvin Lindsey
Co-Chair of the ILHIE Authority Behavioral Health Work Group
Community Behavioral Healthcare Association

Renée Popovits
Co-Chair of the ILHIE Authority Legal Task Force Substance Abuse Subcommittee
Popovits & Robinson, P.C.



Governor's Office of
Health Innovation and
Transformation



Cc: Theodora Binion, Director of the Division of Alcoholism and Substance Abuse, Illinois
Department of Human Services
Elizabeth LaRocca, General Counsel of the Illinois Governor's Office of Health Innovation
and Transformation
Kerri McBride, General Counsel of the Illinois Health Information Exchange Authority
Members of the ILHIE Authority Behavioral Health Work Group
Members of the ILHIE Authority Legal Task Force Substance Abuse Subcommittee

From: McNamee, Cameron [<mailto:Cameron.McNamee@bop.ohio.gov>]

Sent: Thursday, June 26, 2014 4:53 PM

To: Privacy Regulations (SAMHSA)

Subject: Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2 (Docket Number 2014-10913)

To Whom It May Concern,

Attached are written comments provided by the Ohio State Board of Pharmacy regarding Docket Number 2014-10913.

Sincerely,

Cameron McNamee



Cameron J. McNamee

Ohio State Board of Pharmacy

Legislative Liaison

77 S High Street, Room 1702

Columbus, Ohio 43215

Office: 614-466-7322/Fax: 614-752-4836

Cameron.McNamee@bop.ohio.gov | www.pharmacy.ohio.gov

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June 26, 2014

Chad Garner, Director of OARRS
Ohio State Board of Pharmacy
77 South High Street, Room 1702
Columbus, Ohio 43215

The Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road, Room 5-1011
Rockville, Maryland 20857

Subject: Docket Number 2014-10913

To Whom It May Concern:

Thank you for the opportunity to comment on 42 CFR Part 2 and "Addressing Potential Issues With Electronic Prescribing and Prescription Drug Monitoring Programs (PDMPs)." For many years, patients of a Part 2 program have had two options for obtaining the medications prescribed by the Part 2 program provider: receive the drug directly from the provider or take a paper prescription to a pharmacy. As noted in the Notice of Public Listening Session, a paper prescription taken by the patient to the pharmacy is not protected by 42 CFR Part 2, as patients do not have a reasonable expectation of privacy regarding pharmacy prescription records. It would logically follow that when a patient of a Part 2 program indicates to the provider which pharmacy should receive an electronic prescription, the patient would no longer have a reasonable expectation of privacy regarding that prescription record.

Additionally, obtaining consent prior to disclosing electronic prescription information to the PDMP and consent to redisclose that information to those with access to the PDMP would present the following challenges to the operation of Ohio's program:

1. The ASAP format that PDMPs use to collect data does not provide a way for a pharmacy system to indicate that a prescription requires patient consent.
2. PDMP reports are generated upon request in less than 3 seconds to provide health care providers a timely tool to review a patient's controlled substance prescription history. Obtaining patient consent does not fit into that workflow and could jeopardize the regular use of this important drug diversion and patient care resource.
3. How can a PDMP obtain patient consent at a reasonable cost? This also presents an operational barrier in providing timely data on controlled substance history use.

In closing, it is recommended that, based upon the operational issues presented above, all controlled substance medications dispensed by a pharmacy be reported to PDMPs without obtaining prior consent.

Sincerely,
Chad Garner

From: Eric Buehlmann [<mailto:eric.buehlmann@ndrn.org>]

Sent: Wednesday, June 25, 2014 3:58 PM

To: Privacy Regulations (SAMHSA)

Subject: Comment on the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations

June 25, 2014

**The Substance Abuse and Mental Health Services Administration
Public Listening Session Comment on the Confidentiality of Alcohol and Drug Abuse
Patient Records Regulations
Submitted by the National Disability Rights Network**

The National Disability Rights Network (NDRN) provides the following comment to the Substance Abuse & Mental Health Services Administration (SAMHSA) on the recent public listening session to consider revisions to the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations. NDRN is the membership organization of the federally funded Protection and Advocacy (P&A) organizations located in every state and U.S. territory. While SAMHSA considers changes on the type of information covered by the regulations, what consent would be required for disclosure, and other confidentiality and disclosure issues, NDRN requests that SAMHSA assess the impact of the regulations on the unique records access authority provided to each P&A organization under federal law.

Several P&A enabling statutes, including the Protection and Advocacy for Individuals with Mental Illness (PAIMI) Act, 42 U.S.C. § 10801 *et seq.*, provides critical authority to each P&A to investigate possible abuse and neglect of individuals with disabilities. See *e.g.* 42 U.S.C. § 10805(a). This authority allows the P&A to access all records of individuals with disabilities in order for the P&A to conduct an investigation of the facility, including without consent, if the P&A has probable cause to believe that abuse and neglect has occurred at a facility. See 42 U.S.C. §§ 10805(a)(4)(B) and (C); 15043(a)(2)(I); see *also* 42 C.F.R. § 51.41(b)(2) and (3). The P&As are further required to keep confidential records and information obtained as part of an investigation. 42 C.F.R. § 51.41; 45 C.F.R. §§ 1386.21 - .22.

Facilities do at times use the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations to refuse the P&A access to records when the P&A is conducting an investigation of abuse and neglect. In situations where the individual patient cannot provide consent, such a refusal creates a significant barrier to the P&A as it attempts to fulfill the mandate to investigate incidents of abuse and neglect, and can further put patient care and safety at risk. NDRN therefore suggests that as part of any revised regulations, SAMHSA explicitly state that the P&A federal access authority allows the designated P&A organization to access patient records which might otherwise be covered by the alcohol and drug abuse confidentiality regulations, even in cases where patient consent is not possible.

The U.S. Department of Health and Human Services already determined that the Privacy Rule under the Health Insurance Portability and Accountability Act (HIPAA) is not a bar to P&A access to protected health information covered under HIPAA. See HHS, [*May a covered entity disclose protected health information to a P&A system where the disclosure is required by law?*](#) (June 10, 2005) available at http://www.hhs.gov/ocr/privacy/hipaa/faq/disclosures_required_by_law/909.html.

We would be happy to further discuss the P&A records access authority and the barriers the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations can create. Please feel

free to contact Eric Buehlmann, Deputy Executive Director for Public Policy
at eric.buehlmann@ndrn.org, (202) 408-9514, ext. 121, or David Hutt, Senior Staff Attorney
at david.hutt@ndrn.org, (202) 408-9514, ext. 129.

Sincerely,

Curtis L. Decker, JD
Executive Director

Eric Buehlmann
Deputy Executive Director for Public Policy
National Disability Rights Network
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AMERICAN ACADEMY OF CHILD & ADOLESCENT PSYCHIATRY

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Anita Chu, M.D.

June 25, 2014

Pamela S. Hyde, J.D.
Administrator
Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road
Room 5-1011
Rockville, MD 20857

Re: Public Listening Session on 42 CFR Part 2 and Confidentiality of
Alcohol and Drug Abuse Patient Records

Dear Administrator Hyde:

The American Academy of Child and Adolescent Psychiatry (AACAP) appreciates the opportunity to submit comments in response to SAMHSA's public listening session, June 11, 2014, on the Confidentiality of Alcohol and Drug Abuse Patient Records. AACAP is the leading national medical association dedicated to treating and improving the quality of life for the estimated 7-12 million American youth under 18 years of age affected by emotional, behavioral, developmental and mental disorders.

In reading the Federal Register Notice and hearing the comments on the public listening session, AACAP noted several overarching issues that we request SAMHSA consider in moving forward with any regulatory changes. Overall, AACAP supports changes in the confidentiality of alcohol and drug abuse patient records removing the current barrier and promoting equal treatment of all healthcare records. We agree with other commenters that keeping substance use records separate from other healthcare records may inadvertently contribute to the stigma we seek to decrease for patients with substance use disorders. The ongoing distinction does not align with other major areas of healthcare change such as the attempt to decriminalize some aspects of substance use, the parity changes in mental health coverage, and the move toward medical homes through the Affordable Care Act.

Under the current system, any patient with substance use disorders is prohibited from full participation in the best integrated care teams. Patients should have the choice whether or not to share their records so they too can benefit from quality collaborative care. In fact, the inability of physicians and other providers to share critical information may actually pose a risk to

the safety of patients, particularly in light of serious drug interactions. As an organization whose membership specializes in working with children and adolescents, we also support changes to the program that would include youth, as 42 CFR Part 2 in its current form does not cover minors.

On the other hand, AACAP does have several concerns that we request SAMHSA consider if a decision to make regulatory changes moves forward. AACAP is concerned about the broad definition of "substance abuse provider" within the medical home, because substance abuse care is delivered at all levels of healthcare and not just in certified substance abuse centers. AACAP therefore would support regulatory language that prevents disclosure outside of the overall treatment team, and that this team should be inclusive of substance abuse, mental health and primary care. AACAP also supports stronger penalties for unauthorized disclosures to people outside of the treatment team, such as law enforcement. This is of particular concern with the Prescription Drug Monitoring Programs. The goal of the changes proposed by SAMHSA is to encourage the proper and necessary sharing of information, yet many providers continue to experience difficulties with accessing information already under the Health Insurance Portability and Accountability Act. AACAP recommends that SAMHSA strive to educate the community, patients, providers, and the legal community on what is allowed and not allowed under existing and proposed regulations

Thank you for the opportunity to comment. We would be happy to speak with you further about our comments and look forward to providing more detailed comments if any regulatory changes are posted. Please contact Ronald Szabat, JD, LLM, Director of Government Affairs and Clinical Practice at rszabat@aacap.org, 202.587.9666, if we can be of further assistance.

Sincerely,

Paramjit T. Joshi, M.D.
President

2404 Forum Boulevard
Columbia, Missouri 65203
www.missouricare.com
800 322 6027 toll-free
573 441 2100



June 20, 2014

The Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
Room 5-1011
1 Choke Cherry Rd.
Rockville, MD 20857

Dear Sir or Madam:

Missouri Care, A WellCare Company is pleased to submit the enclosed comments in response to the questions posed by the Substance Abuse and Mental Health Services Administration (SAMHSA) on the **"Confidentiality of Alcohol and Drug Abuse Patient Records,"** (42 CFR Part 2) as published in the Federal Register on May 12, 2014. We look forward to partnering with our state and federal partners on implementing regulations that protect the confidentiality of substance abuse treatment information, while at the same time ensuring that such rules do not provide any barriers to coordination of new models of integrated care.

Nationally, WellCare is one of the country's largest health care companies dedicated solely to serving public program beneficiaries. We currently serve over two million enrollees nationwide and offer a variety of products including prescription drug, Medicare Advantage, Medicaid, and Children's Health Insurance Program (CHIP) plans for families, children, and the aged, blind, and disabled. WellCare's mission is to be the leader in government sponsored health care programs in partnership with enrollees, providers, and the government agencies we serve. This mission drives our business, and we design our products and support services in accordance with that mission. It is from this vantage point that we offer the below comments.

It is important that policymakers balance the needs of safeguarding confidentiality with ensuring quality care of the *whole* patient. As such, our overall recommendation is that the 42 CFR Part 2 privacy restrictions should be repealed and SAMHSA should instead ensure confidentiality by applying existing HIPAA rules to substance abuse records. As long as health information privacy requirements related to substance abuse treatment records are treated differently than privacy requirements related to other health care services, there will continue to be a barrier to integrating substance abuse services with other health care services. As a managed care organization, we support integration of all services, including substance abuse treatment, medication coordination and management, and behavioral health, to ensure we support our members' needs holistically.

WellCare appreciates the opportunity to provide comment on this important policy issue. Thank you for your consideration. If your staff would like further detail on any of our recommendations, please feel free to contact me at 314-444-7503.

Sincerely,

Barbara Witte

The Substance Abuse and Mental Health Services Administration
Public Listening Session Comment Template

Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2

This document is meant to provide the public with a simple and organized way to submit comments on the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2, and respond to questions presented in meeting notice which is published in the *Federal Register* at 79 FR 26929. While use of this document is entirely voluntary, commenters may find it helpful to organize their comments.

This document alone is not intended to provide a full and complete opportunity to comment on all of the provisions within the regulation. Please keep in mind that it only reflects those topics included in the meeting notice and a section for “other” comments.

To be considered, all comments (including comments provided through this document) must be submitted according to the instructions in the meeting notice: <https://www.federalregister.gov/articles/2014/05/12/2014-10913/confidentiality-of-alcohol-and-drug-abuse-patient-records>.

Applicability of 42 CFR Part 2

SAMHSA is considering options for defining what information is covered under 42 CFR Part 2. Covered information could be defined based on what substance abuse treatment services are provided instead of being defined by the type of facility providing the services.

FR Citation: 79 FR 26930

Questions:

- How would redefining the applicability of 42 CFR Part 2 impact patients, health care provider organizations, HIEs, CCOs, HIT vendors, etc.?
- Would this change address stakeholder concerns?
- Would this change raise any new concerns?

Public Comment Field:

- How would redefining the applicability of 42 CFR Part 2 impact patients, health care provider organizations, HIEs, CCOs, HIT vendors, etc.? We believe that basing specifications on the services provided rather than on the type of facility would allow more clearly defined protections for the information. We also believe this would make it easier for the covered providers to understand the requirements and to thus comply.
- Would this change address stakeholder concerns? We believe it could remove some barriers to service and improve overall confidentiality.
- Would this change raise any new concerns? We cannot think of any.

Consent Requirements

While technical solutions for managing consent collection are possible, SAMHSA is examining the consent requirements in § 2.31 to explore options for facilitating the flow of information within the health care context while ensuring the patient is fully informed and the necessary protections are in place. Specifically, we 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.
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.
3. Require the consent to name the individual or health care entity permitted to make the disclosure.
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.
5. Require that the consent form explicitly describe the substance abuse treatment information that may be disclosed.

FR Citation: 79 FR 26931

Questions:

- Would these changes maintain the privacy protections for patients?
- Would these changes address the concerns of HIEs, health homes, ACOs, and CCOs?
- Would these changes raise any new concerns?

Public Comment Field:

- Would these changes maintain the privacy protections for patients? It would depend on what is put in place and the organizations' other privacy protocols.
- Would these changes address the concerns of HIEs, health homes, ACOs, and CCOs? For us, it would help to have a couple of individuals within the same team listed.
- Would these changes raise any new concerns? It could depending on what changes are made. We believe the above change would not raise new concerns.

Redisclosure

SAMHSA is considering revising the redisclosure provision to clarify that the prohibition on redisclosure only applies to information that would identify an individual as a substance abuser, and allows other health-related information shared by the Part 2 program to be redisclosed, if legally permissible. This would allow HIT systems to more easily identify information that is subject to the prohibition on redisclosure enabling them to utilize other technological approaches to manage redisclosure. If data are associated with information about where the data were collected (data provenance) which reveals that the data were collected by a practice that exclusively treats addiction, the data would still be protected under the proposed change.

FR Citation: 79 FR 26931

Questions:

- Would this type of change facilitate technical solutions for complying with 42 CFR Part 2 in an EHR or HIE environment?
- Would these changes maintain the privacy protections for patients?

Public Comment Field:

- Would this type of change facilitate technical solutions for complying with 42 CFR Part 2 in an EHR or HIE environment? Yes.
- Would these changes maintain the privacy protections for patients? We believe they would should all other confidentiality requirements be followed.

Medical Emergency

SAMHSA is considering adapting the medical emergency exception to make it more in-line with the statutory language and to give providers more discretion as to when a bona fide emergency exists. For example, amending this standard to allow providers to use the medical emergency provision to prevent emergencies or to share information with a detoxification center when a patient is unable to provide informed consent due to their level of intoxication.

FR Citation: 79 FR 26931

Questions:

- What factors should providers take into consideration in determining whether a medical emergency exists?
- Are there specific use cases SAMHSA should take into consideration? Show citation box
- Are there patient concerns about the impact of this change on their privacy?

Public Comment Field:

- What factors should providers take into consideration in determining whether a medical emergency exists? Factors might include risk to self or others for the situation.
- Are there specific use cases SAMHSA should take into consideration? Intoxication that inhibits self-report or signature of release and imminent harm to self or others.
- Are there patient concerns about the impact of this change on their privacy? If medical emergency is well defined, we believe this would not have a negative impact.

Qualified Service Organization (QSO)

SAMHSA is analyzing the regulations to identify options for allowing Part 2 data to flow to health care entities for the purpose of care coordination and population management while maintaining patient protections. 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.

FR Citation: 79 FR 26931

Questions:

- Are there other use cases we should be taking into consideration?
- Are there specific patient concerns about the impact of this change on their privacy?

Public Comment Field:

- Are there other use cases we should be taking into consideration? For external EAPs there are concerns for when clients call for services, are assessed and referred to affiliates for EAP covered services. It would facilitate continuity of care and remove a barrier to service to allow for communication of assessed issues related to substance use or abuse to be communicated with the affiliate we are referring the client to at time of referral with a verbal versus

Qualified Service Organization (QSO)

written release.

- Are there specific patient concerns about the impact of this change on their privacy? In the above specification, we believe the patient is well served without negative impact on privacy.

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.

FR Citation: 79 FR 26932

Questions:

- Are there factors that should be considered related to how current health care entities are organized, how they function or how legal duties and responsibilities attach to entities that make up an umbrella organization?
- Would this change address concerns related to research?
- Are there specific privacy concerns associated with expanding the authority or releasing data to qualified researchers/research organizations in this way?
- Are there additional use cases that should be considered in the research context?

Public Comment Field: No comment.

Addressing Potential Issues With Electronic Prescribing and Prescription Drug Monitoring Programs (PDMPs)

Part 2 protections include a prohibition on the redisclosure of information received directly from a Part 2 program. A pharmacy that receives electronic prescription information directly from a Part 2 program must obtain patient consent to send that information to a PDMP, and patient consent is also required for the PDMP to redisclose that information to those with access to the PDMP.

Preamble FR Citation: 79 FR 26932

Questions:

- How do pharmacy information system vendors anticipate addressing this issue? Are there specific technology barriers SAMHSA should take into consideration?
- 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.
- Are there patient concerns about the impact of e-prescribing and PDMPs on their privacy?

Public Comment Field: No comment.

Other Comments

Topic:

Public Comment Field: Thank you for the opportunity to comment.



FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL
AND MASSACHUSETTS GENERAL HOSPITAL

June 25, 2014

The Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road
Rockville, MD 20857
Room 5-1011

Re: Comments in Response to 79 FR 26930

To Whom it May Concern:

Partners HealthCare System, Inc. ("Partners"), a charitable non-profit corporation that is the sole member of a number of health care entities in Massachusetts, including Massachusetts General Hospital ("MGH"), Brigham & Women's Hospital ("BWH") and North Shore Medical Center ("NSMC"), wishes to provide these comments to SAMSHA's proposed modifications to 42 CFR Part 2. By way of background, health care entities within the Partners system, including MGH and BWH, have departments which are regulated under 42 CFR Part 2, as well as individual practitioners who must abide by the regulation due to their treatment of substance abuse patients with Suboxone. In order to provide comments on these proposed modifications to the regulations, Partners solicited input from clinicians who provide services to substance abuse patients as well as other providers who provide varied health care services to such patients, including primary care, mental health care and emergency treatment.

Partners recognizes the importance of heightened confidentiality as to substance abuse treatments, and agrees that such heightened confidentiality can be an incentive for a person suffering from substance abuse to agree to seek out and accept such treatment. By the same token, however, the importance of integrated care to the safe, effective treatment of all patients, including those suffering from substance abuse, is beyond doubt. Being able to share clinical information about treatment the patient is receiving and conditions from which they are suffering is a key component of such integrated care. 42 CFR Part 2, in its current form, poses significant barriers to providers being able to provide patients with such safe, effective and integrated care. Therefore, Partners believes that these proposed modifications to the regulations are long overdue and critically important to allowing substance abuse patients to receive the same level of integrated care as any patient, enhancing the likelihood of success of their substance abuse treatment as well as any other treatment they are receiving.

Ironically, the barriers set up to sharing information regarding 42 CFR Part 2 patients with other providers run directly contrary to the imperative to respond to what is becoming an opiate addiction crisis of epidemic proportions. The rate of death from overdose now surpasses the rate of death from motor vehicle accidents. Fourteen percent of beds in the emergency

Office of the General Counsel

department of one of our large academic medical centers are filled with patients being seen for issues related to substance use disorders. Healthcare providers in the state and nationally need as many tools and opportunities as possible to fight this epidemic, but the current language of 42 CFR part 2 constrains those tools and therefore reduces our opportunity to have the level of clinical impact needed by our patients and the general public.

These concerns are especially concerning to providers in clinics regulated by 42 CFR Part 2 as well as other providers throughout the system who provide care to the patients of such clinics. Such patients often have many medical co-morbidities. For example, two-thirds of patients referred by MGH clinicians to its 42 CFR Part 2 Clinic, the West End Clinic (“WEC”), have medical or surgical co-morbidities directly caused or exacerbated by alcohol or drug use. Substance abuse patients’ life expectancy is 10-15 years shorter than the general population. In most cases, the successful implementation of primary care or specialty-clinic based treatment depends on an integrated management of substance use disorder. This type of integration requires many health care providers and disciplines to be involved. The challenge for a large hospital like MGH is that it is comprised of many departments and units, and the need to share information among them regarding common patients is an imperative.

Not being able to share medically necessary substance use disorder information with providers who care for these patients may have deleterious consequences. Due to existing regulation and its limitations, health care providers are put in a position to make a choice between patient safety, on the one hand, and violating 42 CFR part 2, on the other. Even worse, with the regulations current structure, patients are prevented from receiving the highest quality of patient care.

42 CFR part 2 was enacted in the 1970s. The use of electronic medical records, and the focus on integrated care, has grown rapidly over the last decade. Accountable Care Organizations (“ACOs”) are developing ways to better manage chronic health conditions. For the purpose of management of chronic illness, substance abuse treatment information should be available to common providers.

In reviewing the proposed changes to 42 CFR Part 2, Partners determined that the following modifications would address many of the concerns set out above:

1. Consent

- a.] Allow the consent to disclose to include a more general description of the individual, organization, or health care entity to which disclosure is to be made, rather than the current requirement that the consent specifically identify to whom the disclosure will be made. This would allow patients to consent to disclosure to a broader subset of common providers at once, rather than consent one at a time, relieving a significant administrative burden on both patient and provider that often gets in the way of desired disclosure.

- b. o 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. This would enhance further the ability of a 42 CFR provider to obtain consent to disclose to a broader subset of common providers at once, and would significantly enhance the ability to place 42 CFR Part 2 patient information into an Electronic Medical Record, so long as the patient consents to it and is provided with a list of entities who share such EMR.

2. **Emergencies**

- a. o Giving providers more discretion as to when a bona fide emergency exists, thereby allowing them to disclose 42 CFR Part 2 patient information without consent (for example, amending the emergency exception standard to allow providers to use such provision to *prevent* emergencies or to share information with a detoxification center when a patient is unable to provide informed consent due to their level of intoxication) would greatly enhance patient care for these patients, and recognizes the importance of avoiding emergencies rather than waiting for one to occur in order to take advantage of the exception.

3. **Qualified Service Organizations**

- a. Allowing 42 CFR Part 2 data to flow to health care entities for the purpose of care coordination and population management while maintaining patient protections would, as described more fully above, provide such patients with an appropriate level of safe, effective and coordinated care. The potential solution discussed by SAMSHA which included 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 an ACO that is not itself a Part 2 program, and a service provider would be extremely beneficial to meeting the patient care needs of this patient population.

None of the above modifications would put patient information at unnecessary risk of inappropriate disclosure. All such information would continue to be seen and held by providers who already provide care to such patients, and would do so in a safer and more effective manner. As such, we urge SAMSHA to adopt these modifications or similar ones which would have the same impact on care of these patients. Integrated and coordinated care is important for all patients, and patients of 42 CFR Part 2 entities should not be denied such the opportunity to receive it.

Sincerely,

Joshua L. Abrams
Senior Attorney

June 18, 2014

U.S Department of Health and Human Services
The Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road, Rockville, MD 20857, Room 5-1011.

Attention: Confidentiality of Alcohol and Drug Abuse Patient Records- A Proposed Rule
by the Substance Abuse and Mental Health Services Administration on 05/12/2014
FR Doc. 2014-10913 Filed 5-9-14; 8:45 am

Intermountain Healthcare appreciates the opportunity to submit these comments on the Department of Health and Human Services' Substance Abuse and Mental Health Services (SAMHSA) Notice of Proposed Rulemaking relating to the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2, as published in the Federal Register on May 12, 2014.

Background Information

Intermountain Healthcare is a nonprofit, community-based integrated healthcare delivery system headquartered in Salt Lake City, Utah. It operates 22 hospitals and more than 155 clinics. Intermountain has approximately 34,000 employees and about six million patients in our longitudinal Electronic Health Record (EHR). Intermountain employs approximately 1200 physicians and has another 2,500 affiliated physicians who practice at its facilities. Recognized for its success in the provision of high-quality, efficient clinical care, Intermountain is also known for its pioneering work in developing and using electronic clinical-information systems, which are critical in providing this efficient, high-quality care.

Intermountain provides comprehensive mental health and substance abuse services, including the following:

- Acute Inpatient
- Residential Treatment
- Day Treatment
- Chemical Dependency Inpatient Detoxification
- Intensive Outpatient Behavioral Health Programs
- Outpatient programs that offer Buprenorphine treatment
- Multiple physicians who are certified to offer Buprenorphine treatment, many of whom are located in rural areas of Utah

Intermountain's Response to the Specific Question regarding the Applicability of 42 CFR Part 2

A. The Question.

SAMHSA is considering options for defining what information is covered under 42 CFR Part 2. Covered information could be defined based on what substance abuse treatment services are provided instead of being defined by the type of facility providing the services.

B. Intermountain's Response.

This change will make compliance with 42 CFR Part 2 more difficult, not easier.

C. The Rationale.

Intermountain understands that federal regulations currently classify records of patients being provided Buprenorphine for opioid addiction to be under the protection of CFR Part 2, even though

these services are being provided in general medical clinics. Many Intermountain physicians, who are certified to offer Buprenorphine treatment, provide this treatment in rural medical-care clinics where these physicians also provide other medical care. So Intermountain already segregates and protects records of Buprenorphine treatment for substance abuse from other medical records at these rural facilities.

But Intermountain has had difficulty providing this protection of Buprenorphine treatment records, as required by 42 CFR Part 2, because of the following reasons.

- (1) To comply with the specific consent requirements of 42 CFR Part 2, Intermountain has mandated that the Buprenorphine substance-abuse treatment records must be kept on paper, rather than integrated into the patient's EHR. Intermountain does not have the capability to restrict access to EHR records that is required by 42 CFR Part 2.
- (2) A consent management system is necessary to allow the collection of the consents required by 42 CFR Part 2, as well as to allow such consents to be managed appropriately. Even though Intermountain has had a sophisticated EHR for decades, it does not have a consent-management system necessary in its EHR to comply with 42 CFR Part 2.
- (3) The specialized rules for release of substance-abuse information require additional education for clinic staff and providers above and beyond that required by the HIPAA Privacy Rule. With employee turnover, Intermountain must commit significant resources to keeping the clinical staff informed to comply with these rules. Also, because of the 42 CFR requirements for a unique type of court order to produce substance abuse records, Intermountain requires a member of its Legal Department review every court order prior to the production of records, which also adds to the cost of care.

If 42 CFR Part 2 is changed to require segregation according to "type of treatment," that change would increase Intermountain's costs to educate staff, to pay for attorney review, and to further segment the patient's record. For example, if a patient is admitted to a hospital for an acute condition and, it is determined, also needs substance-abuse treatment, it would be nearly impossible for Intermountain—and any healthcare provider with an electronic EMR—to partition the documentation of substance-abuse treatment from the documentation of treatment for other conditions: they are intricately connected.

Conclusions

Intermountain supports SAMHSA's efforts to protect patient privacy and to bring an old, paper based regulation into an increasingly electronic world. We also understand the sensitivity of the individuals who seek treatment for these conditions.

The provision of integrated care poses numerous controversies and challenges in striking a balance between provider access to essential medical information and patient-privacy concerns. Intermountain highly encourages EMR vendors to focus on developing technology that adds layers of protection to mental-health and substance-abuse information without impeding the delivery of care. EMRs should be able to restrict access to sensitive information while enhancing their ability to expand role based access controls. But such sophisticated EMR systems are not widely available, if at all.

In Intermountain's opinion, , the time has come to repeal 42 CFR Part 2 and consider other options that address patient privacy, best patient care, and practicality of implementation in a way that is possible with current technology.

Intermountain proposes the following requirements or guidelines.

1. All identifiable health information should be held to the same confidentiality standard. Intermountain recommends that the standard be the HIPAA Privacy Rule, which already sets the best known and comprehensive standard for healthcare providers to meet to ensure health-information privacy in the U.S. HIPAA's provisions address research approvals for using identifiable information and define what data elements are considered identifiable. If SAMHSA moves to one confidentiality standard, it could resolve concerns about the research restrictions on patients' substance-abuse information. HIPAA requires that its minimum-necessary standards apply when using identifiable patient information for payment and healthcare operations, as well as its significant restrictions on disclosing information to law enforcement. HIPAA also has agreements (business associate agreements) that are more comprehensive than the Qualified Service Organization Agreements (QSOA) currently required by 42 CFR Part 2. HIPAA permits healthcare providers to use or disclose a patient's health information if the patient authorizes that use or disclosure. So if consent-management systems become more widely available in the future, then the framework exists for implementation without making changes to the law.
2. All regulations should optimize treatment and coordination of care. HIPAA does that by permitting patient information to be used for treatment and care coordination.
3. To provide the best care for individuals, patients' records should include all of their treatment, including behavioral health and substance abuse. Because Intermountain treatment providers believe that the primary purpose of the EMR is to treat all aspects of a patient's health, Intermountain currently includes behavioral health treatment records with the patient's general Electronic health record. This has resulted in a more holistic approach to treatment. Current thinking in behavioral health is to provide behavioral-health treatment in concert with other medical treatments for the greatest benefit to patients. Intermountain has found that heart disease is ...particularly significant to mental health issues as well as a large percentage of Emergency Department and Primary Care visits. Treating patients' medical issues optimally requires open communication between all providers: this assures the most effective and responsible healthcare.

It also reinforces the current Administration's efforts to encourage the use of EMRs as the most efficient and effective way to provide health care.

4. The main fears expressed in the listening session are the misuse of substance-abuse diagnosis information. 42 CFR Part 2 requires treatment providers to "wall off" this type of information in an attempt to prevent misuse of the information. Intermountain suggests that SAMHSA reinforce its efforts to prevent the misuse of health information by applying HIPAA restrictions to mental-health records, enforcing existing non-discrimination laws, consider sponsoring other laws that appropriately limit the use of health information, and find ways to encourage the development of electronic medical records that possess the functionality to restrict access to sensitive information while enhancing their ability to expand role based access controls.

Thank you for the opportunity to share our concerns and comments.

Sincerely yours,

Jutta Williams
Chief Privacy Officer
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ClinNext
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CureMD Corporation
Emdeon
e-MDs
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Foothold Technology
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Greenway Medical
Technologies
Healthland
MacPractice, Inc.
McKesson Corporation
MEDHOST
MEDITECH
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NexTech Systems, Inc.
NextGen Healthcare
Practice Fusion
QuadraMed Corporation
Sevocity, Division of
Conceptual MindWorks Inc.
Siemens
SRS Software, LLC
STI Computer Services
Suncoast Solutions
Välant Medical Solutions, Inc.
VersaSuite
Workflow.com LLC

June 25, 2014

Pamela S. Hyde, JD, Administrator
Substance Abuse and Mental Health Services Administration
Choke Cherry Rd.
Rockville, MD 20857
Document Number: 2014-10913

Dear Ms. Hyde:

The member companies of the Electronic Health Record Association (EHRA), with deep expertise in the development and deployment of EHRs in hospitals and physicians' practices, offer our detailed comments on the listening session held by the Substance Abuse and Mental Health Services Administration (SAMHSA) on 42 CFR Part 2. Our response has been developed through the collaborative efforts of the EHRA Privacy and Security Workgroup to ensure that it represents the range of perspectives and interests of electronic health record (EHR) developers and our customers. It addresses the concept and substance of the questions posed by SAMHSA as well as general comments on 42 CFR Part 2.

We appreciate the opportunity to offer this summary to highlight key themes to be considered by SAMHSA staff as they review our detailed response:

EHRA supports meaningful reform of the 42 CFR Part 2 regulations that encourages patient privacy protections, data sharing, and interoperability to enhance patient care.

Confidentiality regulations for substance abuse treatment should not present an inappropriate hurdle to data sharing or health information exchange. Patients receive a higher quality of care when clinicians are equipped with the information they need to provide effective patient care. Unfortunately, the current Part 2 regulations can be a barrier to this data sharing. For example, under the current regulations, the recipient of each disclosure must be named in the consent. However, not all possible parties for whom a disclosure is clinically or otherwise necessary may be known at the time that consent is developed.

The focus should be on encouraging proper use of substance abuse treatment data rather than attempting to restrict disclosure of the data.

The current 42 CFR Part 2 regulations focus heavily on preventing inappropriate disclosures of the substance abuse treatment data. We believe this focus no longer matches the reality of the Internet age where information is more freely available than ever before. For example, using a smartphone’s global positioning system (GPS) to find directions to a substance abuse treatment center may suggest to network providers and map application providers that a patient may be receiving treatment services at that center, but this “disclosure” would not be covered by existing regulations. So, rather than focus on the disclosure, which may happen through various avenues outside the provider workflow, we recommend that the focus should be on the appropriate use of the data. This approach would align with the current Health Insurance Portability and Accountability Act (HIPAA) regulations, which focus on the purpose for which the data is being used. Intentional, malicious disclosures of treatment information should be illegal and addressed by the regulation; however, the regulations must not be overly restrictive such that they become an obstacle to data sharing for treatment.

Electronic health records provide unique advantages to protect patient privacy and security that are not available in paper records.

EHRs have features such as audit trails, reporting, and alerting that allow every view of a patient chart to be tracked. EHRs that have been certified as certified electronic health record technology (CEHRT) under the Office of the National Coordinator for Health Information Technology’s (ONC’s) meaningful use certification program can also track copy and print actions on patient charts. CEHRT audit trails cannot be modified through the EHR and have “tamper evident” controls. Privacy officers can use this data to track employee activity at a level that is simply not available to paper-based charts and thus enhance the security and privacy protections around substance abuse treatment records.

Sincerely,

Michele McGlynn
Chair, EHR Association
Siemens

Leigh Burchell
Vice Chair, EHR Association
Allscripts

HIMSS EHR Association Executive Committee

Pamela Chapman
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Meg Marshall, JD
Cerner Corporation

Ginny Meadows, RN
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Mark Segal, PhD
GE Healthcare IT

About HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 40 companies that supply the vast majority of operational EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner HIMSS. For more information, visit www.ehrassociation.org.

Comments on Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2

Submitted by the National Center on Domestic Violence, Trauma & Mental Health (NCDVTMH)

Date: June 25, 2014

Document Citation: 79 FR 26929

Document Number: 2014-10913

The National Center on Domestic Violence, Trauma & Mental Health (NCDVTMH) is a national special issue resource center funded by the Family Violence Prevention & Services Program (FVPSP); Administration on Children, Youth and Families; Department of Health & Human Services.¹ We are grateful for this opportunity to submit comments.

As we move toward more coordinated care models, advances in health information technology (HIT) create new possibilities for advancements in patient care while maintaining protections for sensitive patient information. Developing the technological solutions for ensuring the protection of sensitive health- and behavioral health-related information is possible—and can be critical to patient safety and well-being.

The domestic violence (DV) field has an important role to play in these conversations. First, the regulatory and technical solutions for handling sensitive *substance use treatment* information have implications for how we will be able to handle sensitive *DV-related* information, such as disclosures of abuse. We know that health and behavioral health care providers are places where DV survivors frequently seek assistance and support. Trust and confidentiality can be critical factors to survivors in making the decision to disclose abuse, while maintaining confidentiality related to disclosures of abuse can be critical to patient safety. Thus, information about abuse derived from these disclosures must be protected to ensure that patients have an opportunity to safely disclose abuse to their providers and to ensure that patients' safety is protected after disclosure is made.

Second, we are interested in the direct implications of changes to 42 CFR Part 2 for those survivors who have sought treatment for a substance use disorder. The number of survivors potentially impacted is significant. Studies show that

¹ These comments are not submitted on behalf of and do not necessarily reflect the opinions of Family Violence Prevention & Services Program (FVPSP); Administration on Children, Youth and Families; and/or the Department of Health & Human Services.

between 67%–80% of women in substance abuse treatment are survivors of domestic violence.² Survivors may use substances to cope with the impact of past experiences of trauma or to emotionally survive ongoing abuse. Abusive partners may also use coercive tactics related to the substance use—including forcing or coercing their partners to use drugs or alcohol or to use more than they wanted, interfering with treatment and/or undermining recovery efforts, and using substance use or intoxication to justify emotional or sexual abuse. At the same time, abusers may use substance use treatment information against their partners to impugn their credibility with family and friends, undermine potential sources of support and assistance (e.g., by telling survivors they will be arrested for drug-related crimes if they call the police), and challenge their parenting ability in custody cases.³

Thus, the disclosure of documentation of abuse and documentation related to substance use treatment poses risks for survivors. Additionally, this information may be linked together, such as when documentation of interpersonal violence is included in substance abuse treatment records, the disclosure of which poses additional risks for survivors. These risks can place survivors in the bind of having to choose between seeking treatment which can be used against them or not accessing services that are important for their health and well-being—a dilemma that directly echoes the originally stated intentions of Congress in creating heightened protections for substance use treatment records via 42 USC § 290dd-2.

While regulatory changes may partially address some of the immediate needs of the field introduced by recent changes in the health care system, achieving advances in patient care while maintaining protections for sensitive patient information will ultimately require true data segmentation. HIT developers and vendors must build the software and hardware necessary to deal with sensitive information and give patients the authority over their own data without unduly burdening their providers. We encourage SAMHSA and other federal agencies to provide adequate incentives (carrots and sticks) to ensure developers and vendors make significant advances in data segmentation.

In the meantime, we are grateful for the opportunity to provide the following comments on specific regulation changes being considered by SAMHSA.

² Patricia Bland, M.A., CDP, *In Harm's Way: Substance Abuse and Safety Issues in the Context of Violence Against Women* (citing studies by Bennett & Lawson, 1994; Downs, 2001; Ogle & Baer, 2003).

³ Warshaw, Lyon, Bland, Phillips & Hooper, *Mental Health and Substance Use Coercion Survey: Report on Findings from the National Center on Domestic Violence, Trauma & Mental Health and the National Domestic Violence Hotline*. NCDVTMH 2014 (forthcoming).

Applicability

NCDVTMH supports changing the applicability of 42 CFR Part 2 so that covered information could be defined based on what substance abuse treatment services are provided instead of being defined by the type of facility providing the services. Documentation related to substance abuse treatment services should be considered sensitive information and subject to the heightened protections of 42 USC § 290dd-2 and 42 CFR Part 2, regardless of the type of facility at which the patient received treatment. As behavioral health services are increasingly integrated into primary health settings, this change in the applicability of 42 CFR Part 2 would represent a necessary and appropriate modernization of the regulation.

We understand that broadening the applicability of the rule to additional classes of providers will have an impact on service delivery in the short term. We strongly encourage SAMHSA and other agencies to put significant pressure on HIT developers and vendors to integrate automatic data segmentation, coding, and prompts to give providers the tools necessary to automatically and easily protect data without interrupting service delivery. Technology could and should be developed and used to balance these competing concerns.

Consent Requirements

NCDVTMH does not support changes to 42 CFR Part 2.31(a)(2), the “to whom” requirement. While the inclusion of programs currently covered by 42 CFR Part 2 in HIEs, health homes, ACOs, and CCOs is an important goal and necessary to providing holistic patient care, this cannot—and need not—be achieved at the expense of equally important privacy protections.

Strong privacy protections in the context of sharing information among groups with changing membership are critical to survivor safety. While some patients may choose to provide more generalized consents if they were permitted by 42 CFR Part 2, the risks associated with providing such consent are significant—especially for survivors of domestic violence. While some members of health care entities may be aware of the interrelated safety and confidentiality needs of survivors and may be fully trained and prepared to take the precautions necessary to ensure the safety of DV survivors, others may not be. Furthermore, in some cases, an abuser may gain direct access to records, either personally or through allied family members or friends, especially in more rural areas, when records are disclosed to new members of health care entities. The records protected by 42 CFR Part 2 can include a range of highly sensitive personal information that abusers can use against their partners in a number of ways. For these reasons, providing consent to the disclosure of records to a general entity

with changing membership will rarely be in the best interests of survivors. Notification to a patient of regular changes to the list of providers or organizations that may access their information is insufficient to mitigate these safety risks. While recognizing that some patients may nonetheless wish to provide such a generalized release, such decisions would need to be made in the context of a robust informed consent process beyond what is currently the industry standard and what is required by any current or proposed regulation or law. Given these current realities, requiring consent forms to specifically identify the entities “to whom” disclosure is permitted is critical to survivor safety.

In addition, we note that allowing a consent form to include a more general description of the individual, organization, or health care entity to which disclosure can be made does not solve the need to provide for technological solutions when patients do not wish to provide this type of consent. Thus, the very real concerns raised by stakeholders that prompted SAMHSA to consider these changes will not be addressed by this proposed change because not all patients will find such generalized disclosures to be within their best interests. Such stakeholders will still need to find technological solutions to ensure these patients are included in coordinated care efforts. We are encouraged by recent technological advancements that will allow for these concerns to be accurately addressed in the near future, allowing for more patient privacy options without unnecessarily sacrificing privacy and safety protections.

Redisclosure

NCDVTMH supports clarification of 42 CFR Part 2.32 to clarify that the prohibition of redisclosure only applies to information that would identify an individual as a substance abuser, and allows other health-related information shared by the Part 2 program to be redisclosed, if legally permissible.

The prohibition on redisclosure is critical to survivor safety, as well as being a necessary privacy protection for all patients. As described in the previous section, while some providers may be fully trained and prepared to respond to the interrelated safety and confidentiality needs of survivors, others may not be. In some cases, an abuser may gain direct access to records, either personally or through allied family members or friends, especially in more rural areas, if redisclosure were permitted absent heightened protections.

Thus, all privacy and signed consents should follow the data, regardless of who is using it. If a provider “pulls” data on a patient, the data received should be automatically subject to the same consents that a patient signed in the originating encounter. Responsibility for adhering to these consents must be built in to the formal health information exchange trust documents—and there must be strong penalties for breaching these privacy concerns. Policy on redisclosure of privacy and signed consents—as well as the technology to do it—

is still in a nascent stage of development. The principle remains that authorizations should follow the data. Thus, once again, we strongly encourage SAMHSA and other agencies to put significant pressure on developers and vendors to develop the technology structure necessary to provide the necessary protection for patient information.

Medical Emergency

42 USC § 290dd–2 provides for an exception to the consent requirements to “meet a bona fide medical emergency.” Clearly, this statutory exception is critical for the safety of patients. Having access to medical information necessary to meet an emergency situation can be life saving. NCDVTMH is concerned that changes to 42 CFR Part 2 to allow providers to use the medical emergency provision to “prevent” emergencies (in addition to merely to “meet” emergencies) would be an overly broad interpretation of the statute. Such an exception would potentially provide access to otherwise sensitive information in a wide range of circumstances, based on the justification that access to the information may prevent an emergency in the indeterminate future. More clarification is needed to determine whether such an exception could be written to facilitate increased patient care while also staying within the scope of the statute and upholding necessary privacy protections.

Qualified Service Organization

At this time, NCDVTMH does not support 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.

The goals of improving care coordination and helping providers to identify patients with chronic conditions in need of more intensive outreach are important ones. But while new opportunities for improving care coordination are exciting, they do not negate the need for strong privacy protections for highly sensitive information such as substance abuse treatment records. On the contrary, patient consent must remain a necessary prerequisite for sharing of highly sensitive information. Allowing the redisclosure of Part 2 information on the basis of a QSOA between a payer or an ACO and a service provider would circumvent the prohibition on redisclosure and other necessary protections provided by this regulation.

As explained above, sharing highly sensitive information regarding substance abuse treatment presents many risks for survivors. As discussed, while some members of health care entities may be prepared to take the precautions necessary to ensure the safety of DV survivors, others may not be. Furthermore,

in some cases, an abuser may gain direct access to records, either personally or through allied family members or friends, especially in more rural areas. For these reasons, sharing of sensitive information should require the patient's informed consent, given in the context of a robust informed consent process that includes a discussion of the potential risks and benefits of information sharing, so that patients can determine what is in their best interest.

With regard to the goal of population health management, NCDVTMH is concerned that the release of much of the information protected by 42 USC § 290dd-2 and 42 CFR Part 2 is unnecessary for this purpose. To the extent that substance abuse treatment records are released for this purpose, de-identification of records is critical. Thus, to the extent that SAMHSA modifies 42 CFR Part 2 to facilitate access to records for the purpose of population health management, we encourage SAMHSA to require de-identification of records.

Conclusion

Thank you for this opportunity to provide comments. We appreciate your consideration and look forward to the next steps in this process. Please do not hesitate to contact us if we can be of additional assistance. You may reach Carole Warshaw, MD, Director, at cwarshaw@ncdvtmh.org or Rachel White-Domain, JD, Project Manager, at rwhitedomain@ncdvtmh.org. We can both be reached at 312-726-7020.

**America's Health Insurance Plans
Substance Abuse and Mental Health Services Administration
Public Listening Session
Regarding the Confidentiality of Alcohol and Drug Abuse Patient Records
Statement for the Record
June 25, 2014**

Submitted By:

**Marilyn Zigmund Luke
Senior Counsel and Compliance Officer**

AHIP commends the Substance Abuse and Mental Health Services Administration (SAMHSA) for convening a public listening session to evaluate the current status of the federal confidentiality regulations.¹ These regulations (often referred to as the “Part 2” requirements) when implemented in conjunction with the Health Insurance Portability and Accountability Act (HIPAA)² requirements, provide a strong framework for keeping individuals’ health information private and secure.

America’s Health Insurance Plans (AHIP) is the national association representing health insurance plans. Our members provide health and supplemental benefits to more than 200 million Americans through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare and Medicaid. AHIP advocates for public policies that expand access to affordable health care coverage to all Americans through a competitive marketplace that fosters choice, quality, and innovation.

Our plans have been at the forefront of designing business processes that protect the comprehensive portfolio of all types of consumer health information, including substance abuse and mental health information. In many situations, health insurance plans have implemented special protections for substance abuse and mental health information based on customer needs and in compliance with changing federal and state requirements. We applaud SAMHSA for initiating public dialog to receive information about current consumer needs and the changes within the health care system that have taken place since the Part 2 regulations became effective nearly four decades ago.

The Affordable Care Act has been transforming the ways through which individuals obtain health care services. We have seen the development of Accountable Care Organizations to increase coordination between health care providers in treating the holistic needs of individuals. Improvements have been made in the ways through which consumers can research and purchase a variety of health insurance products (e.g., using state and federal Exchanges) based on their unique circumstances and individual needs.

¹ 42 C.F.R. Part 2.

² Pub. L. No. 104-191 and corresponding regulations at 45 C.F.R. Parts 160, 162, and 164.

There is also a new trend of building patient-centered medical homes which integrate treatments for physical and mental health and which are designed to foster a collaborative relationship between an individual and his or her primary physician (e.g., this model is being used by some state Medicaid programs). Many health insurance plans are participating in these models which promote high value health care, support the integration of care, are patient-centered, compatible with value-based benefit design, and address the three aims under the National Quality strategy to provide better, more affordable care for the individual and the community.

In addition to the ACA changes, the use of electronic technologies in health care has dramatically increased the sharing of information for the benefit of consumers at the point of care. Electronic prescribing platforms, decision-support tools, health plan member portals, and electronic medical records are all examples of the current ways that consumers and providers have increased access to electronic health information. In addition, states and regional collaborative organizations, in conjunction with private entities, have created electronic platforms for exchanging health information and leveraging the efficiency and availability of health information to improve health outcomes for individuals. These uses and tools were not envisioned when the federal Part 2 regulations were developed.

Electronic processes are also being leveraged to improve the accuracy and efficiency of health care transactions, which benefit consumers by reducing costs. Health insurance plans are working in partnership with physicians, physician organizations, hospitals, other clinicians, and with other health insurance plans to help change the delivery system by using innovative payment models that focus on paying for improved patient care as opposed to the volume of services provided. These delivery platforms did not exist when the Part 2 regulations were developed.

Patient and population needs have also changed since the Part 2 regulations became effective. Historically, individuals may have been reluctant to seek out substance abuse and mental health services based on a lack of knowledge of treatment options, uncertainty about access and coverage, and a fear of being stigmatized for receiving such services. Population-based health

care needs were largely focused on improvements in medical conditions, rather than substance abuse intervention programs or community-based mental health services. Fortunately, there have been tremendous improvements in the appropriate, multi-faceted treatment of health conditions that contribute to substance abuse, access to mental health services, and the quality and delivery of care.

In addition, federal and state officials have recently increased attention at designing ways to better identify and analyze substance abuse trends to target appropriate resources in communities. Health plans use a variety of innovative practices to integrate care and manage high-risk patients with chronic illnesses and co-morbid conditions such as behavioral health and substance use disorders. Use of new payment and delivery models have helped plans build successful primary care programs that combine traditional and new models of care that focus on improving access to care and improving quality and outcomes while reducing healthcare costs. Use of multi-disciplinary teams, targeted care management and co-located services are examples of strategies used by plans to integrate care across the system, identify hard-to-serve populations and improve adherence. Additional health plan strategies include the use of robust health information technologies, documentation in electronic health records, and providing ancillary psychosocial services to promote adherence.

We are submitting our statement to highlight several issues where we believe the agency should focus attention and consider issuing guidance or promulgating new, revised regulations. As our comments below explain, several issues could benefit from further examination by SAMHSA.

Aligning the Part 2 Regulations, HIPAA and State Requirements

When HIPAA was enacted in 1996, the U.S. Department of Health and Human Services was directed to develop privacy regulations (referred to as the Privacy Rule) for “covered entities” which set out the administrative, technical, and physical safeguards to be used to protect the individuals’ health information. One of the key components of the federal regulations was that they served as a “floor” of protection and states are free to enact more stringent privacy

standards, as long as they do not conflict with the federal requirements (i.e., non-conflicting state requirements will not be preempted by the federal rules).

For example, some states align their requirements with the HIPAA rules,³ whereas other states may be more stringent than HIPAA. Under the HIPAA framework, health care entities will typically perform a preemption analysis and will adopt the more stringent requirement for its business operations. Concurrently, these entities must also consider whether the federal Part 2 confidentiality regulations apply, and if so, must decide how to implement these concurrent but different requirements.

SAMHSA, in conjunction with the U.S. Department of Health and Human Services, Office for Civil Rights should issue updated guidance to identify specific states where the most stringent protections exist for substance abuse and mental health information.

Aligning the Part 2 Regulations with HIPAA

We appreciate the past guidance that SAMHSA has issued to provide information on the interrelation between HIPAA and the federal Part 2 regulations.⁴ Several issues remain since SAMHSA released guidance. The primary issue health insurance plans face is implementing two very different regulatory frameworks that apply to disclosures of health information. The Part 2 regulations apply to substance abuse information and the HIPAA privacy and security regulations cover all health information, including substance abuse data.

³ In North Carolina, a treatment facility may release information about a patient regarding mental health, development disabilities and substance abuse with “any other facility when necessary to coordinate appropriate and effective care, treatment or habilitation of the client” and several other exceptions designed to promote and not hinder care and treatment. This law also permits a treatment facility to share information with HIPAA covered entities or their business associates. Individuals are advised that the facility may make such disclosures and are given the opportunity to object to the disclosure. Covered entities and business associates that receive the information are permitted to use and disclose it as permitted under the Privacy Rule. The health information may not be used for discriminatory purposes. Refer to N.C.G.S. Chap. 130A (Art. 6), N.C.G.S. § 122C-52, N.C.G.S. § 122C-55.

⁴ The Confidentiality of Alcohol and Drug Abuse Patient Records Regulation and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs (June 2004), as available via the Internet at: <http://www.samhsa.gov/HealthPrivacy/docs/SAMHSAPart2-HIPAAComparison2004.pdf>.

Health care entities have interpreted the federal Part 2 regulations differently because the definitions between the federal requirements appear to apply to different types of health information. For example, the definition of “patient identifying information⁵” is different from the definition of “records,⁶” and those used in HIPAA regulations for “protected health information⁷” and a “designated record set.⁸” In addition, separate definitions exist for a “program,” “third party payer,” and “qualified service organization.”⁹ The definition of a “qualified service organization” under the Part 2 regulations contrasts with the term “business associate” as used in the HIPAA rules, even though the concepts are similar. The difference in the definitions causes confusion about what health information is affected by which – or both – sets of federal requirements.

It can also be difficult to determine to what information the different federal regulations apply because the Part 2 requirements do not clearly apply to current health care delivery methods. Given the new health care delivery models such as patient-centered medical homes, Accountable

⁵ 42 C.F.R. §2.11 defines the term as “the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social security, or driver’s license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the program.”

⁶ 42 C.F.R. §2.11 defines the term as “any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.”

⁷ 42 C.F.R. §160.103 defines the term as “individually identifiable health information: (1) Except as provided in paragraph (2) of this definition that is: (i) Transmitted by electronic media; (ii) Maintained in electronic media; or (iii) Transmitted or maintained in any other form or medium. (2) Protected health information excludes individually identifiable health information in (i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g; (ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and (iii) Employment records held by a covered entity in its role as employer.

⁸ 45 C.F.R. §164.501 defines the term as “(1) a group of records maintained by or for a covered entity that is: (i) The medical records and billing records about individuals maintained by or for a covered health care provider; (ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals. (2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.”

⁹ 42 C.F.R. §2.11. For example, to be governed by the Part 2 requirements, a “program” must receive federal assistance⁹ and be “(a) an individual or entity (other than a general medical facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or (b) [a]n identified unit within a general medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment, or referral for treatment; or (c) [m]edical personnel or other staff in a general medical care facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers.” Separate definitions exist for “third party payer” and “qualified service organization.”

Care Organizations, health entities that offer and provide care management and referral services in conjunction with other healthcare services, and similar emerging models, understanding when and if the Part 2 regulations apply can be difficult.

We recommend that SAMHSA continue future public dialog to evaluate how to update the Part 2 regulations to align as closely as possible with the HIPAA regulations. Any future changes should be published in the *Federal Register* for public review and comment. The agency may also consider issuing new guidance that clarifies how the Part 2 regulations may apply in different business settings. Such guidance could be issued in conjunction with new educational efforts if regulatory changes will not be implemented.

All Payer Claims Databases (APCDs)

In recent years, many states have begun compiling health care claims in databases that typically compile individuals' medical, pharmacy, and dental claims for state residents who are covered by commercial health insurance plans, as well as governmental health benefits programs such as Medicare and Medicaid. The goals of APCDs are to provide state officials and others (e.g., researchers) with access to timely, comprehensive, and detailed data to improve quality, reduce costs, promote transparency, and identify the best methods for focusing public health resources.

Under the HIPAA requirements, health insurance plans can report data to the APCDs as required by law or for a state's public health oversight function.¹⁰ However, when reviewing the federal Part 2 regulations, questions have arisen in these data reporting contexts because substance abuse and mental health claims have been requested by states as part of the APCD reporting processes. Different public and private entities have interpreted the Part 2 and state requirements differently. The result is that some entities have withheld substance abuse and mental health claims from the APCDs, whereas other entities felt compelled to report the data as required by state and allowed by the federal HIPAA requirements.

¹⁰ 45 C.F.R. §164.512.

To address variations in interpreting the legal requirements, SAMHSA should issue guidance that explains how the federal Part 2 regulations permit or prohibit the reporting of substance abuse and mental health information to state APCDs. This interpretation is vital to meet consumers’ expectations and ensure consistent interpretation of the federal requirements across all states.

Consent and Substance Abuse Information Disclosures

One of the key components of the Part 2 regulations is the requirement for individuals to consent to disclosures of substance abuse records, unless an exception applies.¹¹ Health care providers and programs that comply with the Part 2 regulations are responsible for obtaining such consent before releasing records and notifying a recipient that the record is covered by the Part 2 requirements (i.e., should not be re-disclosed). Anecdotal information indicates that in practice, there are few current processes to validate whether consent was received. Most health care entities that legitimately receive such health information rely in good faith on the sender of the information to comply with the Part 2 requirements. This is particularly important in the medical home and accountable care settings where data sharing for the benefit of patient care is needed for integrated care.

Under HIPAA, health care providers and health insurance plans are allowed to disclose information for treatment, payment, or healthcare operations such as care coordination and quality improvement activities. This careful balance was adopted to mitigate unnecessary barriers in accessing care. In some situations, substance abuse information may be shared through legitimate, electronic processes with other providers or entities (e.g., to another treating physician, to health insurance plans to process an electronic claim for payment) without accompanying verification that consent was received.

¹¹ 45 C.F.R. §2.31 et seq. The regulations in §§ 2.51, 2.52, and 2.53 govern medical emergencies, research, and audits. §2.11 allows “qualified service organizations” to obtain the information necessary to support a program.

While SAMHSA has issued “Frequently Asked Questions” guidance pertaining to Health Information Exchanges,¹² it may be time to revisit the regulations and past guidance to better align with the HIPAA requirements and as they pertain to disclosure and possible re-disclosure of substance abuse information in current electronic environments. In addition, reinforcing the need for treating providers to make reasonable, good faith efforts to obtain individuals’ consent before disclosing substance abuse information would be beneficial.

We appreciate the opportunity to submit our comments. We stand ready to assist the agency in future efforts to evaluate the Part 2 regulatory requirements.

¹² Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange, as available on the Internet at: <http://www.samhsa.gov/healthprivacy/docs/ehr-faqs.pdf>.



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June 25, 2014

Comments from Department of State Health Services (DSHS), Substance Abuse Program Services

Re: 42 CFR, Part 2: Confidentiality of Alcohol and Drug Abuse Patient Records

The individual's privacy is of primary concern to DSHS substance abuse services staff. Confidentiality is important because of the continued risk of negative consequences for individuals seeking treatment services for substance use disorders (SUD),.

While several of the proposed changes to 42 CFR Part 2 would streamline information technology and care coordination processes, implementation is not advised if the privacy of the individual seeking or receiving SUD treatment services is diminished as a result. The health care industry has changed significantly since the 1970's when 42 CFR Part 2 was first enacted, however; the stigma associated with substance use continues. Individuals can and all too often do, lose custody of their children by welfare services because they are receiving medication assisted therapy. Employment and housing can still be denied. The individual's need for privacy continues to outweigh the system's need for streamlining and unburdening.

The privacy of the individual seeking or receiving SUD services is critical to engaging these individuals in those SUD services. If the SUD service providers can no longer ensure enhanced privacy, fewer individuals will seek SUD services, increasing public health and safety costs for communities and states. This is particularly true for pregnant women and the costs associated with poor birth outcomes are substantial.

With the privacy of the individual being of primary concern, DSHS has the following comments and recommendations for each of the proposed changes to 42 CFR Part 2. A scenario is used in the first few sections that may help illustrate the concerns we have regarding the confidentiality of individuals' SUD history and treatment.

Section a: Applicability of 42CFR Part 2

DSHS supports many of the changes described in this section about the applicability of 42 CFR Part 2. Applying 42 CFR Part 2 more consistently has the potential to improve privacy. Currently, (federally assisted) providers that do not “hold themselves out” as providing SUD services are not covered by 42 CFR Part 2 and this can leave gaps in the enhanced privacy for individuals seeking and receiving SUD services.

However, this section also proposes to define certain SUD services as “specialty” SUD services and proposes that 42 CFR Part 2 only apply to those (federally assisted) providers that provide specialty SUD services. Screening, brief interventions, and other pretreatments would not be defined as specialty SUD services and 42 CFR Part 2 would not apply to (federally assisted) providers that only provided those non-specialty services. In Texas, this would effectively exclude our screening and referral entities that serve as the front door to our SUD treatment system across the state. The information they provide to external entities needs to be protected under 42 CFR Part 2, as is the information a formal SUD service provider would provide to those same entities.

DSHS is opposed to reducing the enhanced privacy protections for these non-specialty services when they are provided by a (federally assisted) provider that only provides such services. The screening record (part of the pretreatment process) often contains enough information to trigger involvement and investigation from child welfare systems (regardless of whether or not that individual ever exposed their children to their substance use).

Any information identifying an individual as having a substance use disorder or seeking or receiving SUD services should be considered confidential at law and be maintained at the highest level of privacy possible. No one should have access to this information without the individual’s knowledge and express written consent (unless a Court has ordered the release or the individual is experiencing a medical emergency).

For example: currently, a methadone provider is covered by 42 CFR Part 2, and cannot release the methadone records when other therapy records are forwarded to the child welfare system. However, an outreach program is not covered under 42 CFR Part 2, and the screening records may be included in the records sent to the child welfare investigator. Under the proposed changes to 42 CFR Part 2, the outreach program would continue to be excluded from 42 CFR Part 2, but now for a different reason. The need for the screening records to be protected from redisclosure remains a problem in this example. Unfortunately, the screening record alone triggers continued child welfare involvement, illustrating the importance (in the opinion of DSHS, Substance Abuse) of protecting this type of information. The confidentiality of the methadone screening records should be maintained consistently.

Section b: Consent Requirements

This section details a proposal to adjust the manner in which consents to release information are handled. Current, 42 CFR Part 2 requires that consents to release information contain the specific name of the organization to which information will be disclosed, ensuring that the client specifically consents to release information to each entity. Under the proposed changes, consent forms could be broader, allowing a client to sign a more generalized release for types of entities or organizations. Under proposed changes, the entity permitted to make disclosure would be required to provide clients with a list of entities that may access their information and notify client regularly of changes to this list. The consent form would also have to specifically name the entity that is permitted to make the disclosure and specifically detail the SUD treatment information that will be disclosed. These changes would facilitate better information flow within complex systems comprising multiple units or organizations. DSHS is supportive of this proposal, so long as redisclosure continues to be prohibited and the individual retains the right to limit consent if desired.

This proposal to change 42 CFR Part 2 works well until an individual wishes to limit a particular entity's access to information in the HIE. But the individual must retain the ability to exclude a particular entity from a generalized consent or to revoke a particular entity's access after signing a generalized consent, while allowing other entities continued access.

If an individual decides to opt out of a generalized consent and sign only specific consents for a particular type of provider, there should be a mechanism for the individual to do so – no matter the technical complications involved. If an individual decides to revoke consent for a particular entity after signing a generalized consent, there should be a mechanism to do so.

Section c: Redisclosure

This proposal would ease unnecessary limitations on redisclosure by clarifying that the limitations only apply to information that would identify an individual as having a substance use disorder or receiving SUD services. This could be specific clinical information such as a diagnosis; or it could be the fact that the name of the disclosing entity gives away the services the individual received (for example, West Texas Methadone and Buprenorphine Services, Inc.) Under the proposed clarifications, some of an individual's information could be redisclosed if it does not give away the client's SUD history or treatment. Of course, any disclosure or redisclosure would continue to be protected other confidentiality laws.

Section d: Medical Emergency

The changes that SAMHSA is proposing under this section are related to a possible discrepancy between current 42 CFR Part 2 regulations and underlying statute. SAMHSA proposes to loosen restrictions in regulations on when a provider may disclose information without an individual's consent when a possible medical emergency is involved. It appears that SAMHSA may give more latitude to providers in deciding what

a medical emergency is and would include some language regarding *prevention of medical emergencies*. It appears that SAMHSA would not limit disclosure to medical providers (as their example included a detoxification provider).

Current regulations state that information may be disclosed without consent to a medical provider “for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.” The underlying statute states that information may be disclosed “to medical personnel to the extent necessary to meet a bona fide medical emergency.”

On the surface, it does not appear that SAMHSA has the authority to extend disclosure beyond medical personnel for the purpose of treating a medical emergency. It does not appear that SAMHSA has the authority to extend disclosure to *prevent* medical emergencies.

In the event that this proposal proceeds, it will be critical that clear definitions are provided and that there is no confusion about what constitutes a medical emergency and what constitutes prevention of medical emergencies.

An ideal use case for SAMHSA to consider is the pregnant woman receiving opioid treatment services. Given the fact that a pregnant woman who is receiving opioid treatment services is at risk for medical emergency if she enters withdrawal during her pregnancy, her privacy could be at risk for the duration of her pregnancy. If she misses a dosing appointment, that could be a medical emergency that needs preventing. If her metabolism changes during pregnancy and her dose is no longer adequate, this is a possible medical emergency that may need to be prevented.

However, more critically, there are many in the SUD treatment field that continue to believe in an “abstinence only” treatment philosophy and many of people feel that a pregnant woman receiving opioid treatment services is actually creating a medical emergency for the unborn child, despite research to the contrary. If providers are given too much latitude on how to define a medical emergency, what preventing an emergency means, or to whom they may make disclosure under these circumstances, pregnant women receiving opioid treatment services (and other populations as well) could experience significant privacy losses.

Prior to implementation, DSHS, Substance Abuse believes this proposed change to medical emergency should be evaluated closely due to concerns about the significant erosion of privacy potential for critical populations. To the extent that changes would legitimately improve the outcomes of medical emergencies and prevent deaths and serious injuries: DSHS is cautiously supportive. But DSHS feels the current regulations, as written, are adequate to cover medical emergencies while protecting confidentiality.

In the example provided by SAMHSA, which was to allow disclosure to detoxification providers if and when a client is too impaired to provide consent to release information, current regulations would allow disclosure if the client is experiencing a medical

emergency related to withdrawal or intoxication, so long as the detoxification provider has medical personnel on staff. If the client is not experiencing a medical emergency, the detoxification provider can treat the client and acquire prior treatment records when the client has stabilized. Allowing the release of information without the client's consent because of the possibility or "in case" the client develops a medical emergency upon entering detoxification services, could be overused. Any client entering detoxification services while too impaired to provide background information is a possible medical emergency. This is why most programs are required to have trained medical personnel on staff and to conduct regular monitoring of clients while they withdraw.

Section e: Qualified Service Organization (QSO)

Current 42 CFR Part 2 language defining a QSO:

Qualified service organization means a person which:

- (a) Provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and
- (b) Has entered into a written agreement with a program under which that person:
 - (1) Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the programs, it is fully bound by these regulations; and
 - (2) If necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations.

In the section, SAMHSA provides an acceptable solution to concerns from payers and health management entities regarding their inability to redisclose information covered by 42 CFR Part 2 to associated organizations that provide care coordination and population management without the client's consent. SAMHSA states that they are analyzing current regulations to find options to share this information while maintaining client protections. Current regulations allow such disclosure to QSOs but care management is not listed in the definition of a QSO in 42 CFR Part 2. SAMHSA is considering defining QSOs to also include provision of care coordination services.

Section f: Research

§2.52 Research activities.

- (a) Patient identifying information may be disclosed for the purpose of conducting scientific research if the program director makes a determination that the recipient of the patient identifying information:
 - (1) Is qualified to conduct the research;
 - (2) Has a research protocol under which the patient identifying information:
 - (i) Will be maintained in accordance with the security requirements of §2.16 of these regulations (or more stringent requirements); and
 - (ii) Will not be redisclosed except as permitted under paragraph (b) of this section; and

(3) Has provided a satisfactory written statement that a group of three or more individuals who are independent of the research project has reviewed the protocol and determined that:

- (i) The rights and welfare of patients will be adequately protected; and
- (ii) The risks in disclosing patient identifying information are outweighed by the potential benefits of the research.

(b) A person conducting research may disclose patient identifying information obtained under paragraph (a) of this section only back to the program from which that information was obtained and may not identify any individual patient in any report of that research or otherwise disclose patient identities.

Current 42 CFR Part 2 regulations allow providers (“program directors”) to disclosure of confidential information for the purposes of research as described above. SAMHSA is proposing to extend this ability beyond the program director to health care entities that receive and store information covered by 42 CFR Part 2. It appears the requirements above would continue to apply, with the exception that the health care entity and not the “program director” would be making the determination about the research entity.

DSHS supports this change.

Section f: Addressing Potential Issues with Electronic Prescribing and Prescription Drug Monitoring Programs (PDMPs)

Currently, if a covered entity provides an electronic prescription to a client for a controlled substance, at the pharmacy, the client must consent to have this information entered into the PDMP and for the PDMP to redisclose this information to those with access to their system. The client must consent if he wishes to fill the prescription electronically because pharmacy data systems are currently unable to segment data and disclosure becomes unavoidable.

To protect from possible unwanted disclosure, the client must bring a paper prescription to the pharmacy to be filled. Paper prescriptions aren’t covered by 42 CFR Part 2; because the pharmacy is not actually receiving the information from a covered entity, and therefore; automatic redisclosure to the PDMP and its users is permitted. The end result is that if the client wishes to fill the prescription, the client has no choice but to allow this information to reach the PDMP and its users.

While DSHS’ primary concern is the privacy of the individuals SUD information, the need to address prescription medication abuse is extremely important and DSHS supports the full use of PDMPs as a tool to this end. DSHS recommends that clients be informed about PDMP requirements and the possible users of the PDMP when they are being prescribed a medication in a way that will require data to be entered into that system. The PDMP system in Texas is well-protected from arbitrary queries for law enforcement purposes and so long as a client is not “doctor shopping” or acquiring multiple prescriptions through other means, the client’s information in the system should be safe.

However, clients should be informed that if they do begin to misuse or seek additional prescriptions, the information in the PDMP system could be used against them legally.

For clients receiving opioid treatment services, specifically methadone and buprenorphine, it is possible to dispense these medications through the opioid treatment program itself, bypassing pharmacies altogether. This model protects the information about the controlled substances the client is receiving from the SUD program and, in Texas, the clients are monitored for multiple opioid treatment admissions through a central registry system separate from the PDMP. Any controlled substance prescriptions the client may acquire outside of that SUD program would continue to be entered into the PDMP system.

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA)
DOCKET #: 2014-10913

The Substance Abuse and Mental Health Services Administration Comment Template
Confidentiality of Alcohol and Drug Abuse Patient Records Regulation, 42 CFR Part 2

This document is meant to provide the public with a simple and organized way to submit comments on the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2, and respond to questions presented in meeting notice which is published in the *Federal Register* at 79 FR 26929. While use of this document is entirely voluntary, commenters may find it helpful to organize their comments.

This document alone is not intended to provide a full and complete opportunity to comment on all of the provisions within the regulation. Please keep in mind that it only reflects those topics included in the meeting notice and the section for “other” comments.

To be considered, all comments (including comments provided through this document) must be submitted according to the instructions in the meeting notice:

<https://www.federalregister.gov/articles/2014/05/12/2014-10913/confidentiality-of-alcohol-and-drug-abuse-patient-records>

Applicability of 42 CFR Part 2

SAMHSA is considering options for defining what information is covered under 42 CFR Part 2. Covered information could be defined based on what substance abuse treatment services are provided instead of being defined by the type of facility providing the services.

FR Citation: 79 FR 26930

Questions:

- How would redefining the applicability of 42 CFR Part 2 impact patients, health care provider organizations, HIEs, CCOs, HIT vendors, etc.?
- Would this change address stakeholder concerns?
- Would this change raise any new concerns?

Public Comment Field:

With the ever increasing incidence of patient assessed or diagnosed with co-occurring disorders (dual diagnosis), manifesting both substance abuse and mental health Issues, it is important that the regulations be based upon the treatment services being provided, rather than the type of facility. In short, addiction treatment services are being provided through varied avenues beyond the traditional substance abuse inpatient and outpatient facilities. These include community mental health centers, private mental health therapists' offices, primary care physicians, and employee assistance programs (EAPs). The criticality of addressing this issue in any revision to the regulations is also necessitated by the dramatic change in the healthcare delivery system

since the regulations were first promulgated. Those changes include the dramatic reduction in the number of free-standing and independent addiction treatment facilities in the country; the consolidation of community services under singular mental health/behavioral health umbrellas; the added hurdles that managed care and provider networks have imposed on patients in actually accessing traditional substance abuse treatment - even when coverage is provided for under the health insurance plan; the incorporation of many employee assistance programs into larger behavioral health organizations as part of a continuum of services, in which the substance abuse treatment service is woven into an array of services across the medical and behavioral healthcare spectrum. Specific language should be added to the regulations indicating their applicability to all employee assistance programs, since - while EAPs are not substance abuse treatment services per se - they include a substance abuse assessment process as part of their standard employee assistance program best practices. To protect some patients of employee assistance programs because they have been assessed and/or diagnosed with a substance abuse problem, while not protecting the records and information of those without a comparable diagnosis, seems in fact counter to the spirit of the regulations, and in view of the dual diagnosis and co-occurring disorder reality of today's patients, creates confusion and inconsistencies within the actual practice of carrying out these regulations across the EAP industry. In short, for an EAP to be able to disclose for one group of patients under one diagnosis and not for another, for all intent and purposes, identifies the latter group by default. It goes without saying that good EAP practice necessitates securing the patient's informed and written consent in all cases of disclosure, but carried to its logical conclusion, the above is a potential perceptual issue that begs the question of the need to apply the regulations to all EAPs - especially since EAPs interact and interface on a regular basis with other covered entities under the regulations and routinely receive through appropriate disclosure information protected under the regulations. The regulations should include more specific guidance on how the regulations apply to employee assistance programs since EAP services have significantly expanded and evolved into a broader continuum of services that include assessment, in some cases diagnosis, and in most cases some level of short-term intervention, problem resolution and long-term follow-up.

Consent Requirements

While technical solutions for managing consent collection are possible, SAMHSA is examining the consent requirements in 2.31 to explore options for facilitating the flow of information within the health care context while ensuring the patient is fully informed and the necessary protections are in place. Specifically we are analyzing the current requirements and considering the impact of adapting them to:

1. Allow the consent to include more general description of the individual organization or health care entity to which disclosure is to be made
2. Require the patient be provided with a list of providers or organizations that may be access the information and be notified regularly of changes to the list
3. Require the consent to name the individual or health care entity permitted to make the disclosure

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

FR Citation 79 FR 26931

- Questions:
Would these changes maintain the privacy protections for patients?
- Would these changes address the concerns of HIEs, health homes, ACOs, and CCOs?
- Would these changes raise any new concerns?

Public Comment Field:

While the consent requirements and form should be maintained at a level to assure the patient's privacy, the form itself should be revised to allow the patient to authorize two-way communication between the initial provider seeking the disclosure consent and the provider to whom the disclosure will be made. For example, when an employee assistance professional makes an assessment or diagnosis of a substance abuse disorder and initiates a referral to a treatment provide or resource, it makes sense for the patient to be able to provide their consent on a single form for the EAP to communicate with the provider and the provider back to the EAP—with the appropriate explanation to the patient, and with a copy of the consent form and the redisclosure prohibition provided to the treatment provider—retaining the right to rescind any disclosure as currently spelled out in the regulations.

Redisclosure

SAMHSA is considering revising the redisclosure provision to clarify that the prohibition redisclosure only applies to information that would identify an individual as a substance abuser and allow other health related information shared by the Part 2 program to be redisclosed, if legally permissible. This would allow HIT systems to more easily identify information that is subject to prohibition on redisclosure enabling them to utilize other technological approaches to manage redisclosure. If data are associated with information about where the data were collected (data provenance) which reveals that the data were collected by a practice that exclusively treats addiction the data would still be protected under the proposed change.

FR Citation: 79 FR 26931

Questions:

- Would this type of change facilitate technical solutions for complying with 42 CFR Part 2 in an HER or HIE environment?
- Would these changes maintain the privacy protections for patients?

Public Comment Field:

Medical Emergency

SAMHSA is considering adapting the medical emergency exception to make it more in line with the statutory language and to give providers more discretion as to when a bona fide emergency exists. For example, amending this standard to allow providers to use the medical emergency provision to prevent emergencies or to share information with a detoxification center when a patient is unable to provide informed consent due to their level of intoxication.

FR Citation: 79 FR 26931

Questions:

- What factors should providers take into consideration in determining whether a medical emergency exists?
- Are there specific use cases SAMHSA should take into consideration? Show citation box.
- Are there patient concerns about the impact of this change on their privacy?

Public Comment Field:

The issue of disclosure in a medical emergency has always been a challenge under the regulation, not only in determining what constitutes a medical emergency, but to whom the disclosure can be made. Both issues need to be addressed in the revision to the regulations. Further, with the associated violence that can accompany the active addictive process, the issue of dealing with a patient's potential self-harm/suicide risk or the patient's expressed intent to harm another is not adequately addressed in the existing regulations in terms of how to proceed in making the disclosure without consent and to whom in event of protecting the patient's life or the life of an identified third party. This is particularly troublesome since such disclosures are generally made to law enforcement. It would seem appropriate to assure that if the regulations permit such a disclosure—consistent with many state laws requiring such disclosures to protect life—they should include a definitive prohibition against the use of said information by law enforcement for any purposes other than intervening to save a life.

Qualified Service Organization (QSO)

SAMHSA is analyzing regulations to identify options for allowing Part 2 data to flow to health care entities for the purpose of care coordination and population management while maintaining patient protections. 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 the 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.

FR Citation: 79 FR 26931

Questions:

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

Are there specific patient concerns about the impact of this change on their privacy?

Public Comment Field:

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.

Research

FR-Citation: 79 FR 26932

Questions:

- Are there factors that should be considered related to how current health care entities are organized, how they function or how legal duties and responsibilities attach to entities that make up an umbrella organization?
- Would this change address concerns related to research?
- Are there specific privacy concerns associated with expanding the authority or releasing data to qualified researchers/research organizations in this way?
- Are there additional use cases that should be considered in the research context?

Public Comment Field:

Addressing Potential Issues With Electronic Prescribing and Prescription Drug Monitoring Programs (PDMPs)

Part 2 protections include a prohibition on the redisclosure of information received directly from a Part 2 program. A pharmacy that receives electronic prescription information directly from a Part 2 program must obtain patient consent to send that information to a PDMP, and patient consent is also required for the PDMP to redisclose that information to those with access to the PDMP.

Preamble FR Citation: 79 FR 26932

Questions:

- How do pharmacy information system vendors anticipate addressing this issue? Are there specific technology barriers SAMHSA should take into consideration?
- 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.
- Are there patient concerns about the impact of e-prescribing and PDMPs on their privacy?

Public Comment Field:

Other Comments

Topic: Penalties.

Public Comment Field:

The fine for a first offense should be raised from the \$500 as it currently exists in the records.

Other Comments

Topic: HIPAA and HITech

Public Comment Field:

Reconcile the interface of 42 CFR Part 2 with HIPAA and HITECH provisions and any applicable state breach notification laws.



Minnesota Department of **Human Services**

VIA EMAIL, FAX and U.S.MAIL

June 25, 2014

email: PrivacyRegulations@SAMHSA.hhs.gov

Fax: (240) 276-2900

Substance Abuse and Mental Health Services Administration
United States Department of Health and Human Services
Room 5-1011
1 Choke Cherry Road
Rockville, MD 20857

Re: Comments on Possible Changes to 42 C.F.R. Part 2

On behalf of the Minnesota Department of Human Services, specifically the Office of Inspector General (“OIG”) and the Alcohol and Drug Abuse Division (“ADAD”), we are pleased to submit the following comments and attachments. It is our position that opioid treatment programs, and any other provider or professional that is providing medication-assisted substance use disorder treatment that involves a controlled substance, should be required to disclose the patient’s name and prescription to the prescription monitoring program (“PMP”) and redisclosure of the prescription information should be permitted to any permissible user of the PMP with or without client consent. Public policy strongly supports requiring providers to submit prescribed controlled substances to the PMP. It is untenable to place a prescriber in a position of unknowingly prescribing a controlled substance to a patient without having access to the patient’s current use of previously prescribed controlled substances.

Methadone-associated diversion, abuse, and deaths are, increasingly, a public health concern.

SAMHSA has acknowledged that: “[D]iversion, abuse, and deaths associated with many opioid medications, including methadone, have become a significant public health concern.”¹ From 2006 to 2013, Minnesota’s two most populated counties saw opioid-related deaths grow by 76%.²

¹ Substance Abuse & Mental Health Servs. Admin., U.S. Dep’t of Health & Human Servs., *Data Summary—Methadone Mortality: A 2010 Reassessment* 3 (July 29–30, 2010) [hereinafter *2010 Reassessment*]. See Attachment 1.

² Carol Falkowski, Drug Abuse Diagnosis, *Drug Abuse Trends in Minneapolis/St. Paul Metropolitan Area: June 2014*, at 7, available at http://www.drugabusedialogues.com/drug_abuse_trends_reports/2014_June.pdf.

Between 2007 and 2013, the number of people seeking treatment for non-heroin opioid addiction doubled.³

In 2008, nearly one-in-three opioid-related deaths involved methadone.⁴ And methadone-associated deaths have increased more than fivefold between 1999 and 2009.⁵ Methadone diverted from opioid treatment programs (almost always mixed with other controlled substances) account for some of these deaths. In Minneapolis, a study found that from 1992 to 2002, 42% of methadone-related overdose victims were enrolled in a methadone-maintenance program.⁶

Using the PMP to monitor patients' controlled-substance use "save[s] lives, prevent[s] overdoses, and [brings] people into treatment."⁷

SAMHSA has recognized and supported the benefits stemming from authorized healthcare professionals using PMPs. In a September 2011 letter, the Center for Substance Abuse Treatment Director H. Westley Clark, encouraged OTPs "to use state Prescription Drug Monitoring Programs," or PMPs, "as an additional resource to maximize (patient) safety."⁸ PMPs, he wrote, "may aid in the care of those patients with chronic, untreated pain or chemical dependency and help to identify patients engaged in prescription drug abuse and diversion."⁹ The letter cited one OTP where "23% of the patients had prescriptions for significant quantities of additional opiates, benzodiazepines, and other controlled substances by clinicians outside their practice."¹⁰ SAMHSA acknowledged that when physicians have all the information they need, they make better clinical decisions. But because Part 2 is so restrictive, doctors are forced to guess about whether or not their patient is consuming methadone from an OTP.

A 2011 case study—endorsed by the Center for Substance Abuse Treatment—concluded "that initial and ongoing monitoring of a patient's prescription history ... can play an important role in safe and effective addiction treatment."¹¹ However, when mixed with other drugs, especially other

³ *Id.* at 9. See Attachment 2.

⁴ Leonard J. Paulozzi et. al., *Vital Signs: Risk for Overdose from Methadone Used for Pain Relief—United States, 1999–2010* 61 *Morbidity & Mortality Wkly. Rep.* 493, 493 (2012).

⁵ *Id.* at 494–95. See Attachment 3.

⁶ Angelique Gagajewski & Fred S. Apple, *Methadone-Related Deaths in Hennepin County, Minnesota: 1992–2002*, *J. Forensic Sci.*, May 2003, available at http://www.hawaii.edu/hivandaids/Methadone-Related_Deaths_in_Hennepin_County_Minnesota_1992-2002.pdf. See Attachment 4.

⁷ Prescription Monitoring Program Ctr. of Excellence, *Notes from the Field Keeping Patients Safe* 8 (2011) [hereinafter *Case Study*], available at http://www.pdmpexcellence.org/sites/all/pdfs/methadone_treatment_nff_%203_2_11.pdf. See Attachment 5.

⁸ Letter from H. Westley Clark, Dir., Ctr. for Substance Abuse Treatment (Sept. 27, 2011) [hereinafter *Dear Colleague Letter*], available at <http://atforum.com/addiction-resources/documents/dearColl-pmp2011.pdf>. See Attachment 6.

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.* at 7 (citing *Case Study*, *supra* note 7, at 6).

opioids and benzodiazepines, methadone can be deadly.¹² As a result, it is critical that clinicians “know whether patients are getting another opioid” or other controlled substances.”¹³

Clinicians have observed that patients with addiction issues often lie about their other prescriptions and hide their use of these drugs from their OTP and clinicians.¹⁴ In the case study, where patients’ opioid addiction usually started with prescription drugs, the patients admitted they were taking the prescribed drugs themselves, sharing them with friends and family, or selling them on the street.¹⁵ The case study found that even patients on one- and two-week take-home methadone doses were “furtively obtaining” additional “methadone or Oxycontin or fentanyl.”¹⁶

When confronted by the OTP, most patients in the case study admitted that they were receiving illicit prescriptions, “but [they] didn’t think the [OTP would] find out.”¹⁷ Notably, most patients consented to their OTP telling their prescribing doctor about their methadone-maintenance therapy.¹⁸ And many of the study’s patients “were glad this happened” because “it burned the bridge of access to the drugs they often misused” - prescription painkillers.¹⁹

The case study reported better patient outcomes after the author started using the PMP to monitor his patients’ controlled-substance prescription histories. Using the PMP reduced the incidence of drug dealing in the program’s parking lot.²⁰ This reduced patients’ temptation to relapse and reduced violence on the program’s premise.²¹ Patients who stopped “getting covert prescriptions did better in treatment.”²² The author concluded that using the PMP “save[s] lives, prevent[s] overdoses, and [brings] people into treatment.”²³

Allowing OTPs to disclose patient information to a PMP and allowing doctors to access this will reduce overdoses, decrease diversion, and strengthen patients’ recoveries without compromising privacy.

Giving physicians full and complete access to their patients’ controlled-substance history allows for better treatment plans for each patient. When a patient presents for a pain diagnosis, and is on a daily dose of methadone, determining the best treatment plan will stem from a doctor knowing about the prescribed methadone. In many cases, a treating doctor may determine that a

¹² *2010 Reassessment, supra* note 1, at 4 (“concurrent use of other CNS depressant, such as benzodiazepines” and “other opioids” evaluate the risk of methadone-associated mortality).

¹³ *See id.* at 4

¹⁴ *Id.* at 4–5.

¹⁵ *Id.* at 4.

¹⁶ *Id.* at 6.

¹⁷ *Id.* at 5.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.* at 6.

²¹ *Id.*

²² *Id.*

²³ *Id.*

methadone patient should be prescribed additional controlled substances for his/her condition, but knowing about the OTP treatment will inform how that doctor determines an appropriate course of treatment.²⁴ But these outcomes will only occur if physicians can access their patients' complete medical histories, including methadone-maintenance records

For a variety of reasons, methadone patients may fail to completely inform their doctors about their treatment. The physicians who prescribed the controlled substances to the case-study patients unwittingly prescribed opioids and benzodiazepines to patients receiving methadone-maintenance treatment.²⁵ Physicians only know about methadone-maintenance treatment if a patient volunteers this information. But as the case study illustrates, many patients fail to disclose this information.²⁶ Regardless of why patients don't inform their doctors about the patients' methadone treatment, it is critical for any prescribing clinician to have full and accurate access to information before attempting to treat any patient. Patients receiving methadone treatment are no different.

SAMHSA can correct this by authorizing OTPs to fully report methadone treatment to secure PMPs. It can give doctors access to the information they need to treat their patients, resulting in fewer overdose deaths, less diversion, and better patient outcomes. If Part 2 is not completely repealed (), SAMHSA should expand 42 C.F.R. Part 2's protections to include PMPs, and allowing OTPs to disclose to physicians, through the PMP, that a patient is being prescribed methadone.

SAMHSA should extend Part 2's privacy protections to include PMPs so OTPs may, through a PMP, disclose to physicians that a patient takes methadone regularly.

By extending Part 2's disclosure and use protections to PMPs, SAMHSA can obtain the benefits associated with increased PMP use while still protecting patient privacy. Currently, Part 2's disclosure restrictions govern the following recipients of protected information:

- "third-party payers with regard to records disclosed to them by federally-assisted alcohol and drug abuse programs";
- "entities having direct administrative control over programs with regard to information communicated to them by the program"; and,
- "persons who receive patient records directly from a federally-assisted alcohol or drug abuse program and who are notified of the restrictions on redisclosure of records."²⁷

²⁴ *Id.* at 8.

²⁵ *Id.* at 4.

²⁶ *Id.* at 5.

²⁷ 42 C.F.R. § 2.12(d)(2) (2013).

Part 2's use of restrictions govern "any person who obtains information from a federally-assisted alcohol or drug abuse program" and prevents anyone from using the information to initiate, investigate, or substantiate a criminal proceeding against a patient.²⁸

SAMHSA should expand Part 2's protections to qualifying PMPs. It can do this by:

- defining PMP in § 2.11 so that it excludes PMPs that grant unrestricted access to law enforcement and others uninvolved in patient care, and include only PMPs capable of placing the redisclosure statement on any report containing protected information;
- amending § 2.12(d) so that the disclosure and use restrictions apply to PMPs and individuals who access protected information on them;
- allowing federally-assisted methadone-treatment programs to disclose information to PMPs; and
- allowing qualifying PMPs to re-disclose information to appropriate PMP users.

If implemented, these amendments would allow doctors to access information crucial to their prescribing decision while still protecting patients' privacy. As SAMHSA itself has recognized,²⁹ this would reduce overdose deaths, curb diversion, and improve patients' recovery and outcomes.

SAMHSA has already acknowledged the need for similar regulatory change. During the 2010 Methadone Mortality Reassessment, it committed "to enhance[ing] the usefulness of PMPs in preventing and identifying nontherapeutic use of methadone and other controlled drugs"³⁰ by "identify[ing]" and "remediat[ing]" "knowledge deficits in individual prescribers."³¹

Increased Enforcement Activities Under The Health Insurance Portability and Accountability Act (HIPAA) Affords Additional Protections to Drug, Alcohol, and Mental Health Treatment Records

Policy makers should also consider that the landscape has changed dramatically since the 42 CFR Part 2 were adopted. The Health Insurance Portability and Accountability Act (HIPAA), for example, has established a floor for the protection of all forms of "protected health information," including mental health and chemical dependency treatment records. Although there are clearly differences between what is required or permitted under HIPAA's Privacy Rule and the regulations set out in 42 CFR Part 2, in only a few instances do the requirements under 42 CFR Part 2 have the practical effect of truly affording individuals who receive services from a chemical dependency or mental health care provider greater privacy protection than HIPAA.

²⁸ *Id.* § 2.12(d)(1).

²⁹ See *Dear Colleague Letter*, *supra* note 8, at Enclosure 2.

³⁰ *2010 Reassessment*, *supra* note 1, at 26; cf. *Dear Colleague Letter*, *supra* note 8, at 1 (noting the possibility that SAMHSA may consider revising Part 2 to allow disclosure to PMPs).

³¹ *Id.* at 27.

In addition, privacy enforcement efforts have recently expanded and accelerated across the board under HIPAA. Recent changes have broadened the scope of liability under HIPAA, and federal and state oversight agencies are expanding enforcement and sanction activities. Policy makers should also consider the growing acceptance and applicability of recognized security and privacy standards such as those in NIST Special Publication 800-54 Revision 4 (April 13, 2013), in particular its newly created Appendix J - Privacy Control Catalogue. These developments have strengthened universally accepted privacy protections in a manner that recognizes the need to improve integration of services.

Conclusion

Amending Part 2 so OTPs can disclose information to qualifying PMPs, and allowing these PMPs to redisclose this information to appropriate prescribing providers, would achieve these goals. Since this change gives more prescribing providers the ability to identify diversion and dangerous drug interactions, it would “enhance the usefulness of PMPs” to prevent “nontherapeutic” methadone and opioid use. Finally, this change would bridge the knowledge gap between OTPs and physicians: both would know a patient’s full controlled-drug use history.

Sincerely submitted,

Lucinda Jesson
Commissioner

Attachment 1



**U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES**
Substance Abuse and Mental Health
Services Administration
www.samhsa.gov



Data Summary

METHADONE MORTALITY: A 2010 REASSESSMENT

Sponsored by the
Substance Abuse and Mental Health
Services Administration

Washington, DC
July 29-30, 2010

ACKNOWLEDGEMENTS

Jennifer Fan, Pharm.D., J.D., formerly Public Health Advisor in the Division of Pharmacologic Therapies of the Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), served as the Government Project Officer for this meeting.

Alina Salvatore, R.Ph., M.S., Public Health Advisor, Division of Pharmacologic Therapies, is the Project Officer for meeting follow-up activities. Onaje Salim, M.A., LPC, Team Leader in the Division of Pharmacologic Therapies, provided valuable guidance, as did other experts within SAMHSA and in other Federal agencies and private sector organizations.

Bonnie B. Wilford, M.S., served as Project Director and is the principal editor of this report, with valuable assistance from Gwen Littman, M.D., and Kris Rusch.

Members of the Planning Committee for “Methadone Mortality: A 2010 Reassessment,” graciously agreed to serve as peer reviewers of the document. Their contributions are acknowledged with gratitude. In addition to the individuals listed above, they are:

- Bruce A. Goldberger, Ph.D., DABFT, Director of Toxicology and Professor, Departments of Pathology and Immunology, University of Florida College of Medicine, Gainesville, FL
- Jane C. Maxwell, Ph.D., Research Professor and Director, Center for Excellence in Epidemiology, Gulf Coast Addiction Technology Transfer Center (ATTC), University of Texas at Austin, TX
- Mark W. Parrino, M.P.A., President, American Association for the Treatment of Opioid Dependence (AATOD), New York, NY
- Seddon R. Savage, M.S., M.D., Director, Dartmouth Center on Addiction Recovery and Education (DCARE), and Pain Consultant, Manchester VA Medical Center, and Associate Professor of Anesthesiology, Dartmouth Medical School, Hanover, NH.

DISCLAIMER

The views, opinions, and content of this document are those of the individual authors and other referenced sources, and do not necessarily reflect the views, opinions, or policies of SAMHSA or any other part of the U.S. Department of Health and Human Services (HHS).

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**U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES**
Substance Abuse and Mental Health
Services Administration
www.samhsa.gov



Dear Colleague:

This report provides a brief summary of the presentations and discussions at the July 29-30, 2010 meeting, "Methadone Mortality: A 2010 Reassessment," which was sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA). The meeting brought together more than 90 epidemiologists, clinicians, educators, regulatory and enforcement officials, patient advocates, and policymakers for an in-depth reassessment of the current knowledge base on methadone-associated deaths and a review of progress in addressing the situation.

Methadone has a long, successful history as a potent analgesic and a highly effective medication for reducing the morbidity and mortality associated with opioid addiction. However, diversion, abuse, and deaths associated with many opioid medications, including methadone, have become a significant public health concern.

As the Federal agency tasked with oversight of the Nation's opioid treatment programs, SAMHSA is concerned about these developments. Accordingly, in May 2003, SAMHSA convened a meeting entitled "National Assessment of Methadone-Associated Mortality." Participants were tasked with reviewing the available data on methadone-associated deaths; determining whether and to what extent the reported increase in such deaths might be related to the clinical practices of SAMHSA-monitored opioid treatment programs; and formulating recommendations to address the problem. A follow-up meeting on the same topic was held in July 2007.

For the 2010 meeting, SAMHSA convened a group of experts to reassess the situation, review the progress made to date, and provide advice and guidance on needed modifications or additions to the strategies currently being pursued. This document summarizes the information presented and conclusions reached, as well as strategies and action plans endorsed by the participants.

Those of us at SAMHSA found this to be a very valuable session and trust that this summary and the full report (which is posted on the SAMHSA website) capture both the content and the collaborative spirit that marked the session.

Sincerely,

H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM

Director
Center for Substance Abuse Treatment

GOALS OF THE REASSESSMENT

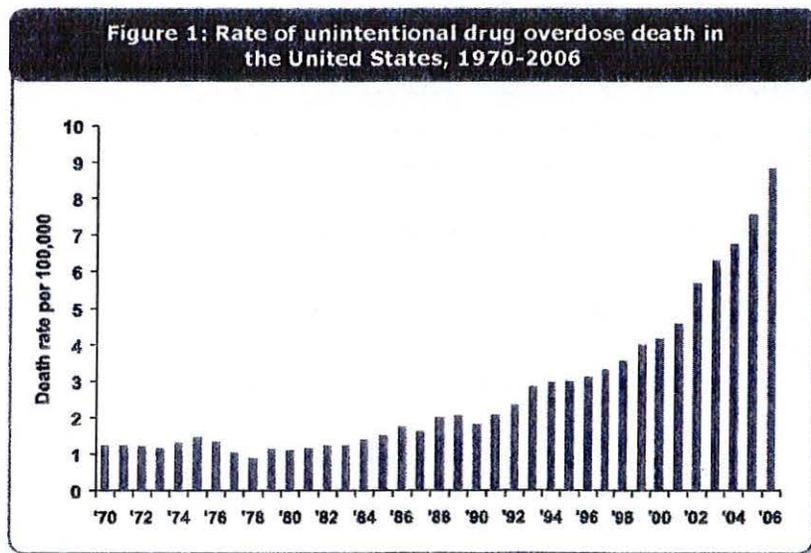
Methadone is an important medication for the treatment of opioid use disorders and chronic pain. It is a well-studied, safe, and powerful medication when prescribed and consumed properly. As a result, methadone has been used for more than 40 years to treat opioid addiction and its use in the treatment of pain has increased in the past 10 years.

Understanding the Problem

Methadone is life-saving, yet it presents special challenges. Some pharmacologic and pharmacokinetic properties of methadone can lead to harm if the drug is misused or used for nonmedical purposes. Methadone's short duration of analgesic effect, coupled with a significantly longer elimination half-life, increase the risk of toxicity. Methadone can cause fatalities among individuals who have not developed tolerance to opiates; for example, deaths have occurred among children and adults who accidentally ingest methadone. Fatal intoxications also have occurred during the first weeks of medically supervised treatment and at the time of dose adjustments.

Additional difficulties are caused by the absence of a common nomenclature and uniform case definitions for use in distinguishing between deaths caused by methadone and deaths in which methadone is a contributing factor or merely present. These difficulties make it difficult to determine the true number and nature of methadone-involved deaths. However, it is clear that the number of methadone-associated deaths has continued to rise since the first National Assessment meeting in 2003 (Figure 1). The increase in methadone-associated deaths has occurred in the context of rising death rates for all prescription opioids, such as oxycodone and hydrocodone.

Figure 1.



Source: National Vital Statistics System

Despite what we do know, the precise causes of the increase in methadone-associated deaths remain unclear. There is substantial agreement that patients are at elevated risk of methadone-associated mortality if they: (1) engage in concurrent use of other CNS depressants, such as benzodiazepines, other opioids, and alcohol; (2) have risk factors for adverse cardiac events, such as prolonged QT syndrome and Torsades de Pointes; (3) are given too large induction doses or are not adequately monitored during induction; or (4) engage in deliberate misuse or abuse of methadone.

The increased scrutiny of methadone that has attended the increase in fatalities requires exploration of the benefits of methadone as a medication, the risks associated with its use, and the need to take timely and effective action to reduce harm to individuals who use methadone to treat addiction or pain.

A Focus on Solutions

SAMHSA's role in monitoring adverse events related to methadone is embedded in both its statutory authority and the agency's commitment to promoting the public health. In 2001, the Secretary of Health and Human Services delegated to SAMHSA the responsibility for regulation and oversight of the Nation's opioid treatment programs (OTPs).

SAMHSA's current actions to address methadone-associated deaths began in 2002, spurred by reports of drug diversion, abuse, and deaths involving many opioid medications, including methadone. SAMHSA already was collaborating with other Federal agencies and with agencies in some of the States most directly affected by rising methadone mortality rates. Their reports, coupled with an increase in requests for consultation and assistance from State authorities and practitioners in the field, created added urgency for SAMHSA to evaluate and address the causes of the increase.

To assist it in developing a comprehensive plan and priorities, SAMHSA acted in July 2010 to convene a multidisciplinary group of more than 90 experts – including representatives of various Federal and State agencies, researchers, epidemiologists, pathologists, toxicologists, medical examiners, coroners, pain management specialists, addiction medicine experts, and others – to re-evaluate and update the findings of the 2003 National Assessment and the 2007 Reassessment. Participants were tasked with:

- Evaluating the best available data on methadone-associated overdoses and deaths.
- Determining whether and to what extent such deaths might be related to the clinical practices of SAMHSA-monitored OTPs as well as to the use of methadone to treat chronic pain.
- Reviewing current activities of SAMHSA and other Federal agencies to address the problem.
- Formulating strategies and action steps to enhance the effectiveness of existing activities and to describe potential new activities and areas of opportunity.

The information presented by the speakers, as well as the discussions and conclusions reached by this distinguished group of experts, are summarized here.

UNDERSTANDING THE PROBLEM: CURRENT DATA AND TRENDS

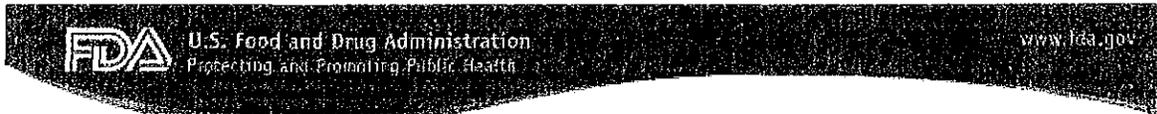
FDA Data on Methadone

Laura Governale, Pharm.D., M.B.A., Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration

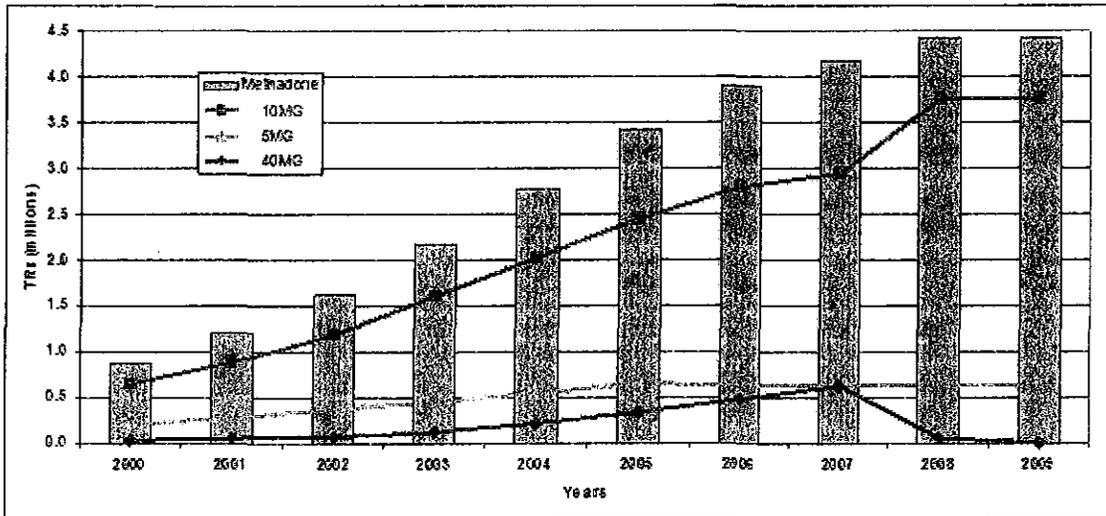
The Food and Drug Administration (FDA) purchases access to drug utilization data through a number of commercial drug utilization data vendors. From these data sources, FDA can track the amount of methadone sold by manufacturers.

Drug utilization data show that, in general, the wholesale distribution and outpatient use of methadone have leveled off in recent years. In 2009, methadone constituted approximately 2% of all prescriptions for opioids, at about 4.4 million prescriptions. The 10 mg tablets, which are used to treat pain, have been the most widely dispensed methadone formulation over the past 10 years (Figure 2).

Figure 2.



Total prescriptions dispensed in U.S. outpatient retail pharmacies for methadone by strength, Years 2000 – 2009,
SDI, Vector One®: National. Extracted July 2010.



Mean therapy days per prescription: 26-28 days

CAFMIS/CRAT Methadone Mortality Meeting
July 29, 30, 2010

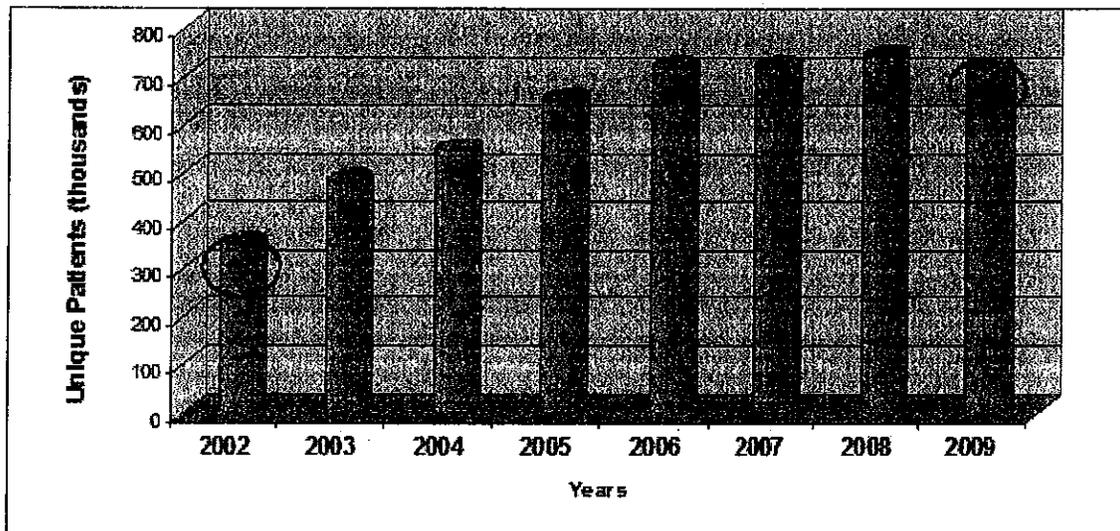
The number of unique patients receiving a prescription for methadone from 2002 to 2009 increased by 103 percent, from about 354,000 patients in 2002 to about 717,000 patients in 2009 (Figure 3).

Figure 3.



Total number of unique patients receiving a prescription for methadone in U.S. outpatient retail pharmacies, Years 2002 -2009

SDI, Total Patient Tracker, Extracted July 2010.



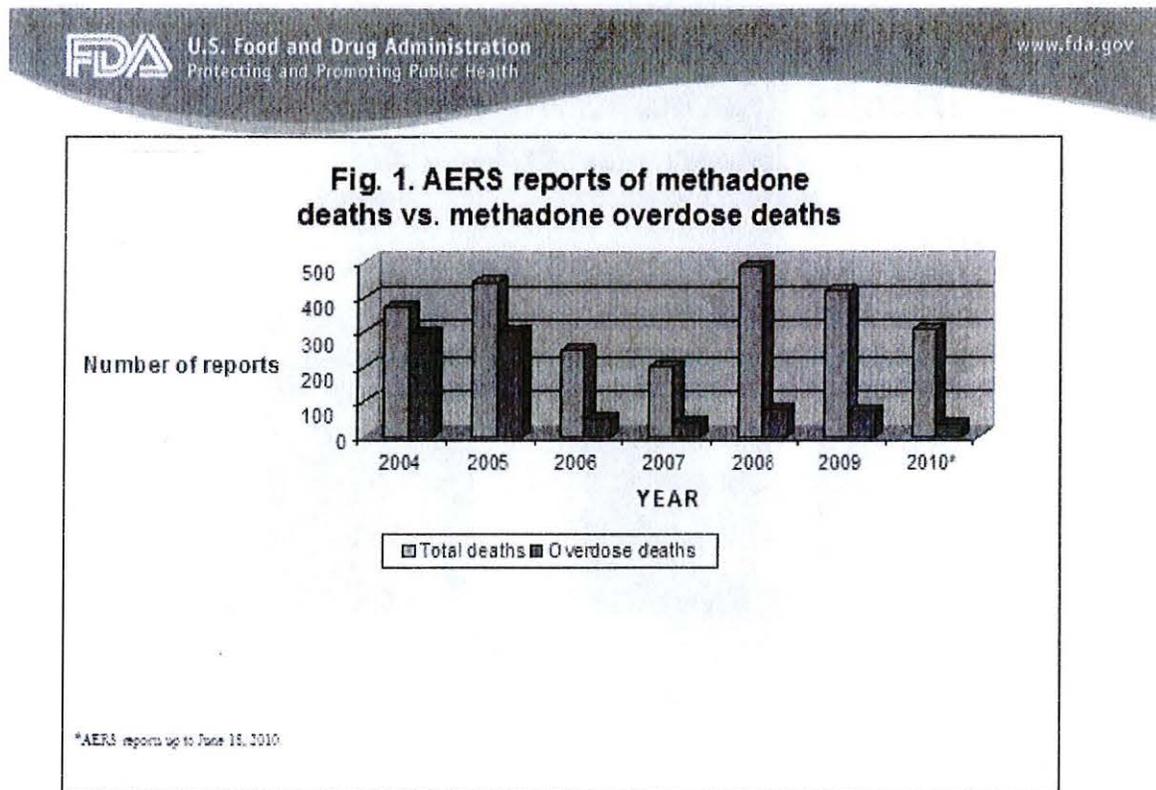
SAMHSA/CSAT Methadone Mortality Meeting
July 28, 2010

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In 2009, the majority of prescriptions for methadone were written by primary care physicians and physician extenders. The indications for which methadone was prescribed included pain associated with musculoskeletal disorders (46%), headaches and nerve pain (17%), and cancer-related pain (11%).

Between 2004 and June 2010, FDA received 2,500 reports of deaths and 989 reports of overdoses associated with methadone from the Adverse Events Reporting System (AERS; Figure 4).

Figure 4.



SAMHSA/C SAT Methadone Mortality Meeting
July 29, 30, 2010

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DEA Data on Drug Distribution (ARCOS)

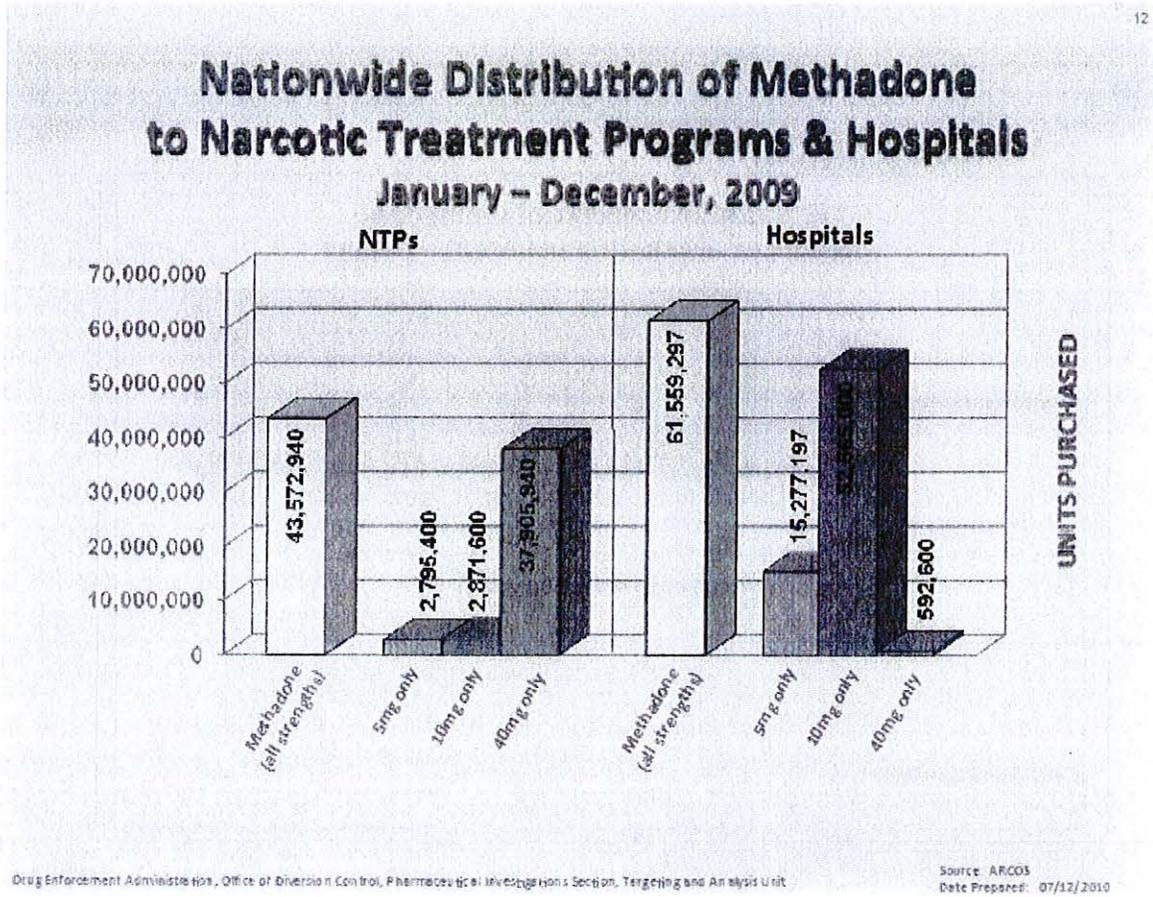
June E. Howard, Chief, Targeting and Analysis Unit (ODPT), Pharmaceutical Investigations Section, Drug Enforcement Administration

Every entity that manufactures or distributes prescription drugs is required to report that activity to the Drug Enforcement Administration (DEA). The DEA's Automation of Reports and Consolidated Orders System (ARCOS) captures information on drug inventories, acquisitions, dispositions, and manufacturing activities. Methadone data are included in ARCOS, although the data on distribution are somewhat limited.

ARCOS data for the period January 2006 through June 2010 show that 150 to 200 million dosage units of methadone (at all strengths and in all formulations) were distributed in each quarter, leveling off to 125 million units in the second quarter of 2010.

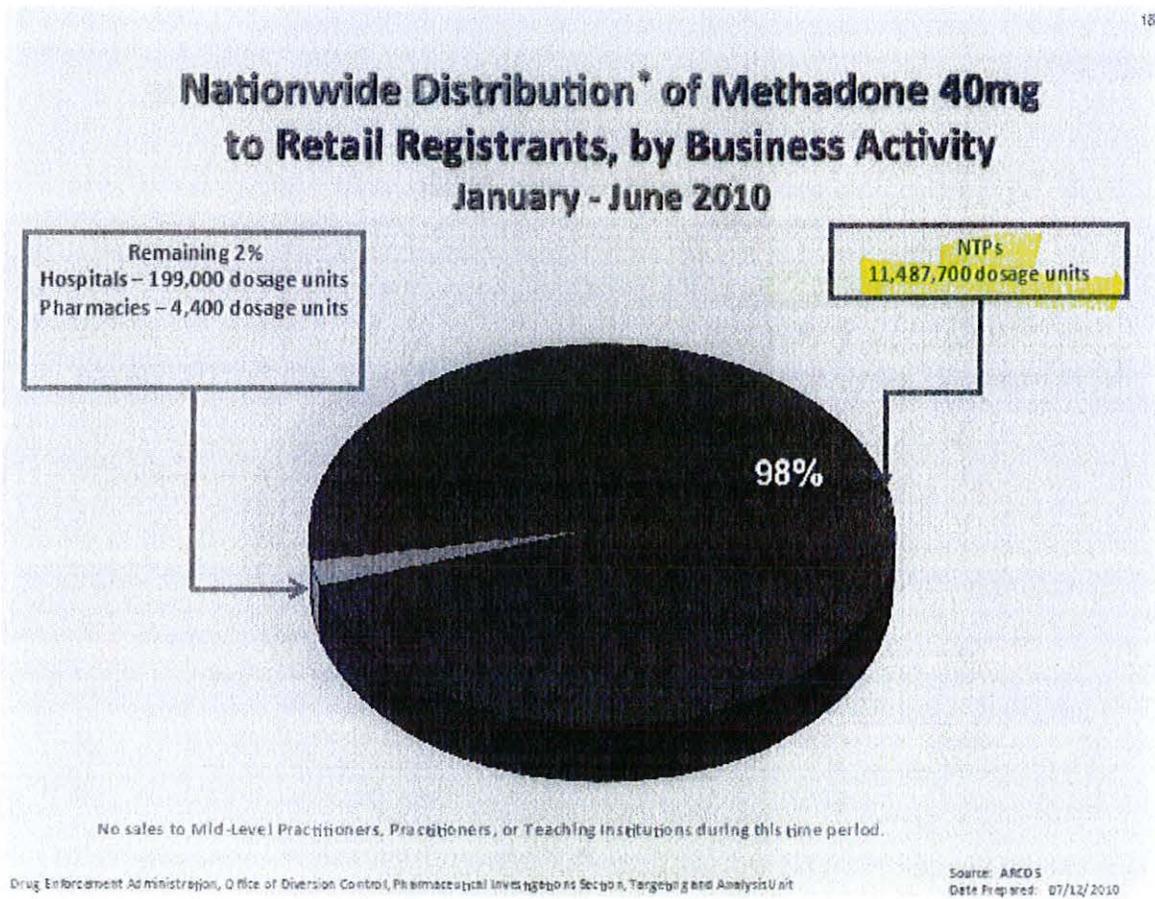
In 2009, 98% of methadone in the 40 mg formulation (about 38 million units) was distributed to OTPs (also known as Narcotic Treatment Programs or NTPs). The remaining 2% was distributed to hospital pharmacies (Figure 5).

Figure 5.



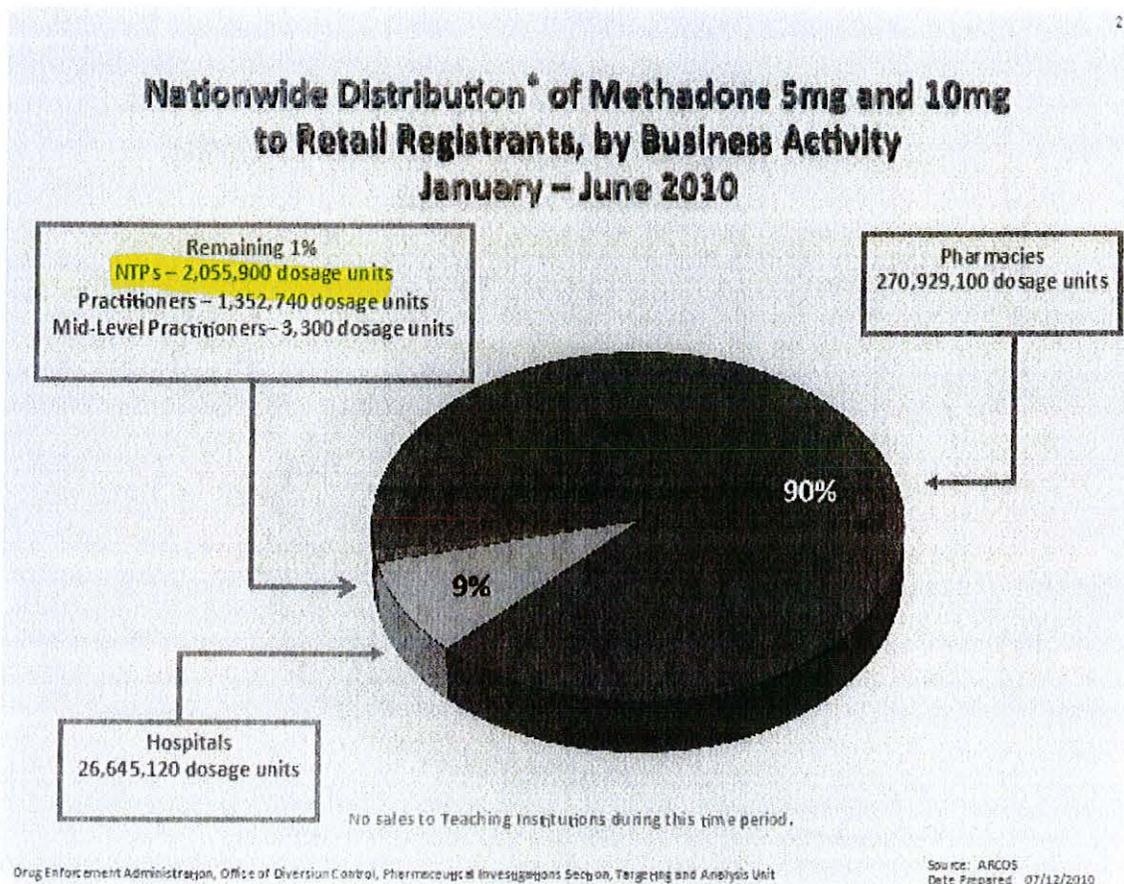
Individual practitioners received approximately 4.5 million dosage units of methadone in 2009 and about 1.3 million units in the first six months of 2010. The patterns of distribution seen in 2009 also were observed in 2010, with the vast majority of the 40 mg formulation going to OTPs/NTPs (Figure 6).

Figure 6.



In contrast, ARCOS data show that a large majority (90%) of the 5 mg and 10 mg formulations of methadone (commonly used for pain treatment) were distributed to retail pharmacies. Of the rest, 9% was distributed to hospitals and 1 percent to OTPs/NTPs (Figure 7).

Figure 7.



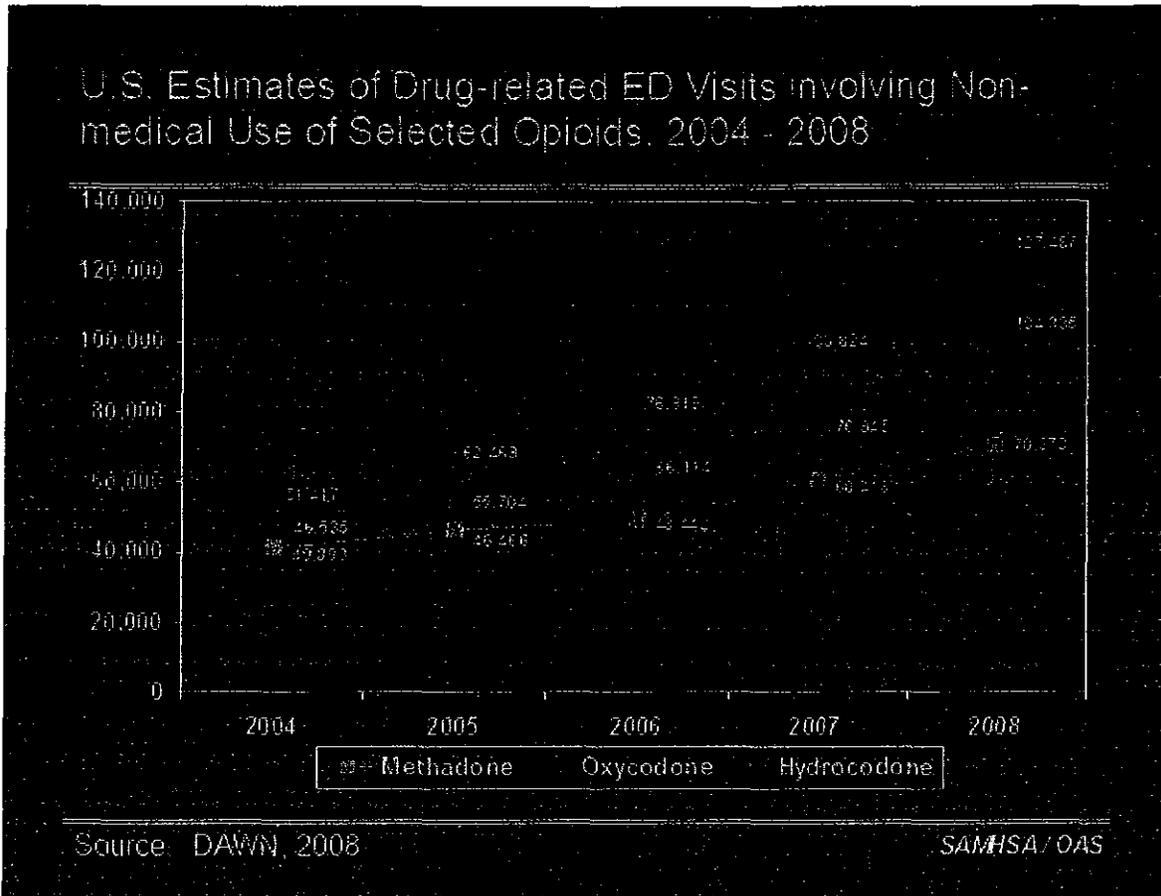
SAMHSA Data on Emergency Department Visits (DAWN)

David J. Skellan, B.S., Drug Abuse Warning Network, Center for Behavioral Health Statistics and Quality [formerly Office of Applied Studies], Substance Abuse and Mental Health Services Administration

The Drug Abuse Warning Network (DAWN) is a public health surveillance system, which collects data from selected emergency departments and medical examiners/coroners. Using DAWN case criteria, reporters in participating institutions classify deaths as drug-related and attempt to determine the motive for drug use. All types of drugs, including illicit, prescription medications, and over-the-counter products--are included in DAWN. Twelve States report data on drug-related deaths.

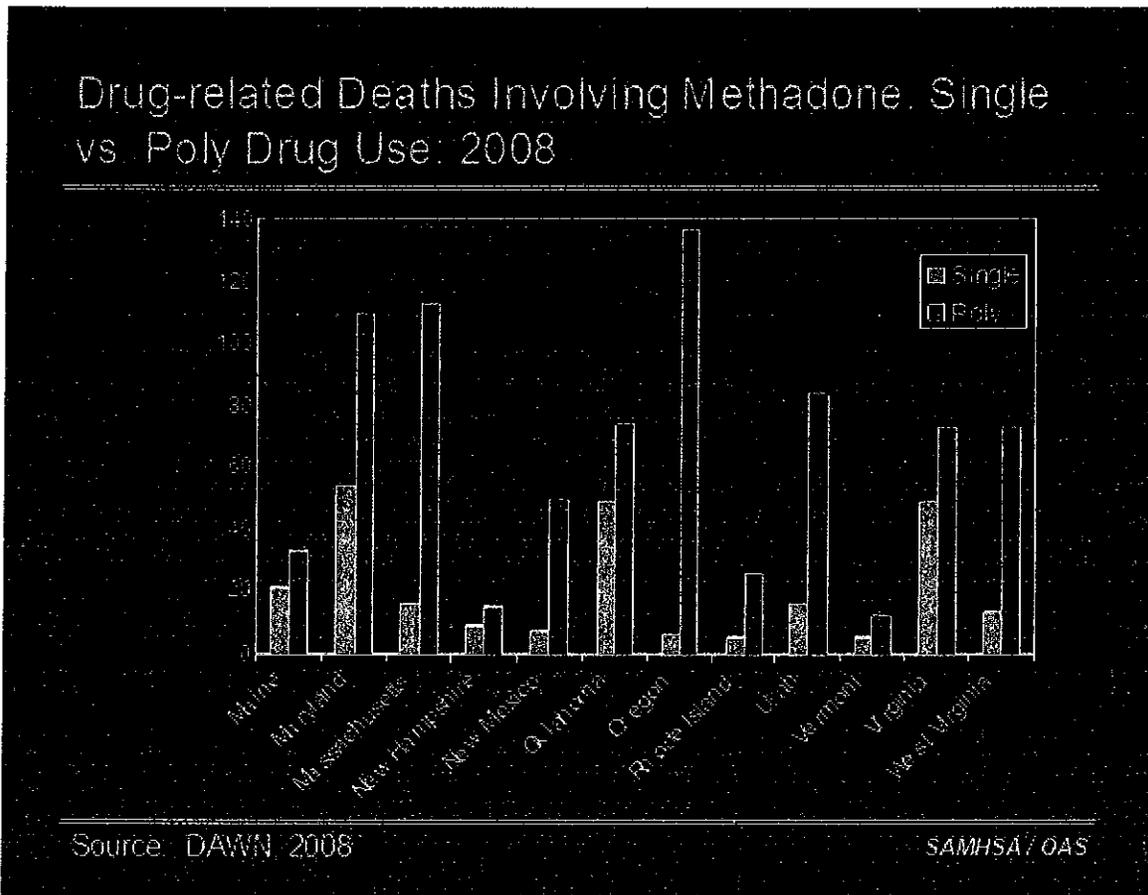
Overall, the number of emergency department (ED) visits resulting from nonmedical use of opioids increased in the period 2004–2008. Visits related to oxycodone and hydrocodone increased by an estimated 36% in 2008 over 2007, while ED visits related to methadone increased by 16% in the same period (Figure 8).

Figure 8.



In the States that currently report death data to DAWN, the number of deaths involving methadone in combination with other drugs is approximately three times the rate of deaths associated with use of methadone alone. In 2008, there were 800 polydrug deaths, compared with 250 methadone-only deaths (Figure 9).

Figure 9.



CDC National Data on Drug-Related Deaths

Margaret Warner, Ph.D., Injury Epidemiologist, National Center for Health Statistics, Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC) maintain the National Vital Statistics System (NVSS) to capture data on deaths from numerous causes, based largely on death certificates. Poisonings also are coded by cause.

NVSS data show that, in 2007, there were 5,692 deaths in the U.S. involving methadone. This represented an increase over 1999, when 826 deaths were reported (Figure 10). The largest portion of these deaths occurred in persons aged 45 to 54.

Figure 10.

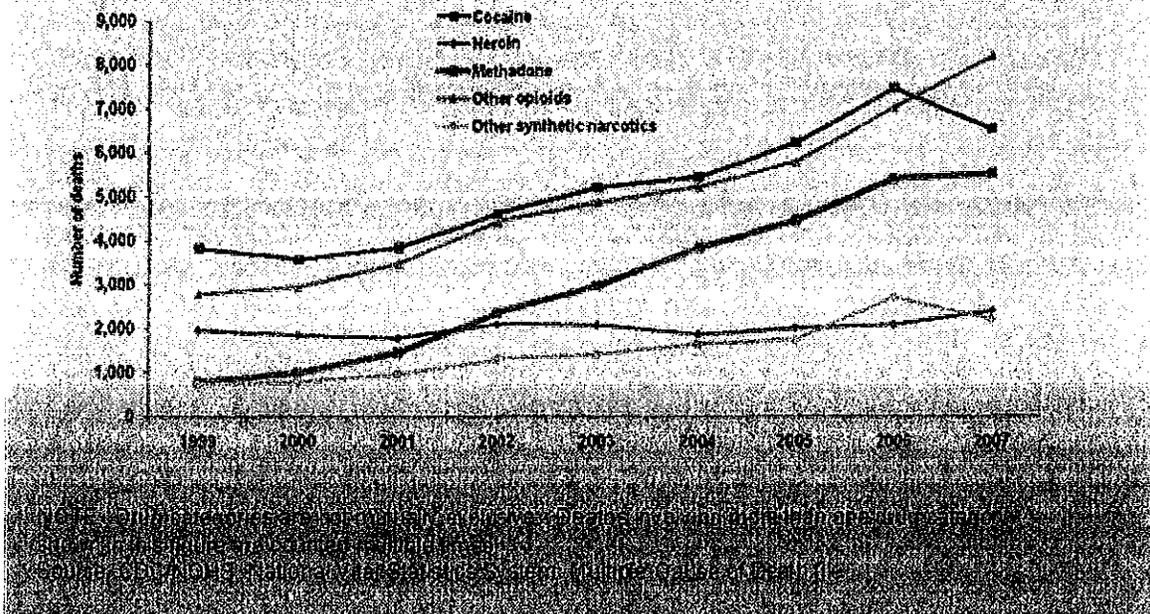
Deaths involving methadone: United States, 1999–2007

	1999	2000	2001	2002	2003	2004	2005	2006	2007
Poisoning unintentional	623	778	1,158	1,911	2,452	3,202	3,701	4,552	4,706
Poisoning undetermined	105	138	186	295	370	441	523	598	591
Poisoning Suicide	56	72	111	149	146	195	232	254	225
Disease	42	62	88	96	125	153	152	187	136
Other Injury	-	-	-	-	-	29	24	30	34
Poisoning homicide	-	-	-	-	-	-	-	-	-

NVSS data show that methadone deaths increased by 2% from 1999 to 2007, while other opiate-related deaths increased by 16% and deaths related to cocaine decreased by 12% (Figure 11).

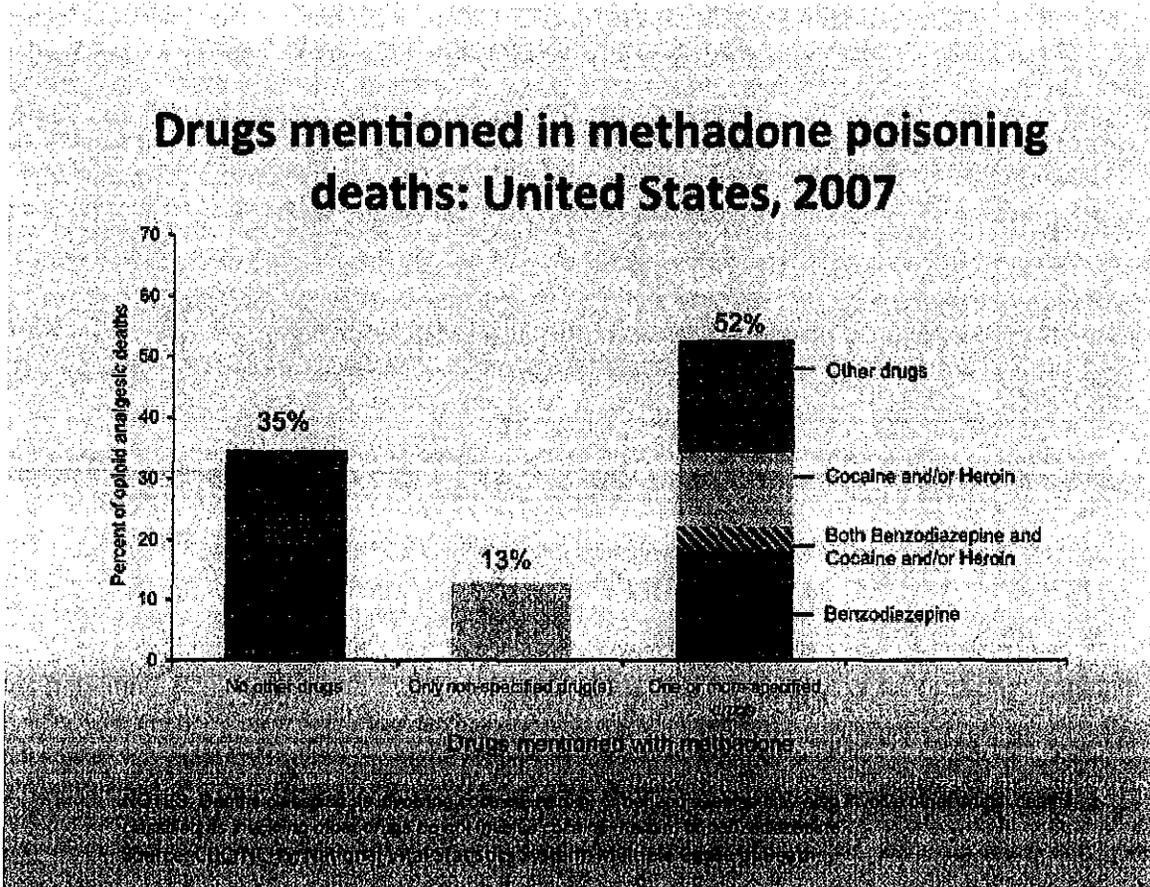
Figure 11.

Poisoning deaths involving opioid analgesics, cocaine and heroin: United States, 1999–2007



Of all methadone-associated deaths, 35% involved methadone alone. In 52% of the cases, methadone was used in combination with another known drug. In 13% of the cases, an unspecified drug was involved (Figure 12).

Figure 12.



CDC State-Level Data on Drug-Related Deaths

Leonard J. Paulozzi, M.D., M.P.H., Medical Epidemiologist, Division of Unintentional Injury Prevention, National Center for Injury Prevention & Control, Centers for Disease Control and Prevention

According to CDC data in the National Vital Statistics System (NVSS), most States reported fewer than 2 methadone-related deaths per 100,000 population in 2007. The most commonly reported death rate was 1 to 2 per 100,000 (Figure 13). However, the data are based on coding on death certificates, and there is a great deal of variability regarding how medical examiners arrive at those codes.

Figure 13.

Rates of Poisoning Death Related to Methadone by State, 2007

Crude Death Rate per 100,000	States in rank order
<1	SD, AK, ND, NE, IL, TX, CA, NJ
1-<2	PA, DC, MS, MN, CO, IA, IN, AZ, WY, SC, MO, NY, MI, ID, HI, KS, CT, OH, VA, AL, MA
2-<3	DE, AR, LA, WI, TN, NM, VT, RI, MT
3-<4	FL, UT, ME, MD, OR, NC, KY
4-<5	WA, NV, NH
5+	OK, WV

Source: National Vital Statistics System, National Center for Health Statistics, CDC

Ten State-level studies conducted between 1987 and 2008 show that, overall, patients in OTPs account for a fairly small percentage of methadone-associated deaths; however, the percentage varies widely from one State to the next, ranging from 4% to 50% (Figure 14). Another 10 State studies suggest that methadone was the leading cause of death in overdoses involving opioids. In some states, methadone has been replaced by oxycodone as the opioid most often involved in overdose deaths. In those states, methadone remains the second most frequently cited opioid.

It should be noted that, in a large number of these deaths, the actual source of the methadone is not reliably known.

Figure 14.

Information on Sources of Methadone Among Drug Overdose Deaths				
State/Author	Year of Deaths	Number	Pct in OTP	Pct w Rx
Texas/Barrett	1987-92	54	9%	na
Minnesota/Gagajewski	1992-2002	31	42%	6%
Maryland/Anon	1998-99	8	50%	na
North Carolina/Ballesteros	1997-2001	198	4%	37%
New Mexico/Shah	1998-2002	143	22%	19-26%
Oregon/DOH	2002	103	~25%	33%
Kentucky/Shields	2000-04	95	10%	48%
Maryland/Anon	2004-05	52	15%	2%
West Virginia/Paulozzi	2006	87	12%	32%
North Carolina/Harmon	2007-08	18	na	17%

RADARS Methadone Study

Richard C. Dart, M.D., Ph.D., Director, Rocky Mountain Poison & Drug Center, and Executive Director, RADARS System

The Researched Abuse, Diversion, and Addiction Related Surveillance (RADARS) System captures data from six sources: drug diversion datasets, surveys of key informants, poison control centers, OTPs, programs that treat impaired health professionals, and college surveys. Each source has its own strengths and weaknesses; together, they identify unique aspects of prescription drug abuse and diversion and the medical consequences thereof.

RADARS data show that deaths associated with oxycodone, buprenorphine, and methadone are increasing substantially. RADARS' poison center research data, which include all intentional exposures among children and adults, show that oxycodone ranks first in terms of deliberate abuse, but that methadone is abused at higher rates given its relatively limited availability.

Methadone is more likely to be diverted than oxycodone or buprenorphine, even though fewer prescriptions are written for methadone than for oxycodone. While all formulations

of methadone are diverted, tablets (which are prescribed for pain) are the most likely to be involved.

Children under the age of 6 were disproportionately involved in unintentional deaths after ingesting methadone, as compared to other prescription opioids. For example, in 2009, 1,105 children under age 6 were exposed to buprenorphine and no child died; 1,655 children under age 6 were exposed to oxycodone and one child died; and 316 children under 6 were exposed to methadone and two children died. This may be because methadone liquid formulations (typically take-home doses) are absorbed quickly, leading to rapid metabolism and death.

SAMHSA Data on Methadone Deaths in OTPs

Jane C. Maxwell, Ph.D., Senior Research Scientist, Gulf Coast Addiction Technology Transfer Center (ATTC), University of Texas at Austin

In late 2008, SAMHSA launched an initiative to collect standardized data on deaths involving patients in OTPs through use of a Mortality Report form. Data submission was voluntary. The data collected were entered into an online database.

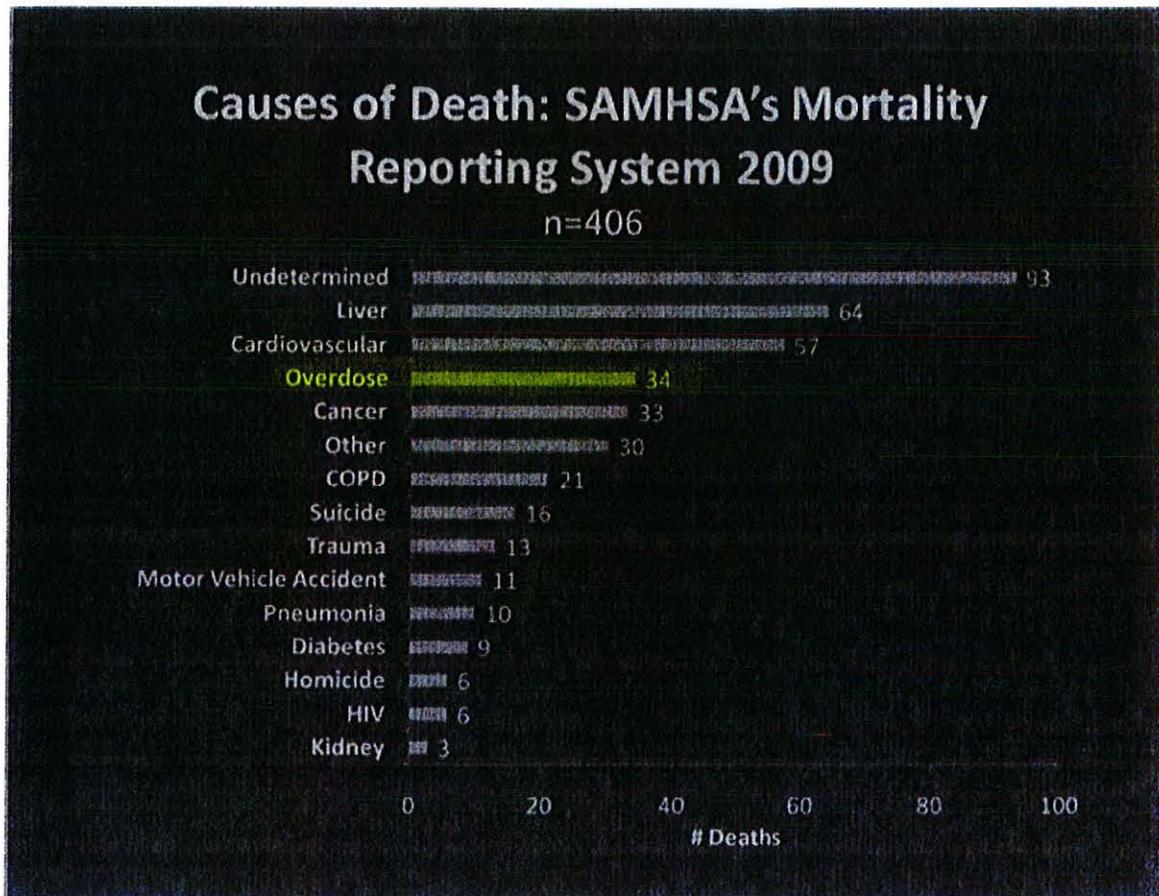
A number of problems were encountered in interpreting the data. For example, the report provided within 48 hours of death is subjective, as it uses information collected from family and friends. As a result, the preliminary certificate issued immediately after death frequently is amended as much as 6 to 8 months later when a coroner or medical examiner issues a final ruling as to cause of death.

In 2009 (the first full year for which data were collected), 406 deaths were reported. Of these, 27% occurred in the first two weeks of treatment. Although the data on cause of death are preliminary, they indicate that persons who died of methadone overdose were more likely to have a history of depression. Also, 32% of the death reports cited the presence of benzodiazepines in addition to the methadone.

According to the data gathered, 67% of methadone decedents were male, with an average age of 49.8 years. The average length of treatment was 4.5 years and the average number of days of "take-home" doses dispensed at the last visit was 5. The average dose was 91.8 mg.

Deceased patients had an average of 1.5 comorbid medical or psychiatric conditions, including mental disorders, depression, or anxiety; liver problems, including hepatitis; cardiopulmonary disorders, including circulatory problems, high blood pressure and COPD; metabolic disorders, particularly diabetes; musculoskeletal disorders; kidney problems; and traumatic injuries. Given the rate of co-occurring disorders, it is not surprising that a large number of deceased patients had been using at least one prescription drug (most frequently a benzodiazepine) in addition to methadone (Figure 15).

Figure 15.



SAMHSA's next steps are to ask the expert panel to consider revisions to the current Mortality Report form and to refine the definitions used.

A FOCUS ON SOLUTIONS: PROPOSED STRATEGIES AND ACTION STEPS

After evaluating the data, participants in the 2010 Reassessment met in a series of working groups to develop strategies and action steps to address specific problems.

Group 1: Improving the Reporting of Methadone-Associated Deaths

Group 2: Improving the Use of Methadone in Addiction Treatment

Group 3: Improving the Use of Methadone in Pain Treatment

Group 4: Research Needs

Group 5: Data and Trend Monitoring

Group 6: Legislation, Accreditation and Administrative Actions

Each group reported its findings, strategies and action steps to the larger meeting. A considerable degree of consensus was noted across the six groups, as exemplified by their agreement that highest priority should be assigned to the following strategies:

1. Take steps to enhance the knowledge of all physicians and other health care professionals about the nature and safe management of chronic pain and addiction.
2. Develop and disseminate educational messages to patients and the public about the hazards of prescription drug misuse, as well as specific steps to assure safe use of methadone and other controlled drugs.
3. Encourage and support studies to fill voids where current knowledge is not adequate to assure patient safety (for example, on the cardiac effects of methadone).
4. Use all appropriate legislative, regulatory, and administrative tools to incentivize the desired changes in treatment systems and individual clinical practice.
5. Increase collaboration among Federal and State agencies and between government agencies and private-sector organizations.
6. Enhance the quality, timeliness, and usefulness of data as a key step in executing the foregoing strategies.

The reports of the Action Planning Groups, with suggested action steps, are summarized below.

STRATEGY 1: Take steps to enhance the knowledge of all physicians and other health care professionals about the nature and safe management of chronic pain and addiction.

- 1-1. Integrate training about addiction and pain management into the core curriculum for undergraduate and graduate education of all physicians, mid-level providers, and dentists. Focus on specific knowledge and skills, such as those needed to conduct screening and brief intervention.
 - a. Include specific instruction in prescribing controlled drugs as part of the undergraduate and graduate curricula.
 - b. Increase attention to the core competencies of caring for addicted patients, including the risks of drug interactions with methadone and those inherent in the concurrent use of methadone and other sedative drugs such as the benzodiazepines.
 - c. Focus initially on primary care practitioners.
 - d. Employ contextual approaches to training practitioners in specialty care (e.g., emergency physicians, Ob-Gyns, oral surgeons, et al.).

- 1-2. Continue to sponsor continuing education and mentoring programs on the management of pain and addiction for physicians, oral surgeons and dentists, and midlevel professionals.
 - a. Target content to the specific needs of primary care practitioners.
 - b. Develop a cadre of experts at the community level, including peer mentors to provide assistance and peer monitors for physicians with prescribing issues (similar to the system employed by Physician Assistance Programs).

- 1-3. Leverage the success of the SAMHSA opioid prescribing courses to reach even more prescribers and other health care professionals.
 - a. Develop virtual resources such as web modules to expand the number of physicians and other health professionals who can access this valuable resource.
 - b. Find ways to increase awareness of the courses, as by partnering with various State agencies, academic institutions, and private sector organizations.
 - c. Make the courses available to medical schools and residency training programs.
 - d. Continue to develop specialized courses to meet the specific needs of the VA, the Indian Health Service, and other groups serving defined populations.

STRATEGY 2: Develop and disseminate educational messages to patients and the public about the hazards of prescription drug misuse, as well as specific steps to assure safe use of methadone and other controlled drugs.

- 2-1. Enhance patient education about the safe use of methadone.
 - a. Work with groups such as the National Council on Patient Information and Education to develop educational materials.
 - b. Employ peer support to encourage safe methadone use.
- 2-2. Improve public understanding of the safe use of methadone and other opioid analgesics.
 - a. Launch a public awareness campaign about safe use of prescription opioids (including safe disposal of unused medications), in partnership with other Federal agencies and private-sector organizations.
 - b. Work with leading medical organizations to develop materials on safe medication use for distribution in medical offices.
 - c. Develop public service announcements and other public information vehicles in partnership with other private-sector groups such as the Partnership for a Drug-Free America.

STRATEGY 3: Encourage and support studies to fill voids where current knowledge is not adequate to assure patient safety (for example, on the cardiac effects of methadone).

- 3-1. Analyze available data and encourage additional studies to develop strategies to prevent, identify and safely manage interactions between methadone and the following:
 - a. Benzodiazepines
 - b. Antiretroviral medications
 - c. HCV medications
 - d. Tuberculosis medications
 - e. Psychotropics (antidepressants, antipsychotics, and anticonvulsants).
- 3-2. Encourage and support studies to identify risks that are highly predictive of poor clinical outcomes, including morbidity and mortality, in patients treated with methadone for pain or addiction.
- 3-3. Conduct a systematic examination of the costs and benefits of implementing the recommendations contained in the report of the SAMHSA Expert Panel on Cardiac Effects of Methadone.

- 3-4. Support a prospective study of patients being treated with methadone for pain or addiction who have QTc prolongation (defined as ≥ 500 msec) to determine whether they develop arrhythmias over a specified period of time.
- 3-5 Encourage studies of chronic pain patients to determine the safety of methadone induction in opioid-naïve versus opioid-experienced patients. (This is highly relevant to the common practice of opioid rotation.)

STRATEGY 4: Use all appropriate legislative, regulatory, and administrative tools to incentivize the desired changes in treatment systems and individual clinical practice.

- 4-1. Use available legislative and regulatory frameworks to reduce the toll of methadone induction deaths.
 - a. Employ quality improvement initiatives (such as those conducted by NIATx) to develop program standards and practices that reduce patient risk. Link adoption of the resulting evidence-based standards and practices to accreditation or reimbursement.
 - b. Consider making naloxone available to patients and/or family members during the induction period and whenever take-home doses are prescribed.
- 4-2. Encourage the adoption of evidence-based practices for methadone induction and stabilization, as by making use of approved guidelines part of the standards for OTP accreditation.
- 4-3. Urge the Accreditation Council on Graduate Medical Education to require core competencies related to safe prescribing of opioids as part of all accredited residency training programs. Similarly, agencies that accredit training programs for allied health professionals should require evidence of competency in safe use of opioids where relevant to the scope of practice.
- 4-4. Require every physician to demonstrate competency in the safe prescribing of opioids in order to obtain or renew his or her DEA registration.
- 4-5. Educate health care professionals and policymakers about the value of prescription monitoring programs (PMPs) and take steps to enhance the usefulness of PMPs in preventing and identifying nontherapeutic use of methadone and other controlled drugs.
 - a. Work with the NASPER-funded PMPs and State licensing boards to develop and apply consistent standards as to what constitutes opioid “use” and “misuse.”
 - b. Increase the use of PMPs to identify patients who are using prescribed benzodiazepines concurrently with methadone or other opioids.
 - c. Enhance physician access to the data PMPs contain.

- d. Support legislation that enables pharmaceutical companies to contribute to State pools to fund PMPs in a transparent way. (This was suggested by a pharmaceutical company representative.)
 - e. Expand PMPs to all States, and take steps to assure interoperability across State borders.
 - f. Expand data collection to include controlled drugs in all schedules. Leverage electronic resources to identify knowledge deficits in individual prescribers and provide remediation as needed.
 - g. Provide information and mentoring on the management of challenging patients through the PCSS or a similar network.
- 4-6. Support the development and implementation of Risk Evaluation and Mitigation Strategies (REMS).
- 4-7. Collaborate with organizations that develop health professions curricula, that accredit educational programs, that write questions for specialty board exams, and that support faculty training and development to assure that the knowledge and skills needed to assess and safely manage or refer patients with pain or addiction are included in health professions training.
- 4-8. Develop a system for certifying the competency of OTP clinical staff, similar to the DATA 2000 requirements for physicians who would prescribe buprenorphine for addiction treatment.
- 4-9. Develop pain management competency standards for accreditation programs other than pain medicine (e.g., for ambulatory care, hospitals, and long term care).
- 4-10. Approach professional liability insurers about the possibility of rate adjustments for physicians practicing in States that adopt prescribing guidelines or PMPs, or for individual physicians who complete continuing medical education programs on safe prescribing of opioids and other controlled drugs.

STRATEGY 5: Increase collaboration among Federal and State agencies and between government agencies and private-sector organizations.

- 5-1. Encourage greater coordination between OTPs and providers of general medical care.
- a. Provide primary care in OTPs, thus making them the patient's "medical home."
 - b. Establish satellite OTPs in Federally Qualified Health Centers (FHQCs).
 - c. Address the expansion of treatment capacity needed to meet the increased demand expected to result from health care reform. For example, expand treatment options by offering medical maintenance with methadone in office-based settings.

- d. Identify a mechanism to observe patients at peak methadone effect in OTPs or at other sites (e.g., pharmacies, FQHCs, primary care settings).
 - e. Find ways to allow communication between OTPs and outside providers, without violating the confidentiality requirements of 42 CFR Part 2.
- 5-2. Work with DEA, pharmacy organizations and State and local officials to encourage the expansion of drug take-back programs and to increase public awareness of their value in limiting unauthorized access to unused opioids and other controlled drugs.
- 5-3. Reach out to agencies and organizations at the State and Federal levels to identify problems and work with them to craft solutions.

STRATEGY 6: Enhance the quality, timeliness, and usefulness of data as a key step in executing the foregoing strategies.

- 6-1. Convene a meeting of epidemiologists, technical experts, and data users to reach agreement on ways to synthesize data from multiple sources to address the need for:
- a. More complete and accurate data on methadone deaths;
 - b. Access to proprietary data (AAPCC, SDI, IMS);
 - c. Better ethnographic data;
 - d. Adding opioids to arrestee drug testing (ADAM);
 - e. Better support of the existing data infrastructure;
 - f. Expanded State-level capacity for surveillance; and
 - g. An assessment of data needs for prevention activities.
- 6-2. Improve the reporting of deaths among OTP patients (particularly those that involve concurrent use of benzodiazepines).
- a. Identify barriers to voluntary reporting.
 - b. Develop better methods of collecting data on patient deaths.
 - c. Educate OTP administrative staff about the need for reporting.
 - d. Consider making reporting an accreditation standard.
- 6-3. Improve surveillance of methadone-associated deaths by medical examiners and coroners.
- a. Work toward greater standardization of case definitions by medical examiners and coroners.
 - b. Provide medical examiners and coroners with reports and other feedback on the uses and consequences of the data they provide.
- 6-4. Develop more detailed and focused analyses of data from all sources.

- 6-5. Study the characteristics of all deaths of patients receiving opioids for the treatment of pain or addiction.
- 6-6. Examine the incidence, prevalence and patterns of concurrent opioid and benzodiazepine use and abuse in opioid-maintained addiction treatment populations and chronic pain populations.
- 6-7. Encourage and facilitate the linkage of data from PMPs with medical examiner/coroner data and OTP death records.
- 6-8. Encourage comparative effectiveness studies, such as those that establish an evidence base for the use of longitudinal opioids in the treatment of pain or addiction.
- 6-9. Pursue a special issue of a peer-reviewed journal on data related to methadone or opioid morbidity and mortality.
- 6-10. Work with DEA and stakeholder groups to enhance the dissemination of geographically targeted data.

CLOSING REMARKS BY DR. H. WESTLEY CLARK

Since the initial 2003 National Assessment meeting in response to the increasing number of methadone-associated deaths, data show that these deaths, as well as all opioid-related deaths, continue to rise. By reconvening experts and representatives of Federal and State agencies, practitioners, patient advocates, and pharmaceutical industry representatives knowledgeable about the issues surrounding methadone mortality, we have reaffirmed our commitment to understand and address these critical issues. The data, clinical challenges, and stakeholder perspectives examined during the 2010 Reassessment meeting were assessed through the prism of the work groups to ensure that our next steps are informed by current research findings, clinical experience, and patient and family viewpoints.

SAMHSA will continue to work collaboratively with our Federal partners, as well as with the States, with medical societies and organizations, with patient advocacy groups, and with other interested parties to develop and implement practical strategies and action steps that will reduce the toll of methadone-associated deaths. Meeting participants have offered many suggestions for consideration by SAMHSA and others. Some of these suggestions reinforce or expand on those made by meeting participants in 2003, while others reflect our expanded knowledge and take us in new directions.

SAMHSA is particularly interested in taking a balanced approach to reducing methadone-associated deaths and values the input provided by the full spectrum of stakeholder groups. Through this approach, we intend to focus on key issues and avoid unintended consequences from the policies and actions we pursue. We are now better equipped than in 2003 to recognize the complexity represented by methadone-associated deaths and to understand the need to engage patients, medical professionals, health professions organizations, and Federal and State agencies in a mutual effort to achieve our goals.

Multiple initiatives are already under way, but there is much more to be done to gain an accurate understanding of the circumstances that lead to these unfortunate deaths and that will enable us to limit the human losses they represent.

This reassessment effort has provided critical information and guidance to SAMHSA as we work to find the best solutions for patients, their families, and the public, and to meet our regulatory and public health responsibilities.

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Attachment 2

Drug Abuse Trends in the Minneapolis/St. Paul Metropolitan Area: June 2014

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ABSTRACT

Rising heroin trends dominated the drug abuse situation in the Minneapolis/St. Paul metropolitan area in 2013. A record-high 14 percent of admissions to addiction treatment programs were for heroin in 2013, of which 40.2 percent were age 18 - 25. In Hennepin County opiate-related deaths rose 57.1 percent from 2012 to 2013 (from 84 to 132), but declined in Ramsey County (from 45 to 37). Statewide, 23 multijurisdictional law enforcement drug task forces seized 203.8 percent more heroin in 2013 than in 2012. Heroin-involved hospital emergency department visits in the Twin Cities nearly tripled from 2004 to 2011 (from 1,189 to 3,493), and those involving prescription narcotic analgesics more than doubled (from 1,940 to 4,836). Cocaine-related treatment admissions continued to decline in 2013, accounting for 4.3 percent of admissions, although deaths increased (from 21 to 37). Of the cocaine-related treatment admissions in 2013, 74.5 percent were age 35 or older. Methamphetamine-related treatment admissions gradually increased in recent years and in 2013 accounted for 10 percent of total admissions. Methamphetamine was present in 32.5 percent of drug items analyzed by NFLIS laboratories in 2013, compared with 22.6 percent in 2012. Marijuana accounted for 15.5 percent of addiction treatment admissions in 2013, of which 27.1 percent were age 17 or less. Exposures involving synthetic THC products (cannabimimetics) and "bath salts" (substituted cathinones) declined from 2012 to 2013, while those involving 2CE analogs ("research chemicals") increased (from 24 to 35), based on Hennepin Regional Poison Center data.

Background

This report analyzes current and emerging trends in substance abuse in the metropolitan area of Minneapolis/St. Paul, Minnesota (the Twin Cities), and is produced twice annually for participation in the Community Epidemiology Work Group of the National Institute on Drug Abuse, an epidemiological surveillance network of drug abuse researchers from 20 U.S. metropolitan areas.

AREA DESCRIPTION

The Minneapolis/St. Paul metropolitan area includes Minnesota's largest city, Minneapolis (Hennepin County), the capital city of St. Paul (Ramsey County), and the surrounding counties of Anoka, Dakota, and Washington, unless otherwise noted. According to the 2010 Census, the population of each county is as follows: Anoka, 330,844; Dakota, 398,552; Hennepin, 1,152,425; Ramsey, 508,640; and Washington, 238,136, for a total of 2,588,907, roughly one-half of Minnesota's 5.3 million population. Minnesota shares a northern, international border with Canada, and a western border with North Dakota and South Dakota, two of the country's most sparsely populated States.

In the Minneapolis/St. Paul metropolitan area 80.1 percent of population is White. African-Americans constitute the largest minority group (9.1 percent), Asians account for 6.1 percent, American Indians 0.7 percent, and Hispanics of all races 6 percent. There are an estimated 77,000 Somali immigrants and 66,200 Hmong immigrants living in Minnesota, mostly in the Twin Cities metropolitan area.

Illicit drugs are distributed and sold within Minnesota by Mexican drug trafficking organizations, street gangs, independent entrepreneurs, and other criminal organizations. Drugs concealed in compartments of private and commercial vehicles are typically transported into the Twin Cities area for further distribution throughout the State. Interstate Highway 35 starts at the U.S./Canadian border in Minnesota, and runs south to the U.S./Mexican border in Texas. Interstate 94 is the direct route between the Twin Cities and Chicago.

DATA SOURCES

Mortality data on drug-related deaths are from the Ramsey County Medical Examiner and the Hennepin County Medical Examiner (through December 2013). Hennepin County cases include accidental overdose deaths in which drug toxicity or mixed drug toxicity was the cause of death and those in which the recent use of a drug was listed as a significant condition contributing to the death. Ramsey County cases include accidental overdose deaths in which drug toxicity was the cause of death. See exhibits 1 - 4.

Hospital emergency department (ED) data are from the Drug Abuse Warning Network, Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, accessed 9/12/2012. These weighted estimates of ED visits are based on a representative sample of non-Federal, general, short-stay hospitals with 24-hour EDs in the 11-county Minneapolis/St. Paul/Bloomington, MN-WI Metropolitan Statistical Area (through December 2011). See exhibit 5.

Addiction treatment data are from the Drug and Alcohol Abuse Normative Evaluation System, Minnesota Department of Human Services (through December 2013). See exhibits 6 - 8.

Crime laboratory data are from the National Forensic Laboratory Information System (NFLIS), U.S. Drug Enforcement Administration (DEA) queried on 5/9/2014 according to location of the seizure. All federal, state and local laboratory data are included in the total number of drug items seized as primary, secondary or tertiary drugs in the 7-county metropolitan area including the counties of Anoka, Carver, Dakota, Hennepin, Ramsey, Scott and Washington in calendar 2013, with the exception of the St. Paul crime lab data, which were not reported after May 2012. See exhibit 9.

Poison Center data on human exposures to various substances are reported to the Hennepin Regional Poison Center (through April 2014). See exhibits 10 and 11.

Law enforcement data are from the multijurisdictional drug and violent crime task forces that operate throughout the State, compiled by the Office of Justice Programs, Minnesota Department of Public Safety (through 2013). In 2013 there were 23 multijurisdictional law enforcement drug and violent crime task forces operating throughout the state, staffed by 186 investigators from over 200 agencies. Price data and trafficking information are from the DEA. Heroin incident report data are from the Minneapolis Police Department. See exhibits 12 and 13.

Prescription drug data are from the Minnesota Prescription Monitoring Program, Minnesota Board of Pharmacy, March 2014. See exhibit 14.

Hepatitis C virus (HCV) and human immunodeficiency virus (HIV) infection data are from the Minnesota Department of Health (through 2013).

Drug Abuse Trends

HEROIN AND OTHER OPIATES

Adverse consequences related to heroin and other opiates continued to escalate in the Twin Cities in 2013, although opiate-related deaths increased markedly in Hennepin County in 2013, and declined in Ramsey County. In Hennepin County there were 132 opiate-related deaths in 2013, compared with 84 in 2012, a 57.1 percent increase. The decedents ranged in age from 18 to 65. At least 57 cases involved heroin (43.2 percent), 14 involved cocaine used in combination with an opiate (10.6 percent), 30 involved methadone (22.7 percent), 15 involved oxycodone (11.3 percent), six involved fentanyl and four the use of methamphetamine in combination with an opiate. Three of the four decedents with opiate and methamphetamine toxicity were American Indian females.

2012 was the peak year for opiate-related deaths in Ramsey County, with a record-high 45; a 25 percent increase from 2011. In 2013 deaths fell to 37, a 17.7 percent decrease. These 37 decedents ranged in age from 20 to 71. At least 6 cases (16.2 percent) involved heroin, 15 cases (40.5 percent) involved methadone, ten (27 percent) involved oxycodone, three involved cocaine used in combination with opiates, two involved fentanyl, and two involved opiate and methamphetamine toxicity.

Heroin-involved hospital emergency department (ED) visits nearly tripled from 2004 to 2011 (from 1,189 to 3,493), and narcotic analgesic-related visits more than doubled (from 1,940 to 4,836), a 149.3 percent increase.

Addiction treatment admissions for heroin and other opiates (prescription painkillers and opium) continued to rise in 2013. The number of treatment admissions for heroin increased 12.4 percent, while treatment admissions for other opiates increased 10.7 percent from 2012 to 2013.

Heroin accounted for a record-high 14 percent of treatment admissions in 2013, compared with 12.9 percent in 2012, 7.8 percent in 2010, and 3.3 percent in 2000. Anecdotally, most of the young patients entering treatment programs report that they initially used prescription opiates before progressing to heroin addiction. Of the 3,063 heroin admissions in 2013, 40.2 percent were age 18-25. Males accounted for 65 percent, Whites 65.4 percent and injection was the most common route of administration (64.4 percent).

Other opiates were the primary substance problem reported by 2,081 admissions in 2013, which is 9.5 percent of total treatment admissions. This compares with 9.0 percent in 2012, 8.4 percent in 2010, and 1.4 percent in 2000. Of these admissions, one-half were female (49.8 percent). One-quarter (25.2 percent) were age 18-25. Whites accounted for 76.4 percent and oral was the most common route of administration (66.5 percent).

From 2012 to 2013, heroin exposures reported to the Hennepin Regional Poison Center went from 127 to 147, a 15.7 percent increase. Hydrocodone and oxycodone exposures declined in 2013. Hydrocodone with acetaminophen was the most frequently prescribed drug reported on the Minnesota Prescription Monitoring Program in March 2014. It accounted for 22 percent of all prescriptions; oxycodone with acetaminophen 9.2 percent; and oxycodone hydrochloride 8.3 percent.

All levels of law enforcement in the metropolitan area and statewide reported heightened activities focused on heroin in 2013. Minnesota multijurisdictional drug and violent crime task forces seized 203.8 percent more heroin in 2013 than in 2012. Heroin incidents reported by the Minneapolis Police Department rose significantly in recent years, although declined somewhat in 2013. Heroin was present in 10.9 percent of the drug items analyzed by NFLIS in 2013, compared with 10.2 percent in 2012. A series of raids carried out by Federal, state and local law enforcement agents in the Twin Cities, Duluth and Rochester, Minnesota in April 2014, resulted in the arrest of 80 individuals charged with varying counts of heroin trafficking.

Mexico, and to a lesser extent South America, were the primary sources of heroin in the Twin Cities and Minnesota. Distribution is Mexican drug cartel-involved. Local heroin includes the chunky, black tar heroin

and the brownish-colored powdered heroin. Mexican heroin typically sells for \$20 per dosage unit and \$100 - \$200 per gram. An "eight-ball" (1/8 of an ounce) costs roughly \$300. An ounce of black tar ranges in price from \$1,600 to \$2,200 and South American from \$1,700 to \$2,400. An ounce of Mexican heroin typically costs \$2,400.

Opium smoking within the Twin Cities' Hmong community remained an ongoing concern. The opium is concealed in various packages that are shipped from Asia.

Due to new State legislation in 2014, naloxone, the antidote to opioid overdose will be more widely available in Minnesota and immunity granted to those who call 911 reporting an overdose. "Steve's Law," named after Steve Rummier, who died of a heroin overdose in 2011, and after whom the Steve Rummier Hope Foundation was formed and named, follows at least 19 other states and the District of Columbia in establishing Good Samaritan laws and/or access to naloxone.

COCAINE

Overall, cocaine-related deaths, emergency department visits, and admissions to addiction treatment programs have declined in the Twin Cities area since 2007. Yet from 2012 to 2013, cocaine-related deaths increased from 18 to 28 in Hennepin and from 3 to 9 in Ramsey County. Cocaine-related hospital emergency department visits declined 36.7 percent from 2006 to 2011.

Cocaine-related treatment admissions declined 59.1 percent from 2007 to 2013, accounting for 4.3 percent of treatment admissions in 2013. Most cocaine-related treatment admissions in 2013 (76.4 percent) were for crack cocaine. Over half (58.7 percent) were African-American, females accounted for 40.4 percent, and almost three-quarters (74.5 percent) were age 35 and older.

Cocaine was present in 22.6 percent of the drug items analyzed by NFLIS laboratories in 2013, compared with 17.9 percent in 2012. A gram of cocaine powder cost \$80 to \$120. An ounce ranged in price from \$1,000 to \$1,400; a pound from \$12,400 to \$16,000; and a kilogram from \$24,000 to \$31,000. African American street gangs remain involved in the street-level, retail distribution of crack cocaine. A rock of crack sold for \$15 to \$20.

METHAMPHETAMINE AND OTHER STIMULANTS

Methamphetamine-related deaths increased slightly from 2012 to 2013, in Hennepin County from 14 to 16 and in Ramsey County from 7 to 8. Methamphetamine-involved hospital ED visits declined from 2004 to 2009, increased sharply in 2010 (71.1 percent), and fell slightly in 2011.

Methamphetamine-related treatment admissions have been rising in the Twin Cities since 2009. In 2013 they accounted for 10.0 percent of total admissions, compared with 5.7 percent in 2009. Of these 2,185 admissions in 2013, smoking was the most common route of administration (66.0 percent).

Methamphetamine was present in 32.5 percent of drug items analyzed by NFLIS laboratories in 2013, compared with 22.6 percent in 2012. Mexican drug trafficking organizations control the distribution of methamphetamine that arrives in Minnesota from Mexico, California and Arizona. Methamphetamine cost \$20 per dosage unit and ranged in price from \$80 to \$100 per gram, \$900 to \$1,500 per ounce, and \$8,000 to \$16,000 per pound.

Khat (pronounced "cot") is a plant that is indigenous to East Africa and the Arabian Peninsula. Users chew the leaves, smoke it, or brew it in tea for its stimulant effects. It is used within the Somali community in the Twin Cities.

Methylphenidate (Ritalin®) is a prescription medication used in the treatment of attention deficit hyperactive disorder. Adolescents and young adults use it nonmedically to increase alertness and suppress appetite.

Crushed and snorted, or ingested orally, each pill sells for up to \$5 or is simply shared with others at no cost. It is sometimes known as a "hyper pill" or "the study drug." In March 2014, 6.3 percent of prescriptions reported to the Minnesota Prescription Monitoring Program were for methylphenidate, and 10.1 percent were for amphetamines.

MDMA (3,4-methylenedioxymethamphetamine), also known as ecstasy, "X," or "e," is typically sold for \$20 per pill, and has stimulant and mild hallucinogenic properties. It produces feelings of energy and euphoria in users, but can adversely heighten body temperature and precipitate feelings of confusion and agitation. "Molly" (slang for "molecular"), refers to an allegedly pure crystalline powder form of the drug MDMA, but analysis has sometimes determined that the tablets actually contain methylone, a chemical often found in "bath salts." There were 19 MDMA exposures reported to the Hennepin Regional Poison Center in both 2012 and 2013.

MARIJUANA

In 2013, 15.5 percent of admissions to addiction treatment programs involved marijuana as the primary substance problem, compared with 16.3 percent in 2012. Of these 3,390 admissions, 27.1 percent were younger than 18; 38.4 percent were age 18–25; and females accounted for 22.8 percent, the lowest percentage of females in any drug category. Marijuana-involved visits at hospital emergency departments grew 52.5 percent from 2004 to 2010, and slightly declined from 2010 to 2011 (from 6,794 to 6,627).

Marijuana/cannabis was present in 8.3 percent of items analyzed by NFLIS laboratories in 2013, compared with 17.8 percent in 2012. Standard grade marijuana sold for \$5 per joint, and up to \$225 per ounce and \$1,500 per pound. Higher quality "BC Bud" marijuana from Canada and the Pacific Northwest enters Minnesota through Montana and North Dakota, with the involvement of Asian drug trafficking organizations. The cost ranges from \$2,800 to \$4,200 per pound. Local indoor cultivation operations continued, sometimes located in unsuspecting homes in residential suburban neighborhoods. In July 2013, law enforcement agents seized 5,500 high grade marijuana plants at a large outdoor grow operation near Hinckley, Minnesota, about 80 miles north of the Twin Cities.

Synthetic cannabinoids (cannabimimetics) refer to synthetically produced chemicals that are sprayed onto dried herbal mixtures, and smoked to mimic the effects of THC, the active ingredient in plant marijuana. They are sold as "herbal incense" with a warning "not for human consumption." Although these products are illegal to sell or possess under State and Federal laws, they continue to be sold online under many names, such as "K2," "Spice," "Stairway to Heaven," or "California Dreams." The Hennepin Regional Poison Center reported 149 THC homolog exposures in 2011, 157 in 2012, and 110 in 2013. From 2010 to 2011 hospital ED visits for synthetic cannabinoids rose from 170 to 418.

Due to new legislation passed by the 2014 legislature, medical use of marijuana will be allowed through a program administered by the Minnesota Department of Health.

HALLUCINOGENS AND OTHER SYNTHETICS

LSD (lysergic acid diethylamide) or "acid," is a synthetically produced, long-acting hallucinogen, that is typically sold as saturated, tiny pieces of paper, known as "blotter acid," for \$5 to \$10 per dosage unit. The Hennepin Regional Poison Center reported 15 LSD exposures in 2012, 45 in 2013, and 11 in 2014 (first quarter).

Substituted cathinones, sold as so-called "bath salts," are consumed to produce effects similar to MDMA. Substituted cathinones may contain mephedrone or many other chemicals alone or in combination, such as MDPV (3,4-methylenedioxypropylvalerone), methylone (3,4-methylenedioxypropylmethcathinone or MDMC), naphyrone (naphthylpropylvalerone or NRG-1), 4-Fluoromethcathinone or 3-FMCO, methedrone (4-methoxymethcathinone or bk-PMMA or PMMC), or butylone (beta-keto-N-methylbenzodioxolylpropylamine or bk-MBDB). These are sold under names such as "Vanilla Sky," "Bliss," and "Ivory Wave." Mephedrone by itself is also known as "Meow Meow," "M-CAT," "Bubbles," or "Mad Cow." Because the actual ingredients

are unknown, the effects are unpredictable and can include agitation, paranoid delusions, and extreme psychosis. The Hennepin Regional Poison Center reported 144 bath salt exposures in 2011, 87 in 2012 and 50 in 2013.

2C-E phenethylamine (2,5-dimethoxy-4-ethylphenylethylamine) and related analogs are sold online as so-called "research chemicals." In January 2014, a 17 year-old female died after 25I-NBOMe use in suburban Woodbury in Washington County. In May, the three juveniles and two adults who were involved in the chain of custody of the drug, were charged with third degree murder. In March 2014 a 22 year-old male and 17 year-old female died after ingesting chemicals in the 2C family in Mankato, Minnesota, located 90 miles southwest of the Twin Cities. The chemicals were purchased locally in small zip lock bags. In June 2013, a 30 year-old male in Ramey County died from probable 25I-NBOMe toxicity. "N-bomb" is also known as "legal acid," "smiles," or simply "25-I," and refers to these closely related synthetic hallucinogens 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe. In 2011, 2C-E use by a group of young people in suburban Blaine, Minnesota, resulted in eleven emergency room visits and the death of a 19 year-old male. Hennepin Regional Poison Center exposures for 2C analogs were 23 in 2011, 24 in 2012, and 35 in 2013.

Analysis has shown that a single packet of a synthetic drug, such as a bath salt or research chemical, can contain a single chemical component or multiple components, and that ingredients and the concentration of ingredients within single brand name change over time. For these reasons, it is especially difficult to identify these substances, and to establish predictability in dosage amounts or effects.

Statewide law enforcement task forces seized 1,017,252 grams of synthetic drugs in 2013, compared with 4.648 grams in 2012. In October 2013 the owner of head shop in Duluth, Minnesota was convicted of 51 counts for the sale of synthetic drugs including bath salts, research chemicals and synthetic cannabimimetics.

ALCOHOL AND TOBACCO

Less than one-half (43.9 percent) of total admissions to addiction treatment programs reported alcohol as the primary substance problem in 2013. Of these 9,601 patients, over one-half (60.2 percent) were 35 and older. Tobacco smoking is widespread among patients admitted to addiction treatment programs. Rates of current smoking range from a high of 84.0 percent of heroin admissions, to a low of 59.6 percent of alcohol admissions.

Drug Abuse-Related Infectious Diseases

Hepatitis C is a chronic liver disease that results from infection with the Hepatitis C virus (HCV). Most people contract HCV by sharing needles or other equipment used to inject drugs. As of December 31, 2013, in Minnesota there were 40,943 persons living with past or present HCV infection, and 7,723 persons living with HIV/AIDS (human immunodeficiency virus/acquired immunodeficiency syndrome), mostly in the Twin Cities metropolitan area. Regarding the mode of exposure among the 301 new cases of HIV/AIDS infection diagnosed in 2013 in Minnesota, male-to-male sex (MSM) accounted for 62 percent of cases among males; injection drug use accounted for 3 percent; and MSM and injection drug use accounted for 7 percent. Among females, heterosexual contact accounted for 89 percent, and injection drug use 3 percent.

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Exhibit 1

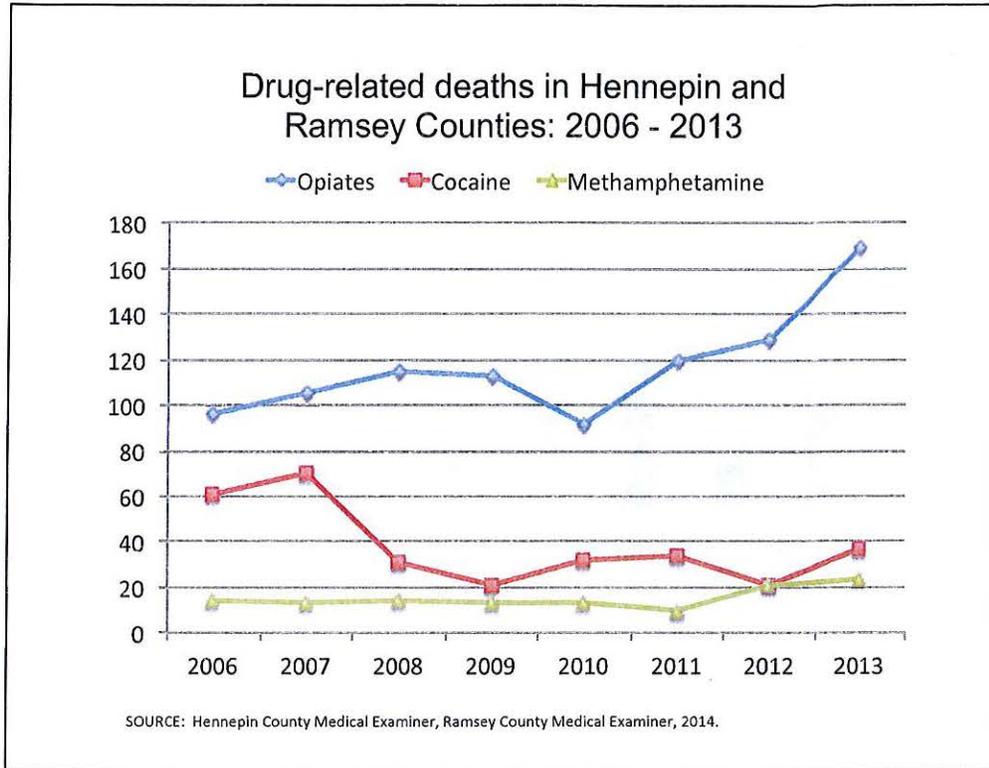


Exhibit 2

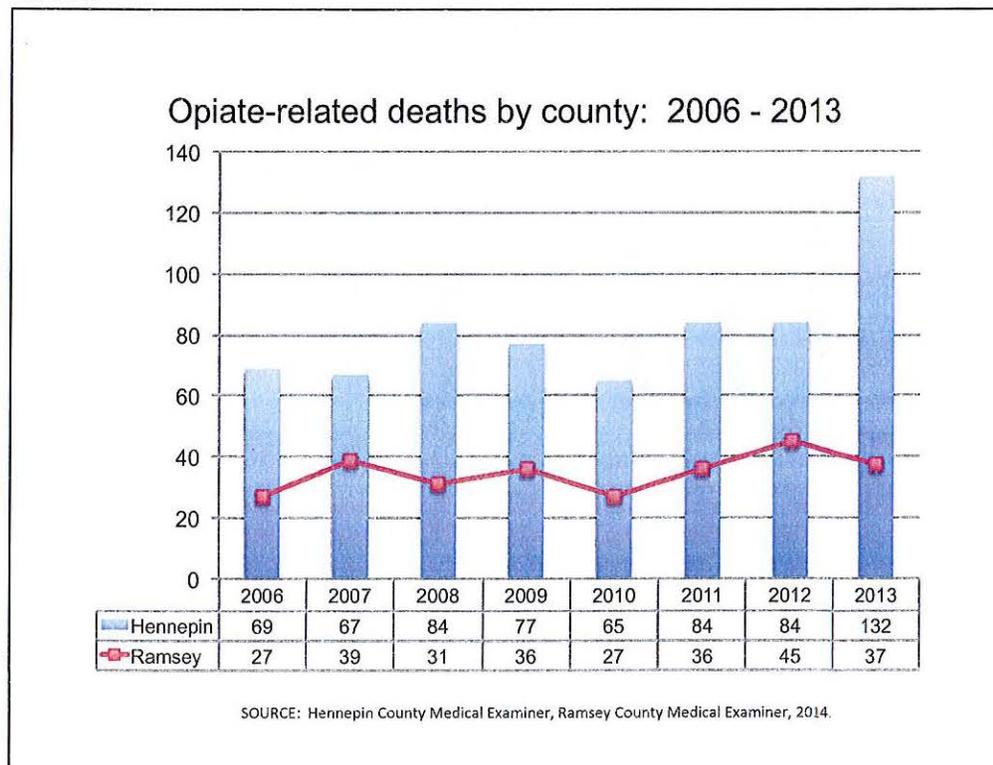


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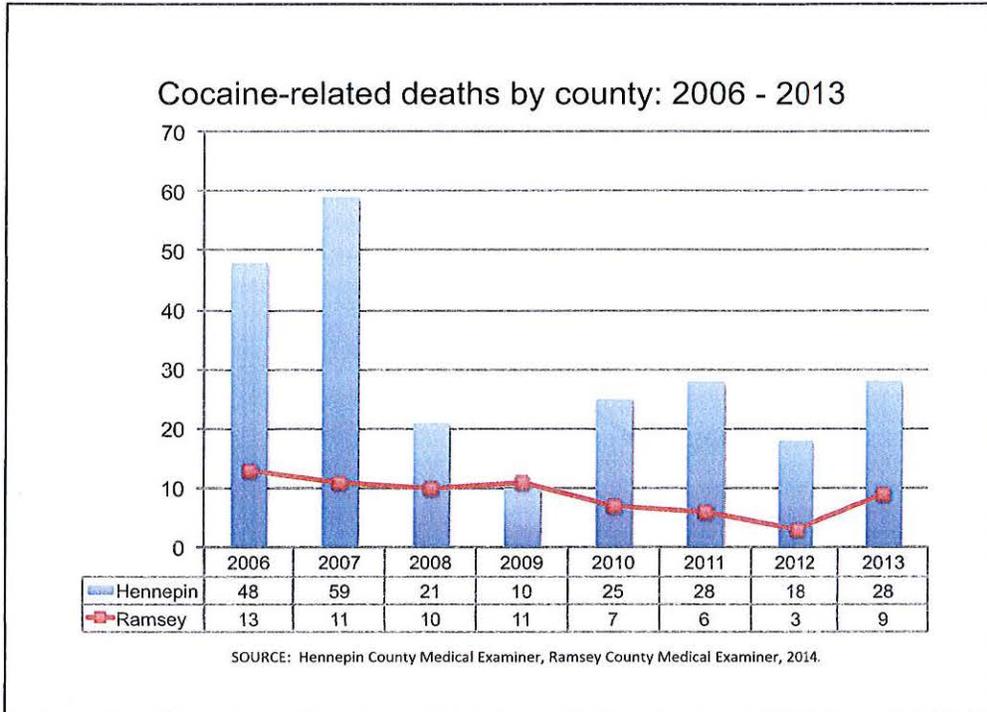


Exhibit 4

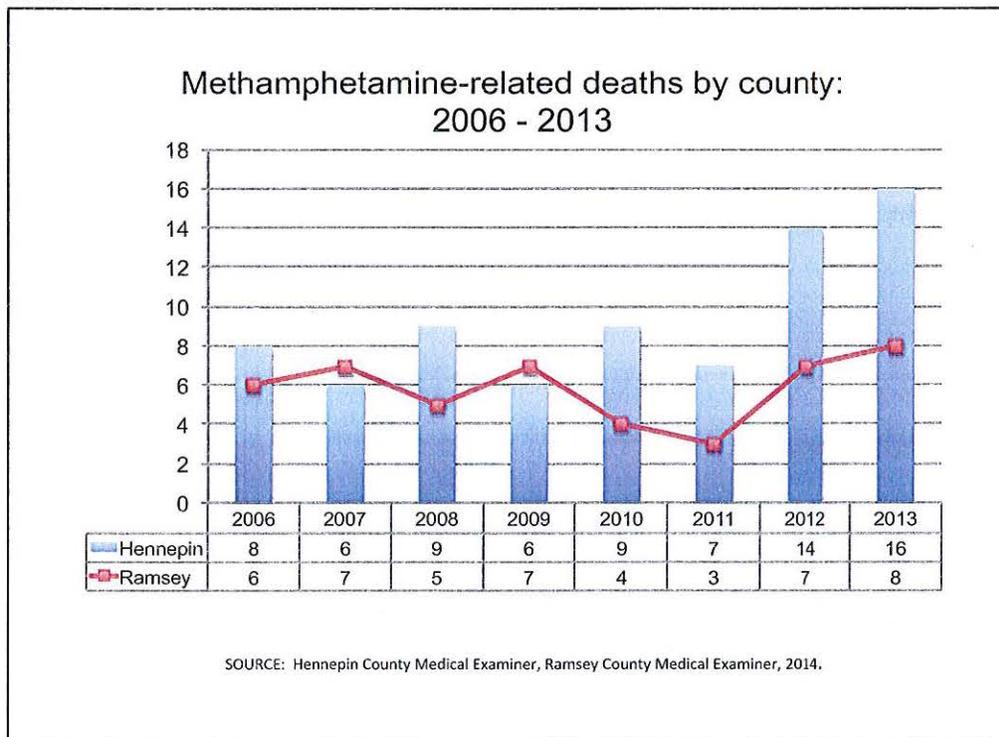


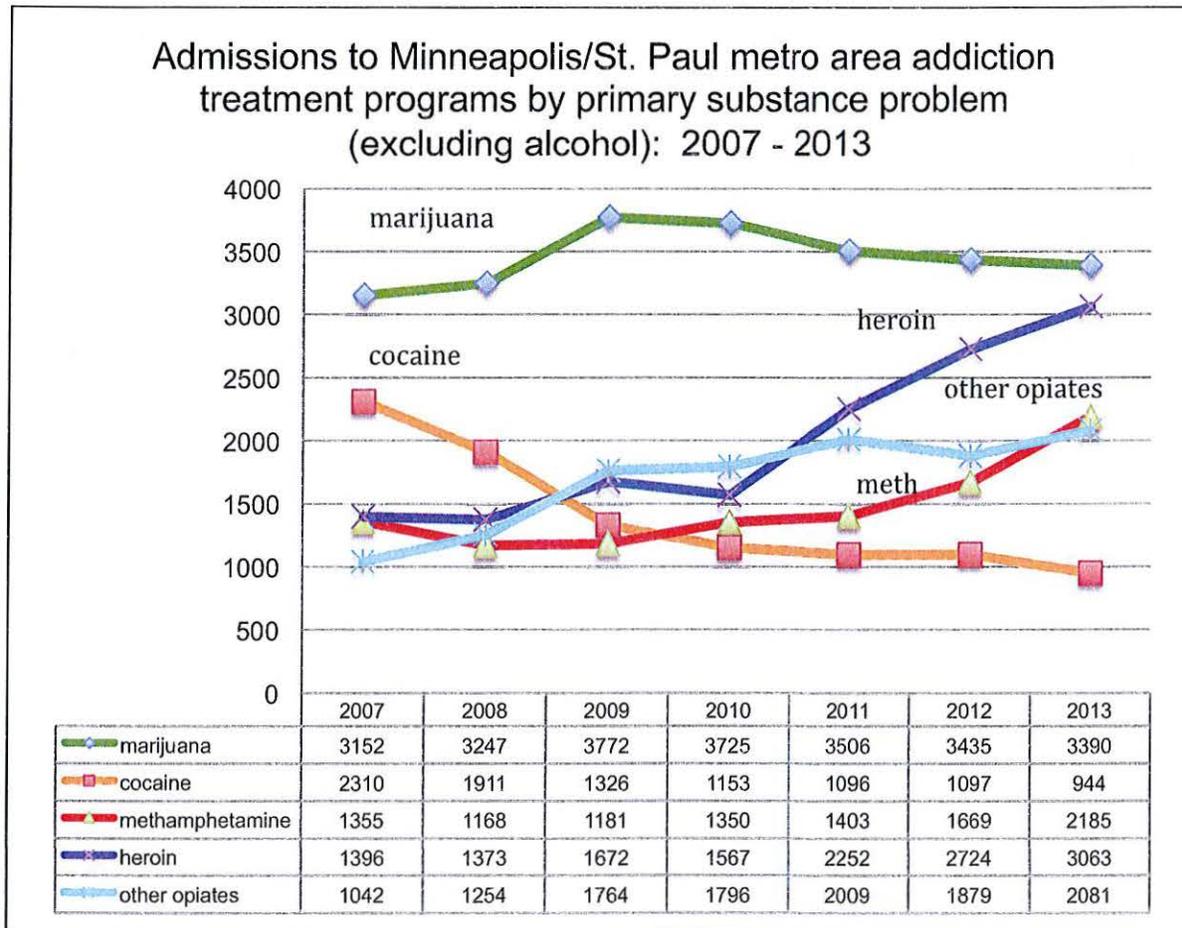
Exhibit 5

Hospital emergency department visits of selected drugs
in the Minneapolis/St. Paul/Bloomington, MN-WI
Metropolitan Statistical Area: 2004 - 2011

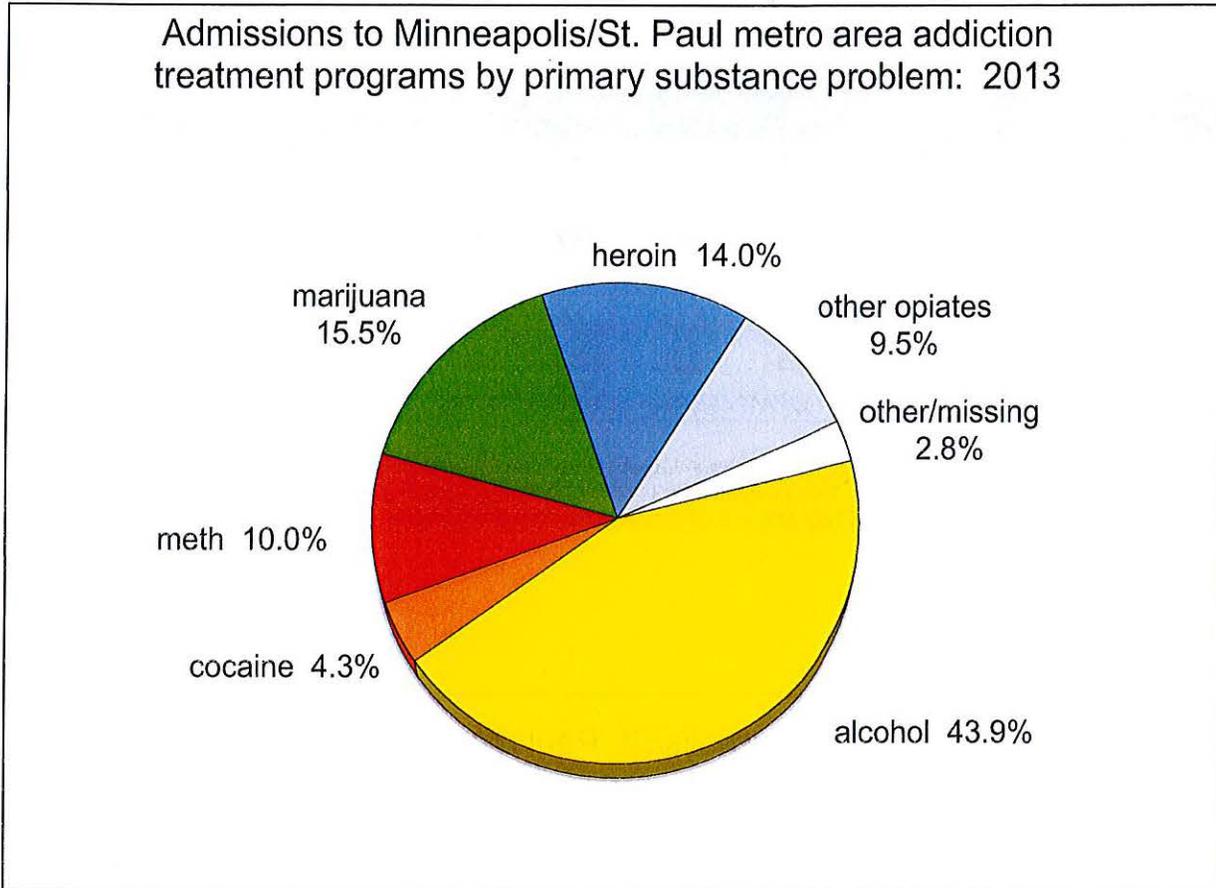
Drug	2004	2005	2006	2007	2008	2009	2010	2011
Cocaine	6,228	6,076	6,764	5,189	5,390	3,843	4,141	4,279
Heroin	1,189	1,023	1,312	1,691	1,651	1,855	2,256	3,493
Marijuana	4,455	4,468	4,302	5,757	5,617	5,596	6,794	6,627
Synthetic cannabinoids	*	*	*	*	*	*	170	418
Methamphetamine	1,741	2,209	1,120	1,103	1,001	970	1,660	1,541
MDMA (Ecstasy)	204	254	252	433	485	475	362	397
Total Narcotic analgesics	1,940	1,872	2,491	3,391	3,905	3,890	4,697	4,836

SOURCE: Drug Abuse Warning Network, Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, accessed 9/12/2012. These weighted estimates of ED visits are based on a representative sample of non-Federal, general, short-stay hospitals with 24-hour EDs in the Minneapolis/St. Paul/Bloomington, MN-WI Metropolitan Statistical Area.

Exhibit 6



SOURCE: Drug and Alcohol Abuse Normative Evaluation System, Minnesota Department of Human Services, 2014.



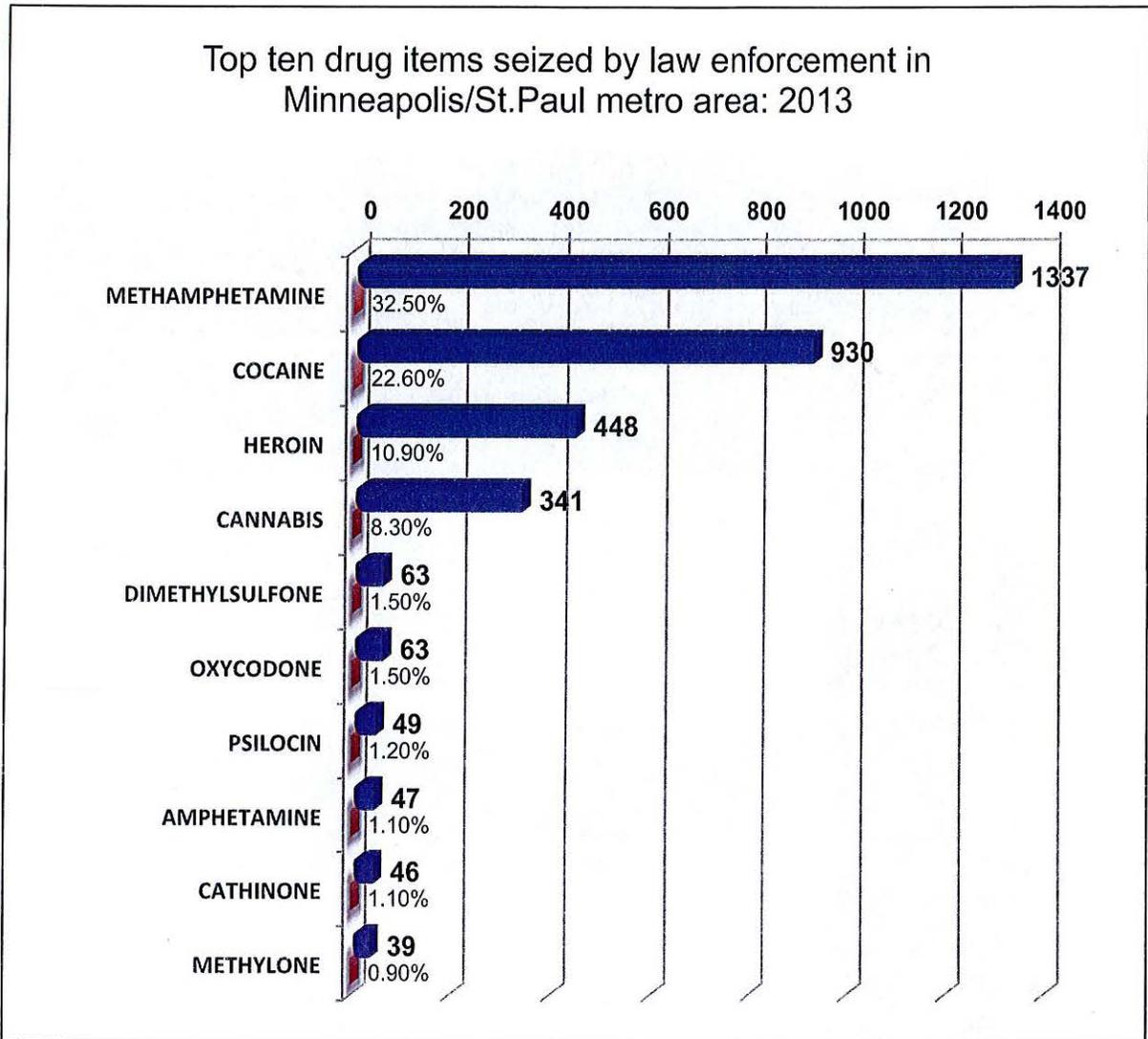
SOURCE: Drug and Alcohol Abuse Normative Evaluation System, Minnesota Department of Human Services, 2014.

Exhibit 8

Characteristics of patients admitted to Minneapolis/St. Paul metro area addiction treatment programs by primary substance problem: 2013

TOTAL ADMISSIONS 21,856	ALCOHOL 9,601 43.9%	MARIJUANA 3,390 15.5%	COCAINE 944 4.3%	METH 2,185 10.0%	HEROIN 3,063 14.0%	OTHER OPIATES 2,081 9.5%
GENDER						
% MALE	68.1	77.2	59.6	63.4	65.0	50.2
% FEMALE	31.9	22.8	40.4	36.6	35.0	49.8
RACE/ETHNICITY						
% WHITE	72.8	49.9	26.5	78.9	65.4	76.4
% AFRICAN AM	14.7	31.2	58.7	2.5	18.2	4.9
% AM INDIAN	3.5	3.4	3.9	3.2	7.1	8.8
% HISPANIC	4.5	7.7	5.4	6.4	4.8	3.9
% ASIAN/PACIFIC ISL	1.9	1.6	1.1	5.0	0.9	2.4
% OTHER	2.6	6.1	4.4	3.9	3.6	3.6
AGE						
% 17 AND UNDER	1.3	27.1	0.8	2.6	1.0	1.2
% 18 - 25	14.7	38.4	6.4	24.5	40.2	25.2
% 26 - 34	23.8	20.1	18.3	38.2	27.0	33.7
% 35 +	60.2	14.5	74.5	34.8	31.8	39.9
ROUTE OF ADMINISTRATION						
% ORAL/MULTIPLE	100	1.82.5	-	5.3	0.8	66.5
% SMOKING		98.2	76.4	66.0	8.1	5.2
% SNORTING		-	23.1	7.7	26.6	17.3
% INJECTION		-	0.5	20.9	64.4	11.1
% UNKNOWN		-	-	-	-	-
% CURRENT SMOKERS	59.6	69.3	76.6	78.4	84.0	71.2

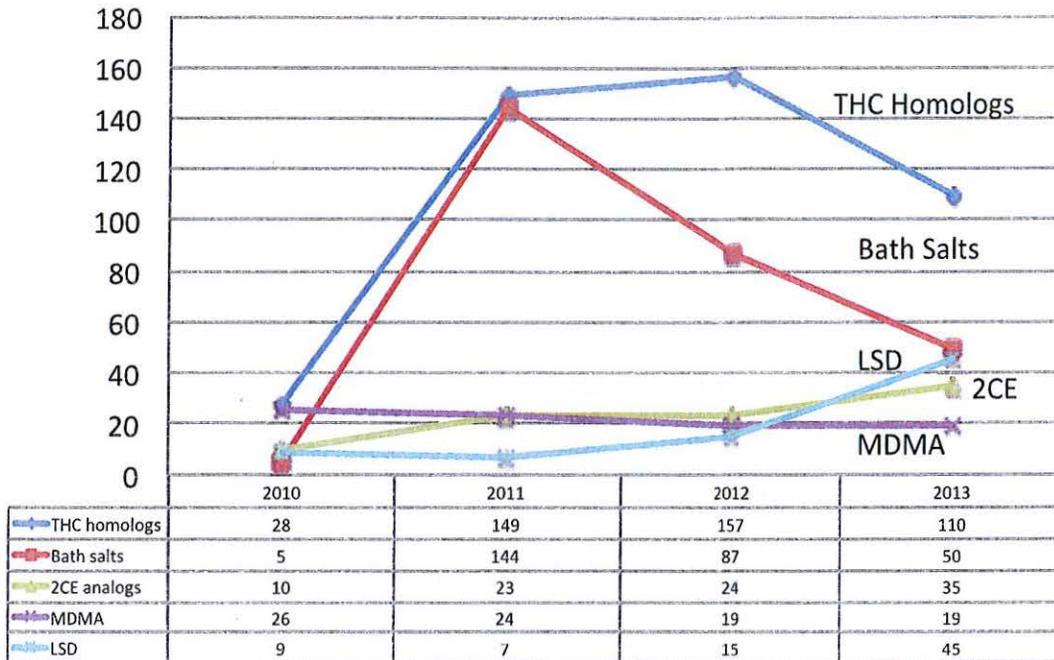
SOURCE: Drug and Alcohol Abuse Normative Evaluation System, Minnesota Department of Human Services, 2014. Unknown primary drug = 262 (1.2%). All other primary drugs = 330 (1.5%).



SOURCE: National Forensic Laboratory Information System (NFLIS), U.S. Drug Enforcement Administration (DEA) queried on 5/9/2014 according to location of seizure. All federal, state and local laboratory data are included in the total number of drug items seized as primary, secondary or tertiary drugs in the 7-county metro area including the counties of Anoka, Carver, Dakota, Hennepin, Ramsey, Scott and Washington in calendar 2013, except St. Paul crime lab data that were not reported after May 2012. Total items = 4,108. All other = 18.4%.

Exhibit 10

Synthetic drug exposures: 2010 - 2013



SOURCE: Hennepin Regional Poison Center, Hennepin County Medical Center, 2014.

Exhibit 11

Selected opiate-related exposures: 2010 through April 2014

	2010	2011	2012	2013	1Q 2014
Hydrocodone	621	655	713	605	135
Oxycodone	580	575	636	579	143
Heroin	52	78	127	147	37

SOURCE: Hennepin Regional Poison Center, Hennepin County Medical Center, 2014.

Exhibit 12

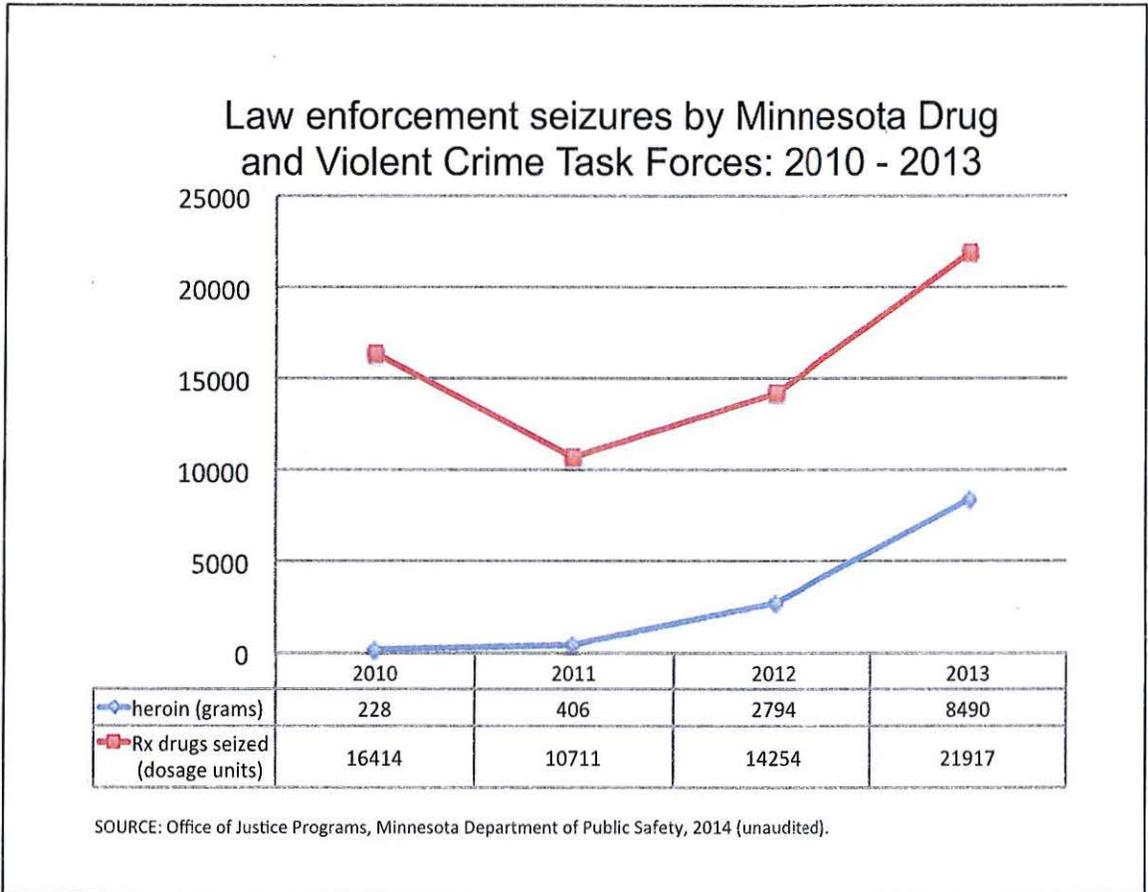


Exhibit 13

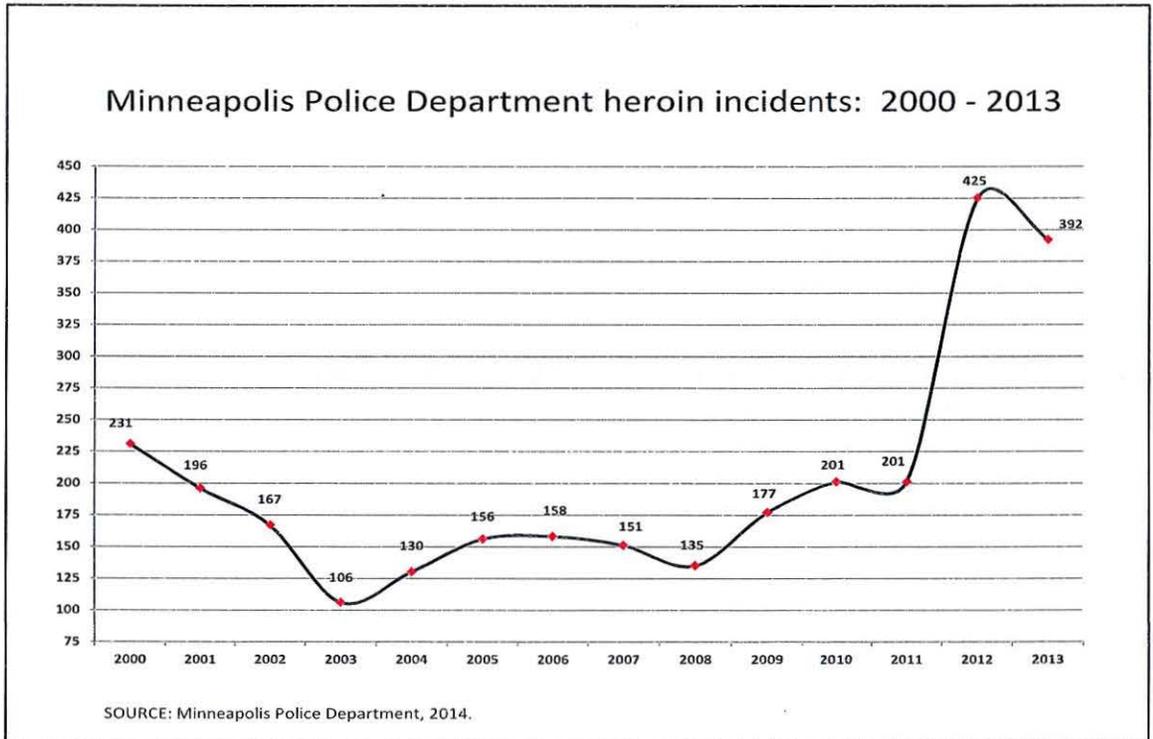


Exhibit 14

Top ten prescriptions dispensed in Minnesota: March 2014

DRUG	# OF PRESCRIPTIONS	% OF ALL PRESCRIPTIONS
Hydrocodone with acetaminophen	108,498	22
Oxycodone HCL (8.3%) and oxycodone with acetaminophen (9.2%)	87,999	17.5
Dextroamphetamine/amphetamine	50,750	10.1
Zolpidem tartrate	41,166	8.2
Lorazepam	38,557	7.7
Methylphenidate HCL	31,780	6.3
Clonazepam	31,195	6.2
Alprazolam	27,781	5.5
Acetaminophen with codeine	13,177	2.6

SOURCE: Prescription Monitoring Program Monthly Report, Issue 15, Minnesota Board of Pharmacy, March 2014. Total prescriptions dispensed and reported to the Prescription Monitoring Program in March 2014 = 503,613.

Attachment 3

Vital Signs: Risk for Overdose from Methadone Used for Pain Relief — United States, 1999–2010

On July 3, 2012, this report was posted as an MMWR Early Release on the MMWR website (<http://www.cdc.gov/mmwr>).

Abstract

Background: Vital statistics data suggest that the opioid pain reliever (OPR) methadone is involved in one third of OPR-related overdose deaths, but it accounts for only a few percent of OPR prescriptions.

Methods: CDC analyzed rates of fatal methadone overdoses and sales nationally during 1999–2010 and rates of overdose death for methadone compared with rates for other major opioids in 13 states for 2009.

Results: Methadone overdose deaths and sales rates in the United States peaked in 2007. In 2010, methadone accounted for between 4.5% and 18.5% of the opioids distributed by state. Methadone was involved in 31.4% of OPR deaths in the 13 states. It accounted for 39.8% of single-drug OPR deaths. The overdose death rate for methadone was significantly greater than that for other OPR for multidrug and single-drug deaths.

Conclusions: Methadone remains a drug that contributes disproportionately to the excessive number of opioid pain reliever overdoses and associated medical and societal costs.

Implications for Public Health Practice: Health-care providers who choose to prescribe methadone should have substantial experience with its use and follow consensus guidelines for appropriate opioid prescribing. Providers should use methadone as an analgesic only for conditions where benefit outweighs risk to patients and society. Methadone and other extended-release opioids should not be used for mild pain, acute pain, “breakthrough” pain, or on an as-needed basis. For chronic noncancer pain, methadone should not be considered a drug of first choice by prescribers or insurers.

Introduction

U.S. physicians have used the synthetic opioid methadone as a treatment for heroin addiction since the 1960s and increasingly as a treatment for chronic noncancer pain since the mid-1990s (1). Individual states began to report increasing numbers of overdose deaths involving methadone in 2003 (2). Subsequently, rates of deaths and emergency department (ED) visits involving methadone have increased nationwide (3,4). Studies using medical examiner data suggested that more than three quarters of methadone overdoses involved persons who were not enrolled in programs treating opioid addiction with methadone and that most persons who overdosed were using it without a prescription (3). In November 2006, the Food and Drug Administration (FDA) issued a warning regarding careful prescribing of methadone because of the sharp rise in overdose deaths among patients receiving methadone for pain (5). FDA also revised the interval for the recommended starting dosage from 2.5–10 mg every 3–4 hours to 2.5–10 mg every 8–12 hours. In January 2008, on request of the Drug Enforcement Administration (DEA), manufacturers voluntarily limited distribution of the largest (40 mg) formulation of methadone to authorized opioid addiction treatment programs and hospitals

only, because this formulation was not approved for the treatment of pain (6).

Recent analyses have shown that methadone was involved in one in three opioid-related deaths in 2008 (7). Moreover, the involvement of methadone in drug overdose deaths, in toxic exposures quantified by poison centers, and in diversion to nonpatients is disproportionate to the number of methadone prescriptions for pain when compared with other opioid pain relievers (3,8). Analysis of ED data indicates that the estimated number of ED visits resulting from nonmedical use of methadone alone or in combination with other drugs in 2009 (n = 63,031) was significantly greater than the estimated number in 2004 (n = 36,806) (4). CDC reviewed national data on trends in methadone use and mortality and data from medical examiners on methadone mortality to determine whether additional recommendations for its safe use for pain treatment are necessary.

Methods

For this report, national death rates during 1999–2009 are based on the National Vital Statistics System multiple cause of death files (9). Methadone-related deaths were defined as those with an underlying cause of death classified by the *International*

Classification of Diseases, 10th Revision (ICD-10) external cause of injury codes as X40-X44, X60-X64, X85, or Y10-Y14 and an ICD-10 code (T40.3) for methadone poisoning. Methadone might have been listed alone or in combination with other drugs.

The amounts of opioid pain relievers distributed for 1999–2010 nationally and by state were obtained from the DEA's Automation of Reports and Consolidated Orders System (ARCOS).^{*} Distributions of methadone to opioid treatment programs were not included. Annual numbers of prescriptions dispensed for methadone and other opioids in outpatient settings for 1999–2009 came from an analysis conducted by FDA in 2010 using a commercial prescription and patient measurement service (Vector One: National [VONA]) that can estimate the number of prescriptions for drugs dispensed by outpatient retail pharmacies in the United States (10).

Population-based counts of drug-related deaths for methadone and other opioids in 2009 came from 13 states in the Medical Examiner component of the Drug Abuse Warning Network (DAWN): Delaware, Massachusetts, Maryland, Maine, New Hampshire, New Mexico, Oklahoma, Oregon, Rhode Island, Utah, Virginia, Vermont, and West Virginia.[†] State medical examiners provided information on all drug-related deaths, and CDC analyzed the deaths involving an opioid, whether in combination with other drugs or by itself. Opioid distribution data for these states were available from the ARCOS system and converted to morphine milligram equivalents (MME) using a standard reference (11).

Comparison of methadone to other major opioids in DAWN data was based on rates of death per 100 kg of opioid analgesic in MME. Drug-specific rates were compared using rate ratios and 95% confidence intervals with the rates for methadone as the referents.

Results

The rate of overdose deaths involving methadone in the United States in 2009 was 5.5 times the rate in 1999 (Figure 1). The mortality rate peaked at 1.8 deaths per 100,000 persons in 2007 and then declined in parallel with the amount of methadone being distributed nationally in 2008 and 2009. The annual rate of methadone prescriptions for pain rose to 1.5 per 100 persons by 2008 and did not increase further in 2009. Methadone accounted for 4.4 million (1.7%) of the 257 million opioid prescriptions in 2009. However, in 2010, methadone accounted for 9.0% of all the MME of all major opioids tracked by ARCOS other than buprenorphine. This proportion varied by state from 4.5% in New Jersey to 18.5% in Washington (Figure 2).

^{*} Information about the DEA's ARCOS system is available at <http://www.deadiversion.usdoj.gov/arcos>.

[†] Information about the DAWN Medical Examiner system is available at <http://www.samhsa.gov/data/2k11/dawn/2k9dawnme/html/dawn2k9me.htm>.

Among the 13 DAWN Medical Examiner states, methadone accounted for 9.8% of the MME tracked by ARCOS. Methadone was involved in 31.4% of the 3,294 deaths involving these opioids, more than any opioid other than oxycodone in 2009 (Table). Among the 748 single-drug deaths, methadone was involved in 298 (39.8%), twice as many as any other opioid. The rate of methadone deaths per 100 kg sold in MME was significantly higher than that for any other opioid for both all deaths and single-drug deaths. The difference between methadone and other opioids was more pronounced in the analysis of single-drug deaths. Even if some of these deaths (e.g., 25%) had been attributable to methadone dispensed from opioid treatment programs, the differences between methadone and other opioids would remain significant. The methadone death rate was still significantly higher than the rate for any other opioid in both comparisons.

Conclusions and Comment

The primary advantages of using methadone over other opioids for pain treatment are its long duration of action, relatively low cost, and availability in liquid formulation for oral use. Its primary disadvantages are its long and unpredictable half-life and associated risk for accumulating toxic levels leading to severe respiratory depression; its multiple interactions with other drugs, including frequently abused drugs such as antianxiety agents; and its ability to cause major disturbances of cardiac rhythm (12).

Increased use of methadone since 1999 might have been prompted by growing costs of treating pain with opioids and increasing reports of abuse of other, more expensive, extended-release opioids (1). Overdose reports and interventions by FDA and DEA might have resulted in declines in the amount of methadone distributed and methadone-related fatal overdoses in 2008, although the number of methadone prescriptions did not decline. The parallel trends in the amount of methadone distributed for use as a pain reliever and in the methadone mortality rate are consistent with methadone prescribed as a pain reliever being the primary determinant of methadone mortality rates (1,3).

Data suggest that some of the current uses of methadone for pain might be inappropriate. According to an analysis conducted by FDA, the most common diagnoses associated with methadone use for pain in 2009 were musculoskeletal problems (such as back pain and arthritis) (46%), headaches (17%), cancer (11%), and trauma (5%). Most methadone prescriptions were written by primary care providers or mid-level practitioners (e.g., nurse practitioners) rather than pain specialists. Nearly a third of prescriptions appear to have been dispensed to patients with no opioid prescriptions in the previous month (i.e., opioid-naïve patients) (10).

FIGURE 1. Rates of methadone distribution for pain, methadone-related overdose deaths, and methadone prescriptions for pain — United States, 1999–2010

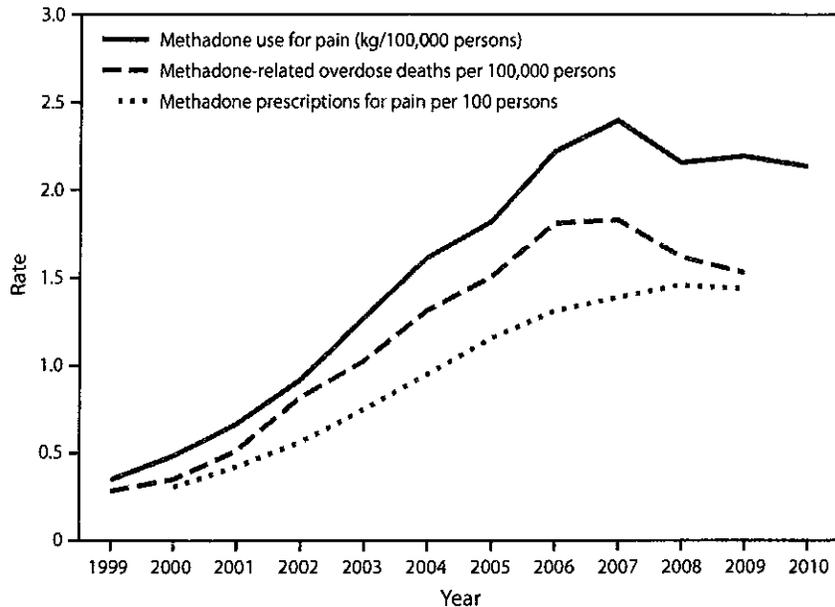
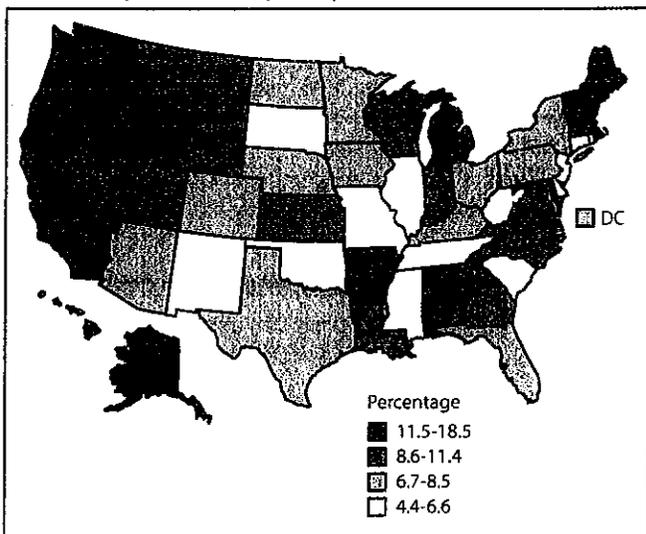


FIGURE 2. Percentage of opioid distribution accounted for by methadone prescribed for pain, by state — United States, 2010



The findings in this report are subject to at least five limitations. First, vital statistics underestimate the number of overdose deaths from specific drugs because the type of drug is not specified on many death certificates. Second, medical examiners in the DAWN system might have varying definitions of drug-related deaths. However, individual medical examiners likely apply the same definitions to all types of opioid analgesics. Third, assigning responsibility to any single drug in multidrug

overdoses is difficult. However, this is not an issue in single-drug deaths, among which the highest risks for methadone were observed. Fourth, some deaths might have resulted from methadone provided in take-home doses by opioid treatment programs, but adjusting for such deaths in this analysis did not change the overall results. Finally, ARCOS data reflect distributions to retail outlets by state, but some drugs might have been used by residents of neighboring states.

This study and others suggest that methadone remains a drug that contributes disproportionately to opioid pain reliever overdoses and associated medical and societal costs. Additional warnings to prescribers about dosage are likely to have limited effect, given the high prevalence of use without a prescription among persons who overdose. The public health goal now should be to mount a concerted effort to reserve methadone for those pain-related conditions for which the benefits

likely outweigh the risks to patients and society, such as use for cancer-related pain or palliative care. This will reduce the amount of methadone available for diversion and nonmedical use.

Methadone and other, extended-release opioids should not be used for mild pain, acute pain, “breakthrough” pain, or on an as-needed basis. For chronic noncancer pain, methadone should not be considered a drug of first choice. This is especially true for conditions for which the benefits of opioids have not been demonstrated, such as headache and low back pain. Only a small fraction of patients with intractable chronic headache treated with opioids experience long-term pain reduction or functional improvement (13). Evidence that any opioids are effective in chronic low back pain is limited (14). Additionally, methadone should not be prescribed to opioid-naïve patients, and, whenever possible, should not be prescribed to patients taking benzodiazepine anti-anxiety agents because of an increased risk for severe respiratory depression. Health-care providers who choose to prescribe methadone should have substantial experience with its use and follow consensus guidelines for appropriate opioid prescribing (15). Providers should instruct patients about the potential risks of methadone and how to store and dispose of it properly.

Public and private insurers and health-care systems can ensure that prescribers of methadone follow dosage guidelines by requiring authorization for starting doses for pain that exceed the recommended upper limit of 30 mg per day (5). Insurance formularies should not list methadone as a preferred drug for the treatment of chronic noncancer pain. Pharmaceutical companies

TABLE. Drug-related deaths involving opioids, by type of opioid — Drug Abuse Warning Network Medical Examiner System, 13 states, 2009

Opioid	No.	Death rate per 100 kg MME	RR	(95% CI)
All deaths				
Buprenorphine	20	0.8	0.02	(0.01–0.04)
Fentanyl	364	7.7	0.28	(0.25–0.32)
Hydrocodone	550	14.3	0.42	(0.38–0.47)
Hydromorphone	74	9.1	0.27	(0.21–0.34)
Morphine	824	20.2	0.64	(0.58–0.70)
Oxycodone	1,097	8.7	0.26	(0.24–0.28)
Methadone	1,034	33.6	1.00	referent
Total*	3,294	10.4		
Single-drug deaths				
Buprenorphine	2	0.1	0.01	(0.00–0.03)
Fentanyl	99	2.1	0.26	(0.21–0.33)
Hydrocodone	42	1.1	0.11	(0.08–0.16)
Hydromorphone	4	0.5	0.05	(0.02–0.14)
Morphine	153	3.8	0.41	(0.34–0.50)
Oxycodone	150	1.2	0.12	(0.10–0.15)
Methadone	298	9.7	1.00	referent
Total	748	2.4		

Abbreviations: MME = morphine milligram equivalent; RR = rate ratio; CI = confidence interval.

* Counts for each opioid might not sum to the total shown for all deaths because some deaths involved more than one opioid.

should introduce a 2.5-mg formulation of methadone to facilitate treatment with the lowest recommended dosage.

Although interventions related to methadone use are urgently needed, government agencies, health-care providers, insurers, and other stakeholders must combine these interventions with measures that will address the problems of misuse and abuse of all opioid pain relievers. Interventions such as the use of prescription drug monitoring programs, appropriate screening and monitoring before prescribing opioid pain relievers, regulatory and law enforcement efforts, and state policies (e.g., “pill mill” laws) aimed at providers and patients involved in diversion of these drugs continue to be essential elements in addressing this public health emergency.

Reported by

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Key Points

- Between 1999 and 2009, the rate of fatal overdoses involving methadone increased more than fivefold as its prescribed use for treatment of pain increased.
- Methadone is involved in approximately one in three opioid-related overdose deaths. Its pharmacology makes it more difficult to use safely for pain than other opioid pain relievers.
- Methadone is being prescribed inappropriately for acute injuries and on a long-term basis for common causes of chronic pain (e.g., back pain), for which opioid pain relievers are of unproven benefit.
- Insurance formularies should not list methadone as a preferred drug for the treatment of chronic noncancer pain. Methadone should be reserved for use in selected circumstances (e.g., for cancer pain or palliative care), by prescribers with substantial experience in its use.

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Attachment 4

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Methadone-Related Deaths in Hennepin County, Minnesota: 1992–2002

ABSTRACT: Methadone maintenance therapy (MMT) is the only currently established medical therapy for heroin addiction. However, MMT still remains controversial. In Hennepin County, Minnesota, methadone is one of the top ten drugs reported in medical examiner investigated deaths and one of the most commonly diverted pharmaceuticals. This report reviews the role of methadone in medical examiner deaths over a 10-year period, 1992–2002. We compare cause and manner of death (accidental, natural, suicide) and methadone blood concentrations for decedents who were members of MMT programs with illicit users and those prescribed methadone for chronic pain. Findings reveal that 65% of decedents with measurable blood methadone concentrations were not participating in MMT programs. A total of 96 cases were identified, with the majority white (90.5%) and male (76.8%). MMTP program members were the minority (34.7%) of the methadone positive deaths and 39% were illicit users. Fifteen percent were chronic pain patients with almost half of this group dying from overdose. Methadone concentrations of drug caused/related deaths (0.18–3.99 mg/L) overlapped with those of deaths not attributable to methadone (0.18–3.03 mg/L) with no definable lethal level. Interpretation of methadone blood concentrations must be done in the context of the clinical history for determining cause of death, and may be confounded by post-mortem redistribution.

KEYWORDS: forensic science, methadone, blood concentration, methadone maintenance treatment, pharmacokinetics

Methadone maintenance therapy (MMT) evolved in America in the 1960s with the report of Nyswander and Dole's clinical trial (1). In their group of 22 patients, they found that methadone maintenance combined with psychological and social services could effectively rehabilitate heroin abusers. Previous trials had been problematic due to inadequate maintenance drugs (1). For example, morphine is a short-acting drug requiring multiple daily doses and parenteral self-administration, with demonstrated fluctuating concentrations throughout the day (1). In addition, patients required progressive increases in dose as tolerance developed (2). Methadone has the advantages of long half-life, high oral bioavailability, and stabilization at one dose with chronic administration (1). Thus, MMT has become an established medical therapy for heroin addiction.

In 1988, the concept of MMT was revisited through the advancement of the metabolic theory of addiction as a physiological imbalance caused by chronic opiate abuse with the use of methadone analogous to insulin (2). Only through the chronic occupation of narcotic receptors would an individual achieve neuroendocrine homeostasis and end drug craving. Equilibrium between tissue-bound and serum methadone concentrations provides a constant, stable occupation of receptors and achieves a pharmacologic blockade against illicit heroin high and its pharmacologic activity (2). Counter-arguments of methadone therapy for opiate abusers includes the chronicity of lifetime treatment, ineffectual prevention of illicit drug use, marked heterogeneity of programs and availability of ancillary services (3). Dole noted that only a minority of patients would eventually wean off methadone (2). Further philosophical issues confound MMT, as some programs treat opiate dependence as an apparent character flaw and distribute

methadone in a reward/punishment manner. If no illicit drug use is detected, the patient will receive his methadone maintenance dose; otherwise it is held until the drug screen is clean (2). Similarly, it has been observed that some treatment staff do not fully support long-term methadone therapy in favor of abstinence, and attempt to wean patients off methadone within one to two years (4). These and other programs have been found to use a low-dose regimen, less than the consensus panel recommended 60 mg/day for all patients (2). Surveys of methadone centers in the early 1990s revealed the average dose to be less than 50 mg/day (4). Centers that serve primarily African Americans were found to correlate with lower dose regimens. A survey of centers in the year 2000 revealed 35% of patients still receiving less than 60 mg/day (4). This is especially concerning in light of recent studies that have shown 80–100 mg/day to be more effective (5).

The pharmacokinetics of methadone varies significantly among patients and within individuals (6–10). This is due to intrinsic differences in metabolism of methadone and changes in pharmacokinetic parameters with changes in physiologic state (7). External factors include interactions with other drugs, which may induce microsomal metabolism (6). The mean oral bioavailability of methadone is 81–95% (range 36–106%) with a mean half-life of 31 h (range 13–58 h) (6,8). In new initiates where blood concentrations are unpredictable until steady state, it is important to understand inter-individual pharmacokinetic variability. In compliant patients, increases of serum concentrations up to 7-fold have occurred with no change in dose (9). The major metabolite of methadone, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) peaks before the parent drug due to first-pass metabolism in the liver. EDDP peaks at mean 149 min (range 57–404 min) while methadone peaks at 220 min (range 106–408 min) (8). Further, different rates of metabolism for methadone and EDDP have been shown among patients, demonstrating the need for indi-

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visualizing pharmacokinetics (8). In addition, some patients develop metabolic tolerance with the onset of withdrawal symptoms and require an increase in medication dose over their current maintenance dose (6). Tennant's investigation into illicit drug use among methadone patients found that some of those patients experienced significant opioid withdrawal symptoms (10). He found that even with monitored dosing some patients had no detectable blood methadone prior to their morning dose. For the above reasons, clinician response to client symptoms of withdrawal or intoxication, instead of measuring blood concentrations, may be more effective (2).

Hennepin County, Minnesota's population of over 1 million is served by six regional methadone clinics serving over 1200 opiate addicts, with more on waiting lists (11). Methadone is one of the top ten drugs reported in medical examiner cases (12). Methadone is also one of the most commonly diverted pharmaceuticals in Hennepin County as patients may sell their methadone dose. The population of methadone users includes MMT members, chronic pain sufferers, and illicit users. The purpose of this report was to perform a retrospective review of methadone-associated deaths over ten years in Hennepin County in order to clarify the role of methadone in deaths where methadone was detected in blood, urine or liver tissue.

Methods

The Hennepin County Medical Examiner's office (HCMEO) database for the years 1992–2002 was searched for cases in which the decedent's urine, blood, and/or liver tested positive for methadone. The case reports were reviewed by one author. Demographics, cause and manner of death, circumstances of death, and toxicology results were collected for analysis. MMT members were compared with illicit users and prescription users. Qualitative screening for methadone in blood, urine, or liver tissue was performed by either immunoassay or by liquid chromatography. HCMEO uses the thoracic inferior vena cava (IVC) as the source of blood for screening and quantitation.

Methadone was quantitated after solid phase extraction from whole blood by gas chromatography mass spectrometry (GCMS) on a Hewlett-Packard 5972 mass selective detector following chromatography on a 5890 gas chromatograph equipped with a 30 m DB-5 capillary column (Agilent Technologies, Palo Alto, CA). A Unix-based Target Thru-Put operating software computer system was used for data compilation. Standards and deuterated internal standards were obtained from Radian Corp (Austin, TX). For example, one mL of whole blood (appropriate standards, controls, and case) was mixed with 50 μ L methadone-d3 internal standard and 4 mL of water was added to this solution and vortexed for 5 min. After sitting for 5 min, it was spun at 3000 rpm for 10 min to remove the supernatant. Two mL of 100 mM phosphate buffer was added, followed by pH adjustment to 6. This specimen was then transferred onto a preconditioned solid phase extraction column (Bond Elut, Varian, Harbor City, CA). Following treatments with water, 100 mM acetic acid, and methanol, the column is eluted with methylchloride, isopropanol, and ammonium hydroxide. The elution was evaporated at 30 to 40°C with nitrogen, reconstituted with 0.1 mL ethyl acetate, and transferred for analysis into the autosampler for injection on the GCMS. The MS was operated in the select ion monitoring mode (SIM), and the following ions were scanned: methadone quantitating ion 294, qualifier ion 223; methadone-d3 quantitating ion 297; qualifier ion 226. Standard curves were derived for each analysis. Area ratios for unknowns were used to calculate the corresponding analyte concentration. Quantitation of methadone was based upon ratios of integrated ion areas to the cor-

responding deuterated internal standard. Ion ratios were calculated by dividing the area of the qualifier ion by the area of the quantitative ion. Analytes were identified based upon comparison of retention time and ion ratios with the corresponding values of calibration standards assayed in the same run. Limit of detection, limit of quantitation and limit of linearity were 50, 50, and 2000 μ g/L. The assay's precision (%CV) at 100 μ g/L was 3.5%.

The mean and range of methadone concentrations were compared amongst the subpopulations and with respect to the cause and manner of death. Statistically significant differences in groups were determined by two tail student *t* tests and ANOVA with $p < 0.05$ demonstrating significance.

Results

Ninety-six Medical Examiner cases were identified in which the decedents tested positive for methadone. The majority of the decedents were white, 90.5%, and male, 76.8%. The mean age was 44.9 y, range 28–86 y. Table 1 describes the blood methadone concentrations observed by group in all deaths. Overall the difference between the blood methadone concentrations of the MMT program member group (mean 1.17 mg/L) and non-member group (mean 0.65 mg/L) was statistically significant ($p < 0.003$). 34.7% of decedents were enrolled in MMT programs at the time of death. 36.3% of these deaths were drug caused or drug related. Three (25%) of these decedents were MMT program members for less than one week, and their deaths were attributed to methadone toxicity. Two of these decedents had blood concentrations of 0.64 mg/L, with the third at 0.19 mg/L. The latter was classified as drug related. All deaths classified as drug-related were attributed to positional asphyxia associated with drug and/or alcohol use. The remainder were listed as polydrug toxicity, except one case, which was classified as doxepin toxicity; with a liver doxepin and metabolite total concentration of 57 mg/kg and a blood methadone concentration of 0.58 mg/L and blood benzoylcegonine (BZE) concentration of 0.59 mg/L. Methadone concentrations in the drug caused/related deaths ranged from 0.18–3.99 mg/L (mean 1.31 mg/L). Benzodiazepines were present in 67% of these deaths at or below therapeutic concentrations. None of the drug deaths (except the above mentioned doxepin death) had another drug present at a concentration considered in the toxic or lethal range. The incidence of other recreational drugs is as follows: BZE, $n = 5$; opioids, $n = 5$; ethanol, $n = 6$. Deaths of MMT program members not attributed to drugs had methadone concentrations ranging from 0.18–3.03 mg/L (mean 1.16 mg/L). 15.7% of the decedents studied were prescribed methadone for chronic pain with 46.6% dying from overdose. The remainder of this group died of natural causes. Methadone concentrations in the chronic pain group ranged from 0.05 to 3.99 mg/L (mean 0.87 mg/L). The mean blood concentration of the overdose deaths was twice that of those dying of natural causes (1.0 mg/L vs. 0.52 mg/L). Only one overdose case had an associated drug that may have contributed to toxicity: with blood concentrations of codeine at 2.25 mg/L and methadone at 1.55 mg/L. There were three incidents each of ethanol and benzodiazepines, one of BZE, and one methamphetamine. Only one of the chronic pain overdose deaths was classified as suicide with the others deemed accidental. All the other suicidal overdoses in this study were in the illicit user group. The remaining two suicides in the study were MMTP members who died via gunshot wound (methadone concentration 1.18 mg/L) and ligature hanging (2.42 mg/L).

The remainder of the decedents, 39%, were classified as illicit users. Blood methadone concentrations in this group ranged from 0.08 mg/L to 1.86 mg/L, mean 0.61 mg/L. The incidence of other drugs is as follows: opioids, $n = 100$; cocaine/BZE, $n = 9$; benzo-

TABLE 1—*Methadone positive deaths in Hennepin County, Minnesota, 1992–2002**.

Manner of Death	Subgroup	Blood Concentration (mg/L)	
		Range	Mean
Accidental (overdose)	MMTP members (<i>n</i> = 13)	0.18–3.99	1.14
	Non-members (<i>n</i> = 18)	0.14–1.86	0.77
	Prescription (<i>n</i> = 2)	0.38; 0.27	
	Illicit users (<i>n</i> = 16)	0.14–1.86	0.82
Accidental (other)	MMTP members (<i>n</i> = 5)	0.26–3.03	1.16
	Non-members (<i>n</i> = 2)		
	Prescription (<i>n</i> = 0)	na	
	Illicit users (<i>n</i> = 2)	0.15; 1.55	
Natural	MMTP members (<i>n</i> = 11)	0.18–2.2	1.1
	Non-members (<i>n</i> = 16)	0.16–0.93	0.48
	Prescription (<i>n</i> = 9)	0.26–0.93	0.52
	Illicit users (<i>n</i> = 7)	0.16–0.77	0.42
Suicide (overdose)	MMTP members (<i>n</i> = 0)	na	na
	Non-members (<i>n</i> = 6)	0.27–1.15	0.53
	Prescription (<i>n</i> = 1)	1.0	
	Illicit users (<i>n</i> = 5)	0.27–1.15	0.64
Suicide (other)	MMTP members (<i>n</i> = 2)	1.18; 2.42	
	Non-members (<i>n</i> = 0)	na	

* Cases without blood concentrations available and undetermined and homicidal deaths excluded; na = not applicable; MMTP = methadone maintenance treatment program; non-members = chronic pain (prescription) and illicit methadone users.

diazepines, *n* = 3; and ethanol, *n* = 11. Overall the incidence of recreational drug use (including ethanol) was not significantly different between the two groups (*p* = 0.2). With rare exception, the decedents were typically found at the scene with no clear reference for time of death. Over 90% of cases had an estimated interval from death to autopsy of ≥ 24 h.

Discussion

This paper is the first to compare the subpopulations of methadone users by cause and manner of death and to contrast blood methadone concentrations between the groups. In addition, other drug use incidence was noted for each group. There was a mean of 9.6 deaths per year in Hennepin County which tested positive for methadone. Other national and international studies conducted in the late 1980s through the 1990s showed rates of 6 (Sheffield, UK); 9 (Geneva, Switzerland); and 18 (Harris County, Texas) methadone positive deaths per year (13–15). The former regions have populations approximately half, and the latter has roughly twice that of Hennepin County. The methadone blood concentrations for MMT program members at 1.14 mg/L averaged nearly twice that of non-members, 0.61 mg/L, and chronic pain patients, 0.87 mg/L. Methadone concentrations in decedents dying from overdoses overlapped with those succumbing to natural disease or external events, e.g., motor vehicle collision or homicide. Members of MMT programs made up a minority (34.7%) of the total deaths with approximately 10% of these decedents being members for less than one week. The incidence of recreational/illicit drug use, in addition to methadone, was lowest for the MMT program members than the other two groups.

One confounding factor in interpretation of blood drug concentrations is the possibility of postmortem redistribution. Two representative studies show evidence of this phenomenon with methadone. Prouty and Anderson (16) report five cases with heart blood: femoral blood ratios of 0.8–1.4. Levine, et al. (17) also found discrepant heart and alternate site [subclavian, inferior vena cava, femoral, pericardial] variation with only 26% of cases showing concentrations within 20%. As in the Prouty-Anderson study no consistency in the direction of change at each site was seen. The

fact that HCMEO consistently samples from the IVC supports comparison of methadone concentrations among the decedents. However, postmortem redistribution is recognized as one possible limitation of our study.

Other studies of methadone deaths were found from European countries, with most national studies dating back to the 1970s (18,19). The most recent study, performed in Texas in 1991 by Barrett et al. (13), demonstrated methadone deaths with a similar population of methadone users as in the current study, with a white male majority. Studies from Washington, D.C., Chicago, and New York had predominately black populations (3,18,19). Barrett et al. (13) also found a substantial number of decedents (22%) dying of methadone or polydrug toxicity within one week of starting a MMT program. In contrast to our findings, only 9% of the Hennepin County MMT program member deaths were due to trauma, compared with 43% of their population. Deaths due to natural causes and apparent accidental overdose each accounted for 36% of MMT program member deaths.

In our study there was no clear association between methadone concentration and toxicity. Threshold toxic blood concentrations for methadone in the literature range from 0.1–1.0 mg/L (13,20). One difficulty in evaluating such deaths is the lack of dosing information to medical examiner investigators. The drug dose history and pattern of prior use or current illicit use was therefore unknown. Relatively low postmortem methadone blood concentrations could be explained by opiate naïve users and the lack or loss of tolerance, due to low purity heroin or recent prison releases who lost tolerance while abstinent. This problem was identified in the deaths of the three decedents who were MMTP members for less than one week. Their death was caused or related to methadone toxicity. A higher risk of methadone toxicity in MMTP initiates has been previously observed (14,21). Drummer describes 10 cases in which the decedents died of methadone toxicity with a mean of three days in MMTP (21). The starting dose ranged from 20 to 70 mg/day, with a mean blood concentration of 0.7 mg/L (15). In Clark's study of methadone related deaths, 7 of the 18 total deaths were MMTP members for only 12 hours to four days (14). The combination of pharmacokinetic variability during initiation of

methadone therapy (8,9) combined with the subjective assessment of tolerance by providers likely contributes to this phenomenon.

Another possible explanation for the wide range of blood methadone concentrations could be prolonged survival time after administration of a toxic dose. Milroy's study of 111 deaths found evidence of bronchopneumonia in 45%, with the speculation of respiratory depression followed by aspiration leading to death (20). Therefore, low methadone concentrations could be accounted for by prolonged peri-mortem interval with continued metabolism of methadone, decreasing the parent drug concentration. Methadone toxicity was listed as the main cause of death in only four of our cases. However, some polydrug overdose cases had toxic concentrations of methadone with relatively little contribution from other drugs present in non-toxic concentrations. One goal of this study was to further delineate a lethal methadone level. None was identified. Interpretation of drug toxicity cannot be made using numbers alone. Generally, our lab considers methadone concentrations greater than 1.0 mg/L consistent with toxicity. However, drug use history and circumstances of death *must* be taken into consideration. The most illustrative example is the accidental death in a fire of an 86-year-old male MMT member who had a blood methadone concentration of 3.03mg/L. His carbon monoxide saturation was 79% suggesting methadone had no role in his death, yet, in other situations, a concentration that high would comfortably be indicative of causing death.

In March 2001, the administrative oversight of MMT programs shifted from the FDA to SAMHSA with significant changes to improve the quality and increase availability of MMT. The changes provide for increased medical supervision and individualized therapy with private physician office-based treatment. These physicians must be affiliated with an opioid treatment program. Major modifications include methadone dispensed in higher dosages and in solid form, while currently only liquid is permitted. In addition, up to a 31-day supply of methadone can be provided, while under the FDA the maximum was 6 days. All programs and clinicians will have to undergo an accreditation procedure for certification (22). Comparison of deaths associated with methadone use after implementation of the new federal regulations will provide more insight into the utility of MMT.

Conclusions

The majority (65.6%) of decedents over a ten-year period in Hennepin County with positive methadone concentrations were not members of MMT programs. We found no definitive lethal methadone blood concentration. There was significant overlap of values between accidental and suicidal overdoses with those dying of natural causes. Also present were the confounding factors of varied opiate tolerance, presence of other drugs, unknown dosing regimens, and potential for postmortem redistribution. Thus, interpretation of blood methadone concentrations must be weighed along with the clinical circumstances surrounding death.

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Attachment 5



Prescription Monitoring Program Center of Excellence

Notes from the Field

2.2 Keeping Patients Safe: A Case Study on Using Prescription Monitoring Program Data in an Outpatient Addictions Treatment Setting

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This project was supported by Grant No. 2009-DG-0016271 awarded by the Bureau of Justice Assistance. The Bureau of Justice Assistance is a component of the Office of Justice Programs, which also includes the Bureau of Justice Statistics, the National Institute of Justice, the Office of Juvenile Justice and Delinquency Prevention, and the Office for Victims of Crime. Points of view or opinions in this document are those of the author and do not represent the official position or policies of the U.S. Department of Justice.



Notes from the Field

Keeping patients safe: A case study on using Prescription Monitoring Program data in an outpatient addictions treatment setting

Summary

A first-person case study is presented on using prescription history data to screen and monitor patients who are opioid addicted for medically unwarranted concurrent use of controlled substances. The Medical Director of a large outpatient opioid addiction treatment program obtained prescription history data on all patients from a newly established state prescription monitoring program (PMP). The Medical Director's analysis of the data indicated that, unknown to clinic medical staff, approximately 23% of patients were being prescribed significant quantities of opiates, benzodiazepines and other controlled substances from providers outside the clinic.

These prescriptions potentially compromised treatment and put patients at risk for dangerous drug interactions, continued addiction, overdose and death. Patients in this group were advised that successful treatment and their own safety required they discontinue seeking uniauthorized or duplicate prescriptions. Most patients complied and were retained in treatment, subject to continued monitoring via the state's PMP. This case study suggests that clinical use of prescription history data is a valuable adjunct in ensuring safe and effective outpatient addictions treatment.

All quotations (sections 2-9, indented in text) are taken from the Medical Director's first person written account of the events in question. Anonymity is preserved to protect doctor-patient confidentiality.

1. Background on methadone maintenance and prescription monitoring

Methadone maintenance therapy, often on an outpatient basis, remains the treatment of choice for many of those addicted to opiates, whether heroin or prescription opioid pain relievers. According to the American Association for the Treatment of Opioid Dependence, just over 1,200 methadone clinics are operating in the continental United States, with an estimated combined patient enrollment of approximately 270,000. A concern among clinicians is the illicit use or diversion of controlled substances by some methadone patients. Patients using substances such as prescription opiates and benzodiazepines beyond that indicated for clinically sound addiction treatment are at risk for dangerous drug interactions, continued addiction, overdose and death. A protocol to help reduce illicit drug use and diversion by such patients would be of great value to ensure successful treatment and increase both patient and public safety. The case study presented here suggests that clinical use of PMP data on patients' prescription histories constitutes just such a protocol.

Prescription monitoring programs, underway in the majority of US states (34) and being planned or implemented in ten others, collect data from pharmacies on prescription sales of controlled substances, recording the type of drug, quantity dispensed, customer and/or patient identifying information, prescriber, pharmacy and date of sale. In response to requests by authorized medical providers, almost all PMPs provide reports on the prescription histories of specific patients.

Using PMP data in an outpatient addictions treatment setting

Providers can, therefore, check to see whether their patients are receiving concurrent prescriptions from other prescribers, an indicator of possible prescription misuse, abuse, fraud or doctor shopping. Most PMPs have or are moving to online systems in which authorized end-users can retrieve data on a patient's prescription history from their offices. The present report suggests that quick, online (but strictly controlled) access to PMP data for medical providers can play a critical role in addictions treatment.

The Medical Director reporting data for this study was the director of a large outpatient methadone clinic. The text in sections 2-9 is drawn verbatim from his written first-person narrative, which takes us from the discovery of his state's newly implemented PMP to the consequences for treatment and patient safety of consulting prescription histories. Italics for entire sentences have been added for emphasis by the PMP Center of Excellence, whereas single words in italics or underlined were emphasized in the Medical Director's original account.

2. Discovering and using the PMP

I first learned about our state's prescription monitoring program (PMP) from an email forwarded to me by one of the administrators at the opioid treatment program (methadone clinic) where I worked. He originally received the information from a person working in the office of the state opioid treatment authority. As soon as I knew we had a functioning prescription monitoring program, I did all I needed to do to get access to this database, which was relatively simple. I had to sign a notarized statement to send to database officials, along with a copy of my driver's license. I was given an ID and a password for the database. *I consider the database one of the best tools I have to help identify and treat opioid addiction.*

Our PMP requires only a patient's first and last name and birth date to obtain database information. There's even an option if you have only an approximation of the birth date, so doctors can still find the needed information. There is a delay between the time a patient picks up a prescription and when that information is uploaded onto the site. In most cases, it takes two weeks or less. When I've had patients use these pharmacies, I've called these pharmacies to explain why it is so important to me that they participate in the PMP.

I'm not particularly computer savvy, but it didn't take long to become proficient in searching the online database. I've become very efficient at this website and can check a patient in about 20 seconds, though much more time is required if I find any prescriptions.

3. The importance of PMP screening: dangers of concurrent substance use during methadone treatment

I feel that it's my obligation to use the PMP to screen all of the patients being admitted to methadone maintenance treatment. Since most people seeking treatment for opioid addiction in our state are addicted to prescription opioids, and not heroin, checking the PMP database was, and is, a goldmine of information. Many of the patients who were opioid addicted got at least part of their opioids by prescription from their doctors, and often were prescribed other

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controlled substances that they used non-medically, or sold. These people often didn't seem to realize how addictive and dangerous prescription medications can be, and mistakenly thought prescription pills were safer than what they considered "hard" drugs.

Methadone is a strong opioid, and can be fatal when mixed with other drugs or medications. Benzodiazepines, combined with methadone or other opioids, have caused many overdose deaths in our state. Many opioid-addicted patients seeking treatment at opioid treatment programs are also addicted to benzodiazepines. By addicted, I mean they use them inappropriately and non-medically, whether they get them by prescription or off the street. Opioids can cause overdose deaths even if not mixed with other drugs. *For this reason, it's critical to make sure we know whether or not the patient is getting another opioid in addition to the methadone we are prescribing.*

4. Findings from PMP data: concurrent prescription use by some methadone patients

When I became the Medical Director of the opioid treatment center I checked all patients' PMP data myself. One of the regulations of our PMP website is that the physician can't delegate this task to anyone else. I was overwhelmed and dismayed about what I found the first time I checked our patients on this database. *Approximately 23% were getting significant prescriptions about which we had no prior information.*

It didn't take me long to decide that, at least for the time being, I would ignore patients getting occasional prescriptions for 20 or 30 hydrocodone pills. As a matter of triage I had to focus on the more serious cases: those getting prescriptions for methadone, Oxycontin, fentanyl, or relatively large amounts of benzodiazepines (e.g., prescriptions for 2 milligrams of Xanax taken twice a day), or combinations of these. Most worrisome were the patients filling prescriptions for methadone, besides dosing with the methadone we prescribed at the clinic. I can recall at least eight or nine doing this. About half of them said they were selling or giving the methadone pills prescribed by community doctors to friends or family. The other half claimed to be taking the extra methadone themselves, with no good explanation about why they hadn't asked for dose increases at our treatment program.

Benzodiazepines were mostly alprazolam, diazepam, or clonazepam. *Some patients said they had been taking these prescriptions, and found methods to avoid detection on observed urine drug screens (a fascinating topic of its own), some said they were giving them to friends or family members, and some admitted selling them. None of their community-based physicians knew they were being treated at an opioid addiction treatment program. No one at our treatment center knew they were seeing another doctor, or what they were being prescribed, prior to access to this data via the prescription monitoring program.* These patients, like all treated by our program, were asked at intake about what medications they were being prescribed, but obviously did not disclose these prescriptions to our staff.

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5. Clinical interventions and patient responses

There were too many patients for me to meet individually with all of them to discuss results of the database, though I saw many of them. Because of the large number of patients involved, program managers and patient counselors had to help me.

My approach with a patient would be to say, "Look, we have this new way of checking for other powerful prescriptions and this is what I found for you. Can you explain to me what's going on?" There were several common ways patients responded.

The majority of patients said something like, "Yeah, I'm getting them. I know I'm not supposed to, but I didn't think you'd find out." Most patients agreed to sign release of information (ROI) forms allowing me to call the other doctor, or multiple doctors in many cases, to tell them the patient was being treated with methadone for an addiction and consult about the best course of treatment.

If one or more opioid prescriptions were being filled, I had to ask the patient if they were taking these themselves. Many were. These patients needed methadone dose increases, since they were still able to feel euphoria from other opioids. This meant their methadone dose wasn't high enough for opioid blockade. As long as the patient agreed to stop getting other opioids, they could stay in treatment with us, and the patient was better off. Many such patients later said they were glad this had happened. They said it burned the bridge of access to drugs they often misused.

Other patients acknowledged filling the prescriptions, but denied taking the medications themselves. I really didn't need to know what they were doing with them (selling or giving them to others), so long as they signed a ROI and stopped getting them. Most did stop. I re-checked these patients a month or so later, to make certain. If I found they were still getting prescription medications even after our talk, and if they refused to sign the ROI, I decided they weren't appropriate for treatment at our program. In these cases, prior to discharge I slowly (e.g., over weeks or months) tapered their methadone to low levels, while advising them of other treatment options, for instance detox or a non medication-assisted program.

Some patients denied they were getting these medications at all. Since pharmacies can make errors when they upload data, I was careful to double-check names, birthdates, and the home addresses, to make sure they matched. If they did, I told the patient that it is possible this was a case of medical identity theft, and I would investigate. Only one time, out of about a hundred of such cases, was there actual medical identity theft. In all the rest of the cases, our patients were lying when they said they had not filled the prescription in question.

Surprisingly, more than a few patients were belligerent and angry. Many declared that their other medications weren't any of my business. I claimed that as long as they were asking me to prescribe methadone for them, it certainly was my business. This is particularly true if they're still filling prescriptions for the very medications to which they were addicted, and for which they had sought treatment.

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6. Patient safety the paramount concern

The issue of patient safety for me was the first consideration. I wanted to keep patients in treatment if it was reasonably safe to do so, and deciding what was "safe" and what wasn't was a judgment call. I talked to the other doctors at our clinic, but as Medical Director, the decision ultimately fell to me. If it had been more than three weeks since the patient last filled the prescription in question, I made sure the patient wouldn't be prescribed that medication again, by talking with her other doctor, and we continued to dose the patient. All take home doses were stopped, of course, and the patient had to come to the clinic every day.

I constantly asked myself if I was handling situations as I should. I felt anger towards these patients, that they weren't taking their recovery seriously, and I worried the anger would color my judgment about the best course of action. I was angrier with long-term patients who were supposedly doing well. Thirty or forty patients on take-home level five or six (meaning they only came to the clinic to be dosed once every week or once every two weeks) were found to be furtively obtaining methadone or Oxycontin or fentanyl, and I felt their deception was greater. I felt they treated our efforts to help them recover from a potentially fatal illness, opioid addiction, with disdain.

My anger cooled after many months of repeatedly checking the PMP database for new patients and old patients. I began to realize this furtive activity of still getting pills was part of the old lifestyle of addiction, and its grasp doesn't release quickly. It doesn't release at all for some people. *Plus, it's still important for me to remember that the majority of methadone patients didn't get prescriptions after entering treatment with us, and did do well in this form of treatment.*

Improvements in treatment and public safety: patient and staff perceptions

Many patients voiced appreciation of our efforts. They said after we checked the prescription database, there was much less drug dealing in the parking lot. The majority of patients were dedicated to their recovery and found the drug dealing to be a temptation and a vexation. Much of the parking lot violence was related to this dealing.

Most of the counselors and nurses, who had direct contact with patients, were supportive, and glad to have this new tool to use. *Over and over, counselors said patients who stopped getting covert prescriptions did better in treatment afterward. Many of the patients also thanked us for addressing the issue. Some felt they were in better recovery, and others enjoyed a safer parking lot.*

I've worked in the field of addiction for nine years. *The prescription monitoring database is the best tool I've been given. I know these databases have saved lives, prevented overdoses, and brought people into treatment. I know there's less drug dealing when the databases are used. This decreased drug dealing was an unexpected but pleasant unintended consequence of using the database.*

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8. Ongoing prescription history screening as a clinical tool

I now check patients entering the opioid treatment program on our prescription monitoring database when they are admitted, and several times per year. It's much better to let patients know from the start that we check the database, so it doesn't turn into a kind of "gotcha" situation like it did on the first go-round. I can have an honest conversation about all prescription medications. I can explain why continuing old addictive habits will hurt their recovery. Most patients respond in a positive way. A few decide they don't want to stop getting prescribed opioids, even though they misuse them, run out early, then go into withdrawal. I tell them that if they change their mind, they're welcome back, leaving the door to treatment open.

I also prescribe buprenorphine (better known by its brand name Suboxone) in a private office, treating opioid addiction. The majority of my patients were addicted to pain pills prescribed by doctors. I check each patient on the prescription database the night before I see them, for every visit. *It's a delight to look at the database and see multiple opioid prescriptions from multiple doctors before starting treatment, and after starting treatment, the only opioid they fill is buprenorphine.* Since I check the database before every visit, if the patient has relapsed, the prescriptions don't continue very long before I talk with them about their commitment to their recovery, and what they want to do about their problem.

9. Barriers to PMP participation, recommendations for improvements

The main obstacles to physician use of the databases that I see are avoidance, time restraints, and apathy. *Most doctors feel uncomfortable talking to patients about alcohol and drug use.* There still is a value judgment attached to this disease. Some doctors think addicts are bad people, not sick people. They have a hard time believing that their "nice" patients could have an addiction. Plus, doctors have to do more and more, in less time per visit. Where would they find time to check the prescription database for everyone they see? And some docs just don't care. If the patient's addicted...so what. Let them take their dirty little habit elsewhere to be cured.

I suggest these improvements: link all states on one database. We had a Suboxone patient who occasionally traveled to a neighboring state. Something seemed off about him. I got permission from two adjoining states to access their databases. He was being prescribed very large amounts of methadone, filled in both of these states. I know for sure he can't be taking both Suboxone and methadone, as he would be in withdrawal, so he must have been selling one of them. This could have been detected months to years earlier if all states' databases were linked.

Make cross-state access relatively easy for physicians. Our office is close to another state, but no physician is permitted access to that state's database unless they have a license to practice medicine in that state. Some states seem to have made it difficult to even find their database online. I searched for over an hour, using search engines, to locate a state's site, to see what their requirements were.

Using PMP data in an outpatient addictions treatment setting

And advertise the benefits to doctors. I think our state has an excellent program, and the administrators that run the program are top-notch. They have published information in a physician organization's newsletter, increasing the numbers of physicians who use the PMP system.

10. Conclusion

The Medical Director's first person narrative bears powerful witness to the dangers of medically unwarranted prescription drug use among methadone patients, as well as the value of PMP data for safe and effective addictions treatment. Before the establishment of the state's PMP and the Medical Director's use of it, this methadone clinic's staff was unaware that some patients were using or diverting controlled substances prescribed by providers outside the clinic.

Knowledge of patients' prescription histories derived from the PMP database allowed staff to intervene appropriately to reduce medically unwarranted drug use, revisit patients' commitment to treatment, and in some cases adjust methadone dosing to more appropriate levels. According to the Medical Director, most patients confronted with evidence of illicit prescription drug use were retained in treatment, and some expressed appreciation for the interventions.

Use of PMP data became an indispensable clinical tool in monitoring patient compliance with treatment protocols. Besides keeping patients safe and improving the prospects for successful treatment outcomes, interventions made possible by these data helped reduce the diversion and illicit sale of controlled substances, according to the Medical Director, clinic staff and patients themselves.

This case study strongly suggests that initial and ongoing monitoring of a patient's prescription history using PMP data can play an important role in safe and effective addictions treatment. State substance abuse service agencies might profitably consider making PMP data available to Medical Directors and clinicians involved in patient care.

This study also highlights the importance of proper safeguards when using PMP data in addiction treatment settings. These include maintaining patient confidentiality and notifying patients in advance, with their consent, that the PMP will be consulted as an aid to effective clinical practice. Such protocols respect patients' dignity and autonomy while helping to ensure they are retained in the recovery process. For further information and resources on patients' confidentiality, consent, and proactive engagement in treatment, we refer readers to the American Association for the Treatment of Opioid Dependence (<http://www.aatod.org/>), the Substance Abuse and Mental Health Services Administration (<http://www.samhsa.gov/>), and to each state's single state agency for substance abuse services, listed at <http://www.samhsa.gov/grants/ssadirectory.pdf>.

SEP 27 2011

Dear Colleague:

The purpose of this letter is to encourage physicians, physician assistants, nurse practitioners, pharmacists, and other Staff in Opioid Treatment Programs (OTPs) to utilize State Prescription Drug Monitoring Programs (PDMPs) as an additional resource to maximize safety of patient care pursuant to applicable state guidelines. The illicit use of prescription drugs (i.e. opioids, stimulants, and sedatives) is a major public health problem. In addition, prescription drug issues affect patients in OTPs.

Prescription Drug Monitoring Programs (PDMPs) – PDMPs are statewide programs that collect data on various controlled substance prescriptions and enable prescribers (including OTP program physicians), pharmacists, regulatory boards and law enforcement agencies (under certain restrictions) to access this information pursuant to applicable State guidelines. Additionally, PDMPs may aid the care of those patients with chronic, untreated pain or chemical dependency and help to identify patients engaged in prescription drug abuse and diversion. To date, forty-eight states and one US territory have enacted PDMP legislation. Thirty-five states have operational PDMPs and an additional thirteen have enacted legislation to implement a program.

PDMPs can be particularly useful to physicians in OTPs. A “case study” developed by the PMP Center of Excellence at Brandeis University (attached) narrates an OTP medical director’s first-person written account of the physician’s experience using a PDMP as an adjunct in ensuring safe and effective outpatient addictions treatment¹. When accessing the PDMP, the physician found that 23% of their patients were being prescribed significant quantities of opiates, benzodiazepines and other controlled substances by clinicians outside their practice. None of the employees at the treatment center were aware the patients were being prescribed these medications.

OTPs and PDMPs – The Substance Abuse and Mental Health Services Administration (SAMHSA) OTP inspections reveal that PDMP reports are already included in many OTP patient records. At least one State requires OTPs to access the State PDMP for patients admitted to treatment, and periodically through treatment. SAMHSA believes that when OTPs access the PDMP database it would assist them in identifying those few who are engaged in doctor-shopping and spot irregularities with what the patients are reporting with what they are actually

¹PMP Center of Excellence Notes from the Field, “Keeping Patients Safe: A Case Study on Using Prescription Monitoring Program Data in an Outpatient Addictions Treatment Setting,” 2011.

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filling. In many cases, monitoring the PDMP may assist the prescriber to revise their treatment plans, possibly preventing a serious adverse event. SAMHSA intends to develop additional guidance on the use of PDMPs in the OTP setting. Until these guidelines are complete, the Agency suggests that OTPs review the enclosed material to help address questions from patients and others.

Confidentiality Requirements – SAMHSA has received questions regarding Federal Confidentiality and how it applies to OTPs and PDMPs. In an attempt to assist with implementation of the rules SAMHSA has prepared the attached guidance. Please refer to Enclosure 1 “OTPs, PDMPs and Confidentiality Issues.” Please note that the Enclosure is intended as educational guidance to assist with the implementation of the confidentiality requirements, however, the information is not legal advice.

In conclusion, SAMHSA urges physicians, physician assistants, nurse practitioners, pharmacists, and other appropriate staff in OTPs to access PDMPs as an invaluable additional resource to monitor patient compliance with treatment protocols.

For additional information or questions, please contact Jinhee Lee, PharmD, Public Health Advisor, at (240) 276-0545 or by e-mail at jinhee.lee@samhsa.hhs.gov

Sincerely,

[Signed by H. Westley Clark.]

H. Westley Clark, MD, JD, MPH, CAS, FASAM
Director
Center for Substance Abuse Treatment

Enclosures:

Description of OTPs, PDMPs, and Confidentiality Issues

PMP Center of Excellence Notes from the Field, “Keeping Patients Safe: A Case Study on Using Prescription Monitoring Program Data in an Outpatient Addictions Treatment Setting”

OTPs, PDMPs and Confidentiality Issues*

SAMHSA has prepared this guidance regarding the implementation of federal regulations at 42 CFR part 2 for educational purposes only. This information is not intended to serve as legal advice.

State PDMPs collect and retain prescription drug information and disclose such information to legally authorized users. Most PDMP state laws require that providers who dispense more than a 48 hour supply of a schedule II-V controlled substance must report that transaction, including patient health information, to the State PDMP. Opioid Treatment Programs (OTP) and Drug Addiction Treatment Act of 2000 (DATA 2000)-Waived physicians are substance abuse treatment programs under the Federal confidentiality rules, therefore, disclosures of patient-identifying information by such programs to State PDMPs are not permitted unless an exception applies consistent with the federal confidentiality regulations.

The legal framework established in the Public Health Service Act (42 U.S.C. 290dd-2) and Federal confidentiality regulations (42 CFR Part 2) protect records relating to a patient received or acquired by a federally-assisted substance abuse program, and include any information that could reasonably be used to identify an individual. Patient records may not be disclosed by federally-assisted substance abuse programs without patient consent, unless an exception specified in the regulations applies.

State laws require PDMPs to establish and enforce policies and procedures to ensure that the privacy and confidentiality of patients are maintained and that patient information is protected and not disclosed to anyone who is not authorized to access this information. In addition, covered entities under the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) may not use or disclose protected health information except as provided under HIPAA.

How do the Federal confidentiality rules apply to PDMPs?

PDMPs generally do not meet the definition of a federally-assisted substance abuse programs for the purposes of 42 CFR part 2. Therefore, authorized disclosures by State PDMPs would not be considered disclosures of substance abuse patient records and not subject to these regulations.

May an OTP provide patient-identifying information to a PDMP under federal confidentiality rules?

Disclosures of patient-identifying information by federally-assisted programs (including OTPs and DATA-waived physicians) are permitted with written patient consent under 42 CFR part 2. However, redisclosures of such information is prohibited. Since one of the goals of PDMPs is to make information available to authorized users, currently it would not be feasible to ensure that the information will not be redisclosed. Therefore, OTPs and DATA-waived physicians should not disclose patient-identifying information to PDMPs. The question of disclosures of information to PDMPs with patient consent may be considered further by SAMHSA.

Is Patient Consent Necessary to Access Information from a PDMP?

A request for information by an OTP physician from a State PDMP would not be considered a disclosure of patient health information under 42 CFR part 2, therefore, patient consent is not required.

Should patients be notified of PDMP Access?

Programs should consider notifying patients that prescription information is monitored by the State PDMP. This also serves the purpose of facilitating open communication with patients about their prescriptions. Programs can clarify to patients that prescription medication histories are routinely monitored by PDMPs.