

42 CFR Part 2 was enacted to protect the patient. Not the behavioral health provider. Not the primary care provider. Not the state Health Information Exchanges. It is about the patient. Specifically it says:

### §2.3 Purpose and effect.

(b)(2) "These regulations are not intended to direct the manner in which substantive functions such as research, treatment, and evaluation are carried out. They are intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment."

There is no addiction treatment paradigm, no best practice and certainly no evidence-based practice that indicate patient outcomes improve when the patient does not fully disclose the nature of their addiction. In fact, every single treatment paradigm is targeted to breaking through patient denial about their addiction by helping them to fully disclose these details and recognize its impact on their lives.

As a former state and nationally certified addiction treatment provider, I would not have been able to encourage this disclosure knowing the therapeutic value was so significantly diminished by making them so vulnerable. I doubt this would be a problem, though, because who would seek treatment if it means that they are making themselves vulnerable by doing so?

With this in mind please consider the following remarks and recommendations:

1) 42 CFR Part 2 is no longer an obstacle in the electronic exchange of patient health information.

With the development of the HL7 data standard Data Segmentation For Privacy (DS4P) and the successful pilot of the Consent2Share (C2S) technology standard by SAMHSA and the VA, and finally the approval of these standards by the Chief Privacy Officer at the Office of the National Coordinator for Health Information Technology, there is no longer a reason to cite Part 2 as an obstacle to sharing patient health information in health information exchange.

These data and technology standards support full adherence to the statute by any certified EHR and the provider using it. Therefore, discussion of 42 CFR Part 2 as an obstacle to the effectiveness, efficiency and quality of patient health care should be abandoned. It is, in fact, no longer a relevant concern.

Recommendation: Energy should be directed to ensuring that these data and technology standards are fully adopted and applied in ALL certified EHR solutions, as rapidly as is possible, and that providers fully understand what they mean and how they are applied.

2) There are significant shortcomings in the statute itself that it is time to address.

a) The patient's right to confidentiality should be at least as enforceable as the rights afforded by HIPAA. Instead, the current system for ensuring enforcement is not viable or even credible.

42 CFR Part 2 is enforced by criminal law, not civil law. The patient whose rights have been violated has no recourse in civil court if there is no decision to bring criminal charges against the perpetrator. As Dr. Westley Clarke, Director for CSAT has noted many times, there is no record of any criminal charges ever brought against any individual or organization for violating this federal statute since it was put into place in 1975 (Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1175)).

Of course this does not mean all providers everywhere are incredibly vigilant in adhering to this statute. It means that in the past 40 years it has never once been enforced. A statute that is not enforced has no meaning to those who are not concerned about violating it.

Recommendation: Make the statute as enforceable as HIPAA.

b) The financial penalties for violation are insignificant.

Financial penalties for violation are negligible (\$500 - \$5000). With the advent of EHRs and certification criteria, HIPAA violation penalties were greatly increased. 42 CFR Part 2 violations were not addressed. What exactly is the disincentive to violate 42 CFR Part 2 when there is no recourse for the patient in civil court, and no significant consequences to the provider?

Recommendation: Create some actual consequences to violating patient confidentiality, at least as great as those for violating HIPAA.

c) Organizations that in fact meet the criteria for 42 CFR Part 2 consider themselves exempt from 42 CFR Part 2.

Despite the attempt to clarify this in the SAMHSA FAQs (A10)- primary care providers who in fact meet this criteria continue to claim exemption, and their advocacy group representatives continue to argue against the applicability of 42 CFR Part 2 in their situation.

This situation persists because adherence to 42 CFR Part 2 is incorrectly perceived as cumbersome and also because there is no viable enforcement structure. No penalties, no criminal charges, and a patient who is powerless to respond to the breach.

Recommendation 1: Develop an online training series that offers not just an explanation, but also use case scenarios via animation to educate call providers in their responsibilities re: this information. The SAMHSA FAQs are helpful but they are also quite dense and do not offer any actual practice scenarios.

Recommendation 2: Remove all doubt. Vest this information with the protections afforded by 42 CFR Part 2 regardless of the information origin and whether or not the provider is a "treatment provider."

Thanks in advance for your attention to this.

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I am the medical director of an addiction treatment program (both inpt and outpt) situated in multiple hospital system which has recently become an ACO. We use the EPIC medical record system and have data sharing in place with a multi state system.

Our addiction treatment includes hospital based care of severely ill hospitalized patients, medications in the outpt setting as well as care for pregnant women with addiction problems through the course of their pregnancy and delivery. Providing this care outside of the electronic medical record would be extremely unsafe.

It is essential that SAMHSA act to ensure that safe care can be provided for these complex patients in a way that meets all regulatory requirements.

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Dear SAMHSA:

I write as a long-time researcher and observer of formal organizations that provide alcohol and drug abuse treatment, and an addiction medicine and primary care physician who treats many patients with alcohol and drug use disorders. Exceptionalism around alcohol- and drug-, not to mention HIV-, related health information served its purpose in the past, but I applaud SAMHSA for reconsidering this antiquated set of regulations. These regulations were developed before the advent of the **Health Insurance Portability and Accountability Act of 1996 (HIPAA)**, which now ensures confidentiality and privacy for all protected health information (PHI). The additional bureaucratic burdens of 42 CFR Part 2 for the records of patients with alcohol or drug use disorders exacerbates the problems of stigma, inadequate access to care and poor coordination and quality of care that these patients face in the mainstream health care system. As the rest of the health care system moves towards unified electronic health records (EHRs) and integrated systems (e.g. Accountable Care Organizations [ACOs] and Patient-Centered Medical Homes [PCMHs]) that provide incentives for population management and care coordination, the creation of firewalls within EHRs to comply with 42 CFR Part 2 will institutionalize the marginalization of patients with alcohol and drug problems. Now is the time for SAMHSA to acknowledge fully and publically that alcohol and drug use disorders and the programs that treat these disorders should be a full and equal responsibility of the mainstream health care system, and that these patients and their disorders should be treated in the same manner as other patients and their disorders. I strongly advocate that SAMHSA seek repeal of 42 CFR Part 2 and make the health records of patients with alcohol and drug use disorders subject to the same requirements as other PHI under HIPAA. Such deregulation would be widely applauded as reducing unnecessary administrative waste. It would also advance true parity in the management of alcohol and drug use disorders, which was Congress's intent in adopting the Mental Health Parity and Addiction Equity Act of 2008.

Best Regards,

Peter D. Friedmann, MD, MPH, FASAM, FACP

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Hello,

Regarding section b below- does the actual person who performs a records audit on behalf of an oversight organization have to be the person who physically copies and removes the records from the D&A agency, or can the oversight organization request that the D&A agency copy and send the records to the oversight agency?

The situation: As the single state agency (ssa) overseeing monitoring of the SAPT block grant, a sample of drug and alcohol treatment invoices from a treatment provider are compared to the client case notes and records of service from the client file at the treatment provider to validate payment.

The client case notes and records of service are identified via a unique client number. All client names and other identifying information is redacted. An audit and evaluation form is signed by ssa staff, which states that 42 CFR will be adhered to.

Does the actual ssa staff person have to copy and remove the requested records from the facility, or can the requested records be copied and removed from the facility by facility staff, and be delivered to the ssa staff.

Thank you

§ 2.53 Audit and evaluation activities.

**(a) Records not copied or removed.** If patient records are not copied or removed, patient identifying information may be disclosed in the course of a review of records on program premises to any person who agrees in writing to comply with the limitations on redisclosure and use in paragraph (d) of this section and who:

(1) Performs the audit or evaluation activity on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third party payer covering patients in the program, or which is a quality improvement organization performing a utilization or quality control review; or

(2) Is determined by the program director to be qualified to conduct the audit or evaluation activities.

**(b) Copying or removal of records.** Records containing patient identifying information may be copied or removed from program premises by any person who:

(1) Agrees in writing to:

(i) Maintain the patient identifying information in accordance with the security requirements provided in § 2.16 of these regulations (or more stringent requirements);

(ii) Destroy all the patient identifying information upon completion of the audit or evaluation; and

(iii) Comply with the limitations on disclosure and use in paragraph (d) of this section; and

(2) Performs the audit or evaluation activity on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third part payer covering patients in the program, or which is a quality improvement organization performing a utilization or quality control review.

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As a nurse practitioner working in a methadone clinic, I believe there should be some way to show providers that our clients are in MMT on the prescription monitoring program. Suboxone shows on the PMP, even when it is given from our clinic physician. I have found 5 clients being prescribed methadone by providers while coming to the methadone clinic where I am employed. I am sure they were diverting. Their urines were showing that they only had methadone and if I hadn't done the prescription monitoring program (PMP) they never would have been caught.

Please consider this.

Susan Gurney FNP, PMHNP

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June 9, 2014

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Re: Confidentiality

Dear Sirs and Madams:

It is imperative that the confidentiality provisions put into place by Congress in 42 CFR Part 2 to protect the anonymity of patients seeking treatment for addictions to opiate drugs stay in place and not be weakened in any manner due to today's movement towards electronic access to patient records across the spectrum of medical providers.

The reasons for this are many and are the same today as those that motivated Congress to put 42 CFR Part 2 into place originally.

First and foremost is the fact that prospective patients will be wary to seek treatment if they know that this knowledge will be disseminated, and through that distribution possibly become known by friends, family, employers, insurers and other providers of medical services to them. The stigma and discrimination that patients in addiction treatment are routinely subjected to for seeking medical assistance for what has become proven to be a chronic medical condition is as much or more widespread today than at any other time in our history. The National Alliance for Medication Assisted Recovery (NAMA-Recovery), as the preeminent patient advocacy organization in the United States is on the front lines of battling this discrimination and routinely hears the horror stories of patients mistreated by misinformed medical professionals on a daily basis. And if the discrimination and stigma exhibited by medical personnel is this widespread, it is even more so among the general population. Patients

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## Affiliated Groups and Chapters

AZ NAMA Recovery, NAMA Recovery NorCAL (CA)

CT Organizing Network, CT NAMA Recovery

CT Capitol NAMA Recovery, Delaware NAMA Recovery

FL NAMA Recovery, Atlanta NAMA-R (Suboxone)

Chicago NAMA Recovery, The MAG IND

Maryland NAMA Recovery, Massachusetts NAMA Recovery

NJ NAMA-R Advocates, S Jersey NAMA Recovery

NYC NAMA Recovery, Advocates for Change (Syracuse)

Choice, Advocacy & Recovery Solutions (OH)

Rhode Island NAMA-R, Tennessee NAMA Recovery

Texas NAMA Recovery, New England NAMA Recovery (VT)

Wisconsin NAMA Recovery

## International

Australian IV League, HOPE (Bulgaria)

Méta d'âme' (Canada), CRAMA (Croatia)

Brugerforeningen (Denmark), ACCES (France)

Inner Voice of Drug Users (India)

Methadone Indonesia, UISCE Ireland

I-ACT (South Africa), Italy Gruppo SIMS, Recovering Nepal

Landelijk Steunpunt Druggebruikers (Netherlands)

LIBERATION (Poland), INTEGRATION (Romania)

Svenska BrukarForeningen (Sweden)

Assoc. Substitution Therapy Receivers in Ukraine

Methadone Alliance (UK), National Users Network (UK)

## Projects

Medication Assisted Recovery Support Project (MARS)

Stop Stigma Now

*Together, we can make a difference.*

need the protection of confidentiality to protect them from this widespread discrimination that results in substandard medical care and even death in too many instances.

As examples, for patients in methadone treatment for opioid addictions, these patients typically get no medical care at all or are abused by medical providers by not being given pain medications for conditions warranting them. The reason given for their conditions is blamed on the methadone or they are told that they have to first get off the methadone treatment before they can get medical care. And because of the potential cardiac situation exhibited by a very small minority of patients, people are denied their methadone while they are an in-patient – this with no taper given and the doctor at their methadone program not alerted or consulted, something that would never happen in other specialties. We personally know of 3 instances where this has occurred. Imagine going to the hospital because you have pain in your chest and then being put into withdrawal for having sought medical attention. We also know of several instances where patients in a coma were not given their doctor prescribed methadone and it was obvious they were in withdrawal and suffering. The families complained profusely and after some 48+ hours of not getting their medication it was given to them after NAMA-Recovery intervened. One of these patients died the following week and he only went into the hospital for tests, but for the first 3 days he was only given half his regular methadone dose, began to deteriorate, went into a coma and died 6 days later. He had HCV was admitted for a biopsy and some tests, but the discrimination he was subjected to in this observer's opinion killed him. This is what happens too often when patients tell medical professionals about their status as addiction treatment patients. To weaken 42 CFR Part 2 will make these types of injustices rampant across this nation and have worried patients not seeking needed medical interventions for fear of the stigma they will be subjected to, to the point of it risking their lives.

We know of only 1 study that evaluated the medical care that methadone patients routinely get outside of the clinic environment<sup>1</sup>. It was done 20 years ago. It compared medical care given in a clinic setting with care given in an outside clinic. First they could not find a medical clinic to be the patients outside care provider even though the providers were assured they would be paid for missed appointments, a prejudicial fear they expressed. After 3 attempts the researchers finally found a clinic willing to give medical care to methadone patients. The study found that only around 30% of the patients treated in the outside clinic got medical care. The quality of the medical care was not evaluated in the study, only the problems with access experienced by the patients.

Medical professionals do not get their information about methadone treatment in medical school or from the scientific literature. Rather it comes from the media and they believe the myths and misunderstandings about methadone treatment and opioid addiction. Even worse since stable methadone patients have learned not to tell clinicians for their own protection the typical methadone patients that a doctor sees are those that are brought into the Emergency Room with multiple problems including secondary drug use. They make the assumption that all methadone patients are like this when multiple studies have proven that this is not the case at all.

Until the medical profession is educated about methadone and addiction, methadone patients need the right to first develop a relationship with a physician or medical professional before they tell them they

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<sup>1</sup> Umbricht-Schneiter, A., Ginn, D.H., Pabst, K.M. and Bigelow, G.E. 1994. Providing medical care to methadone clinic patients: Referral vs on-site care. **American Journal of Public Health** 84(2): 208-210.

are a methadone patient in addiction treatment. Most patients understand it is important for a physician to know what medications you are taking, however they also realize through negative learning experiences like those illustrated above that first they have to develop a relationship with a given medical professional and during that time make a judgment if the physician will be objective and provide competent treatment or impose his prejudices upon the patient at the real risk to the patient's welfare.

Another serious concern is that once this information goes into the the electronic health information networks that there will be no protection to patients at all. These records could easily accessible by employers, courts and other governmental agencies and not always through legal means. We are inferring that it would be easy for anyone to get access either by payment or having a friend that works in a hospital or doctor's office. And while there may be rigid violations for any illegal access it would be nearly impossible to prove it.

42 CFR Part 2 is essential to protect this patient population from a medical system and a society that is behind the times and knows virtually nothing about addiction treatment using medications like methadone, a treatment that our National Institutes of Health has called the "Gold Standard" for the treatment of opioid addiction. Do not weaken 42 CFR Part 2 to make electronic record keeping easier. Patients will die as a result, real people with families and friends like any other individuals in our population. They deserve better. 42 CFR Part 2 gives them that choice.

Kind regards,

Joycelyn Woods  
Executive Director

Roxanne Baker  
President

To Whom it May Concern,

It is imperative that the confidentiality provisions put into place by Congress in 42 CFR to protect the anonymity of patients seeking treatment for addictions to drugs stay in place and not be weakened in any manner due to today's movement towards electronic access to patient records across the spectrum of medical providers.

The reasons for this are many and are the same today as those that motivated Congress to put 42 CFR into place originally.

First and foremost is the fact that prospective patients will be wary to seek treatment if they know that this knowledge will be disseminated, and through that distribution possibly become known by friends, family, employers, insurers and other providers of medical services to them. The stigma and discrimination that patients in addiction treatment are routinely subjected to for seeking medical assistance for what has become proven to be a chronic medical condition is as much or more widespread today than at any other time in our history. The National Alliance for Medication Assisted Recovery (NAMA-Recovery), as the preeminent patient advocacy organization in the United States is on the front lines of battling this discrimination and routinely hears the horror stories of patients mistreated by misinformed medical professionals on a daily basis. And if the discrimination and stigma exhibited by medical personnel is this widespread, it is even more so among the general population. The misinformation and stigma routinely spouted by the media is widespread and the cause of these misconceptions on the part of the general population. Patients need the protection of confidentiality to protect them from the widespread discrimination that results in substandard medical care and even death in too many instances, let alone the prejudice from ordinary people and family members that must be endured. Lessening 42 CFR will only make this situation more difficult for patients and prevent many from seeking desperately needed treatment.

As examples, for patients in methadone treatment for opioid addictions, these patients typically get no medical care at all or are abused by medical providers by not being given pain medications for conditions warranting them. The reason given for their conditions is blamed on the methadone or they are told that they have to first get off the methadone treatment before they can get medical care. And because of the potential cardiac situation exhibited by a very small minority of patients, people are denied their methadone while they are an in-patient – this with no taper given and the doctor at their methadone program not alerted or consulted, something that would never happen in other specialties. We personally know of 3 instances where this has occurred. Imagine going to the hospital because you have pain in your chest and then being put into withdrawal for having sought medical attention. We also know of several instances where patients in a coma were not given their doctor prescribed methadone and it was obvious they were in withdrawal and suffering. The families complained profusely and after some 48+ hours of not getting their medication it was given to them after NAMA-Recovery intervened. One of these patients died the following week and he only went into the hospital for tests, but for the first 3 days he was only given half his regular

methadone dose, began to deteriorate, went into a coma and died 6 days later. He had HCV was admitted for a biopsy and some tests, but the discrimination he was subjected to in this observer's opinion killed him. This is what happens too often when patients tell medical professionals about their status as addiction treatment patients. To weaken 42 CFR will make these types of injustices rampant across this nation and have worried patients not seeking needed medical interventions for fear of the stigma they will be subjected to, to the point of it risking their lives.

We know of only 1 study that evaluated the medical care that methadone patients routinely get outside of the clinic environment<sup>[1]</sup>. It was done 20 years ago. First they could not find the patients a medical clinic to be the patients outside care provider even though the providers were assured they would be paid for missed appointments, a prejudicial fear they expressed. After 3 attempts the researchers finally found a clinic willing to treat. But only if the patients got their medical situations evaluated – it was around 30% that were accepted. The quality of the medical care was not evaluated in the study, only the problems with access experienced by the patients.

Medical professionals do not get their information about methadone treatment in medical school or from the scientific literature. Rather it comes from the media and they believe the myths and misunderstandings about methadone treatment and opioid addiction. Even worse since stable methadone patients have learned not to tell clinicians for their own protection the typical methadone patients that a doctor sees are those that are brought into the Emergency Room with multiple problems including secondary drug use. They make the assumption that all methadone patients are like this when multiple studies have proven that this is not the case at all.

Until the medical profession is educated about methadone and addiction, an education that they do not presently get in medical school, methadone patients need the right to first develop a relationship with a physician or medical professional before they tell them they are a methadone patient in addiction treatment. Most patients understand it is important for a physician to know what medications you are taking, however they also realize through negative learning experiences like those illustrated above that first they have to develop a relationship with a given medical professional and during that time make a judgment if the physician will be objective and provide competent treatment or impose his prejudices upon the patient at the real risk to the patient's welfare. 42 CFR is essential to protect this patient population from a medical system that is behind the times and knows virtually nothing about addiction treatment using medications like methadone, a treatment that our National Institutes of Health has called the "Gold Standard" for the treatment of opioid addiction. Do not weaken 42 CFR to make electronic record keeping easier. Patients will die as a result, real people with families and friends like any other individuals in our population. They deserve better. 42 CFR gives them that choice and those most important protections.

Kind regards,

J.R. Neuberger  
Member, Board of Directors  
Corporate Secretary  
National Alliance for Medication Assisted Recovery (NAMA-Recovery)

[1] Umbricht-Schneiter, A., Ginn, D.H., Pabst, K.M. and Bigelow, G.E. 1994. Providing medical care to methadone clinic patients: Referral vs on-site care. **American Journal of Public Health** 84(2): 208-210.

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NAMA-Recovery website: [www.Methadone.org](http://www.Methadone.org)  
METHADONE is MEDICINE  
Methadone IS Recovery!

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Nanette C. Wollfarth, CMA Chapter Coordinator

June 25, 2014

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Re: Confidentiality

Dear Sirs and Madams:

I was at the June 11<sup>th</sup> Listening Session for 42 CFR Part 2 and was very disturbed as to how it was organized. Methadone patients are the primary group that will be impacted by any changes and yet not one patient spoke. All day long the majority of the speakers were not the ones being impacted by any change in 42 CFR Part 2. I contacted the organizers informed them I represented patients and asked to speak. Since they had no patients speaking I would have thought they would have asked me for advise and if not me to ask AATOD if they could recommend a patient representative. The answer to my request was that I could speak at the end during the public comments. When I arrived I was not listed as an in-person speaker but as being on the web and as the only patient speaking was only given three minutes while other groups and organizations had several speakers and could make several points. There should have been a patient speaking for each panel during the session and it is SAMHSA's responsibility to insure that the patients' voice is heard. It is troubling that the premier group in the world representing MAT patients was not contacted.

Here are some of the issues that were raised and the reason that patient confidentiality and privacy is more important today than it was three decades ago.

**Affiliated Groups and Chapters**

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CT Organizing Network, CT NAMA Recovery  
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NJ NAMA-R Advocates, S Jersey NAMA Recovery  
NYC NAMA Recovery, Advocates for Change (Syracuse)  
Choice, Advocacy & Recovery Solutions (OH)  
Rhode Island NAMA-R, Tennessee NAMA Recovery  
Texas NAMA Recovery, New England NAMA Recovery (VT)  
Wisconsin NAMA Recovery

**International**

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Brugerforeningen (Denmark), ACCES (France)  
Inner Voice of Drug Users (India)  
Methadone Indonesia, UISCE Ireland  
I-ACT (South Africa), Italy Gruppo SIMS, Recovering Nepal  
Landelijk Steunpunt Druggebruikers (Netherlands)  
LIBERATION (Poland), INTEGRATION (Romania)  
Svenska BrukarForeningen (Sweden)  
Assoc. Substitution Therapy Receivers in Ukraine  
Methadone Alliance (UK), National Users Network (UK)

**Projects**

Medication Assisted Recovery Support Project (MARS)  
Stop Stigma Now

Continued

*Together, we can make a difference.*

Confidentiality is very important to methadone patients because of the stigma and prejudice they experience not only from the medical profession but in every aspect of their lives. I would estimate that at least 30% do not tell their immediate family and by that I mean the persons that they are living with. Most methadone patients know it is important to tell doctors that they are taking methadone, however from experience they have learned that they will get better health care if they develop a relationship and then tell the doctor. When a doctor knows that you are a methadone patient on day one it is unlikely that you as a methadone patient will get any medical care usually one of three things will occur: 1. your symptoms will be blamed on the methadone and you will be advised to get off of it, 2. you will never be given pain medication for anything, and 3. you will be told that methadone is not good to take and that it is bad and you should get off of it.

*Doctors in Emergency Rooms need to know what the patient has taken for patient safety.*

While this is true generally doctors should not assume that everything in a patients record is correct or there. Patients go to doctors outside of the system all the time so that that information is missing. If they have taken illicit drugs or been given a medication from a friend or family member that will not be in the medical record either. And even when the information is there it does not mean that doctors know what to do with that information as in the death of Libby Zion at New York Hospital. Methadone patients rarely enter Emergency Rooms in an unconscious state so the best way to know what medications they are taking is to ask them. Doctors insisting that the OTP records be included in the electronic health information system is misleading and demonstrates their lack of understanding of the health care system when it comes to methadone and the prejudice patients experience.

Certainly one way to alert Emergency Room staff that an unconscious patient is taking methadone would be to make it mandatory for Opioid Treatment Programs to give patients a card that they can carry on them. Methadone patients should not be mandated to carry the card because this was the case once in New York and several patients were stopped because they lived in communities with drug trafficking. When it was discovered that they were methadone patients they were beaten up by the police. After several instances of that occurring the state agency still mandated that every patient get a card but that the decision to carry it was with patients and that patients should be advised about the consequences if they carried it or did not. While the majority of OTPs in the US issue a card it is not enforced and neither is it a required regulation.

*At the Listening Session many stated that most patients don't even know what 42 CFR Part 2 is.*

While methadone patients may not know that 42 CFR Part 2 is the code for the confidentiality regulations they do understand the need for confidentiality and are concerned about it. They may not understand the statute itself and all the rights that it confers but they do know that their information cannot be released without their consent. And that is very important to them. A significant number of methadone patients would not have entered treatment without their records being protected.

Continued

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*The records need to be merged with the general hospital records so that behavioral health institutions can plan for better health care and continuity of care.*

Behavioral health care institutions should know all the services in their area anyway so that they can refer a patient when it is required. Does this happen? Sometimes. However I doubt very much that merged records would create a more comprehensive system. Neither would it make a better system because institutions are not looking for more comprehensive care but cheaper care. The point is that a good program will refer and use the various systems in the area that is available merged records or none.

*The consent release form is too restrictive or does not allow for certain information.*

Persons that say this appears to be more of a case of not knowing how to fill out the consent form properly. What more is necessary but the date, that the consent last for 6 months, the material to be released and the agency to release it to. What more is needed?

**Some unforeseen consequences of making 42 CRF Part 2 less restrictive.**

Methadone prescriptions may be allowed on state prescription monitoring systems and the majority of these data bases are run by criminal justice agencies. Several states whose prescription monitoring systems are run by police have indicated that they want to use these data bases to also search for warrants.

Most methadone patients when they enter treatment try to resolve their criminal justice issues including warrants. This would place a very real barrier for persons needing treatment. And although warrant searching is not being done presently it is likely that eventually it will occur. Methadone patients need protection from this and 42 CFR Part 2 does it.

Once OTP records enter the electronic hospital system there is no guarantee that there will be any protection for anyone in treatment. Clerks, secretaries and I suspect janitors can even access records. This would make it very easy for an employer to pay hospital staff or the boyfriend/girlfriend of a probation/parole office to access the records and find out about any medications. And it would be nearly impossible to know who accessed the records. This needs to be considered very carefully because once these records are included you cannot get them back.

At the present police are not allowed to enter OTPs and if they need anything or bring a patient that has been arrested to the clinic to dose they must wait outside. This is true of anyone working in the criminal justice system and the rationale is that they could see another patient that possibly has a warrant or they want to question. Without 42 CFR Part 2 protecting patients from this any patient with legal trouble would be afraid to go to the program and probably leave treatment even though they were attempting to resolve the legal problems.

Continued

*Together, we can make a difference.*

The technology is available to make OTP records part of the electronic health information system with a firewall. Therefore when part of a patient's information needs to be released it can be. The reason that it is not available is no one wants to do it. However methadone patients are not the only group protected, for example medical records for persons with HIV are protected and the reason is because of the stigma and prejudice. And any methadone patient that is HIV+ will tell you that it is far more stigmatizing to be a methadone patient than a HIV patient. As long as there are groups that need to be protected it will be necessary to put a barrier on their records.

What about current patients that already in treatment being told that their treatment information was confidential and that no one could access it unless they released it. The trust that has developed between treatment staff and patients would be destroyed. This was one of the most important issues when 42 CFR Part 2 was initiated. Treatment professionals from throughout the US stated that confidentiality was important to maintain trust. In 1972 the confidentiality regulations had been published in the Federal Register but before comment could be assessed a murder occurred near a New York City Methadone Program. The police presented a court order to view photographs of the patients and the program refused creating the case of Newman vs People since Dr. Newman was the director of the program. Dr. Newman refused to release the photographs was found in contempt of court and ordered to spend 30 days at Rikers Island. He was given two days to appeal and during this time a letter signed by the Special Action Office for Drug Abuse Prevention (S.A.O.D.A.P.) General Counsel was hand-delivered by the Deputy Director of S.A.O.D.A.P.. What the letter said is as important today as it was then. It addressed the importance of assuring addicts that treatment records would be maintained in confidence: "Because a high proportion of heroin addicts are involved in a life style which puts them in fear of criminal prosecution, any effort to modify that life style through participation in a treatment program is bound to be compromised if the addict believes that such participation will generate records which increase the risks he already feels. Stated more positively, all the operators of treatment programs with whom we have talked believe that it is important for them to give assurance of confidentiality to persons entering treatment, and we share this view." On the day that Dr. Newman was supposed to report to Rikers Island, July 25, 1972 the F. D.A. made the confidentiality provisions of the Federal Register Notice on Methadone published April 6, 1972 to be effective immediately.

Changing the regulation would be an enormous task. It took about ten years to change 42 CFR Part 8 and since confidentiality is even more important there needs to be even more thought put into any change. More important methadone patients need to be part of changing anything that protects them in 42 CFR Part 2. Since buprenorphine patients experience the same stigma and discrimination as methadone patients it would be insightful to include them if any changes are made.

There is no data on methadone patients about the discrimination they experience in: 1) health care, 2) employment, 3) schools and training programs, 4) family, 5) criminal justice agencies, 6) child welfare agencies and 7) other institutions. NAMA-R receives several grievances a month from patients about criminal justice and child welfare agencies who are told that they must get off methadone and are often given a time limit that is contrary to Best Practice. Not only is this done but often patients are

Continued

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arrested and given jail time when they are not able to meet the time limit given to them. Methadone patients that work in health care report that medical professionals are the worst when it comes to treating methadone patients. I am attaching several reports from patients regarding the typical treatment that methadone patients experience when they reveal their status to medical professionals.

If any changes are made to 42 CFR Part 2 SAMHSA will also have the responsibility to respond to the negative situations that methadone patients experience when accessing health care. Hospitals and health care facilities should be fined perhaps through American With Disabilities cases and included in the outcome should be education of the medical professionals about methadone treatment. SAMHSA will also have the obligation to insure that anyone that wrongfully takes any medical information from the hospital electronic information system is penalized.

However, changing the regulations might not matter one bit because most states and especially those states with large numbers of methadone patients have a similar state regulation in place. Thus even if the federal statute were reversed you would have all the state regulations in place and many states seeing that patients are no longer protected at the federal level could tighten up their state regulations. This would certainly make SAMHSA appear to be indifferent towards the prejudice and stigma that methadone patients experience.

NAMA Recovery has offered our services to SAMHSA in helping to decide if any changes should be made to 42 CFR Part 2 and we continued to offer our support.

Joycelyn Woods  
Executive Director

Roxanne Baker  
President

enclosure

**From:** Lisa Hathaway [<mailto:donotreply@eventbrite.com>]  
**Sent:** Monday, June 09, 2014 10:04 AM  
**To:** Tipping, Kate (SAMHSA)  
**Subject:** 42 CFR Part 2 Listening Session - Question from Lisa Hathaway

Lisa Hathaway ([lisa.hathaway@bcbsfl.com](mailto:lisa.hathaway@bcbsfl.com)) has a question for you about your event 42 CFR Part 2 Listening Session.

Will SAMHSA also be considering the conflict with other federal laws and 42 CFR 2? For example: 1) HIPAA-you can share member PHI for treatment and health plan operations; 2) with CMS for Medicare Advantage Organizations and Part D Sponsors, you must provide CMS with mental health information through for risk adjustment with the HCC (hierarchical condition codes) and you are paid based on a member's HCCs thru the risk adjustment; 3) similar to the MAOs and Part D, for the Qualified Health Plans on the Exchange, there is now also risk adjustment and a similar system of where you are paid based on risk adjustment. So, there are other federal laws that require sharing of diagnoses and data for mental health and substance abuse conditions and drug treatment. Thanks for adding this to the considerations for the law.  
Lisa A. Hathaway, Assistant General Counsel Florida Blue 904-566-7878

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## Recommendations concerning proposed modifications of 42 CFR Part 2 confidentiality protections

Submitted June 9, 2014, to the  
Substance Abuse and Mental Health Services Administration  
(FR Docket # 2014-10913)

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Thank you for the opportunity to submit comments regarding possible modifications of federal regulations governing confidentiality of alcohol and drug patient records (42 CFR Part 2). My personal interest and involvement in this issue date back more than four decades, when I was the defendant (and, ultimately, the prevailing party) in *People v. Newman*[1], "... the leading case construing 21 USC 1175"[2]. 21 USC 1175 initially authorized the restrictions upon disclosure and use of drug abuse treatment records that for the most part remain in effect today.[3]

Violations of an individual's need, desire and right to confidentiality generally are rationalized with the argument that compelling *societal* interests demand it. The key changes being considered by SAMHSA's "listening session," however, relate to modifications that are intended primarily to *benefit patients* through integration of medical records and enhanced medical care coordination. Specifically, the changes would "expand the authority for releasing data to ... third-party-payers, health management organizations, HIEs (health information exchanges), and care coordination organizations." As part of an integrated, electronic medical record the data presumably would be available to virtually all providers of care.

Whatever the rationale, the argument against weakening the safeguards of confidentiality afforded patients (including applicants for treatment and former patients) is summed up clearly and succinctly by SAMHSA itself in the announcement of this hearing: "... *treatment for substance abuse disorders is still associated with discrimination.*" Yes, indeed!  
Misunderstanding of addiction, of addicts and of addiction treatment is near-universal in our society and – sadly - is widely evident among healthcare workers,

hospitals, clinics, insurers, etc. Accordingly, while the broadest possible knowledge of a patient's history can be helpful in reaching a diagnosis and deciding on the optimal therapeutic course, knowledge of an addiction history is far more likely to result in negative consequences for the patient.

It might be argued that stigmatization of those who are or who have been dependent on drugs would diminish if more visibility were given to those who need and have received help, and if they – and their records – were not subject to special restrictions. I have heard colleagues for whom I have greatest respect point to the enormously gratifying strides in recent decades in overcoming bias based on sexual orientation, progress attributed in large measure to the willingness of many gays and Lesbians and others to “come out of the closet.” “Coming out,” however, must be an individual choice, and not the result of closet doors being smashed open to expose those inside!

Individuals must be free to authorize release of information, but such authorization must not be coerced, and must not be a *sine qua non* for the provision of treatment. Every effort must be made to ensure that patients are fully informed as to the potential benefits as well as the risks of disclosure. They must be allowed to decide for themselves whether to permit release of information that, given societal attitudes of today, can very literally destroy lives.

SAMHSA and other concerned parties are urged to heed the words of Justice Louis Brandeis (*Olmstead vs United States*, 1928): “Experience should teach us to be most on our guard to protect liberty when the government's purposes are to be beneficent.”

Thank you again for the opportunity to share these views with you.

[1] *People v. Newman*. 32 NY 2<sup>nd</sup> 1972

[2] Dept. HEW. “Confidentiality of Alcohol and Drug Abuse Patient Records.” 1975. *Federal Register*. 40(127), Sect. 265-1(d), p.27821

[3] <http://cfr.vlex.com//vid/2-statutory-confidentiality-patient-19797521>, accessed June, 2014

These comments are from Bay-Arenac Behavioral Health, located in Michigan, which is a state funded Community Mental Health Center for two counties and a state designated Coordinating Agency for Substance Abuse services for a six county region.

Our overall comments are:

1. SAMHSA should not require consent among “covered entities” for communications for purposes of coordination of care.
2. SAMHSA should broaden the applicability of 42 CFR Part 2 in order to accommodate the new health care environment where increasingly complex service delivery systems and modalities are involved in SA treatment, payment and operations.
3. SAMHSA should permit consents to name agencies and entities to whom information can be released versus specific individuals.
4. Serious civil and criminal consequences should remain in place for the disclosure of this information beyond the state and federally funded health care “covered entity” context.

### **Not Require Consent Among Covered Entities**

We strongly recommend that SAMHSA consider creating a “covered entity” conceptual framework for SA confidentiality that is similar to that for HIPAA. If necessary this could be limited to state or federally funded health care programs, as these are within the federal governments locus of control. The “covered entities” could have privacy notice obligations and permissible use of information for treatment and operations. This would greatly improve the ability of providers to meet the requirements being placed upon them by state and federal payers to integrate efforts to support patients in their recovery, and it would greatly improve clinical outcomes. It would eliminate the need to obtain a consent for administrative purposes.

We assume it is the intent of 42 CFR Part 2 to prevent those (who are not providing health care) from knowing about a patients drug and alcohol treatment and history because they may discriminate against that patient for purposes of employment, housing or other opportunities. We do not think it is the intent to prevent those who are providing health care from communicating with each other and improving the likelihood of recovery for the patient. Addiction by its nature is a disease that can cause patients to “manage” relationships including those with health care providers in order to meet their needs for drugs or alcohol. Patients who experience the poorest clinical outcomes are those who refuse to provide consent for release of information for coordination of care but then seek to obtain what are often duplicative and contraindicated services from multiple health care providers.

As examples:

- The State of Michigan is transferring management of substance abuse services from designated regional coordinating agencies to health plans. At this point in time, it is assumed each of the thousands of patients receiving care under this system will have to sign a consent to release information to the new health plan in order to comply with 42 CFR Part 2. This is a waste of resources and it is unknown what would happen if a patient refused.
- Our psychiatrists have expressed concern that they must prescribe without full information regarding medications prescribed by other prescribers or without knowing the drug and alcohol history gleaned by other health care providers because a patient refuses to provide consent for coordination of care. In some instances optimal treatment options may not be utilized due to concerns over possible adverse effects or a physician may be concerned about accepting a

patient into treatment because they believe they cannot adhere to their professional obligations to provide proper treatment.

### **Broaden the Applicability**

Whatever the level of confidentiality and consent required, we strongly recommend SAMHSA apply the same standard across the entire health care industry, much like HIPAA was applied.

As SAMHSA notes, the exclusivity of substance abuse treatment among providers is fading (it should be noted provider SA licensing requirements remain intact) and is being replaced by integrated service delivery models, such as integrated health care clinics. The lines between types of providers are blurring and the distinction relative to confidentiality is becoming less meaningful. It is becoming harder to determine if and when your organization should comply with 42 CFR Part 2, and as a result, you apply the consent requirements to populations for whom compliance is probably technically not required in order to be safe.

Also, the value of applying 42 CFR Part 2 to only SA treatment providers is becoming less clear. Just as much damage is done if SA information is released by any health care provider to someone without a need to know. The standard for SA confidentiality is higher than for other health conditions, including mental health treatment. Societal culture is changing and alcohol/drug abuse is more openly discussed than several decades ago, and is perhaps less distinct in this way from other health conditions than it once was. Does research still provide an adequate rationale for holding this particular set of health conditions out as necessitating a higher confidentiality standard than exists for other health conditions?

Relevant examples:

- As a community mental health center, our treatment records contain social work and psychiatric assessments which indicate whether or not a patient reports they had/have a substance abuse condition. We are not the treating provider for substance abuse.
- Our service access and eligibility center staff screen patients for both mental health and substance abuse conditions and make referrals to various appropriate providers, both mental health agencies and substance abuse treatment providers.
- One of our mental health treatment models, integrated dual diagnosis treatment (IDDT), treats mental health conditions in a way that coordinates the mental health and substance abuse services being received, but does not deliver the actual substance treatment. So our treatment plan may reference all services being received, although our agency is not the substance abuse treatment provider.
- Our agency has worked closely with other health care providers (such as primary care physicians and others not in the behavioral health field), and they do not concern themselves with 42 CFR Part 2, although they may be helping a patient resolve their alcohol or drug addiction, but do not hold themselves out to be an SA treatment provider.

### **Permit Consents to Name Agencies and Entities**

We strongly recommend SAMHSA eliminate the requirement to identify an individual in the "To Whom" section on the consent. Newer modalities of care and integrated service delivery systems more often involve treatment teams, physician extenders, and other models which render naming an individual difficult. Requesting repeated releases from a patient to accommodate changes in the named

individual when the patient has already agreed to receive care from the involved provider does not make sense. We strongly encourage SAMHSA to allow the consent to include a more general description of the individual, organization, or health care entity, or a health information exchange, to which disclosure is to be made.

**Other Points of Interest in Michigan:**

- Recent state legislative action in Michigan mandated the creation of a consent which complies with federal and state privacy and confidentiality requirements for all health care services including mental health care and substance abuse treatment. This action was driven by a state level health information exchange leadership group which recognized the barriers created by diverse consent management practices among health care providers.
- Currently substance abuse treatment data is being excluded from a statewide initiative to improve coordination of care for all Medicaid patients due to unresolved privacy concerns.

Thank you for the opportunity to submit comments.

Janis Pinter  
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Thank you greatly for allowing us to make comments in advance of the public hearing.

I represent a large county level 1 hospital and trauma center that has Part 2 Program. The Part 2 Program treaters would like to share all patient information with their colleagues in various departments in order to coordinate care and best serve the needs of each individual patient. This includes information like a medication list that could prevent the prescription of counter indicated materials all the way down to patient schedules that could assist in coordinating care in a large facility across multiple specialties. Should a QSOA agreement be entered or are these the types of communications that are considered "between a program and an entity having direct administrative control"? Most importantly the providers don't want to be limited in sharing treatment information that might identify a patient as being in a substance abuse program that could avert a medical catastrophe. There may be no emergency necessitating the "breaking the glass" until it is too late.

The statutory provisions create a significant barrier within institutions to provide patient care. We would like that loosens restrictions and/or definitively states what can be shared:

**Current:**

(3) *Communication within a program or between a program and an entity having direct administrative control over that program.* The restrictions on disclosure in these regulations do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of alcohol or drug abuse if the communications are

(i) Within a program or

(ii) Between a program and an entity that has direct administrative control over the program.

**Anticipated:**

(3) *Communication within a program or between a program and an entity having direct administrative control over that program.* The restrictions on disclosure in these regulations do not apply to communications of information between or among personnel having a need for the information in connection with their duties to provide patient care or arise out of the provision of diagnosis, treatment, or referral for treatment of alcohol or drug abuse if the communications are

(i) Within a program or

(ii) Between a program and an entity that has direct administrative control over the program.

The provisions of the statute create a barrier to patient care by hindering the flow of real time medical information necessary to avoid catastrophic events to minor inconveniences. Obtaining patient consent can alleviate some of these issues, but the consent requirements are very restrictive and delay the flow of information. For instance, a hospital can open/acquire additional clinics or bring in outside services

and grant them access to their medical records systems under a BAA. These partners initially cannot gain access to the 42.2CFR records without creating a new release or a possibly a QSOA.

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Removing my right to have my mental health records reviewed without consent is a mere precept for the on going battle of the liberals to next ban gun rights! Yes, it's a hidden agenda & I'm not buying it. Oppose this attempt to eliminate consent from whom the mental health records belong, is only the first of what will be future presentence of this administration to come, where voting or supporting non-liberal agendas will equate to the how the IRS has handled the tea party! It will lead to inability for conservatives, prior military with PTSD being able to protect their privacy & eventually their families I'm sure. We are not fools, please refuse to fold to such an out right attempt to the manipulation of our mental capacity to all venues of political involvement with this power of non consent to the most valuable asset we all own-- our sanity & it's representation!!!

For more info contact:  
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**Comments of James C. Pyles, Counsel,**  
**American Psychoanalytic Association**  
**Public Listening Session**  
**79 Federal Register 26,929 (May 12, 2014)**  
**FR Doc. 2014—10913**  
**Substance Abuse and Mental Health Services Administration**  
**June 11, 2014**

**Issue**

The American Psychoanalytic Association (APsaA), one of the oldest mental health professional associations in the country, has been asked to address whether narrowing the applicability of 42 C.F.R. Part 2 would:

- (a) adversely impact patients and health care provider organizations,
- (b) whether the change would address stakeholder concerns, and
- (c) whether this change would raise any new concerns.

APsaA believes this suggested change would:

- (a) adversely affect patients by eroding the trust that is essential to quality mental health care and providers by creating greater complexity and conflict in patient privacy laws and standards of ethics,
- (b) not address shareholders' concerns by diminishing burdens, and
- (c) raise new concerns among patients, families and practitioners that the privacy of sensitive mental health information will not be protected.

The overall issue throughout the “notice of public listening session” is whether SAMHSA should reduce the privacy rights and protections of individuals in federally-assisted substance abuse treatment programs in order to “reduce the

burdens” on certain “stakeholders,” e.g., new health care organizations such as ACOs and health homes?<sup>1</sup>

These “stakeholders” have sought this change in the regulations because complying with the patients’ wishes with respect to privacy is “difficult” for them.

It is important to be clear about what these stakeholders are seeking—they wish to more freely use and disclose a patient’s sensitive substance abuse treatment information *regardless of the patient’s wishes and over the patient’s objections*. Under existing law, they may use and disclose a patient’s substance abuse information:

- (a) with the patient’s consent, or
- (b) without consent
  - (1) to the extent necessary to meet a bona fide medical emergency,
  - (2) for the purpose of conducting scientific research, management audits, financial audits or program evaluations, and
  - (3) if authorized by a court order to avert a substantial risk of death or bodily harm.<sup>2</sup>

APsaA believes that SAMHSA should assist integrated delivery systems in accommodating patients’ expectations, privacy rights, privacy laws and ethical standards, rather than seeking to alter patients’ expectations, privacy laws and ethical standards to accommodate the current capability of new health care delivery models. As SAMHSA concedes in the notice, “technical solutions for managing consent collection are possible.”<sup>3</sup> SAMHSA should not be seeking to reduce the privacy burden on integrated delivery systems by increasing the privacy burden and risk for patients and practitioners.

<sup>1</sup> 79 Fed. Reg. at 26,930.

<sup>2</sup> 42 U.S.C. 290dd-2(b).

<sup>3</sup> 79 Fed. Reg. at 26,931.

## **Consideration of “Stakeholders” Views**

SAMHSA states that the purpose of the listening session is “to obtain direct input from stakeholders on updating the regulations.”<sup>4</sup> There is no indication that SAMHSA plans to give the views of patients or consumers additional weight, and there is an assumption that the regulations need “updating.” In fact, patients are the most important “stakeholders” because they have the most at stake, and the health care delivery system cannot operate without their voluntary cooperation. As HHS determined in issuing the HIPAA Privacy Rule, “the entire health care delivery system is built upon the willingness of individuals to share the most intimate details of their lives with their health care providers.”<sup>5</sup> APsaA believes that SAMHSA should give the greatest weight to the concerns of patients and consumers in determining whether their privacy rights should be weakened.

## **Weakening the Privacy Protections in Federally-Assisted Substance Abuse Programs, in the Midst of an Electronic Health Information Privacy Breach Epidemic, Would Erode the Trust That is Essential for Quality, Cost Effective Health Care and Create an Ethical Conflict for Mental Health Practitioners.**

1. As the Supreme Court noted in 1996, effective mental health services are “*rooted in the imperative need for confidence and trust*” even more than with physical medicine. *The “mere possibility of disclosure” may impede the development of the confidential relationship necessary for successful treatment.* The Court’s holding has been followed in over 400 cases.<sup>6</sup>
2. When HHS issued the HIPAA Privacy Rule in 1996, it found that “privacy is necessary to secure effective, high quality health care.”<sup>7</sup> HHS found that the public’s trust in the health care delivery system was being eroded by the unwanted disclosure of medical records.<sup>8</sup> More specifically, HHS found Americans were delaying or avoiding treatment for stigmatizing diseases such as cancer, HIV/AIDS, and other sexually transmitted diseases and that, *every year more than 2 million* Americans

<sup>4</sup> 79 Fed. Reg. at 26,929.

<sup>5</sup> 65 Fed. Reg. at 82,467 (Dec. 28, 2000).

<sup>6</sup> *Jaffee v. Redmond*, 116 S. Ct. 1923, 1928 (1996).

<sup>7</sup> 65 Fed. Reg. at 82,467 (Dec. 28, 2000).

<sup>8</sup> 65 Fed. Reg. at 82,467.

- did not seek treatment for mental illness due to privacy fears* at an annual cost of nearly \$1 billion.<sup>9</sup>
3. Since HHS' findings in 1996, the nation has experienced an electronic health information privacy breach epidemic. Just since 2009 when health information privacy breaches began to be reported as required by the HITECH Act, *more than 31 million Americans have had their health improperly disclosed* in breaches involving 500 or more individuals, and thousands more have been the victims of smaller breaches.<sup>10</sup> Between 2005 and 2008, the privacy of nearly 40 million electronic health records was breached.<sup>11</sup>
  4. As electronic health information privacy breaches have escalated, the public's trust that privacy laws will protect them as declined, and 97% of the public believe that health care providers and insurers should not be able to share their health information without their consent.<sup>12</sup> *Two-thirds of Americans are concerned that the privacy of their health information will be breached* in an electronic health information system and many are withholding information to prevent it from being improperly disclosed. The concern is particularly high with respect to mental health and "drug misuse" information.<sup>13</sup>
  5. It is now well established that *electronic health information systems cannot be made entirely secure*.<sup>14</sup> But the damage that can be done by electronic breaches is unlimited because the health information of millions of individuals can be stolen "in a matter of seconds," it can be stolen by thieves operating from anywhere in the world, and once stolen, electronic health information can never be recovered.<sup>15</sup>

<sup>9</sup> 65 Fed. Reg. at 82,777-779.

<sup>10</sup> Health information privacy breaches through May 17, 2014, Office of Civil Rights, Dept. of Health and Human Services.

<sup>11</sup> "The Financial Impact of Breached Protected Health Information," American National Standards Institute, et al. p. 21 (March 2012).

<sup>12</sup> *Id.* at p. 23.

<sup>13</sup> "Concern About Security and Privacy, and Perceived Control Over Collection and Use of Health Information Are Related to Withholding Health Information from Healthcare Providers," I. Agaku, et al., J. of Am. Med. Inform. Assoc. (Aug. 2013).

<sup>14</sup> "You WILL Be Hacked, Cope With It," Infosecurity Magazine (Nov. 19, 2013), <http://www.infosecurity-magazine.com/view/35708/you-will-be-hacked-cope-with-it/>; HHS finding, ". . . there is no such thing as a totally secure system that carries no risks to security." 68 Fed. Reg. at 8346 (Feb. 20, 2003).

<sup>15</sup> "The Financial Impact of Breached Protected Health Information," p. 15.

**Narrowing the Applicability of 42 C.F.R. Part 2 to “Specialty” Substance Abuse Services and Excluding “Pre-Treatment” Services is Inconsistent With the Statute and Will Further Erode the Trust of Patients, Families and Practitioners.**

The statute on which 42 C.F.R. Part 2 is based could hardly be more broad. The statute states that the privacy protections, including the right of consent, are to apply to:

“Records of the identity, diagnosis, prognosis, or treatment of *any patient* which are maintained *in connection with* the performance of *any program or activity relating to* substance abuse education, prevention, training, treatment, rehabilitation, or research which is conducted, regulated, *or directly or indirectly assisted by* any department or agency of the United States. . .”<sup>16</sup>

There is no indication that Congress intended for the privacy protections to apply only to “specialty” substance abuse services or that pre-treatment substance abuse services (e.g., screening, brief interventions) were to be excluded.

Further, it is unlikely that the public or practitioners will be able to draw a bright line between segments of an integrated delivery system that are providing “pre-treatment” substance abuse services for which there is no right of consent and segments providing substance abuse services for which consent is required. Greater complexity in the law will only lead to a further erosion of trust in the effectiveness of privacy protections and lower quality services as patients engage in self-protective measures.

**SAMHSA Should Not Encourage or Condone Noncompliance With Privacy Laws and Standards of Professional Ethics.**

The notice states that among the reasons SAMHSA is considering reducing the patients’ privacy rights are that the new integrated delivery systems “generally do not have sophisticated consent management capability” and that

<sup>16</sup> 42 U.S.C. § 290dd-2(a).

“[c]urrently most EHRs don’t support data segmentation.”<sup>17</sup> However, the HITECH Act clearly contemplates that health care providers will use “[t]echnologies that protect the privacy of health information and promote security in a qualified electronic health record, including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care (or disclose information about a condition) because of privacy concerns. . . .”<sup>18</sup> SAMHSA acknowledges that substance abuse treatment information is the type of information that could cause people to refuse to seek treatment if they fear they would compromise their privacy.<sup>19</sup>

Further, the HITECH Act requires covered entities to grant an individual’s request for restrictions on the disclosure of health information if the individual pays for the services out of pocket.<sup>20</sup> HHS has determined that covered entities, including health care providers, must have the capability to segment certain health information to comply with the patient’s right to pay privately. Further, HHS has determined that all providers subject to HIPAA should have that capability because it is needed to comply with HIPAA’s “minimum necessary” rule.<sup>21</sup>

HHS has repeatedly made clear that the “minimum necessary” rule is to be “consistent with, and not override, professional judgment and standards.”<sup>22</sup> The professional standards of the American Psychoanalytic Association provide as follows:

Confidentiality of the patient’s communications is a basic patient’s right and an essential condition for effective psychoanalytic treatment and research. A psychoanalyst must take all measures necessary to not reveal present or former patient confidences without permission, nor discuss the

<sup>17</sup> 79 Fed. Reg. at 26,931.

<sup>18</sup> Section 3002(b)(2) of the HITECH Act.

<sup>19</sup> 79 Fed. Reg. at 26,930.

<sup>20</sup> Section 13,405(a) of the HITECH Act.

<sup>21</sup> 78 Fed. Reg. at 5628 (Jan. 25, 2013); 42 C.F.R. § 164.522(a)(1)(vi).

<sup>22</sup> 67 Fed. Reg. at 53,197 (Aug. 14, 2002); 65n Fed. Reg. at 82,544 (Dec. 28, 2000).

particularities observed or inferred about patients outside consultative, educational or scientific contexts.<sup>23</sup>

The ethics standards of the American Psychiatric Association provide similarly that:

A psychiatrist may release confidential information only with the authorization of the patient or under proper legal compulsion.<sup>24</sup>

See similarly the ethics standards for social workers:

Social workers may disclose confidential information when appropriate with valid consent from a client or a person legally authorized to consent on behalf of a client.<sup>25</sup>

Changing the substance abuse treatment rule to permit disclosure of sensitive health information without consent would put those rules in conflict with the ethical standards of psychoanalysts, psychiatrists and social workers.

Finally, the Supreme Court in Jaffee v. Redmond recognized a “psychotherapist-patient privilege” in federal law that can only be waived by the patient or to avert a serious threat of harm to the patient or others.<sup>26</sup> The Court also recognized that all 50 states have similar laws. Congress made clear in the HITECH Act that such privileges are not to be waived by privacy laws.<sup>27</sup>

So the existing privacy provisions in 42 C.F.R. Part 2 are consistent with current federal and state law, patient expectations and standards of professional ethics and should not be weakened to accommodate the current capabilities of integrated delivery systems. Rather, such systems should be required to comply with current privacy laws, patient expectations and ethical standards in order to preserve the trust that is essential for quality, cost effective health care.

<sup>23</sup> “Principles and Standards of Ethics for Psychoanalysts,” American Psychoanalytic Association, section IV (June 2008).

<sup>24</sup> “The Principles of Medical Ethics,” American Psychiatric Association,” section 4.2 (2013).

<sup>25</sup> “Code of Ethics, National Association of Social Workers,” section 1.07(b) (2008).

<sup>26</sup> Jaffee v. Redmond, 116 S. Ct. at 1929, 1932, n. 19.

<sup>27</sup> Section 13,421(c) of the HITECH Act.

June 13, 2014

Ms. Cathy J. Friedman  
SAMHSA Public Health Analyst  
The Substance Abuse and Mental Health Services Administration  
1 Choke Cherry Road  
Room 5-1011  
Rockville, MD 20857

Re: Supplemental Comments of the American Psychoanalytic Association  
After June 12 Listening Session: Confidentiality of Alcohol and Drug  
Abuse Patient Records—79 Fed. Reg. 26929, FR Doc. 2014-10913

Dear Ms. Friedman:

On behalf of the American Psychoanalytic Association (APsaA), I want to thank you for the opportunity to comment on whether SAMHSA should reduce or narrow patients' privacy rights under 42 C.F.R. Part 2 to reduce the burden on new health care delivery models such as ACOs and health homes. As stated in our written comments submitted on June 11 and for the nine reasons listed in my testimony on the record in the Listening Session on June 12 (copy attached), APsaA feels strongly that it is essential for access to quality substance abuse treatment services to preserve or enhance the existing privacy rights of patients. I also thought it might be helpful if I shared some observations about the comments we heard during the course of the Listening Session.

**1. SAMHSA Should Put the Interests of Patients First**

The comments presented at the Listening Session fell generally into two categories:

- (a) those by patient and consumer representatives and by representatives of mental health practitioners who are subject to established standards of professional ethics in favor of preserving

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and strengthening the privacy protections in the substance abuse rule; and

- (b) those by behavioral health clinics, health information exchanges, and health IT vendors in favor of abolishing all or some of patients' rights under the substance abuse rule.

So an initial question is, whose interests is SAMHSA principally charged with protecting? APsaA believes that SAMHSA should first and foremost protect the interests of patients. This is why the "stakeholder" approach will always lead to a result that is *not* "patient-centered" because patients will always be outvoted by the numerous and growing number of "stakeholders" seeking to further their own interests and profitability. Applying an approach that gives equal weight to all "stakeholders" in determining what privacy rights a patient should have, makes no more sense than using a "stakeholder" approach to decide how to treat a cancer patient. That would require convening a meeting of the patient and all conceivable "stakeholders" including, oncologists, surgeons, administrators, the billing department, the laundry and janitorial services, drug company representatives, the medical equipment suppliers, the health IT department, in-house and outside counsel, etc. and weighing all of their views equally. The patient's views will always be outweighed in such an approach.

In fact, quality health care can only be provided if there is a relationship of trust between the patient and the practitioner—and those were the representatives at the Listening Session who most often favored preserving the patients' privacy rights. All health information starts out private and under the patient's control—in the patient's head or in the patient's body. Health care is only possible when the patient *voluntarily* (assuming they are competent) discloses that information to a practitioner.

Studies we cited at pages 3-4 of our initial comments show that patients will not disclose information necessary for their treatment if they do not trust

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that the practitioner will use and disclose the information only as they consent. As the Supreme Court noted in Jaffee v. Redmond, 116 S. Ct. 1923, 1929 (1996), failing to allow the patient to control disclosure of mental health information does not make more information available, but rather makes *less* information available because it is “unlikely to come into being.”

Several references were made to “balancing” the individual’s privacy interests against the public’s interest in more integrated health care and “big data.” However, the Supreme Court in Jaffee expressly rejected such a “balancing component” based on the finding that privacy is essential to quality mental health care, and access to quality mental health services is in the best interest of *both* the individual and the public. 116 S.Ct. at 1929. So for this reason as well, the interests of the patients should be given top priority when considering whether to narrow or reduce patients’ privacy rights.

Those who wish to disclose or gain access to the patient’s sensitive mental health information without the patient’s consent or over the patient’s objections are essentially taking the position that they could provide much better health care if they could just get the patient out of the way. That is *not* patient-centered health care.

Putting the interests of the patients first would also help blunt recent criticism that SAMHSA is “preoccupied” with “broadly defined behavioral health concerns” rather than focused on severely mentally ill patients.<sup>1</sup> And reducing privacy protections in an election year in the middle of a rapidly expanding health privacy breach epidemic and a strong public backlash against unfettered NSA surveillance may not be wise politically.

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<sup>1</sup> See “Memorandum: Committee’s Investigations of Federal Programs Addressing Severe Mental Illness,” Majority Staff, Subcommittee on Oversight and Investigations, p. 6-7 (May 15, 2014).

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2. **SAMHSA Should Preserve and Enhance Clear and Unambiguous Privacy Protections that Are Consistent with Established Standards of Professional Ethics.**

For decades prior to the issuance Amended HIPAA Privacy Rule by the Bush Administration in 2002, the national standard for patient health information privacy was set forth in the American Medical Association's Standards for the Ethical Practice of Medicine which stated that a patient's health information may not be disclosed without consent, and any conflicts between a patient's right to privacy and a third party's need to know "should be resolved in favor of the patient, except where that would result in a serious health hazard or harm to the patient or others."<sup>2</sup> So those who claim that the patient's right of consent somehow creates a threat to the patient's health need to understand that this has been the standard of practice throughout the history of medicine as well as the history of the country.

In the eleven years since the effective date of the Amended HIPAA Privacy Rule on April 14, 2003, the public has lost confidence that the health privacy laws will protect them and the regulated industry does not know what is expected under complex and conflicting privacy laws and rules.<sup>3</sup> This has resulted in poorer quality health care at higher cost. So SAMHSA should *not* use the HIPAA Privacy Rule as a model, and the inconsistency of Part 2 privacy protections with the HIPAA Privacy Rule should *not* be a justification for conforming Part 2 to HIPAA.

The privacy protections in 42 C.F.R. Part 2 are much clearer and less conflicting and ambiguous than the protections in the Amended HIPAA Privacy Rule. By statute, they apply to "any patient" in connection with "any program or activity" that is "directly or indirectly" assisted by "any Department or agency of the United States."<sup>4</sup> It may be, as one commenter stated, that few patients know

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<sup>2</sup> 65 Fed. Reg. at 82,472.

<sup>3</sup> "The Financial Impact of Breached Protected Health Information," ANSI, et al., pp. 20-23 (March 2012).

<sup>4</sup> 42 U.S.C. § 290dd-2(a).

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what Part 2 is, but nearly every patient will be more comfortable and trusting if they know that their substance abuse information cannot be used or disclosed without their written consent.

By contrast, the HIPAA Privacy Rule only applies to three types of “covered entities” (health plans, health care clearing houses and health care providers) and their business associates, and the Rule expressly permits uses and disclosures of an individual’s health information for broadly defined treatment, payment, and health care operations without consent and even over the patient’s objections.<sup>5</sup> The Rule further permits numerous additional unauthorized uses and disclosures for special public interest purposes.<sup>6</sup> Some of these uses and disclosures (other than treatment) are subject to the “minimum necessary” rule which HHS has determined must be applied in a manner that is consistent with and does not override professional standards and judgment.<sup>7</sup> There is an exception for “psychotherapy notes” which cannot be used or disclosed without the patient’s permission, except in narrow circumstances.<sup>8</sup> It is simply impossible for any patient (and most practitioners) to understand what privacy rights patients have in a given situation under the Amended HIPAA Privacy Rule.

The inadequacy of the Amended HIPAA Privacy Rule was partially addressed by Congress in the HITECH Act of 2009 which restricted some unauthorized uses and disclosures, restored the patients’ right to prohibit disclosures for payment and health care operations without consent if they paid out of pocket and expressly stated that privileges (like the psychotherapist-patient privilege recognized by the Court in Jaffee) would remain available to individuals.<sup>9</sup> Unfortunately, these revisions made the HIPAA Privacy Rule even more unintelligible to patients and providers.

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<sup>5</sup> 45 C.F.R. § 160.102; 164.506(a).

<sup>6</sup> 45 C.F.R. § 164.512.

<sup>7</sup> 45 C.F.R. § 164.502(b); 67 Fed. Reg. at 53,197 (Aug. 14, 2002).

<sup>8</sup> 45 C.F.R. § 164.508(a)(2).

<sup>9</sup> HITECH Act, sections 13,405(a); 13,421(c).

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The confusion in the HIPAA Privacy Rule was created when the Bush Administration reversed a determination by the Clinton Administration to have the HIPAA Privacy Rule be consistent with centuries of professional ethics. The Original Health Information Privacy Rule issued by the Clinton Administration in 2000 acknowledged that the right of consent for uses and disclosures is recognized in most standards of ethics and has been the established practice in the United States.<sup>10</sup> The Bush Administration reversed this determination in 2002 and eliminated the right of consent for treatment, payment and health care operations, over the strong objections of patient, consumer and practitioner organizations and at the behest of the provider community, led by the hospitals.<sup>11</sup>

When practitioner organizations, including APsaA, pointed out that such a reversal of privacy policy would put the HIPAA Privacy Rule in direct conflict with standards for the ethical practice of medicine and psychiatry, the Bush Administration did not deny the conflict, but tried to resolve it by saying that the Privacy Rule was intended to be merely a federal “floor” of privacy protections and was not even intended to serve as “best practices.”<sup>12</sup> We heard commentary in the Listening Session from representatives of health information exchanges who said they were diligently designing their systems to comply with only this “floor” of protections. So experience has shown that the “floor” of federal privacy protections has also become the “ceiling.” Hopefully, this is not a result that SAMHSA would support for the privacy of substance abuse information.

If SAMHSA were to modify the Part 2 rule to provide that it only applies to “specialty substance abuse services,” most patients (and many providers) will not be able to distinguish between “specialty” providers and non-specialty providers. The net result will be a further erosion of trust by patients and more uncertainty for providers.

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<sup>10</sup> 65 Fed. Reg. at 82,472, 82,474 (Dec. 28, 2000).

<sup>11</sup> 67 Fed. Reg. at 53,210.

<sup>12</sup> 67 Fed. Reg. at 53,212.

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Finally, sending a strong and clear message to the provider, vendor and health information exchange communities that SAMHSA plans to uphold the privacy protections of patients that are consistent with established standards of ethics will expedite the development of technologies that preserve and protect rather than destroy patients' privacy rights. The longer SAMHSA hints that it may be willing to "update" privacy protections to accommodate the interests of ACOs and health homes, the more development of essential technologies required by law will be delayed. As I stated, our objective should be to develop technologies that address patient expectations and facilitate the ethical practice of medicine and psychiatry rather than try to shape patient expectations and ethical standards to fit the current capabilities of the latest health delivery model.

**3. The Right to Health Information is a Fundamental Right That Is Essential For Quality Substance Abuse Treatment.**

HHS determined when the Original HIPAA Privacy Rule was issued that "[p]rivacy is a fundamental right," "is one of the key values on which our society is built," and "is also necessary for the effective delivery of health care, both to individuals and to populations."<sup>13</sup> HHS further noted that "there is significant intrusion when records reveal details about a person's mental state, such as during treatment for mental health." And further that, if "the right to be let alone" means anything, then it likely applies to having outsiders have access to one's intimate thoughts, words, and emotions" (citing the Supreme Court's holding in Jaffee).<sup>14</sup>

HHS also noted that "few experiences are as fundamental to liberty and autonomy as maintaining control over when, how, to whom, and where you disclose personal material."<sup>15</sup> So, as I stated during the Listening Session, consent=control=privacy=liberty. If you have no right of consent, you have no

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<sup>13</sup> 65 Fed. Reg. at 82,464, 82,467.

<sup>14</sup> 65 Fed. Reg. at 82,464.

<sup>15</sup> Id.

# POWERS

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control over your personal health information. If you have no control over the disclosure of that information, you have no privacy, and if you have no privacy, you have no liberty. Surely patients suffering from substance abuse, who are competent, deserve to have their liberty protected.

Do not hesitate to contact me if APsaA can be of further assistance.

Very truly yours,

James C. Pyles  
Counsel  
American Psychoanalytic Association

Attachment

**Should SAMHSA “update” substance abuse regulations by narrowing patient privacy rights to reduce the “burdens” ACO’s and Patient-Centered Medical Homes?**

APsaA’s answer is “No” for the following reasons:

1. SAMHSA should put the interests of patients first because these “stakeholders” have the most at stake.
2. SAMHSA should help ACO’s and health homes comply with privacy laws, patients’ privacy expectations and standards of professional ethics rather than helping them violate those laws, expectations and ethics.
3. Such a change is not supported by the substance abuse statute which provides a right of consent for the disclosure of substance abuse information “in connection with the performance of any program or activity relating to” federal assisted substance abuse “education, prevention, training, treatment, rehabilitation or research”.
4. As recognized by the Supreme Court and over 400 federal court decisions over the last 15 years, effective mental health and substance abuse treatment is based on a relationship of trust between the patient and the practitioner, and minimizing privacy protections would erode that trust.
5. Narrowing the consent requirements under the substance abuse privacy rule would add to the confusion that already exists among the public and practitioners—the HIPPA Privacy Rule initially complied with professional ethics but after the changes by the Bush Administration does not based on the argument that HIPAA is only a “floor” of federal privacy protections.
6. We are in the midst of an epidemic of electronic health information privacy breaches with more than 31 million Americans having had their health privacy breached since 2009. Two-thirds of Americans are concerned that their health information privacy will be breached electronically and 97% of the public believes their health information should only be disclosed with their consent.

7. Electronic health information systems cannot be made secure.
8. The standards of professional ethics of APsaA, the APA and NASW all require patient consent for the disclosure of personal mental health information.
9. A patient-practitioner privilege has been recognized by the Supreme Court at the federal level and by all 50 states, and the HITECH Act confirmed that such privileges are not waived. This privilege can only be waived by the patient except in emergencies to prevent death or injury.

**Should SAMHSA “Update” Substance Abuse Regulations  
By Narrowing Patient Privacy Rights To Reduce  
The “Burdens” ACO’s And Patient-Centered Medical Homes?**

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June 27, 2014

Ms. 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: Further Comments on Confidentiality of Alcohol and Drug Abuse Patient Records—79 Fed. Reg. 26929, FR Doc. 2014-10913

Dear Ms. Friedman:

Please accept the following comments to supplement the comments of the American Psychoanalytic Association filed with SAMHSA on June 11 and 13 and the oral comments I presented at the Listening Session on June 12. Several recent developments add important evidence to the points that we made that health information privacy remains a basic right of all competent Americans even in the digital age, that honoring and respecting a patient's right to privacy will always be less efficient than ignoring that right, and that health information technology is raising threats to the quality of health care.

On June 25, the Supreme Court issued its decision in Riley v. California and U.S. v. Wurie. The Court held unanimously in both cases that the police must obtain a warrant before searching someone's cellphone incident to an arrest because:

Mobile application software on a cell phone, or "apps," offer a range of tools for managing detailed information about all aspects of a person's life. There are apps for Democratic Party news and Republican Party news; apps for alcohol, drug, and gambling addictions; apps for sharing prayer requests; apps for tracking pregnancy symptoms; apps for planning your budget; apps for every conceivable hobby or pastime; apps for improving your romantic life. Decision p. 20 (emphasis supplied).

So, information about an individual's alcohol and drug addictions are the very types of information the Court found to be included in the individual's right to privacy protected by the Constitution.

Further, the Court also noted that "[a]n Internet search and browsing history, for example, can be found on an Internet-enabled phone and could reveal an individual's private interests or concerns—perhaps a search for certain symptoms of disease, coupled with frequent visits to WebMD." Decision at p. 20 (emphasis supplied). Finally, the Court noted that, while generally the Court applies a balancing test to determine whether a search is

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“unreasonable” under the Fourth Amendment, it rejected a balancing test because of the type and volume of information that can be compiled in a cell phone and held **“that officers must generally secure a warrant before conducting such a search.”** Decision at pp. 9-10.

The Court also acknowledged that respecting the privacy rights of individuals would impede certain societal interests, such as fighting crime. But the Court found:

Our cases have recognized that the Fourth Amendment was the founding generation’s response to the reviled “general warrants” and “writs of assistance” of the colonial era, which allowed British officers to rummage through homes in an unrestrained search for evidence of criminal activity.

So the Court confirmed that society’s interest in efficiency must give way to the individual’s right to privacy.

Finally, a recent study adds to findings of an Institute of Medicine study that electronic health records are adding medical errors which are not being reported. See “An Analysis of Electronic Health Record-Related Patient Safety Concerns,” Meeks, DW, et al., Journal of the American Medical Informatics Association (April 2014). Finding:

EHR-related safety concerns involving both unsafe technology and unsafe use of technology persist long after ‘go-live’ and despite the sophisticated EHR infrastructure represented in our data source. Currently, few healthcare institutions have reporting and analysis capabilities similar to the VA.

While it is unclear whether electronic health information systems will ever fulfill their promise of better health care at lower cost, it is clear that they are not capable of providing those results today or in the foreseeable future. Accordingly, it is not sound health policy to diminish the traditional privacy rights and expectations of patients in order to facilitate the interests of new and unproven health delivery models to make broader use of unreliable electronic health information systems.

Very truly yours,

James C. Pyles  
On behalf of the American Psychoanalytic  
Association

To Whom it May Concern:

Thank you for the opportunity to provide comments as a result of the listening session that you arranged. These are the comments I made during the call.

If additional clarification is needed, please contact me.

Laura H. Tyler, PhD, LPC  
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#### 42 CFR, Part 2 Public Listening Session

June 11, 2014

##### a. Applicability of 42 CFR Part 2

Laura H. Tyler – University of Arkansas for Medical Sciences’ Psychiatric Research Institute

Thank you...

Patient protection or safety is the principle that underlines 42 CFR Part 2. Rather than offering varying definitions of “*program*”, it would be more patient-centric to offer choice by utilizing informed consent. Via a formal informed consent, a patient could agree to a treatment program that includes an integrated approach. By having the patient consent to integrated treatment including an authorization to disclose drug and alcohol records to the EHR, the patient could choose the **condition** that care would be integrated. The treatment program would still have to be HIPAA compliant with regard to Treatment, Payment and Operations and information could only be shared within the care system on a “need to know” basis. This could substantially improve patient access to integrated care and the capacity to have an integrated EHR in a *program* setting that was part of a larger system such as an academic medical institution.

Further defining “*program*” would have the unintended consequence of preventing integration in complex treatment facilities that offer a wide array of screening, assessments, pre-treatments, brief interventions as well as a full continuum of services. Privacy protections should be afforded to the patient and managed by them. For example, a patient who is pregnant and diagnosed with a substance abuse disorder should be able to choose integrated care in a setting that best meets her preferences and needs. The patient should be allowed to “set aside” the inherent restrictions in 42 CFR Part 2 in favor of their choice to select a comprehensive provider who can address their holistic needs. Patient

safety is compromised when information is segmented. Regardless of setting, the patient should be given the choice to have their information integrated within a system and included in an EHR.

This approach would still require the management of Part 2 re-disclosure; however, this could be addressed with some expansion of the Qualified Service Organization agreements.

### **e. Qualified Service Organization Agreement**

Laura H. Tyler – University of Arkansas for Medical Sciences’ Psychiatric Research Institute where I serve as the Administrator

Flexibility and simplicity are missing in 42 CFR Part 2 when it comes to management of the redisclosure of information in an environment that is increasingly electronic and individuals are increasingly being viewed holistically. This lack of flexibility produces barriers for patients who desire to access care as well as among independent providers and other stakeholders who are seeking to work collaboratively on behalf of a shared patient. Part 2 makes it more difficult to achieve care coordination, measure quality/or outcomes and receive payment. Part 2 segments the patient population it is intended to protect and reinforces stigma.

If extensive overhaul of the law is not possible, there is a need for broader and more simplistic use of QSOAs or combined QSOAs/BAAAs. The QSOA is a two-way agreement as described by the FAQs. This is unnecessarily constraining. Expanding the ease of use of an HIO via a website notification of the HIO’s members and QSOAs would expedite information exchange and ease administrative and financial burden associated with serving individuals with substance use disorders. Ways to more globally expand the use of the HIO/exchange and allow multiple-party consent are needed. Uses of QSOAs need to consider how to facilitate safe and less complex exchange of information thereby enhancing integration of care, access to care and care quality. There is also a need for revisions that have the effect of reducing barriers to information exchange and eliminate the need to create and maintain costly duplication in documentation systems. In essence, more practical approaches are needed that give patients more choice in how they manage their information.

In focus groups that we held related to integration within an EHR, the vast majority of patients within our **covered program** identified their desire to have more flexibility to broadly share information to facilitate coordinated and safer care. Patients have asked how they could waive their protections related to redisclosure. Patients should be allowed to opt in and consent to set aside prohibitions on redisclosure.

If broad revisions are not possible to accomplish inclusion, it is critical that more technologically friendly methods such as the use of a website for a list of current and future QSOAs be allowed in lieu of individual notices and consents for any change in QSOAs.

Thank you for exploring ways to bring the law and current technological advancements and integration of care models more in synch. Ultimately, this will reduce stigma, improve access to care and enhance outcomes for individuals who deserve quality care that is integrated.

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It is important to disclose substance abuse history to medical professionals as research, including research conducted in my own lab, has revealed that such history may have lasting implications in terms of immune response. It is also important that patient rights and privacy are maintained when sharing this information as substance abuse is still stigmatized by many. In my opinion, the current CODE OF FEDERAL REGULATIONS regarding PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS adequately provides researchers and medical professionals access to patient information while still ensuring the patients right to privacy. It is important that as researchers, we follow the regulations set out for RESEARCH ACTIVITIES and ensure that our personnel are aware of issues of confidentiality. Further, it is important that we do our best to ensure that our employees and those with access to sensitive information are individuals of good judgment.

Submitted respectively,

Sulie L. Chang, Ph.D.

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Director, Institute of NeuroImmune Pharmacology  
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Regarding:

Agency: HHS Substance Abuse and Mental Health Services Administration

Docket number: 2014-10913

It looks like the proposed rule changes will substantially reduce the privacy and confidentiality of personal medical records. This is especially troubling in light of the current movement toward electronic health records. Once a piece of data gets onto the Internet, the World Wide Web, or other electronic systems, all control of who has access to that data is lost. This is the situation whether the access is intended (by health care providers or organizations) or unintended (by hackers, the NSA, or any criminal / snooping entity).

Therefore I oppose these rule changes. Please: Protect the privacy of my medical records by abandoning these proposed rule changes.

Hello –

I tried to get into the queue to comment on the below during your call – please feel free sharing this openly.

Jeff Livesay  
Associate Director  
Michigan Health Information Network Shared Services

**Admin Support:** [bom@mihin.org](mailto:bom@mihin.org): Phone: 517-336-1431

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**From:** Jeff Livesay

**Sent:** Wednesday, June 11, 2014 11:00 AM

**To:** 'Tatiana Melnik'; [tim.pletcher@cmich.edu](mailto:tim.pletcher@cmich.edu)

**Cc:** PracticeGroups@healthlawyers.org

**Subject:** New Michigan Law and standard consent form: RE: SAMHSA Issues Notice of Public Listening Session on 42 C.F.R. Part 2, the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations

**Importance:** High

Hi,

I am having trouble with the SAMHSA webinar today but understand some states such as Illinois are trying to develop a statewide standard consent form for this type of information.

Michigan has successfully created such a form and 3 weeks ago Governor Snyder signed into law a Public Act requiring that it be implemented by January 1, so now we are working on the statewide education and rollout plan.

Attached is a presentation made last week by four of the leaders on this effort – from the slide showing the participants, you can see this was truly a statewide effort. I was the co-chair of the Privacy Working Group that carried this through for Gov. Snyder's HIT Commission, and our Lt. Governor was also integral to the effort with Judge Curtis Bell from a Diversions perspective. Senator Jim Marleau, Chair of

our Senate Health Policy Committee, was the legislative champion. This level of support is key for getting this type of legislation passed.

Please feel free to share the attached presentation, which contains the current draft of the standard consent form, with anyone you wish.

Best regards,

Jeff Livesay  
Associate Director  
Michigan Health Information Network Shared Services

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**From:** Tatiana Melnik [<mailto:tatiana@melniklegal.com>]  
**Sent:** Wednesday, May 14, 2014 9:18 PM  
**To:** [tim.pletcher@cmich.edu](mailto:tim.pletcher@cmich.edu); Jeff Livesay  
**Subject:** FW: SAMHSA Issues Notice of Public Listening Session on 42 C.F.R. Part 2, the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations

Hi Tim and Jeff:

In case you haven't heard, please note the below and forward it to others as appropriate. The Part 2 regulations haven't been touched since 1987, so this would be a good time to give SAMHSA input.

Tatiana

Tatiana Melnik, Attorney  
*Helping companies and individuals protect their data and information.*  
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**From:** Behavioral Health Task Force Leadership [<mailto:PracticeGroups@healthlawyers.org>]  
**Sent:** Wednesday, May 14, 2014 5:34 PM

To: [tatiana@melniklegal.com](mailto:tatiana@melniklegal.com)

**Subject:** SAMHSA Issues Notice of Public Listening Session on 42 C.F.R. Part 2, the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations

AHLA Practice Groups

***email alert***



To: Behavioral Health Task Force Members

From: Behavioral Health Task Force Leadership  
Jack Dempsey, Co-Chair  
Gerald "Jud" DeLoss, Co-Chair  
Teresa Meinders Burkett, Vice Chair of Membership  
David Humiston, Vice Chair of Strategic Activities  
Kristen McDermott Woodrum, Vice Chair of Educational Programs  
Suzanne Scrutton, Vice Chair of Publications  
Barbara Zabawa, Vice Chair of Research and Website

Date: May 14, 2014

**SAMHSA Issues Notice of Public Listening Session on  
42 C.F.R. Part 2, the Confidentiality of Alcohol and  
Drug Abuse Patient Records Regulations**

By Barbara Zabawa\*

The federal rules that govern the use and disclosure of alcohol and drug abuse records (AODA record rules) have not been touched since 1987, despite the substantial revolution in health care technology, payment, and delivery.

Recognizing these changes and even more on the horizon, on Monday, May 12 the Substance Abuse and Mental Health Services Administration (SAMHSA) within the U.S. Department of Health & Human Services issued notice of a public listening session to obtain input from stakeholders on updating the federal AODA record rules. In the notice of the listening session, found at 79 Fed. Reg. 26929 (May 12, 2014), SAMHSA hints at a future rulemaking and desires all interested parties to share their views prior to such a rulemaking.

There are two primary driving forces behind the listening session and future rulemaking: (1) integrated and coordinated care initiatives, such as accountable care organizations or health information exchange (HIE) organizations; and (2) electronic health record (EHR) systems. Both of these forces in health care have the potential for greater sharing of information, including AODA records. The current AODA record rules create difficulties to accomplish the goals of coordinated care and EHR

systems. Specifically, the AODA record rules apply to federally funded individuals or entities that "hold themselves out as providing and provide, alcohol or drug abuse diagnosis, treatment or treatment referral," including units within a general medical facility that hold themselves out as providing diagnosis, treatment, or treatment referral. As more substance abuse treatment is provided in general health care settings, it is difficult to determine whether the AODA record rules apply to the myriad of health care organizations involved in coordinated care efforts.

Furthermore, the current rules have strict consent requirements that prohibit listing future un-named providers on the consent form. Each time a new provider joins coordinated care organizations, the organization needs to update the consent form.

The strict redisclosure provision of the current rule forces most EHR systems to separate AODA records from the rest of the patient's medical record or apply the AODA record protections to the entire medical record. Either approach may stifle efforts to share important information between care providers and improve patient outcomes.

Sharing AODA records for purposes of care coordination and population management also is restricted by the current AODA record rules. The current rules prohibit the sharing of AODA records for these purposes without consent.

Finally, the current AODA record rules limit the ability of payers, HIEs, and care coordination organizations to use AODA records for research, audit, or evaluation purposes, functions of growing importance as the health care sector moves toward using health information to improve health care quality and outcomes.

The overarching concern with regard to any updates to the AODA record rules is ensuring that the rules continue to adequately protect patient privacy. SAMHSA indicates its wish is to facilitate information exchange while respecting the legitimate privacy concerns of patients due to the potential for discrimination and legal consequences of sharing sensitive AODA information. SAMHSA realizes that protecting the confidentiality of AODA records is still necessary so that patients feel free to seek treatment without fear of compromising their privacy.

To find the appropriate balance between sharing AODA records and protecting patient privacy, SAMHSA welcomes attendance at the listening session, to be held on Wednesday, June 11 from 9:30 am to 4:30 pm, either in person or via webcast. In addition, SAMHSA invites comments regarding the need for updates to the AODA record rules. [Learn more](#) about the listening session and the areas SAMHSA invites for comment.

*\*We would like to thank Barbara J. Zabawa (WPS Health Insurance, Monona, WI) for authoring this email alert.*

*The Behavioral Health Task Force is supported by the following work groups: Military/Veterans; Payers; Providers/Clinicians; Risk Management; Rural; and State/Government.*

Member benefit educational opportunity:  
Participate in the [webinar](#) about acute and post-acute relationships in an ACO world: the devilish details (May 22).

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**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:**

I believe it is vital to keep protecting the confidentiality of persons receiving AOD (SUD) treatment under 42 CFR Part 2. County entities tend to serve those whose voice is compromised (e.g. mandated treatment, multiple systems involved) and so it is understandable that they would propose lighter restrictions for ease of information flow between providers and other practitioners, etc. However, instead of it being a stigma issue, I would argue that these protections increase safety for more people to seek services, especially for employees or professionals. Further, electronic health records are not secure, no matter what “protections” are in place – those with AOD disorders need to be informed, and consent to, this information release.

HIPAA’s sanctions have become horrendous – throwing AOD under this would make it even less attractive to enter this (or any) health field and make fewer persons want to open a business serving this population. One breach (recent example: \$1 million fine for the front desk failing to check the ID of expected auditors) can take a substance abuse facility or a small community clinic down.

For example, I had maybe 2-4 visits with a mental health provider (related to a major decision as to whether to move abroad and possible change citizenship status) within my large health provider network (Kaiser) in 2003 or 2004. For this, they gave me the diagnosis of “depression.” However, this is still listed as a “chronic” condition on my health record even though I have not had any related services since then. They have also not honored my request to remove this. Imagine if this was for an AOD disorder! Impossible – I would never go to my health provider for this type of service based on this experience. I would go to a private entity and pay out of pocket. However, some people might not have the option to see a private provider based on cost. I might consider using my insurance only if I could be guaranteed confidentiality in my health record, through 42 CFR Part 2.

## 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:

1. No
2. No
3. Yes, and to whom
4. No
5. Yes

Again, unless there is a clear distinction of who the information may go to, there is no protection. If at all, I believe information should only be limited to the physician or provider (not nurses) without an explicit consent in place.

The only possible exception is a centralized list of medications and a medication history across HIEs, health homes, ACOs, and CCOs – this is important to avoid drug-seeking behavior and over medication for the AOD population, but all behavioral/health and PHC clients.

## 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:**

Yes. But the concern is that the exception would be overlooked, especially by those not in the substance abuse 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:**

Agree. Medical emergency = when there is a serious threat to safety of self/others. This includes overdose or severe withdrawal, where risk of seizures, hallucinations, chronic lack of sleep (several days), etc.

NOTE: Postpartum psychosis is always a medical emergency due to the high risk of suicide (5%) and infanticide (4%). See Postpartum Support International and any reference document on this. This should extend to mood disorders as postpartum psychosis is of a manic quality. This has implications for perinatal substance abuse treatment.

Privacy goes under the bus to save a life. However, re-disclosure should be limited to stabilization of the emergency only.

**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:**

PHI is not safe. It is leaky at best, even with encryptions in place. It's a slippery slope.

I am very concerned that this will include County databases that may expose data to CPS and probation entities in addition to healthcare entities, especially for those with co-occurring disorders.

### Qualified Service Organization (QSO)

There are HIPAA breaches reported frequently, from STD status to health records, blasted on Face book by employees who should know better. AOD information has potential serious consequences (“bad” vs. “sick” to those not in the AOD field), more so than any other health condition, including mental health (“sick” vs. “bad”). This cannot be overlooked. I have seen AOD information affect the treatment of health providers who are in recovery *by other health providers* who are not. Remember, people in recovery are doctors and lawyers too!

Even 12-Step meetings have a guideline (tradition) that protects anonymity.

### 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:

Audits and specific research is already covered under 42CFR part 2 so I am not sure why this additional permission is necessary, except as it pertains to the QSO which I believe compromises health data (see above).

There are so many layers of administration already over services provided. I see this as potentially opening the door toward providers having to use a variety of scales (according to different agendas) that will further reduce actual services being provided and increase the administrative load.

### 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?

## Research

### Public Comment Field:

There should be a centralized pharmacy database that is mandatory for all health providers!

But, this would not require consent but fall under HIPAA already.

Meaning, surely the Part 2 program should not be the agency releasing this information anyway; rather, it should be the doctor/doctor's office, which is governed by HIPAA? The exception would be a physician employed by a part 2 program but surely their health records are already separate from the AOD data?

## Other Comments

### Topic:

### Public Comment Field:

Please consider all recovery addicts/alcoholics when you decide to compromise privacy. Many stakeholders (the alleged 85% in support of change) may not actually be in recovery themselves or even understand the recovery model. Similarly, most health practitioners use the medical model and do not understand the social model of recovery. It is easy to be gallant with other people's information but would they use the same measure on themselves?

Health providers and, especially, insurance providers, are subject to judgment of others too. There are unforeseen repercussions not just by the probation and child welfare system. A possible solution: Mandatory CEs for health providers on AOD recovery.

Medications are a health issue and all Rx meds should be able to be shared.

## **Comments to the Proposed Rule by the Substance Abuse and Mental Health Services Administration related to Confidentiality of Alcohol and Drug Abuse Patient Records**

**FR Doc. 2014-10913**

As providers of Substance Abuse and Mental Health Services we support changes to Federal Statute United States Code, Title 42, section 290dd-2 governing the confidentiality of substance abuse treatment information. While confidentiality of information for persons receiving substance abuse treatment is vital and should be protected, new models of integrated care to better serve this population are needed. Further, the use of electronic medical records and prescription drug programs require sharing of pertinent medical information across providers caring for patients.

Of most concern is the need to achieve better coordination and integration of medical and behavioral health care for persons with addiction. Coordinated care programs have demonstrated significant efficiency, outcome, and cost benefits and as a provider of such programs, we would like to eliminate barriers to delivery models where behavioral health and substance abuse services are coordinated with medical care sites.

### **a. Applicability of 42 CFR Part 2**

The strategy of defining covered information based on what substance abuse treatment services are provided, rather than by the type of facility providing the services, may be beneficial to “screening and pre-treatment providers” but still represents a challenge to comprehensive providers of substance abuse, behavioral health and medical care. Certainly, information privacy can also be separately addressed for providers of more complex or specialty care while excluding those involved solely in pre-treatment & screening services.

### **b. Consent Requirements**

Under an integrated care model “future un-named providers” should not apply to members within the integrated health care system that become involved with the care of the patient through direct referral of a licensed professional and an affiliated care manager. We are in favor of the proposal that Consent should include a more general description of the health care entity to which disclosure is to be made and that the “individuals” would be restricted to those within the health care system directly involved in the patient’s care. Electronic medical records generally do have capabilities of restricting access by provider/caregiver and a means to audit who has gained access to an individual’s record.

The requirement that 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, is unwieldy. Rather, a patient should be informed that only persons associated with an organization who are directly providing care for a patient would have access to their record. Billing and associated back office functions generally have limited access to pertinent billing data or data required by law or regulation.

We agree that the consent form should explicitly describe when substance abuse treatment information may be released outside of the treating organization.

### **c. Redisclosure**

Redisclosure presents problems for integrated health care since data segmentation is the antithesis of coordinated care across an integrated health care network. We agree that SAMHSA should clarify that redisclosure only applies to information that would identify an individual as a substance abuser, but to allow other pertinent health-related information shared by the Part 2 program to be redisclosed to a patient's direct caregivers within the organization.

### **d. Medical Emergency**

We agree that SMAHSA should amend 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.

### **e. Qualified Service Organization (QSO)**

We support options for allowing Part 2 data to flow to health care entities for the purpose of care coordination and population management while maintaining patient protection including 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.

Darleen Won

Darleen Won

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I told my male dentist I take methadone for my R/A as a personal choice. The younger the Doctor, the more likely they will respond positively to your methadone use. I did not specify my dose, and he did not ask. I was given Xanax instead of Vicodin for pain and sleep after each extraction. He knew Vicodin would not be effective in methadone users. Also, women doctors have 100% responded negatively to my methadone use, even though I have been clean for 5 years.

So, request a younger, male doctor, and be prepared to change doctors if you Can't reach a respectful relationship.

You must use common sense in your disclosures. No, I do NOT want my Methadone use in my electronic records. It is my decision, not the government.

June 18, 2014

Kate Tipping  
Public Health Advisor  
Substance Abuse and Mental Health Services Administration  
1 Choke Cherry Road, Room 5-1011  
Rockville, MD 20857  
*Via email: [PrivacyRegulations@SAMHSA.hhs.gov](mailto:PrivacyRegulations@SAMHSA.hhs.gov)*

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

Dear Ms. Tipping:

The National Association of Chain Drug Stores (NACDS) thanks the Substance Abuse and Mental Health Services Administration (SAMHSA) for conducting a listening session to gather stakeholder perspectives in advance of updating the rules under 42 CFR Part 2 related to the confidentiality of alcohol and drug abuse patient records. We appreciate this opportunity to respond specifically to SAMHSA's questions related to potential issues with electronic prescribing and prescription drug monitoring programs (PDMPs.)

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' 125 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 800 supplier partners and nearly 40 international members representing 13 countries. For more information, visit [www.NACDS.org](http://www.NACDS.org).

Over the years, 49 states have enacted laws and/or rules that require pharmacies to report prescription information to state PDMPs when dispensing controlled substances. Each state's PDMP laws and/or rules dictate the specific schedules of controlled substances that pharmacies must report upon dispensing. Notably, no state allows patients to opt out of having a particular prescription medication reported to the PDMP. Where language under 42 CFR Part 2 is inconsistent with states' PDMP laws and/or rules in this regard, we encourage SAMHSA to harmonize the rules with states' prescription reporting requirements.

PDMPs are useful tools for practitioners to identify and prevent misuse and abuse of prescription drugs. For this reason, it is imperative that PDMP databases be populated with complete and accurate prescription information so that

practitioners can make informed healthcare decisions for their patients. This holds true for the provision of quality care to patients undergoing substance abuse treatment. -

Excluding controlled substances prescriptions written as part of substance abuse treatment services from PDMP reporting undermines the effectiveness of PDMPs and practitioners' ability to use the information within these programs to the benefit of their patients. During the June 11 listening session that SAMHSA conducted on 42 CFR Part 2, it was noted repeatedly that patients can be reluctant to share their full prescription history with their healthcare providers out of fear of the stigma associated with taking certain medications used in substance abuse treatment. However, this information is critical for practitioners to have so that they can provide the best care possible to their patients. In addition, in most cases, pharmacies do not know a patient's diagnosis, so it would be impossible for a pharmacy to know when a medication is being used for substance abuse treatment. -

NACDS thanks SAMHSA for considering our comments regarding updates to 42 CFR Part 2. Please do not hesitate to contact me at 703-837-4183 or [knicholson@nacds.org](mailto:knicholson@nacds.org) if we can provide any further insight or assistance on this matter. -

Sincerely, -

Kevin N. Nicholson, R.Ph., J.D. -  
Vice President, Public Policy and Regulatory Affairs -

I am the chair of the board of directors for a 300-employee mental health system and have continuing contact with staff and with people in the surrounding communities. As compared to 20-30 years ago, I find that even new employees are highly sensitized to the issue of patient privacy. This has been part of their training and the culture of the organization reinforces this training. Privacy for people seeking mental health and substance abuse treatment seems to be a common value even beyond the service organization -- in other agencies and even among community members. It is very rare that we ever encounter a privacy incident with a patient. All these observations have convinced me that privacy regulations can be modified where it will be in the interest of stronger, more efficient services.

Jerry Evans, Ph.D.  
Director of Research & Evaluation  
Community Health Initiatives  
309 Deer Run  
Carbondale, CO 81623-8776  
970-704-0587 voice  
[www.CHI-Colorado.org/](http://www.CHI-Colorado.org/)

I fully support the Privacy/Regulations policies.

Joseph J. Bevilacqua, Ph.D



## **Public Listening Session: Confidentiality of Alcohol and Drug Abuse Patient Records**

Substance Abuse and Mental Health Services Administration (SAMHSA)  
June 11, 2014

### **Testimony of Jessica V. Barnett on Behalf of the Massachusetts Center for Health Information and Analysis**

#### ***Consent Requirements Session (10:45-11:45 a.m.):***

Good morning. My name is Jessica Barnett, and I am the Chief Privacy Officer for the Massachusetts Center for Health Information and Analysis, also known as CHIA. CHIA is an independent state agency, which houses, among other things, the Massachusetts All Payer Claims Database or APCD. As a matter of state law, public and private payers are required to report claims and enrollment data to CHIA, data that may include identifying information about patients receiving substance abuse treatment.

The public notice for the consent requirements session referenced HIEs, health homes, ACOs, and CCOs. In addition to these entities, CHIA respectfully urges SAMHSA to consider APCDs and similar data repositories when evaluating any proposed amendments.

APCDs, such as CHIA, are uniquely situated to serve the substance abuse patient population by providing a comprehensive source of multi-payer data that will enable state agencies and other qualified researchers to evaluate the success of policy initiatives, such as state and federal Mental Health Parity laws, which are designed to improve coverage for and increase access to substance abuse treatment for those in need.

In order to best serve this population, policymakers, researchers, advocates, and the patients themselves need to know whether these laws are working, and if not, where to focus future efforts at improvement.

However, if the consent requirements of 42 CFR Part 2 are amended in a way that prohibits or renders impracticable the integration of substance abuse treatment data into APCDs and similar data repositories, the revised regulation will have the unintended consequence of preventing CHIA and other agencies like it from fulfilling their role as a critical data resource for evaluating public policy initiatives that are designed to serve the very same population that 42 CFR Part 2 seeks to protect.

In order to balance the need to maintain patient privacy and to permit APCDs and other state-mandated data repositories to serve the substance abuse patient population, CHIA proposes that SAMHSA amend the consent requirements of 42 CFR Part 2 to make clear that holders of Part 2 data, including those that are not Part 2 programs, such as payers, may comply with state laws requiring the disclosure of Part 2 data to APCDs or other data repositories without obtaining patient consent.

As a corollary to this proposed no-consent rule for disclosures required by state law, and to ensure that patient privacy is protected, the revised regulation should specify that APCDs and other data repositories that receive Part 2 data in this manner become holders of Part 2 data themselves and are subject to applicable privacy and security requirements contained in the regulation. The revised regulation should then make explicit which of its requirements apply to APCDs and similar holders of Part 2 data and spell out the uses and disclosures that are permitted for such entities.

CHIA intends to submit more detailed written comments on this proposal to SAMHSA by the June 25<sup>th</sup> deadline. I would also be glad to answer any questions.

Thank you again for the opportunity to speak.

***Qualified Service Organization (QSO) Session (1:15-2:00 p.m.):***

Good afternoon. My name is Jessica Barnett, and I am speaking for the second time today on behalf of the Massachusetts Center for Health Information and Analysis, or CHIA, which houses the Massachusetts All Payer Claims Database, or APCD.

SAMHSA has indicated that it is considering expanding the definition of QSO to include care coordination services and to allow a QSO agreement 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. You have also inquired whether there are other use cases that should be considered with respect to QSOs.

CHIA respectfully submits that to the extent APCDs and other state-mandated repositories for health information become holders of Part 2 information, such entities should also be authorized to execute QSO agreements with service providers, including agreements for services such as data processing and analysis; services related to treatment or coordination of care; and legal, consulting, or other professional services.

Such services are necessary for APCDs to conduct their operations and to fulfill their statutory mission of providing high-quality data and analysis in support of health care policy initiatives. For example, this would permit a state agency to which Part 2 is reported to engage an expert in the area of substance abuse to analyze the data in furtherance of a specific project or initiative, such as monitoring compliance with Mental Health Parity laws. An agency that holds Part 2 data would also be able to engage expert assistance in profiling specific data elements that may include Part 2 information, in order to improve data quality.

CHIA intends to address this topic in further detail in its written comments to SAMHSA. I am also available to address any questions. Thank you.

***Research Session (2:00-2:45 p.m.):***

Good afternoon. My name is Jessica Barnett, and I am speaking for the third time today on behalf of the Massachusetts Center for Health Information and Analysis, or CHIA, which houses the Massachusetts All Payer Claims Database, or APCD.

CHIA respectfully urges SAMHSA to include state-mandated APCDs and other similar repositories for health care information on the list of organizations that are explicitly authorized to release Part 2 data to qualified researchers and research organizations. As discussed earlier today, APCDs are uniquely situated to serve the substance abuse patient population by providing a critical source of multi-payer data for the evaluation of public policy initiatives in the area of substance abuse treatment.

I have mentioned the evaluation of state and federal Mental Health Parity laws as one example. Other examples include an effort by the Massachusetts Senate to evaluate access to substance abuse treatment in Massachusetts; an initiative by MassHealth, the Massachusetts Medicaid program, to improve continuity of care for its members; and a proposed project by the Massachusetts Department of Public Health, Bureau of Substance Abuse Services, to use APCD data to identify populations in need of substance abuse treatment and those with unmet or underserved needs.

APCDs can best fulfill their role as a data source for such projects if they are permitted to disclose Part 2 data to state agencies and other qualified entities for approved research purposes, with appropriate protections for patient privacy. CHIA intends to address this topic more fully, and to propose specific privacy protections that SAMHSA may wish to include, in the written comments that we are preparing. Again, I would be happy to answer any questions. Thank you.

June 24, 2014

**VIA ELECTRONIC MAIL**

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

**Comments of the Massachusetts Center  
for Health Information and Analysis Concerning  
Proposed Changes to 42 CFR Part 2**

Please accept the following written comments concerning proposed changes to the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2, in response to SAMHSA's public notice at FR Doc. 2014-10913.

**Introduction: The Role of APCDs in Health Care Reform**

As SAMHSA has acknowledged, in the 25 years since the confidentiality regulations for alcohol and drug abuse patient records set forth at 42 CFR Part 2 were last updated, "significant changes have occurred within the U.S. health care system that were not envisioned by these regulations, including new models of integrated care that are built on a foundation of information sharing." These models involve new types of health care organizations, such as Health Information Exchanges (HIEs) and Accountable Care Organizations (ACOs), as to which SAMHSA has specifically requested guidance in order to "clarify the requirements [of 42 CFR Part 2]."

The Massachusetts Center for Health Information and Analysis (CHIA) respectfully urges that in considering changes to 42 CFR Part 2, SAMHSA consider and explicitly address the needs of another new type of health care entity, the All-Payer Claims Database (APCD), as well as other similar state-mandated repositories for health care information. CHIA is the home of the Massachusetts APCD, as well as a repository for many other types of health care information, including Total Medical Expense and Relative Price data, hospital financial data, and hospital inpatient discharge, emergency department, and outpatient observation data. Public and private payers and providers are required by Massachusetts law to report this data to CHIA.

State-mandated APCDs and data repositories, such as CHIA, have an important role to play in federal and state health care reform efforts across the country. For example, by providing a source of comprehensive multi-payer data, APCDs provide a critical resource for understanding patterns and trends in health care costs, delivery, and utilization; increasing transparency in the health care market; and evaluating various health care reform initiatives, such as patient-centered medical home pilots, ACOs, and health insurance rate review.

In addition, as a central repository for claims information, across payers, for a broad range of services, including medical, pharmacy, and dental claims, APCDs have the potential to play an important role in the treatment and coordination of care of patients. APCD data may also be used to enhance clinical data for specific studies or outcome measures.

Among the many potential uses for APCD data are analyses designed to support policy efforts aimed at improving coverage for and access to substance abuse treatment, such as federal and state Mental Health Parity Laws. In order to best serve the substance abuse population, policymakers, researchers, advocates, and the patients themselves need to know whether these laws are working, and if not, where to focus future efforts at improvement.

However, if 42 CFR Part 2 is amended in a way that prohibits or renders impracticable the integration of substance abuse treatment data into APCDs and similar data repositories, the revised regulation will have the unintended consequence of preventing CHIA and other agencies like it from fulfilling their role as a critical data resource for evaluating public policy initiatives that are designed to serve the very same population that 42 CFR Part 2 seeks to protect.

CHIA has elected to comment on three of the topics identified by SAMHSA, specifically as they relate to state-mandated APCDs and health care data repositories: (1) consent requirements; (2) qualified service organizations (QSOs); and (3) research.

## **Topic 1: Consent Requirements**

SAMHSA has solicited 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.” CHIA respectfully submits that SAMHSA should also consider the impact of consent requirements on the integration of data covered by 42 CFR Part 2 (“Part 2 data”) into APCDs and other repositories of health information.

In order to facilitate the compliance of payers, providers, and other entities with state health care information reporting requirements, without undermining the privacy protections of 42 CFR Part 2, CHIA proposes the following clarifications of 42 CFR Part 2:

- The revised regulation should clarify that Part 2-covered entities (including substance abuse treatment providers and programs, third-party payers, and other entities as defined in a revised regulation) may disclose Part 2 data to state agencies

or other entities housing state-mandated APCDs or health care data repositories, as required by state law, without obtaining patient consent.

- As a corollary to this proposed no-consent rule for disclosures required by state law, and to ensure that patient privacy is protected, the revised regulation should specify that APCDs and other data repositories that receive Part 2 data in this manner become “holders” of Part 2 data and are subject to applicable privacy and security requirements contained in the regulation.
- The revised regulation should then make explicit which of its requirements apply to APCDs and similar holders of Part 2 data and spell out the uses and disclosures that are permitted for such entities. At a minimum, permitted uses and disclosures should include:
  - Disclosures within the agency or between the agency and an entity that has direct administrative control over the agency;
  - Disclosures to a qualified service organization, which provides services to the agency, such as data processing or analysis, or legal, consulting, or other professional services;
  - Disclosures with Part 2-compliant patient consent;
  - Disclosures without patient consent for the purposes of:
    - Medical Emergencies;
    - Qualified Research Activities; or
    - Audit and Evaluation Activities; and
  - Disclosures in compliance with an authorizing court order.

## **Topic 2: Qualified Service Organizations (QSOs)**

SAMHSA has indicated that it is considering expanding the definition of QSO to include care coordination services and to allow a QSO agreement 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 also has inquired whether there are other use cases that it should take into consideration.

CHIA respectfully proposes that SAMHSA should, in connection with the revisions proposed above under Topic 1 (Consent Requirements), revise 42 CFR Part 2 to authorize state agencies or other entities that house state-mandated APCDs or data repositories that receive, process, and store Part 2 data, but that are not Part 2 programs, to execute QSO agreements with providers of services necessary for the running of such APCDs and data repositories, e.g.,

data processing and analysis; services related to treatment or coordination of care; and legal, consulting, or other professional services.

Such services are necessary for APCDs to conduct their operations and to fulfill their statutory mission of providing high-quality data and analysis in support of health care policy initiatives. For example, this would permit a state agency to which Part 2 data is reported to engage an expert in the area of substance abuse to analyze the data in furtherance of a specific project or initiative, such as monitoring compliance with Mental Health Parity laws. An agency that holds Part 2 data would also be able to engage expert assistance in profiling specific data elements that may include Part 2 information, in order to improve data quality.

### **Topic 3: Research**

SAMHSA has indicated that it 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 also has inquired whether there are additional use cases that should be considered in the research context.

CHIA respectfully proposes that SAMHSA should include state agencies and other entities that house state-mandated APCDs or other health care data repositories, such as CHIA, among the types of organizations that are explicitly authorized to release Part 2 data to qualified researchers and research organizations. As discussed above, APCDs provide a valuable source of comprehensive multi-payer data that may be utilized in support of health care reform efforts: to analyze trends in health care costs, delivery, and utilization; to promote transparency; and to evaluate specific health care reform initiatives.

CHIA has received requests for data from state agencies and other researchers for projects specifically intended to benefit the substance abuse patient population. For example, the Massachusetts Senate has requested an analysis of access to substance abuse treatment in Massachusetts; MassHealth, the Massachusetts Medicaid program, is engaged in an effort to improve continuity of care for its members; and the Massachusetts Department of Public Health, Bureau of Substance Abuse Services, has proposed to use APCD data to identify populations in need of substance abuse treatment and those with unmet or underserved needs. APCDs can best fulfill their role as a data source for such projects if they are permitted to disclose Part 2 data to state agencies and other qualified entities for approved research purposes, with appropriate protections for patient privacy.

To ensure adequate protection for patient privacy, SAMHSA could require APCDs, and other data repositories seeking to release Part 2 data for research purposes, to establish criteria for review of research requests that will permit the reviewing entity to determine whether:

- the data recipient is qualified to conduct the research;

- the data recipient has a research protocol under which the Part 2 information:
  - will be maintained in accordance with the security requirements set forth in 42 CFR Part 2;
  - will not be redisclosed except as permitted by 42 CFR Part 2;
- the rights and welfare of patients will be adequately protected; and
- the risks in disclosing the Part 2 information are outweighed by the potential benefits of the research.

Please feel free to contact CHIA with any questions about the above proposal.

Respectfully submitted,

Áron Boros, Executive Director  
Jessica V. Barnett, Chief Privacy Officer  
Commonwealth of Massachusetts  
Center for Health Information and Analysis  
2 Boylston Street  
Boston, MA 02116

## Agencies

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

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42 CFR 2

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2014-10913

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<https://federalregister.gov/a/2014-10913>

June 14, 2014

**Comments from Rick Waldema r, M.A., CAP,  
P.O. Box 2456,  
Inverness, FL 34451**

## To Whom it May Concern:

Thank you for the opportunity to comment on proposed changes to Confidentiality Rules/42 CFR 42, I have spent 40 years in professional settings that have operated under confidentiality rules, and have continued to gain respect for my clients' desires and needs for confidentiality and privacy.

I worked in a community mental health center for 20+ years, and have now been working for 16 years at West Central Florida Driver Improvement Inc., a DUI School serving 5 counties under licensure from the Florida Department of Highway Safety and Motor Vehicles, I am employed in the capacity of Clinical Supervisor, Evaluator, and Class Instructor. The DUI School makes referrals on a daily basis to a wide range of counseling settings, communicates with courts, DHSMV, and other entities, and 42 CFR 2 is a governing way of life. The following comments are mine and not those of West Central Florida Driver Improvement.

My overall response to any consideration of changing 42 CFR 2 is to recommend that individual protections always be strengthened, never loosened, and that considerations driven by changing technologies and service delivery systems take a distant back seat to the individual's protection. It appears that most of the current proposals run very contrary to my priorities.

Page 2 of 4 To: Department of Health and Human services  
Substance Abuse and Mental Health Services Administration  
From: Rick Waldemar M.A., CAP Inverness, FL

Re: **BACKGROUND** section, Federal Register:

*"...significant changes have occurred within the U.S. health care system that were not envisioned by these regulations, including new models of integrated care that are built on a foundation of information sharing ...*

*"...SAMHSA has heard from stakeholders that some of the current consent requirements make it difficult for these new health care organizations including health information exchange organizations (HIEs), Accountable Care Organizations (ACOs), and others to share substance abuse treatment information."*

- It is possible that "making it difficult...to share substance abuse treatment information" is a good feeling for the individual. I personally do not want my information shared in any cavalier fashion, between entities of which I have no knowledge. I am certain that few advocates for the changes would consider the relaxed protocols cavalier, but that may well be the actual effect.

*"...There continues to be a need for confidentiality protections that encourage patients to seek treatment without fear of compromising their privacy. SAMHSA strives to facilitate information exchange while respecting the legitimate privacy concerns of patients due to the potential for discrimination and legal consequences..."*

- Several years ago, while working in a counseling setting in Florida, I was required to fill out many SISAR data forms, where individuals' information was sent to Tallahassee. The clients I was working with at the time were likely not especially aware of the State of Florida's data-mining. I was concerned, however. From my SISAR experiences, I realized that there are already efforts "compromising their privacy." I read the present proposals with even more concern than simple SISAR forms.
- SAMHSA has raised discrimination and legal consequences as the basis of "legitimate privacy concerns." This view has its own level of alarm and caution because it totally ignores the right of individuals' privacy for privacy's sake. The long-standing concept of "its none of your business" has much higher standing in my mind than either discrimination or legal consequences (as important as these may be.)
- Your omission here is telling.

Re: **APPLICABILITY** of 42 CFR Part 2 section, Federal Register:

*"...the regulations could be applied to any federally assisted health care provider that provides a patient with specialty substance abuse treatment services. In this scenario, providers would not be covered if the provided only substance abuse screening, brief intervention, or other similar pre-treatment substance abuse services ...*

*... Would this change raise any new concerns?"*

- This is a significant list! The services cited, albeit, as "examples," substance abuse screening, brief intervention, or other so-called pre-treatment services, should certainly be included in Confidentiality Rules and protections.

Re: **CONSENT REQUIREMENTS** section, Federal Register:

Page 3 of 4 To: Department of Health and Human services  
Substance Abuse and Mental Health Services Administration  
From Rick Waldemar M.A., CAP Inverness, FL

*Re, the "To Whom" consent requirement: "...Currently, a Part 2 compliant consent cannot include future un-named providers which requires the collection of updated consent forms whenever new providers join these organizations ..."*

- This restriction should absolutely remain in place. The individual should be in charge of who gets access.
- I am skeptical of a loosening up of where information goes, while "ensuring the patient is fully informed and the necessary protections are in place." You can't have it both ways. "Necessary protections" in my opinion, would prevent "future un-named providers" from access. Obviously, the proposals are moving in a direction favorable to these "future un-named providers" at the expense of individuals' protections.

*"...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..."*

- Notified regularly? A logistical nightmare after the fact. Does the proposal envision organizations Emailing lists of new providers every few weeks or months? Does the patient/client/individual have any recourse for non-disclosure as these lists grow and grow? Will organizations have a patient sign paperwork at registration that if the patient wants any updates, they can go to website www.so-and-so? In that case the burden is shifted to the individual to keep up with developments and obviously the average patient will not do that.

*"SAMHSA welcomes 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.*

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

- No. Absolutely not.

*"Would these changes raise any new concerns?"*

- Yes- every time another organization is added to any of these lists.

*Re: **RE-DISCLOSURE** section, Federal Register:*

*The question is asked, "Would these changes maintain the privacy protections for patients?"*

Page 4 of 4 To Department of Health and Human Services  
Department of Health and Human services Substance Abuse and  
Mental Health Services Administration From Rick Waldemar  
M.A., CAP Inverness, FL

➤ *No, they would not.*

Thank you again for the opportunity to offer input. I don't like the direction we are headed, and I hope my concerns are shared by SAMHSA. It is time to return to recognizing the importance of each individual's privacy. I look forward to hearing from you.

Sincerely,

Rick Waldemar M.A., CAP  
Certified Addictions Professional #689,  
conferred by Florida Certification Board

P.O. Box 2456 Inverness,  
FL 34451

RSW; dms

To whom it may concern,

Federal substance abuse privacy laws are antiquated because of modern technology. These laws were designed to protect patient privacy in an era before electronic records. In the current reality of health information exchanges, such as Quality Health Networks in western Colorado, the law actually interferes with good patient care.

Our physicians here at Grand River Health, as well as all others in western Colorado have direct access to all clinical information in the Quality Health Networks exchange except for this very important mental health information. Patient safety is compromised in many ways, e.g. drug to drug interactions. Patient harm can and does occur waiting for charts to be copied and sent. It is also possible that the patient's mental health condition will cause them to refuse to sign a release of information to their detriment. Please help us to join the digital age in this area and improve patient care and safety.

Thank-you for listening,

**Bill Noel** | Chief Operating Officer

**Grand River Health** |

501 Airport Road

PO Box 912

Rifle, CO 81650

970.625.6448 | **Office**

970.625.6486 | **Fax**

**Grand River Hospital and Medical Center, exceptional healthcare, locally**

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Dear Sir/Madame,

I have taught a confidentiality law course for 20 years and know both the CFR 42 Part 2 and the HIPAA law well. I would not recommend any changes at this time.

Robert L. Malphrus

Skagit Valley College

Mt. Vernon, Washington



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

201 W. Preston Street • Baltimore, Maryland 21201

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

June 18, 2014

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

To Whom It May Concern:

In response to SAMHSA's solicitation of comments concerning the confidentiality of alcohol and drug abuse patient records regulations, 42 CFR Part 2, the Maryland Department of Health and Mental Hygiene (Department) offers the following comments regarding current restrictions on re-disclosure of patient information. Further, the Department requests that the exceptions to the requirement for specific individual consent – in order to share patient and treatment information – be broadened for the purposes of enhancing the provision of care and formulating and implementing policy that meets the needs of persons receiving substance use disorder treatment. The section below provides a brief discussion of the Department's comments.

I. Sharing information with other providers for purposes of treatment:

Under the current regulations, treatment providers who are covered programs may provide information regarding that treatment to the Maryland Alcohol and Drug Abuse Administration (ADAA). However, ADAA is prohibited from then re-disclosing that information to other treatment providers who are also providing treatment to the same individual, except with specific consent of the individual or in the case of a medical emergency. Thus, ADAA cannot share information with correctional institution medical clinics or other treatment providers who are currently or may in the future be providing care to an individual with a substance abuse disorder. This delays clinically appropriate assessments and treatment recommendations when addressing emergent situations in those with substance use disorders, without prior patient consent. DHMH requests that the re-disclosure restrictions be revised to permit sharing information for purposes of providing treatment beyond the current emergency exception. This will ensure better continuity of care for the patient and improved clinical decision making.

II. Sharing information among State agencies for purposes of managing care and payment for treatment:

The State of Maryland makes use of more than one State agency in managing care for persons receiving federally-funded treatment services and in arranging for payment for such services; *e.g.*, the State's substance use disorder agency, administrative services organizations, managed care organizations, and the State's Medicaid agency. Current regulations do not permit sharing information between these agencies without specific consent, which severely hampers the State's ability to efficiently and effectively pay for and plan for treatment services for these individuals. The Department requests that the regulations be amended to adopt the HIPAA rule for sharing information among state agencies.

III. Limited Data Sets:

Currently, rules for data sets are too restrictive under 42 CFR Part 2 and do not allow for the use of database identifier codes. Existing HIPAA rules governing "limited data sets" do permit such use. The Department requests that the regulations be amended to adopt the HIPAA rule for research and for public health operations under Data Use Agreements.

IV. Sharing information for research and planning purposes:

The Department requests that additional exceptions be permitted for government agencies when using or creating Centralized Data Banks for public health research and planning purposes. Specifically, the elimination of specific patient consent to re-disclose data for matching purposes is needed to conduct cross references when obtaining, matching and sending data between government agencies for research and planning purposes. Likewise, patient data provided to a qualified researcher employed or obtained by a state agency may not be re-disclosed to other agencies for cross referencing, unless specific patient consent is obtained. Current regulations require redundant safeguards when creating databases to cross reference information, resulting in unnecessary costs and reduced efficiency.

V. Opioid Treatment Program Information Sharing with Somatic Care:

Current regulations do not permit opioid treatment programs to share treatment information with somatic care providers without specific consent from the patient, whose condition may preclude him or her from making an informed and advantageous decision as to the consent. As most states currently have operational prescription drug monitoring programs (PDMP), opioid treatment programs-based practitioners can often easily identify whether their patients are receiving prescriptions for controlled substances from somatic care providers. However, because opioid treatment programs providers are precluded from sharing treatment information with either PDMP programs or health care providers, the latter often must provide care without knowing what has been prescribed by the opioid treatment programs provider. This can lead to poor treatment outcomes including inappropriate prescribing, increased morbidity, and increased risk of overdose.

In light of the risk of adverse reactions, including overdose, from the simultaneous use of methadone and other controlled substances, requiring patient consent places providers in the

untenable position of choosing between continuing to provide care without the ability to coordinate with other prescribers and denying care completely. The regulations should be revised to permit the opioid treatment programs to contact the prescriber without patient consent, or require opioid treatment programs to report PDMPs, or both.

VI. Clarification of Central Registry Use:

Current regulations do not specify whether various entities may be included in the Central Registry; specifically: pain management clinics that do not use methadone, providers of buprenorphine clinics, prescription drug monitoring programs, etc. The Department requests further clarification on this issue in order to maintain effective Central Registries.

VII. Programs Treating Co-Occurring Mental Health and Substance Use Disorders:

42 CFR Part II applies to programs that hold themselves out as a drug treatment program and to information that would identify a patient as an alcohol or drug abuser either directly by reference to other publicly available information or through verification of such an identification by another person. 42 CFR 2.12(a)(1)(i). These regulations are not applicable unless the program holds itself out as a drug treatment program, but not all information maintained by the drug treatment program is covered by the regulations. Therefore, for programs treating those with co-occurring disorders, whose number is expanding in response to changes in healthcare, the various types of health information are to be managed differently: information that is not drug treatment information is covered by HIPAA, while health information that is drug treatment information is covered by 42 CFR Part II. Segmenting health information based on its type is challenging and fraught with potential unintended violations of 42 CFR Part II. The Department requests that the regulations be amended to be no more restrictive than HIPAA in the limitations imposed on drug treatment programs.

Thank you for the opportunity to submit comments on the confidentiality of alcohol and drug abuse patient records regulations, 42 CFR Part 2. While the Maryland Department of Health and Mental Hygiene plans to participate in the upcoming Public Listening Session, questions regarding these comments may be directed to: Kathleen Rebbert-Franklin, Acting Director of the DHMH Alcohol and Drug Abuse Administration, at [Kathleen.rebbert-franklin@maryland.gov](mailto:Kathleen.rebbert-franklin@maryland.gov) or (410) 402-8615.

Sincerely,

Charles E. Lehman  
Acting Deputy Secretary  
Health Care Financing

Gayle Jordan-Randolph, M.D.  
Deputy Secretary  
Behavioral Health and Disabilities

Whenever the **patient has any dependency** on a caregiver/family for food, clothing, shelter, transportation to doctors appointments, supervising medications and providing the general support around the persons illness-they need to know certain information-such as when the next appointment is, what meds they should be taking and dose, why are they taking them, their diagnosis, what are the symptoms of their diagnosis vs side affects of meds.

Care givers need to know **the patients general plan of care**-otherwise it continues the crazy making relationship found in no other illness where the patient is dependent.

Caregivers/family do not need to know private conversations, whats discussed in psychotherapy unless there is a duty to report "danger to self and others"

I hope SAMHSA recognizes there is a vast difference in care for those patients who lack capacity and insight into their illness, and have dependencies on family members (as physical health care does) vs those who are self reliant....or you are again demonstrating you are incapable of managing brain disorders such as schizophrenia, and illnesses that can manifest symptoms of psychosis, delusion, confusion, agitation and hallucinations.

there already is vast difference in health care delivery and philosophy between SAMHSA/Behavioral health care and Medicine, for those that lack capacity to understand an informed consent. Your decisions and actions here, will prove or disprove your general overall ability to manage and treat ILLNESS vs focusing only focusing on recovery and mental HEALTH.

Unless you can incorporate physical health care standards within your philosophy, policies and procedures, I like many others believe its well out of your "scope of practice" and understanding to continue managing brain/mental disorders.

Mary Palafox RN  
714-323-0423

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**Page:**

26929 -26932 (4 pages)

**CFR:**

[42 CFR 2](#)

**Document Number:**

2014-10913

**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:**

I'm sorry but I could not write on your PDF form. Please accept this.

As a school-based NJ Student Assistance Coordinator, I [and our program] intervene, assess without formal diagnostic evaluation, and refer, and do follow-up substance abuse counseling.

The existing 42 CFR Part 2 is a critical component in much of my success. Students will share detailed personal information with me subsequent to my review of 42 CFR Part 2 boundaries with them. We establish rapport and a working relationship when they understand that I "cannot turn them in"!

I read some of the questions and potential modifications to the requirements. If what I do is considered officially within your definition of assessment and brief intervention, I would vote to MAINTAIN the strict requirements as they are. They are a powerful tool that make a difference for teenagers to trust a counselor in these personal, alcohol and other drug use concerns.

Thank you.

Raymond Danziger

[professional affiliation below]

C: Tim Conway, Lakeland Regional High School Director of Guidance

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If you have received this EMAIL in error, please notify me immediately by phone (973.835.1900 ext. 166) or by email, and please trash and delete this email.

*Raymond Danziger, Ph.D.  
Student Assistance Coordinator,  
Peer Leader Advisor  
Chair, AWARE ASAP (Municipal Alliance)  
Lakeland Regional High School  
205 Conflintown Road  
Wanaque, NJ 07465  
973.835.1900 x166  
[rdanziger@lakeland.k12.nj.us](mailto:rdanziger@lakeland.k12.nj.us)*

June 18, 2014

Dear SAMSHA,

I feel that letting all medical providers gain access to the medical records of those on methadone treatment would be a huge mistake. Given the many years of experience I have had in the addiction and mental health field I can state there are many providers that harbor bias towards methadone therapy. The patient's who have put their lives back together using methadone therapy face numerous obstacles and prejudice from those who know nothing about opioid treatment including medical professionals. Please keep the medical records of those on methadone therapy away from the mainstream medical professionals and only to those professionals who the patients request.

Thanks

C. CURZIO

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I just want to register my support of SAMHSA's efforts to REDUCE barriers to sharing data presented by 42 CFR, Part 2, especially in the QSOA and research categories listed on your comment template (I was unable to add comments directly to the pdf).

Through my organization, the UCLA Integrated Substance Abuse Programs, I have worked with primary care organizations including FQHCs to integrate care for years. During that time, many thousands of patients have been asked to sign a release of information to get around 42 CFR Part 2, and our partners have reported that not a single one of them has declined. Patients want and expect this information to be shared across their health care providers. The regulations have, however, served to greatly confuse and concern provider staff and administrators. Please do not make these regulations any stricter, and do whatever you can to allow integrated care to work.

Thank you.

Darren Urada, Ph.D.  
Associate Research Psychologist  
UCLA Integrated Substance Abuse Programs  
Semel Institute for Neuroscience and Human Behavior  
11075 Santa Monica Blvd., Suite 200, Los Angeles, CA 90025  
ofc: (310)267-5227 fax: (310)312-0538

If your e-mail to this address bounces, please try [durada@pacbell.net](mailto:durada@pacbell.net)

**Dear Congress, House of Representatives, Senate, and Mr. President:**

**On behalf of the USA, and all citizen's, especially the soldiers placing their lives on the lines for OUR CIVIL FREEDOMS.**

**42 C.F.R. Part 2's core privacy protections MUST be maintained I recently LOST my job over the fact that after a letter was sent to my HR and boss, with my "general restrictions" when I returned to work, wasn't ENOUGH of an explanation for my Company, and I am a single mother who CAN'T afford to be without work.**

**I followed all the HR rules, the 7 medical doctors I had all sent letters, and explained that I was under their care for at least 2 weeks. My Company, sent a response that they needed MORE information as to my "medical issues." My doctors offered to fill out ANY and ALL state FMLA, STD, or Company forms. NOTHING was sent to my doctors on my behalf. My doctors even went as far as calling my HR department and got no returned calls.**

**I URGE you to look at the statics for not only social stigma, but right away once they heard the words Neuro/Mental, I was let go, told they didn't think it would work out. I followed the rules and still lost. Now getting a job in my field, with that information on my file, will follow me. DO NOT VIOLATE ANYMORE OF OUR CIVIL RIGHTS!**

## **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

***While behavioral health care should be integrated with physical health care, and communication between health care providers should be encouraged, the regulations' protections are as necessary today as they were when they were issued in the 1970s in light of ongoing stigma and discrimination faced by people with substance use disorders.***

***42 C.F.R. Part 2 enables people with substance use disorders to seek treatment without fear of exposure of their treatment records—without their permission—to law enforcement, employers, insurers,***

***other health care providers, or others. Changes to the regulations would threaten these critical patient protections.***

I believe its my right as an addict currently in MMT to be the one to tell my doctors that I'm on methadone. Not every doctor is that understanding and knowledgeable about methadone maintenance treatment. It's disheartening when you do tell a doctor about your medication and all of a sudden there whole demeanor changes. As addicts we are hard enough on ourselves, we don't need doctors to do it along with us.

**From:** yvonne parker [mailto:julio1912@yahoo.com]

**Sent:** Wednesday, June 18, 2014 9:03 PM

**To:** Privacy Regulations (SAMHSA)

**Subject:** Privacy

Since a large number of substance abusers also have a mental illness the concern should be the necessity for outside agencies to acquire private information without an individual's consent. I think since stigma is alive and well and that's not going to change anytime soon. Therefore, I think it's important that the individual's consent is requested whenever possible unless it is life and death situation where the individual can not give consent.

To Whom it May Concern:

The cost of methadone treatment is prohibitive only as it is due to the stigma that's associated with care of the individual. People die for lack of care - not here, not in this community, not enough treatment slots, and fear for lack of education. It is almost criminal to have to defend individuals' rights to treatment of an illness so destructive to the person and community as a whole.

If medical personal at this juncture are ill prepared to comprehend addictive disorders, the needs of the patients involved, the array of available comprehensive treatment including the efficacy of methadone treatment, notwithstanding effects on their own practices, how can stigma die? We should not have to assure medical records of patients treated with methadone are kept so privately as a physician to whom the patient may be referred may inappropriately instruct the patient (by telling the patient to end treatment) and then refuse to treat the illness for which referred.

SAMHSA must be a formidable force seen as promoting healthy lifestyles for all without prejudice and despite political affiliates. Health care is a human right. As a nurse committed to practicing for all equally, it seems a serious offensive to maintain such an antiquated outlook in delivery of health care today. We ought to set the standard for all. Let us stop stigma now by educating the masses - one group at a time.

"Drops do pierce the stubborn flint, not by force, but often falling" (a quote).

Thanks for listening.

Desrie B Renaud, RN, MSHS, EDD  
Educational/Nursing Leadership Consultant  
Phone#: 631 654 5141

Dr. Desrie

**DESRIE B. RENAUD, RN, MSHS, EDD**  
Educational/Nursing Leadership Consultant  
AlmaDor Business Resources, LLC  
Phone - 631-654-5141; Fax - 631-654-5103  
E-mail: [dbro@email.phoenix.edu](mailto:dbro@email.phoenix.edu)

For the last 7 years I have been sick and have not received the care or support that I have needed . When I was a young adult in my early twenties I was pretty stupid and made bad choices , and some of those choices got me put in rehabs and a mental hospital once! But ever sense then my medical care has gone to crap all because the nurses and doctors take one look at my charts and immediately pas judgement and don't listen to my concerns or cries.

I'm always told that it's all in my head without any doctor or nurse taking the time to actually physically check, I'm so afraid to go to a doctor or er or anything medical related place, to get help now , I won't even go if I'm having seizures. , and it scares my family to death! But going to another medical industry "professional ", and having them treat me like a person who isn't worthy of their care, is worse to me and would do more damage to myself , then just getting through my medical issues. They have damaged me more then any drug I have ever taken in the past, could have ever done . I will never trust another " medical professional " as long as I live!

**From:** Michelle Jackson [mailto:michahjackson@gmail.com]

**Sent:** Thursday, June 19, 2014 7:02 AM

**To:** Privacy Regulations (SAMHSA)

**Subject:**

Thank you for the opportunity to comment. The policy is both helpful and harmful. From a community support perspective it

Perpetuates the problem with systemic barriers. It makes the task of care coordination complicated and results in frustration creating more gaps in system. On the other hand it provides protection that often time dither enables an individual in active addiction to manipulate the system resulting in waste, redundancy and lack of progress.

Sent from Gmail Mobile

Regulations need to change to open the door for innovative care and the delivery of that care. Easing the confidentiality restrictions that would allow for licensed providers to open up satellite clinics in medical facilities and truly sharing the patients rather than segregating the SUD patients for confidentiality reasons.

42CFR holds providers to a higher standard than witnessed in medical settings. On numerous occasions I have personally visited patients admitted to a hospital only to have medical professionals enter the room discuss the patients condition in front of me or even discuss the patients treatment and condition with me. No release is in place or requested.

Concerns regarding electronic signatures on releases. Many doctors offices are having patients sign paperwork sight unseen. I have experienced office visits where I'm told I'm signing the HIPAA confidentiality statement but not offered a copy of the statement or the ability to read it prior to signing.

Medical information is being shared with more and more people via HIE and in NYS PSYCKES (mental health information). I'm sure the patient is not fully aware of all of the people their personal health information is made available to. We can not expect the patient to understand what all these services and acronyms stand for.

We are encouraged to enter into QSOA's with a network of providers to share confidential health information. Of concern is that if one of our QSOA providers experiences a breach in their EHR we are automatically held responsible for notifying our patients whose record may have been breached via our QSOA. In other words the OMIG will be all over all agencies connected or a part of the QSOA.

SUD providers are asked to uphold a standard that has not necessarily been recognized or enforced in numerous states. We often encounter federal agencies, federal agents and federal courts that do not follow guidelines to obtain confidential information. Many will often state as a federal agency the regulations do not apply to them. In my career only one court made a weak attempt at following the federal guidelines to obtain records. This was after I sent a letter and the federal regulations to the court. Legally I have been advised to send a letter of notification of the federal regulations and if the court chooses to ignore it send them whatever they want. The regulations only cover SUD providers so the secondary market for sharing the information is wide open.

We go through all types of precautions to protect the records on one hand and then with HIE, Health Homes, DSRIP, etc. we are encouraged to enter into agreements, partnerships, etc. to disclose as much information as possible. Medical institutions freely share information with the patients friends and families. Sharing a persons SUD records with a medical provider will open the floodgates as to how many more people will know about the persons use and treatment history.

I would suggest reviewing the regulations to allow for SUD programs to provide services in other medical settings. And open up the APG guidelines to allow SUD programs to provide a full line of medical care by including M.D.'s as a part of their overall service.

Best regards,

Robert Schaffer, LCSW

*This information is being disclosed to you from records protected by Federal Confidentiality Rules (42 CFR Part 2 and HIPAA). The Federal Rules prohibit you from making further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains - or as otherwise permitted by 42 CFR Part 2 and HIPAA. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal Rules restrict any use of this information to criminally investigate or prosecute any alcohol or drug abuse patients.*

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**“PURSUANT TO SECTION 33.25 OF THE MENTAL HYGIENE LAW, THE ATTACHED RECORDS AND REPORTS SHALL NOT BE FURTHER DISSEMINATED, EXCEPT THAT YOU MAY SHARE THE REPORT WITH: (i) A HEALTH CARE PROVIDER (ii) A BEHAVIORAL HEALTH CARE PROVIDER, (iii) LAW ENFORCEMENT, IF YOU BELIEVED A CRIME HAS BEEN COMMITTED; OR (iv) YOUR ATTORNEY.”**

The Substance Abuse and Mental Health Services Administration  
Public Listening Session - Submission of Written Comments

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

Comments relating to Consent Requirements and Redisclosure:

*Regulations may be changed per recommendations without need for statutory amendment:*

The **statutory authority** for these regulations imposes protections for patient identifying records maintained by a covered program in connection with substance abuse education, prevention, training, treatment, rehabilitation, or research by restricting disclosure except in specified circumstances. The statute permits disclosures:

- With prior written consent, in accordance with prescribed regulations
- Without consent -
  - To medical personnel to extent necessary to meet medical emergency
  - To qualified personnel for research, audit, or evaluation; such personnel may not identify individuals in any reports
  - If authorized by court order based on good cause

Of note, 42 USC § 290dd-2 imposes no prohibition on redisclosure of records

The **regulations** adopted under this statutory authority spell out details that operate to impose more restrictive conditions for disclosure of patient identifying information. The regulations may be amended according to the recommendations herein and remain compliant with the provisions of the statute.

*Regulations restrict patient choice and impede quality of care and safety:*

As currently written, the consent and redisclosure regulations restrict a patient's choice relating to sharing of treatment information with a health information exchange, integrated service delivery system, or accountable care organization. The requirements that the consent must specifically identify the person/entity permitted to make a disclosure, as well as the specific person/entities to whom a disclosure may be made, and the prohibition on redisclosure by the recipient of protected information, stymie the whole purpose of permitting one's information to be part of a HIE, integrated system, or ACO - to facilitate access/sharing of a comprehensive health record by/with all providers within the HIE, integrated system, or ACO who may end up treating the patient. Inability to authorize this type of information sharing may have profound impact on care received. Additionally, the absolute prohibition on redisclosure also impedes efforts to avoid adverse drug interactions, drug overdoses, and prescription medication abuse through prescription drug monitoring programs.

Modifying these regulations where the purpose of consent to disclosure is for treatment, payment, or operations purposes, or to support prescription drug monitoring programs, can support the appropriate sharing of information -focused on patient care and safety, and

patient choice - while preserving the high level of protection for this information in other contexts, e.g. law enforcement. We suggest the following changes to the existing regulations:

*Recommended amendments:*

§ 2.31 Form of written consent.

**(a) Required elements.** A written consent to a disclosure under these regulations must include:

- (1)** The specific name or general designation of the program or person permitted to make the disclosure. Where a patient has consented to disclosure by a participant in a health information exchange, integrated service delivery system, or accountable care organization, that consent also authorizes disclosures by and among all participants in the health information exchange, service delivery system, or accountable care organization for purposes of treatment, payment, or healthcare operations as those terms are defined at 45 CFR 164.501.
- (2)** The name or title of the individual or the name of the organization to which disclosure is to be made. For disclosures to a health information exchange, integrated service delivery system, or accountable care organization, this element is satisfied by identifying the health information exchange, integrated service delivery system, or accountable care organization, and thereby authorizes the use and exchange by and among participants in the health information exchange, integrated service delivery system, or accountable care organization for purposes of treatment, payment, or healthcare operations as those terms are defined at 45 CFR 164.501. Health information exchanges, integrated service delivery systems, and accountable care organizations must provide to the patient a list of current participants in the health information exchange, integrated service delivery system, or accountable care organization, and identify a place where the individual may access a current list of participants at any time in the future.
- (3)** The name of the patient.
- (4)** The purpose of the disclosure.
- (5)** How much and what kind of information is to be disclosed. This element may be satisfied by a list of categories of information to be shared.
- (6)** The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under § 2.15 in lieu of the patient.
- (7)** The date on which the consent is signed.
- (8)** A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.
- (9)** The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

**(b) Consent for disclosure of patient identifying information to a health information exchange.** Where state law provides for disclosure of patient identifying information to a health information exchange without a patient's express authorization or consent, after

the patient has been given prior notice of the intent to disclose information to the health information exchange and patient is given an opportunity to opt-out of the disclosure, documentation of the required notice and patient's decision not to opt-out of disclosure to the health information exchange shall constitute written consent for purposes of these regulations.

## § 2.32 Prohibition on redisclosure.

*Notice to accompany disclosure.* Each disclosure made with the patient's written consent, with the exception of disclosures made to a health information exchange, integrated service delivery system, accountable care organization, or pharmacy, must be accompanied by the following written statement:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

Information disclosed to a health information exchange, integrated service delivery system, accountable care organization, or pharmacy may be redisclosed only in the following circumstances:

- (a) By and among participants in a health information exchange, integrated service delivery system, or accountable care organization for purposes of treatment, payment, or healthcare operations as those terms are defined at 45 CFR 164.501;
- (b) By and among healthcare providers, as that term is defined at 45 CFR 160.103, for purposes of processing and filling electronic prescriptions, and
- (c) To statutorily authorized pharmacy oversight bodies for purposes of state or federal prescription drug monitoring programs.



**Agency:** Department of Health and Human Services, Substance Abuse and Mental Health Services Administration

**Docket:** 2014 – 10913

**Regarding:** Potential changes to the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2

Founded in 2006, Community Oriented Correctional Health Services (COCHS) is a philanthropically funded nonprofit organization that works to improve connectivity between jails and the greater health care system. We thank you for your commitment to improving access to mental health and substance use disorder services for all Americans, and we appreciate the opportunity to comment on potential changes to the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2.

A significant number of people with substance use disorders come into contact, at some point in their lives, with the criminal justice system. Jails admit approximately 12 million people each year, usually for a brief period of time, and often for behavior that is directly related to substance use. Sixty to eighty percent of all people booked into jail have at least one illegal substance in their bodies at the time of booking; more than two-thirds of all jail inmates meet the DSM-IV criteria for substance dependence or abuse; and the prevalence of substance use disorders is approximately six times higher among jail inmates than it is among non-institutionalized adults.

The possibility that law enforcement agencies could use information obtained from treatment providers to pursue criminal charges could deter many people who need treatment from seeking it out, particularly people with past justice-system contact. It is important that any changes to 42 CFR Part 2 maintain the regulations' current balancing of confidentiality and consent-enabled communication, where treatment information cannot be used to investigate or prosecute a patient without a specific court order. We support changes that would facilitate information-sharing between treatment providers, researchers, pharmacies, and other health care partners, but it is crucial that the regulations continue to prevent law enforcement agencies from having open access to treatment information, which would deter many of society's most vulnerable individuals from pursuing the treatment they need.

I would like to address the confidentiality issue at hand on putting methadone/suboxone clients into a database that allows doctors to automatically be notified that a patient of theirs is being treated for alcohol and/or drug dependence. I feel that releasing information about being on methadone or suboxone is a personal matter and should be handled as such. I feel, as a methadone patient myself, that I would feel much more comfortable letting a doctor know about my personal issue myself when I feel comfortable enough to do so, rather than have my doctor already know this information about me before I even get the chance to build a relationship with a doctor. I hope this helps in making a compassionate decision based on how other clients of methadone/suboxone feel as well. It is our right to have privacy when it comes to our medical issues, and/or addiction issues, and how we choose to handle these issues. Thank you for your attention to this matter.



PRO-A Pennsylvania Recovery Organizations Alliance  
900 S Arlington Ave, Suite 254A  
Harrisburg, PA 17109-1014

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

June 20, 2014

RE: Confidentiality of Alcohol & Drug Abuse Patient Records Regulations, 42 C.F.R. Part 2.79 Fed.  
Reg. 26929; Docket No. 2014-10913.

To Whom It May Concern:

We are writing you today in response to the request for public comment on 42 CFR Part 2 confidentiality regulations. We are the Pennsylvania Recovery Organization – Alliance, the statewide recovery community organization of Pennsylvania. Founded in 1998, PRO-A is focused on decreasing barriers to life saving services, reducing stigma associated with drug and alcohol dependency and to advocate for individuals and their families that are coping with this devastating illness.

To be clear, we are deeply opposed to any movement to weaken existing confidentiality protections.

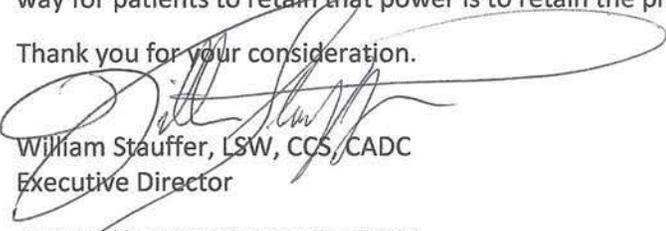
42CFR Part 2 regulations are critically important to our recovery communities across Pennsylvania. We are opposed to modifying these fundamentally important regulations and in our experience know that without the strong protections it has provided over the last 40 years, access to services will be impeded and we will face even more discrimination than we already do.

The right of confidential communications is paramount for us to seek life saving access to services without very real repercussions. Addiction is a highly stigmatized disease process. The erosion of these regulations and reliance on the much weaker HIPAA standards would result in patient records being easily accessed in order to criminally investigate or prosecute our families, to deny us of insurance, housing and employment, or to be used against us in divorce or child custody proceedings among a myriad of other ways. Many of us many will be afraid to enter treatment or to seek help. Even more lives will be lost.

As an example of the pressure put on our systems to provide unnecessary but incredibly sensitive and personal information, we recently conducted a large survey of our drug and alcohol counselor workforce of Pennsylvania. We obtained between a 20 and 25 percent response rate from the entire workforce, with 837 respondents. Among our other findings, 58% of the respondents indicated that they are pressured to provide more information than is necessary and allowable under the confidentiality laws. 42 CFR Part 2 regulations are a bulwark to the integrity of the patient counselor relationship. They must be preserved.

We believe that citizens seeking help must be able retain the power to decide when and to whom their records are disclosed, even for treatment and payment purposes, given the continued prevalence of discrimination in our society. This includes disclosures to the general health care system, HIEs, health homes, ACOs, and CCOs and beyond. The best way for patients to retain that power is to retain the protections currently delineated within 42 CFR part 2.

Thank you for your consideration.

  
William Stauffer, LSW, CCS, CADC  
Executive Director

cc: Honorable PA DDAP Secretary Gary Tennis  
The Legal Action Center

PRO-A 900 S Arlington Ave, Suite 254A Harrisburg, PA 17109  
717-545-8929 F 717-545-9163 [www.pro-a.org](http://www.pro-a.org) [Billstauffer@pro-a.org](mailto:Billstauffer@pro-a.org)

**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:** No comment at this time

## 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:** No comment at this time

## 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:** It is very difficult to tell what you are stating here. You must maintain the strictest confidence with substance abuse. If an entity wants substance abuse information the patient must sign a release to allow.

### 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:** No comment at this time

### 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:** This would be in direct violation of rights. This needs to remain the same. We are now treading on making decisions for people - there is enough control in this Country. You need a consent from the patient!

### 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 at this time

## 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 at this time

## Other Comments

Topic:

**Public Comment Field:** Please be very careful when making decisions that change peoples lives. The patient is the most important. We lose sight of that sometimes. Substance abuse is a very private delicate matter.

**From:** Maria LaFriniere [<mailto:MariaL@ctsi.nsn.us>]  
**Sent:** Friday, June 20, 2014 12:29 PM  
**To:** Privacy Regulations (SAMHSA)  
**Subject:** Patient Confidentiality Comments

Please find attached comments.

*In Wellbriety*

*Maria LaFriniere  
Strategic Prevention Framework  
Project Coordinator  
(541) 444-8267  
Confederated Tribes of Siletz  
Behavioral Health  
PO Box 320  
Siletz, OR 97380*

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

From: Hatcher, Anne [mailto:hatchera@msudenver.edu]

Sent: Friday, June 20, 2014 3:33 PM

To: Privacy Regulations (SAMHSA)

Subject: comments to proposed changes

Changes to 42CFR Part 2 Proposals

The following are my responses to the questions posed:

#### Consent Requirements

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

The name of the individual or health care entity permitted to make the disclosure should be provided to the patient.

The consent form signed by the patient should explicitly describe the substance abuse treatment information that may be disclosed.

#### Redisclosure

I agree with the SASHA proposal to limit redisclosure to information related to the individual as a substance abuser and allows other health information to be shared/redisclosed.

#### Medical Emergency

I agree with the SAMSHA proposed changes

#### Qualified Service Organizations

I agree with the proposed changes

#### Research

I object to sharing treatment data to third-party payers, health management organizations, HIEs and care coordination organizations.

Potential Issues with Electronic Prescribing and Prescription Drug Monitoring Programs The primary concern about electronic prescriptions is the privacy issue for persons in addiction treatment .

Anne S. Hatcher,  
NAADAC Ethics Chair

Anne S. Hatcher, EdD, CACIII, NCACII  
Professor Emeritus, Center for Addiction Studies Department of Human Services Metropolitan State  
University Denver



June 20, 2014

The Substance Abuse and Mental Health Services Administration  
1 Choke Cherry Road, Room 5-1011  
Rockville, MD 20857  
Sent Via Email: [PrivacyRegulations@SAMHSA.hhs.gov](mailto:PrivacyRegulations@SAMHSA.hhs.gov)

RE: Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2  
FR Doc. [2014-10913](#) Filed 5-9-14

To Whom It May Concern:

On behalf of the Oregon Primary Care Association (OPCA) I submit the following comments in support of amending 42 CFR Part 2 to allow better care coordination while maintaining the ability of patients to keep information confidential. OPCA is a non-profit membership organization comprising Oregon's 32 community health centers. Our members operate 201 health clinics statewide that provide coordinated care to 340,000 rural and/or medically underserved patients annually. Oregon's community health center patients are primarily uninsured or insured through Medicaid.

OPCA's member health centers have struggled with the confusing and burdensome current consent requirements that have resulted in difficulty coordinating with Oregon's Coordinated Care Organizations (CCOs) and others in the sharing of necessary information for appropriate medical, mental health and dental treatment. This can result in patients being prevented from fully participating in integrated care efforts even when they are willing to provide consent.

Our member health centers believe in care coordination and the improved health outcomes it produces, and we empower our patients to be engaged in their care and to make important decisions about their treatment. This includes supporting our patients to choose to keep their records confidential, or to decide with whom to share them.

OPCA is encouraged that SAMHSA strives to facilitate information exchange while respecting the legitimate privacy concerns of patients due to the potential for discrimination and legal consequences. And we support SAMHSA's stated intent to clarify the rules associated with information exchange in our new coordinated care world to reduce burdens associated with specific consent requirements that do not serve to protect patient privacy or facilitate patient care.

On behalf of Oregon's 32 community health centers and the 340,000 patients we annually serve, I thank you for considering our input.

Sincerely,

John Hummel  
State and Federal Policy Director

**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:**

Suggest repealing the governing statute and align with industry standards around labeling data as sensitive. IHE and HL7 are doing a lot of work here from a technical stand point; HIPAA and the corresponding DURSA requirements at the HIE level cover a lot of the related policy issues.

## 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:

Consent could more closely follow SSA guidelines; Again HIPAA has good governance around this. Consideration could also be given around notifications as an addition to the workflow for patient engagement. TPO is interesting but could be onerous to implement; needs to consider emerging care coordination.

## 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:

This is certainly worth pursuing: marking data as sensitive based on the sending source; CCDA and XDS can accommodate this. Also need to consider source of requestor of information -- this same group should have higher access.

## 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:

This seems too restrictive; what in the case when early intervention would remove the need for emergent encounters. Need to consider entire spectrum of care and who else might be engaged on collaborative care. Are the patients capable of determining what is in their own best interest?

## 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:

As stated above; try to leverage existing policies, procedures, workflows around this type of sensitive data. Substance abuse is as personal as protecting a pregnant teen for example.

## 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:

Technology exists to anonymize data -- with the ability to re-identify patients if a study should prove beneficial.

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

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- Are there patient concerns about the impact of e-prescribing and PDMPs on their privacy?

### Public Comment Field:

Surescripts and other pharmacy vendors should be included in the over-all care coordination team. The technology and policies exist and are emerging to protect a variety of protected classes.

## Other Comments

Topic:

### Public Comment Field:

The recognition that change is required is very encouraging; the presumption that Substance abuse folks are any more special than sexual health or behavioral health patients is inaccurate, demeaning and proscriptive. Consider adopting existing policies where possible and engaging in the wider population to learn and engage in the wider body to help determine future courses of action. SAMHSA and the broader community will all benefit from a more collaborative approach.

I also do not believe patient records from Drug and Alcohol treatment centers or behavioral treatment centers of any kind should ever be made available to healthcare workers (of any kind). These records especially should be left confidential and private unless the patients themselves have asked otherwise. This could cause a great amount of damage to those of us who have been in treatment.

To whom it may Concern,

I'm a fairly new MMT patient.

I need my privacy and don't feel it's right to get this taken away.

It's not like we're criminals and need to be red flagged anywhere anytime.

It's imperative for this basic human right to be taken away.