

I am astounded to find that this injustice may happen against MAT patients. Why would you change the 42 CFR Part 2? They have enough stigma and prejudice to deal with without this happening. If MAT patients are put into a 50 state system pegged as drug addicts they will never have the opportunity to live a normal life. I hate to think if a MAT patient broke his leg and went to a hospital and came up on a prejudicial software database labeled a drug addict. I believe that the hospital would not help that person in the way that every other person is treated. And older people often need pain medicine. Do you think if a patient labeled a MAT patient even if it is from 50 years earlier, they would be given the same pain medications others would get? This is so unfair and unnecessary. Why now if it was not needed before? We are crossing the lines with people's civil liberties here. This is terribly wrong.

Dear SAMHSA:

I understand that you are considering changing the confidentiality regulations for methadone treatment. It is important that the confidentiality regulations remain as they are and not be changed.

I am a methadone patient and I am concerned what could happen if my status as a methadone patient were known. I know that I would have trouble getting medical care because doctors always blame any medical problem on the methadone. Doctors and nurses don't understand methadone and they tell me to get off.

I am also concerned that employers and schools will be able to find out that I am a methadone patient if changes to the confidentiality regulations happen.

Please don't change the confidentiality regulations that has protected me and all patients from the discrimination against us.

Thank you.

Why after 50 some years of MAT recovery is it even remotely necessary to make MAT patients medical records open to persons in a nationwide database. If these patients were on insulin you would not be considering this. You are opening them up to unfair treatment and surveillance by police who constantly monitor on the state prescription monitoring systems. This is also against their civil liberties. I would think the NAACP would be opposed to this. No one needs access to these records. They have not before and do not now. This is prejudicial and I believe against the law. I will withhold my name because I'm afraid of repercussions. If I'm afraid to sign my name, can you imagine how it would be for patients if their records were in a nationwide database.



June 23, 2014

Sent electronically

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

Dear Ms. Friedman;

On behalf of Allina Health, thank you for the opportunity to provide early input into the potential for change in the current 42CFR Part 2 rules governing records protections for patients in substance abuse programs.

Allina Health is a family of 12 urban and rural hospitals, 80 clinics with over 800 physicians, and specialty care services dedicated to meeting the lifelong health care needs of communities throughout Minnesota and western Wisconsin. We provide a continuum of care, from disease prevention programs, to technically advanced inpatient and outpatient care, to medical transportation, pharmacy, durable medical equipment, home care, palliative care, and hospice services. The organization has 3 hospital based substance abuse programs as part of the comprehensive mental health service line. Allina Health was an early adopter of the electronic health record and our 12 hospitals and 800 eligible providers have successfully attested to receive the Electronic Health Record (EHR) incentive payments for the past three years.

Allina Health takes patient privacy very seriously and as a covered entity has implemented a comprehensive privacy and security program in order to meet the many requirements of the Health Insurance Portability and Accountability Act (HIPAA) to protect patient information and uphold patient trust.

Although Part 2 rules were established at a time when there were no protections to the records, the HIPAA rules now provide a firm foundation for the protection of all patient records, not just those of patients in substance abuse treatment programs. Allina Health believes that the Part 2 rules are no longer necessary and should be eliminated or revised to mirror HIPAA rules. We support the application of one set of rules providing the essential protections for all patients. The administrative burden of complying with both Part 2 and HIPAA rules is ominous and creates many issues in our ability to manage all the needs of our patients across the continuum of care.

We appreciate that SAMHSA recognizes the limitations of the current Part 2 rules and seeks input into potential revisions. However, we firmly believe that revisions to the rule will not address the issues our patients and providers experience. We ask that SAMHSA work with

Congressional leaders to remove the Part 2 rules, or at minimum, to revise the rule to explicitly defer to HIPAA PHI protections for all HIPAA covered entities.

HIPAA rules already provide parameters for protections in all areas in which SAMHSA seeks input for revisions. By continuing to segment the substance abuse patients from the general patient population we serve to perpetuate the stigma of substance abuse and prevent the ability to serve the whole patient and coordinate all essential care. This is a disservice to the patient and does not fit into a new care model where the industry is working to break down barriers between primary care and specialty providers and all locations of care delivery. By continuing to segment the condition of substance abuse with different rules, we cannot support an integrated approach to care delivery and are creating significant unnecessary resource utilization and cost for providers, patients, and payers, including the federal government.

Applicability

In an environment where most providers have implemented the electronic health record, it becomes extremely difficult to facilitate the application of specific restrictions based on condition, service or program/facility. Allina Health vehemently opposes any change in current rule that would shift the Part 2 applicability to specific services provided. This approach would be nearly impossible to operationalize in an organization with an integrated health record and integrated care delivery model.

Consent Requirements

We agree that these requirements need to be addressed. We support revisions that would mirror HIPAA rules or that these requirements are eliminated fully for all covered entities that must comply with the consent requirements under HIPAA.

Re-Disclosure Prohibitions

These prohibitions create significant barriers to our ability to facilitate comprehensive care for our patients. We support disclosure for treatment, payment, and operations as specified under the HIPAA rule. The disclosure authorization informs patients that re-disclosure is a risk. We support the preservation of the current restrictions to law enforcement.

Medical Emergency Exception

Allina Health supports the application of the HIPAA rule parameters that support disclosures for treatment, payment, and operations purposes.

Requirements Related to Qualified Service Organizations

Although we see this provision rarely used, Allina Health can support broadening to include care coordination, but would prefer to see the HIPAA and HITECH rules applied that would require business associate agreements and covered entities to fully comply with the those rules.

Research

Allina Health supports the application of existing HIPAA protections in regard to records access and disclosures for research purposes.

Again, thank you for the opportunity to provide input. We greatly appreciate that SAMHSA is considering revisions. We hope that you consider our comments as you work to move this old rule into the new world of integrated care delivery and electronic health records.

Sincerely,

Nancy G. Payne, RN, MA
Director Organizational Integrity and Regulatory Affairs



Cathy J. Friedman
SAMHSA, Public Health Analyst
Substance and Abuse & Mental Health Services Administration
1 Choke Cherry Road
Rockville, MD 20857

Via Email: PrivacyRegulations@SAMHSA.hhs.gov

RE: Docket No. 2014-10913 - Confidentiality of Alcohol & Drug Abuse Patient Records, 42 C.F.R., Part 2, Fed. Reg/Volume 79, No. 91, pages 26929-26932

Dear Cathy Freedman,

Thank you for the opportunity to join in the SAMHSA discussion of the Federal confidentiality rules (Title 42 CFR of the code of the Federal regulations, Part 2) in relation to the major changes in our national health care system.

Please accept these comments submitted on behalf of the Drug and Alcohol Service Providers Organization of Pennsylvania. We are a statewide association of alcohol and drug addiction treatment and prevention programs providing addiction treatment services to all sixty-seven counties in the state. We represent the full continuum of these drug and alcohol services, including prevention, education, hospital and inpatient non-hospital detoxification, inpatient residential treatment, outpatient, intensive outpatient, partial hospitalization, halfway houses, transitional living, criminal justice treatment and dual-diagnosis programs.

The Federal confidentiality rules have long played a critical role in ensuring that people with untreated alcohol and other drug addictions are able to seek treatment for this often fatal illness that effects 1 in 4 of our families.

We are deeply concerned that many of the issues under discussion will dramatically loosen confidentiality protections which currently, stalwartly protect the privacy of thousands of patients and frightened families seeking help for addiction to alcohol and other drugs.

The unmet need for addiction treatment in the country is frighteningly high and is estimated by SAMHSA at over 20 million individuals. (SAMHSA, *2012 National Survey on Drug Use and Health, September 2013*). Many of these individuals stay out of treatment because of concerns regarding privacy. We are concerned that loosening of confidentiality protections may make this situation worse.

Already, we pay a horrific price for this unmet treatment need both in dollars and family devastation. In fact, over thirty years of research and studies have demonstrated with mind-numbing consistency that untreated alcohol and other drug problems cause a hemorrhage of uncontrollable spending in both the health care and the criminal justice systems. A similarly mind-numbing number of studies have demonstrated that proper treatment of addiction reaps a harvest of financial savings in the health care and criminal justice systems and assists in stabilizing our families and communities.

There are many obstacles to entering addiction treatment. However, the chasm between the numbers of Americans receiving treatment and the numbers estimated to be in need is shocking. The chasm broadcasts loudly that stigma and shame – life endangering stigma and shame – continue to enshroud people with alcohol and other drug addictions.

SAMHSA's own publications make this case as well. According to data from the 2010 National Household Survey on Drug Use and Health, about one-third of those not going to treatment stayed out because they feared what others would think of them both in their place of employment and in their neighborhood.

In this context, how could anyone doubt the importance of maintaining the strictest of confidentiality protections?

If I may, the national health care delivery system has indeed changed. However, the nature of alcohol and other drug addictions has not.

For this reason, we must take care that the design of our health care policy and systems meet the patient's need, not the reverse. In fact, if we fail to meet the patient where he/she is, we shall fail famously, expensively (in health care costs and crime) and, we shall fail quite predictably.

1 . Background

Indeed, there have been "significant changes" in the U.S. health care system over the last 25 years, including the advent of electronic records electronic infrastructure and other technology. This is reality. At the same time, the nature of stigma and the nature of this shame-based illness remain unchanged. This is also reality.

a. Intake and screening services, like federally assisted addiction treatment facilities, should be covered under the requirements of 42 CFR, Part 2. However, we are concerned about the meaning of "other similar pre-treatment services". What are these services?

b. Maintain patient written consent requirements. This is a necessity. The statement in this section that HIEs, ACOs, CCOs, etc., have a growing number of providers and "generally do not have sophisticated consent management capabilities," makes the case that individual "To Whom" consent requirements must be maintained. The lack of "sophistication" of these entities is not an acceptable argument to compel changes that could endanger the patient's ability to get help.

For this reason, we are alarmed by #1 , #2 and #4 and urge you to reject these ideas. The patient must not be asked to sign away consent to a world of interconnected health care systems, unknown future entities and vendors with one general consent and signature. One consent each time, to one individual, for specified information, for a defined period of time – this must be the rule.

The Background document notes that the consent requirements "make it difficult" for the new health care organizations to share patient information . Indeed. That is exactly the point. Given the sensitivity of this information, such sharing shouldn't be easy and must never be casual.

The Background document itself delineates the importance of confidentiality – "Behavioral health is essential to overall health and the costs of untreated substance abuse disorders, both personal and societal, are enormous. However, treatment for substance abuse disorders is still associated with discrimination. In addition, there may be potential serious civil and criminal consequences for the disclosure of this information beyond the health care context. There continues to be a need for confidentiality protections that encourage patients to seek treatment without fear of compromising their privacy."

Would the changes being considered maintain privacy protections for patients? ABSOLUTELY NOT.

Would these changes address the concerns of the HIEs, ACOs, etc.? Probably, but for what purpose are we designing the health care system, the proper care of the patient or the convenience of the acronym?

- c. Redisclosure – We recommend making no changes to the current rules on redisclosure. Limitations on redisclosure are at the heart of the confidentiality rules.
- d. Medical Emergency – We are not aware of any problems with the current rule.
- e. QSO – We urge you to reject the idea of allowing care coordinators (an ambiguous and in many cases, contradictory term) and payers from accessing patient information through QSOs. Almost by definition, a QSO can be any type of entity, and could potentially include managed care organizations. This leaves the barn door wide open.
- f. Research – We urge you to maintain current rules and regulations.
- g. Prescription Drug Monitoring Programs – This problem illustrates the need for a uniform set of strong federal privacy protections, not a need to weaken those protections .

In closing, deciding to go to treatment for addiction is hard enough now. Let's not make things worse – and let's not sacrifice a patient's access to treatment on the altar of administrative convenience.

Sincerely,

Deb Beck
President/DASPOP

6/23/14



**COMMENTS OF THE LEGAL ACTION CENTER IN RESPONSE TO
U.S. DEPT. OF HEALTH & HUMAN SERVICES,
SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMINISTRATION,
NOTICE OF PUBLIC LISTENING SESSION,
79 FED. REG. 26929 (MAY 12, 2014)
DOCKET NO. FR DOC. 2014-10913
(SUBMITTED JUNE 25, 2014)**

I. Introduction to LAC Comments

The Legal Action Center (LAC) is the only non-profit law and policy organization in the United States whose sole mission is to fight discrimination against people with histories of addiction, HIV/AIDS or criminal records, and to advocate for sound public policies in these areas.

LAC staff regularly consults about confidentiality and related legal issues with alcohol and drug prevention and treatment professionals around the country, as well as health, mental health, public health and managed care providers, welfare and child welfare systems, lawyers and law enforcement officials, courts and other criminal justice agencies, employment assistance programs, and federal, state and local policy makers. Over three decades of experience and expertise in applying and interpreting the federal law and regulations (42 C.F.R. Part 2) are reflected in the comments we submit in response to the Substance Abuse and Mental Health Services Administration's (SAMHSA) May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929). As you consider these and other comments from stakeholders, we urge you to give the greatest weight to the comments made by patients and consumers, as it is their rights and access to their sensitive health information that will be affected by any changes to 42 C.F.R. Part 2.

LAC believes that behavioral health care should be integrated with physical health care, and that communication between health care providers should be encouraged. At the same time, LAC believes that 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and that a move toward the looser privacy standards of the Health Insurance Portability and Accountability Act (HIPAA) would not sufficiently protect people seeking and receiving substance use disorder (SUD) treatment. Patients seeking and receiving SUD treatment should retain the right to control how their records are disclosed, even for health and payment purposes, given the continued prevalence of prejudice and discrimination in our society. LAC believes that it is both necessary and technologically possible to integrate SUD and other health care and to effectively exchange SUD treatment data while maintaining the core protections of 42 C.F.R. Part 2.

Our recommendations concerning the critical issues SAMHSA poses can be summarized as follows:

- LAC supports maximizing inclusion of SUD records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining privacy protections

that are as essential today as they were when enacted in the 1970s. People with SUDs still face loss of employment, housing, and child custody; insurance and health care discrimination; criminal arrest, prosecution and incarceration; and a host of other negative consequences. 42 C.F.R Part 2's privacy protections greatly minimize the possibility that a patient's own treatment records could be used against them in all those situations. In order to encourage people with SUDs to seek treatment, 42 C.F.R. Part 2's more stringent privacy protections must be maintained rather than accede to HIPAA standards, which many have criticized for their insufficient protection of patient privacy, and which would allow many more disclosures that would lead to those harmful consequences for patients.

- LAC supports the goals set out in the request for comments and many of the specific suggestions for adjusting how the regulations currently operate. LAC believes that the current regulations, together with existing plus additional guidance from SAMHSA, can accomplish many (if not all) of the intended goals of integrating substance use disorder and other health care and improving communication between them more effectively.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, EHRs must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. In addition, EHRs must also be designed to comply with the HITECH Act, which provides that individuals have a right to restrict the disclosure of health information in electronic or any other form when they pay out of pocket for services provided.¹ It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA and HITECH-compliant even if 42 C.F.R. Part 2 did not exist.

II. Why the HIPAA Standard is Insufficient to Protect Patient Privacy

Before we answer the specific questions posed by SAMHSA in its May 12, 2014 Notice of Public Listening Session ("Notice"), we would like to address the suggestion by some stakeholders that a potential solution to the challenges posed by 42 C.F.R. Part 2 (hereinafter referred to as "Part 2") to initiatives such as new models of integrated care and electronic health information exchange is to do away with Part 2's heightened privacy protections in favor of a HIPAA standard.

Acceding to a HIPAA standard for SUD patient information would eviscerate the core protections of Part 2 – in particular the requirements for patient consent, the prohibition on redisclosure, and the heightened standards for disclosure to law enforcement and judicial and administrative bodies – and would likely lead to dire consequences for Part 2 patients and their families. While Part 2 requires patient consent for most disclosures, thus allowing patients to control the flow of information that holds the potential to do them great harm in the wrong hands, HIPAA does not require consent for disclosures made for the purposes of treatment,

¹ 45 C.F.R. § 164.522(a)(1)(vi).

payment, and health care operations (TPO). HIPAA's definition of TPO is so broad as to allow virtually unfettered access to patient's health information by those in the health care system; such an exception would be a death knell for Part 2's patient consent requirement and prohibition on redisclosure. Furthermore, where Part 2 requires a special court order for disclosures to law enforcement and to judicial or administrative bodies (such as divorce and child custody proceedings)² with heightened review standards, HIPAA permits such disclosures in whatever manner is required by state law, meaning as soon as a health care provider receives a subpoena, judicial or administrative order, or even a discovery request. Given the disastrous consequences patients often face when their SUD histories are disclosed to law enforcement or judicial or administrative bodies, adopting this standard for SUD patient records would do great harm to patients and their families.

While allowing all SUD patient information to flow to all parts of the health care system without restriction may seem benign or even desirable at first blush, we believe it is likely that such a change would backfire, resulting in disclosures that damage the lives of patients and their families more often than improve their care. Allowing virtually unfettered disclosure of SUD patient records without consent to the full range of individuals and organizations involved in health care (including payment and operations) and law enforcement, and allowing those entities to redisclose those records without restriction, as HIPAA does, would result in many people not obtaining the care they need for fear of being arrested and prosecuted, losing custody of their children, and suffering employment, insurance and other discrimination.

In its 40 years serving SUD treatment providers and SUD patients, LAC has seen these consequences first-hand time and again. Although we hope to see the day when prejudice and discrimination are no longer the reality for people with SUDs, that day has unfortunately not yet arrived. In just the past several months LAC has received numerous requests for assistance from people facing SUD-based prejudice and discrimination. For example, we have heard from:

- a young father in recovery who was being denied visitation with his children because he was in methadone treatment, despite the fact that he was not using any illegal substances;
- a mother in recovery who had her 2-month-old infant removed from her custody after the hospital where she gave birth reported her for having legally prescribed methadone in her system;
- a young mother who was being threatened with eviction from a shelter because she was taking prescribed methadone for her opioid addiction (another young mother had already been evicted from the same facility for the same reason, and had become homeless; neither woman was using illegal substances); and
- a young man whose employer refused to allow him to return to work after he successfully completed treatment for alcoholism, saying that he was a safety threat even though his physician had cleared him to return to work with no restrictions.

In addition, since January 1, 2012, LAC has received 93 requests for assistance from SUD treatment programs whose patient records were being sought by law enforcement or a court

² For example, under 42 C.F.R. Part 2, a court ordinarily may not even order disclosure of treatment records for the purpose of prosecuting a patient. *See* 42 C.F.R. §§ 2.61-2.65.

without obtaining appropriate court orders as required by Part 2. This represents requests from only the 10 states to which we provide hotline assistance.

LAC is not alone in recognizing the importance of patient privacy protections. When the U.S. Department of Health and Human Services (HHS) issued the HIPAA Privacy Rule in 2000, it stated, “While privacy is one of the key values on which our society is built, it is more than an end in itself. It is also necessary for the effective delivery of health care, both to individuals and to populations.”³ HHS also said that, “Unless public fears are allayed, we will be unable to obtain the full benefits of electronic technologies.”⁴

Yet the issuance of the HIPAA Privacy Rule has done little to allay fears of sharing health information through electronic health systems, and in fact those concerns are growing. A 2010 study in the *Journal of the American Medical Informatics Association*⁵ found that of the outpatient mental health clinicians surveyed:

- 83% disagreed with including their own psychiatric records among routinely accessed EHR systems;
- 80% said that if they were a patient, they would not want health care providers to have the ability to routinely access their mental health records; and
- 63% said they are less willing to record highly confidential information in EHRs compared with paper records.

According to a report issued by the American National Standards Institute in 2012, an online poll of 2,000 adults revealed that 97% of the public believe that health care providers and insurers should not be able to share their health information without their consent.⁶ A 2013 study found that about two-thirds of U.S. adults were concerned about a breach in the security of their protected health information (PHI) during transfer between health care professionals by fax or electronically, and concerns over the safety of PHI was associated with higher likelihood of withholding medical information from a health care professional.⁷

The fears that these professionals and adults have regarding electronic health information privacy breaches are unfortunately well founded. According to HHS, more than 1,000 medical record breaches involving 500 or more people have been reported to HHS since federal reporting requirements took effect nearly five years ago.⁸ In total, large health data breaches reported by

³ 65 Fed. Reg. 82462, 82467 (Dec. 28, 2000).

⁴ 65 Fed. Reg. 82462, 82466 (Dec. 28, 2000).

⁵ See Ronald M. Salomon et al., “Openness of patients' reporting with use of electronic records: psychiatric clinicians' views,” *J. of Am. Med. Informatics Ass'n* (2010);17:54-60, doi:10.1197/jamia.M3341, available at <http://jamia.bmj.com/content/17/1/54.full>.

⁶ Am. Nat'l Standards Inst. et al., *The Financial Impact of Breached Protected Health Information* (Mar. 2012), p. 23.

⁷ I. Agaku, et al., *Concern About Security and Privacy, and Perceived Control Over Collection and Use of Health Information Are Related to Withholding Health Information from Healthcare Providers*, *J. of Am. Med. Informatics Ass'n* (Aug. 2013).

⁸ Joseph Conn, “Major medical records breaches pass 1,000 milestone as enforcement ramps up,” *Modern Healthcare* (June 13, 2014), available at <http://www.modernhealthcare.com/article/20140613/BLOG/306139996/major-medical-records-breaches-pass-1000-milestone-as-enforcement#src=serp>.

health care providers and their business associates have affected the medical records of about one in ten U.S. residents, or 31.7 million people.⁹

The very real risks to and breaches of individuals' privacy resulting from adoption of the HIPAA standard and the development of interoperable EHR systems have led many to call for the adoption of broader protections for *all* health information, giving it protections like those afforded by Part 2. The reports and recommendations issued by the National Committee on Vital Health Statistics in its consensus-driven *Recommendations on Privacy and Confidentiality, 2006-2008* advocate for this type of change, as do numerous other stakeholders.¹⁰

HHS seemed to recognize the risks that could come when health care payers are given access to health information when, in the final rule implementing the HITECH Act (which amended HIPAA in 2009), it provided that individuals have the right to restrict the disclosure of health information in electronic or any other form when they pay out of pocket for services provided. This right should not be limited to people who have the financial means to pay for health care out of pocket, but should be afforded to all individual, regardless of the means of payment.

Below are the Legal Action Center's comments on the specific questions posed by SAMHSA in its May 12, 2014 Notice.

III. LAC Comments

a. Applicability of 42 C.F.R. Part 2

LAC agrees with SAMHSA that the current definition of which providers fall under Part 2 has been the source of some confusion. It makes no sense for the application of Part 2 to depend on whether entities "hold themselves out" as providing substance abuse services, rather than on what substance abuse treatment services they are providing. Thus we welcome a new definition of the applicability of Part 2 that clarifies which providers and what information is covered by Part 2. Such clarification would help HIEs, HIT vendors, etc. to understand what information is covered by Part 2 and requires heightened protection.

The definition suggested by SAMHSA, that Part 2 would apply to any federally assisted health care provider that provides a patient with "specialty substance abuse treatment services," removes the "holds itself out" language and is a step in the right direction. However, this proposed definition raises new questions. What is the difference between a "specialty substance abuse treatment service" and a "non-specialty substance abuse treatment service"? Is the provision of buprenorphine a "specialty substance abuse service"? It would certainly seem so, and in fact we cannot see how the provision of buprenorphine could be considered otherwise. If that is the case, then would all physicians who prescribe buprenorphine be covered by Part 2?

⁹ "One in 10 U.S. Residents Affected by Large Health Data Breaches," *iHealthBeat* (June 16, 2014), available at <http://www.ihealthbeat.org/articles/2014/6/16/one-in-10-us-residents-affected-by-large-health-data-breaches>.

¹⁰ U.S. Dep't of Health & Human Svcs, Nat'l Comm. on Vital & Health Statistics, *Privacy Report: Recommendations on Privacy & Confidentiality, 2006-2008* (May 2009), available at <http://www.ncvhs.hhs.gov/privacyreport0608.pdf>.

The definition suggested by SAMHSA also states that “providers would not be covered [by Part 2] if they provided only substance abuse screening, brief intervention, or other similar pre-treatment substance abuse services.” This makes clear that providers who only provide SBIRT services “would not be covered by Part 2.” However, in order to for this provision not to run afoul of Part 2’s authorizing statute, which explicitly extends confidentiality protections to SUD prevention,¹¹ “screening, brief intervention, or other similar pre-treatment substance abuse services” would have to be differentiated from other types of prevention services. We think an attempt at such differentiation would be difficult to impossible, and would create a large amount of confusion. It is important to maintain the statute’s protection of SUD prevention records, as prevention programs around the country depend on these protections to reassure their program participants that information shared will be held in confidence.

b. Consent Requirements

Before we address SAMHSA’s specific suggestion for possible changes to Part 2’s consent requirement, we note that we are very gratified that SAMHSA continues to support and appreciate the importance of obtaining patient consent for the release of patient information. Based on our nearly 40 years of experience advising SUD programs and their patients, LAC continues to believe that patients in SUD programs should retain the power to decide when and to whom their records are disclosed, including disclosures to the general health care system, HIEs, health homes, ACOs, and CCOs, and that the best way for patients to retain that power, and to ensure that care is, in fact, patient centered, is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.

Like SAMHSA, we also believe that there are ways to resolve some concerns that have been raised about Part 2’s consent requirements in order to facilitate “the flow of information within the health care context while ensuring the patient is fully informed and the necessary protections are in place.” In addition, we agree with SAMHSA’s assessment that “technical solutions for managing consent collection are possible” – in fact, such solutions are already under development. As such, we urge the continued development of technical solutions for consent management as well as the development of organizational policies and procedures that provide patients with meaningful consent options.

Comments on First and Second Suggested Consent Changes:

SAMHSA’s first suggested change is, “Allow the consent to include a more general description of the individual, organization, or health care entity to which disclosure is to be made.” Its second suggested change is, “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.”

¹¹ See 42 U.S.C. § 290dd-2(a) (“Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity related 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 shall, except as provided in subsection (e) of this section, be confidential....” (emphasis added)).

With respect to the first suggested change, we believe that there is a simple way to address concerns raised by some stakeholders that Part 2's current "to whom" provision is too narrow. Part 2 currently requires that a consent form must list the "name or title of the individual or the name of the organization to which disclosure is to be made."¹² We believe that "title of the individual" to whom disclosure is to be made could be interpreted as allowing "treating provider" to be listed as the title of the individual to whom disclosure is to be made.

In addition, patients could consent to the disclosure of their alcohol and drug information to their *future* treating providers, in addition to their current treating providers. With respect to the second suggested change, in order for consent to disclosure to future providers (such as providers that join an HIE or ACO after the date consent is signed) to be informed and meaningful, we suggest that a consent that permits disclosure to future providers should be accompanied by:

- a limitation on disclosures only to future providers to with a treating relationship with the patient;
- effective notification of the patient when any new provider is added to an entity to which they have provided such consent;
- an easy opt-out mechanism that is always available but is also reiterated each time patients are notified that a provider has been added.

We believe implementation of this interpretation of the "to whom" requirement could be accomplished by a change to the regulations or by sub-regulatory guidance.

We believe our recommendation permitting patients to consent to the disclosure of their alcohol and drug information to their treating providers, including future treating providers, appropriately balances the concerns of HIEs, ACOs, and other health care entities with the need to provide patients with meaningful consent options. Permitting disclosure to treating providers and future treating providers maintains the core protections of 42 C.F.R. Part 2 – the prohibition on disclosing, and redisclosing, patients' SUD records without their consent – while at the same time making it easier for patients who choose to consent to such disclosures to participate in integrated care models and HIT, including HIEs. Such an interpretation is consistent with both Part 2 and statutory language.

A potential additional benefit of this change is that fewer health care providers will need to access patient information by "breaking the glass" (accessing a patient's SUD information without consent in a medical emergency, as permitted by Part 2), since most providers treating a patient in a medical emergency will be covered by a treating provider (including future treating providers) consent. Currently, when Part 2-protected records are accessed without consent in a medical emergency, they lose the protections of Part 2. An expanded consent interpretation that allows providers to access SUD records in a medical emergency by consent, rather than by "breaking the glass," will ensure that more alcohol/drug records remain protected by Part 2.

To the extent that SAMHSA is considering allowing an HIE or ACO together with all of its affiliated/member providers to be listed as an "organization" in the consent form's "to whom" field, we strongly urge against such a change. Allowing an HIE, ACO, or other new health care

¹² 42 C.F.R. § 2.31.

model to call itself an “organization” would have broad implications, namely the proliferation of disclosures of SUD records without meaningful patient consent. Depending on the size of the HIE or ACO, potentially vast networks of health care providers (and other personnel) would have access to patients’ alcohol and drug records after the patient signs a single consent form. In the ACO context, member providers and personnel would be free to redisclose the SUD records amongst themselves without patient consent; in the HIE context, any provider affiliated with the HIE would be able to redisclose SUD records with any other affiliated provider without patient consent. This is particularly worrisome given widespread lack of knowledge of Part 2’s protections – and the reasons for those protections – among non-Part 2 providers, and the risks associated with freely flowing electronic health information, including breaches.

Another possible consequence of defining or reinterpreting the meaning of “organization” in the context of Part 2 consent is that the expanded meaning of “organization” may apply elsewhere in the regulations, such as in reference to Qualified Service Organizations (QSOs). If, for example, an HIE along with all of its affiliated providers could be considered a QSO, then patients’ SUD records could be disclosed without consent by a Part 2-covered program to the HIE as well as all of its affiliated providers, as long as a QSO Agreement (QSOA) was in place. Because Part 2 contains no requirement that patients be notified of a Part 2 program’s QSOAs, patients would not even be aware that these consent-less disclosures were occurring. The implications of this type of re-interpretation of QSOs and QSOAs would be a virtual gutting of Part 2’s consent-based patient protections.

Comments on Third and Fourth Suggested Consent Changes:

With regard to SAMHSA’s proposals regarding changes to the “by whom” consent requirements, we are not familiar with a current challenge that such a change would address, and would have concerns that such changes may only serve to make the consent process more onerous. We believe that the current language regarding the description of the programs or people permitted to make disclosures is sufficiently clear.

Comments on Fifth Suggested Consent Change:

We are unclear about what is meant by “explicitly describe the substance abuse treatment information that may be disclosed,” and what concern this suggestion is meant to address. The current regulations require written patient consent to describe the amount and type of information to be disclosed, and the purpose of the disclosure.¹³ In addition, current regulations require that “any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.”¹⁴ We believe the current regulations provide sufficient specificity with regard to what information will be disclosed and for what purpose.

¹³ 42 C.F.R. § 2.31.

¹⁴ 42 C.F.R. § 2.13(a).

c. Redisdisclosure

SAMHSA is considering revising the redisclosure provision (42 C.F.R. § 2.32) “to clarify that the prohibition on redisclosure only applies to information that would identify an individual as a substance abuser, and allows other health-related information shared by the Part 2 program to be redisclosed, if legally permissible.” SAMHSA gives as the reason for such a revision that “most EHRs do not support data segmentation,” and that such a revision will “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.” We support further clarification that Part 2’s Prohibition on Redisdisclosure does not apply to information that does not identify an individual as having an SUD or being in SUD treatment, including how that relates to and can facilitate communications between substance use treatment providers and HIT systems.

The possible revision SAMHSA is suggesting would restate exactly what the current regulations allow. The current prohibition on redisclosure states that information cannot be redisclosed unless it is permitted by written consent “*or as otherwise permitted by 42 CFR Part 2* [emphasis added].”¹⁵ Part 2’s restrictions on disclosure only apply to information that “would identify a patient as an alcohol or drug abuser...”¹⁶ Thus, currently under Part 2, information that does not identify a patient as a “substance abuser” is not protected and can be redisclosed. Therefore, no revision to Part 2’s redisclosure provision is necessary. SAMHSA can clarify any confusion about the applicability of Part 2’s redisclosure provision through the issuance of sub-regulatory guidance.

Moreover, adoption of SAMHSA’s proposed revision would not ease the technological challenge of data implementation. Data segmentation would still be necessary to ensure proper implementation and adherence to the prohibition against redisclosing information that would identify an individual as a substance abuser. Thus we do not see any reason why Part 2’s prohibition on redisclosure should be revised.

d. Medical Emergency

We do not see the need to change Part 2’s definition of medical emergency, and worry that broadening that definition to encompass situations that are not emergencies would create an impermissible end-run around Part 2’s requirement to obtain consent from the patient. At the same time, we strongly support further guidance making clear that health care providers can “break the glass” and disclose information in situations where a patient is not able to give consent and information in a patient’s medical records is needed to treat a medical emergency, including medications s/he is taking that could dangerously cross-react with a medication that might be prescribed to treat the emergency.

LAC does not believe there should be a changes to Part 2’s current medical emergency exception that states that information may be disclosed without consent “for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires

¹⁵ 42 C.F.R. §2.32.

¹⁶ 42 C.F.R. §2.12(a)(i)

immediate medical intervention,” and opposes any revision that would allow providers to use the medical emergency provision to prevent emergencies.

As SAMHSA noted, the statute only allows disclosure, without a patient’s written consent, “to medical personnel to the extent necessary to meet a bona fide medical emergency.”¹⁷ A speculative concern that an emergency might happen in the future does not and should constitute a bona fide medical emergency that allows for an unconsented-to disclosure. Invoking the medical emergency exception and accessing a patient’s protected SUD records without consent should be allowable only when: (1) there is an actual emergency in which a patient’s prior consent cannot be obtained by the provider treating the emergency – because the individual is actually unconscious or incapacitated/unable to give consent; and (2) there is need for immediate action requiring immediate access to the person’s records.

The current rule already gives providers the discretion they need to interpret it appropriately in fact-specific situations. We do not believe that there should be any attempt to try to write into regulatory language specific scenarios (such as the example SAMHSA offers of changing the existing standard in order to “prevent emergencies or to share information when a patient is unable to provide informed consent due to their level of intoxication”), because attempting to anticipate and spell out all of the potential scenarios that *might* conceivably arise would be an exercise in futility, and would rob those faced with such a list of the crucially important discretion the current standard must continue to afford them.

e. Qualified Service Organization (QSO)

In its May 12 Notice, SAMHSA states that it has “heard concerns from payers and health management organizations related to disclosing information that is subject to 42 C.F.R. Part 2 to health care entities (ACOs/CCOs) for the purpose of care coordination and population health management; helping them to identify patients with chronic conditions in need of more intensive outreach” (emphasis added). SAMHSA proposes expanding the definition of a QSO to allow for Qualified Service Organization Agreements (QSOAs) for the purposes of care coordination and population health management.

SAMHSA has always taken the position that a QSOA is a two-way agreement between two parties – one a Part 2 program and the other a Qualified Service Organization (QSO) that is providing a service to that Part 2 program. We strongly support that position and urge SAMHSA not to open up the QSOA exception so as to allow Part 2 information to flow between multiple entities. To do so would be a complete evisceration of Part 2’s consent requirements.

To the extent that, for the purpose of care coordination and population health management, there might be one entity that is gathering data from difference data sources, a QSOA would be an acceptable tool for a Part 2 program to disclose protected information to that information gathering entity. If, however, Part 2 information would need to flow to all entities involved in care coordination and population health management, then a QSOA should not be allowed for such a purpose, and SAMHSA should remain staunch in its position that patient consent would

¹⁷ 42 U.S.C. § 290dd-2 (b)(2)(A)

be needed. Indeed it is quite simple for a consent to be drafted that allows communication among multiple parties.

Should SAMHSA also be proposing that a QSOA can be used for payment purposes, Part 2 currently requires that a consent be used for such a purpose, and we strongly agree that consent should remain the only option for disclosing information for payment purposes. This interpretation is the only one that is consistent with Part 2's authorizing statute.

Finally, we are not sure if, when SAMHSA proposed that "One potential solution includes ... to allow a ... QSOA to be executed between an entity that stores Part 2 information, such as a payer or an ACO that is not itself a Part 2 program, and a service provider," SAMHSA meant the term "service provider" to refer to a program covered by Part 2, or to another type of entity. We strongly believe that a QSOA should remain an agreement only between a Part 2 program and an entity that provides a service to that program.

In sum, to the extent that SAMHSA may be suggesting any significant broadening of the rules surrounding QSOAs, we believe this would not only run afoul of Part 2's authorizing statute, but it would also create an end-run around Part 2's core protections – namely the requirement that patient consent be obtained before making a disclosure of SUD information, and the prohibition on redisclosure. Allowing QSOs to disclose Part 2 information to one another would eviscerate Part 2's consent and redisclosure protections and damage patient trust.

f. Research

If SAMHSA is suggesting that third party payers, HIEs, etc., should be able to disclose Part 2 information already in their possession to researchers, we support the underlying rationale for this suggested change, i.e., that researchers should have the ability to get access to information for research purposes. However, we are concerned that the protections contained in Part 2's research exception (found at 42 C.F.R. §2.52) will not be enforceable if entities other than Part 2 treatment providers have the authority to release Part 2 information in their possession to researchers. How will HIEs, third party payers, etc., be able to determine that a researcher will maintain the Part 2 information in accordance with the security requirements set out in §2.52(a)(2)? How will they be able to assess whether the potential benefits of the research outweighs any risks to confidentiality as required by §2.52(a)(3)? Who at these organizations will be the equivalent of a "program director" and have the authority to make these decisions? Will they know enough about §2.52 to inform the researchers about the limitation about how the Part 2 information can be redisclosed under §2.52(b)?

In sum, we would support qualified researchers gaining access to Part 2 information for scientific research purposes, from sources other than Part 2 programs, if there is a way to ensure that all of Part 2's research protections in §2.52 will be complied with.

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

LAC understands, and finds both justifiable and necessary in light of the current regulation, SAMHSA's current interpretation requiring Part 2 programs to obtain patients' proper written consent before disclosing patients' electronic prescription information to a pharmacy, requiring the pharmacy to obtain proper patient consent before disclosing the Part 2-protected information to a PDMP, and requiring the PDMP to obtain proper patient consent before re-disclosing Part 2-protected information to others. As stated earlier in these comments, it is critical that SUD patients retain control over who has access to their records in light of ongoing prejudice and discrimination, and the potential unintended consequences of permitting widespread disclosure of those records.

According to the National Alliance for Model State Drug Laws, as of December 2013, 18 states allow law enforcement to access their PDMPs with a search warrant, subpoena, court order, or other judicial process. Furthermore, 13 states allow law enforcement to be registered users of their PDMPs.¹⁸ Law enforcement attempts to access SUD patient records, and the deterrent impact of law enforcement access against people seeking SUD treatment, was a primary reason for creating Part 2's protections in the first place. Any change to Part 2 that would allow law enforcement to access patients' SUD information without their consent would directly contravene the most basic purposes of Part 2, and would violate Part 2's authorizing statute.¹⁹

Furthermore, discrimination by non-Part 2 health care providers and insurers continue to cause real concern among SUD patients. Any change to Part 2 that would allow patients' SUD information to flow without their consent to pharmacies, PDMPs, and all those with access to PDMPs would not only violate Part 2's authorizing statute but could also cause damage to patients, including discrimination by health care providers, insurers, and others. We support SAMHSA's continued interpretation of Part 2 as requiring patient consent for disclosure of their SUD prescription information to pharmacies, PDMPs, and those with access to PDMPs, and for redisclosure by any of those entities.

IV. Conclusion

The health care environment is changing rapidly, moving toward more integrated care and the electronic exchange of health information. It is important for behavioral health to be included in integrated care and HIE in order to provide the best care for the millions of individuals in the U.S. who suffer from substance use disorders, and also to reduce costs associated with those disorders. At the same time, the privacy protections afforded to SUD information by Part 2 remain as critical today as they were when enacted in the 1970s. People with substance use disorders still face loss of employment, housing, and child custody; insurance discrimination; criminal arrest, prosecution, and incarceration; and a host of other negative consequences. In

¹⁸ Nat'l Alliance of Model State Drug Laws, *Law Enforcement Access to State PMP Data* (2013), available at <http://www.namsdl.org/library/C4AA9EA3-65BE-F4BB-AAFBAB1F5736F070/>.

¹⁹ 42 C.F.R. Part 2's authorizing statute states: "Except as authorized by a [Part 2] court order ... no [Part 2] record ... may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient." 42 U.S.C. § 290dd-2(c).

order to encourage people with substance use disorders to seek treatment, we strongly urge that Part 2's privacy protections be maintained. We also urge that, where possible, the issues identified by SAMHSA as causing confusion be addressed through additional and revised sub-regulatory guidance by SAMHSA, without the need for regulatory change.

LAC also encourages the continued development of technology, along with corresponding policies and procedures, that will enable patients with SUD records – and other types of sensitive health records – to maintain control and choice regarding disclosures of their health information. We believe granular control in health information technology (HIT) is possible and imminent. We also hope that incentives for the adoption of HIT will be extended to behavioral health providers, and that SAMHSA and other departments of HHS will continue to pilot cutting-edge behavioral health HIT initiatives. Finally, we agree with stakeholders who stressed at the June 11, 2014 Listening Session the importance of educating health care providers, Part 2 programs, and Part 2 patients about consent, Part 2, and substance use disorders generally.

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

From: Babak Imanoel [<mailto:babakimanoel@gmail.com>]

Sent: Wednesday, June 25, 2014 3:34 PM

To: Privacy Regulations (SAMHSA)

Subject: 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:

My name is Babak Imanoel, DO and I am writing on behalf of BH Health Services, which is a Methadone Maintenance Program located in Westminster, Maryland.

While BH Health Services supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, 42 C.F.R. Part 2's core privacy protections MUST be maintained.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), BH Health Services, Inc. supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder

(SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.

- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment.

If patient records can be easily accessed in order to criminally investigate or prosecute a patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.

- LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.

- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.

- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in

mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist. We also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

Babak Imanoel, D.O.
Medical Director and President,
BH Health Services, Inc.
450 East Main Street
Westminster, MD 21157
Tel: 410-871-3005
Fax: 443-293-8711

Babak Imanoel, D.O.

This email or facsimile transmission may contain CONFIDENTIAL, PRIVILEGED and or PROTECTED INFORMATION intended solely for the use of the individual or entity to whom it is addresses. If you are not the intended recipient, please notify the sender by email or fax immediately. Please do not disseminate or copy and delete or destroy immediately.



South Carolina Association for the Treatment of Opioid Dependence

June 25, 2014

South Carolina Association for the Treatment of Opioid Dependence
5 Charleston Center Drive
Charleston, SC 29401

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

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:

The South Carolina Association for the Treatment of Opioid Dependence (SCATOD) is a provider's association representing all 17 Opioid Treatment Program's (OTP's) in the state and we treat thousands of patients with an opioid use disorder (primarily) and other substance use/mental health disorders. I am the current President and I am speaking on behalf of the association.

While SCATOD supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

All too often, our patients are subjected to stigmatization by other people and systems due to their substance use disorder. This is enhanced when people are on Medication Assisted Treatment (MAT), especially methadone, and can impact several facets of one's life. We already deal with patients hesitant to share their treatment status with employers for fear of getting fired. We have patients that struggle to find adequate health care once their status is known as being on methadone. We live in a state that insurers already find ways to limit treatment for people with a substance use disorder, which is a chronic disease, which does not happen with other chronic diseases like diabetes, hypertension, etc. We believe that the core privacy protections need to be maintained to reduce any intentional/unintentional stigma and or barrier to the population that is dealing with a substance use disorder.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), SCATOD supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- SCATOD continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records

of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

W. Jonas Coatsworth MA, LPC, CAC-II
South Carolina Association for the Treatment of Opioid Dependence (SCATOD)
President
(843) 958-3364



June 25, 2014

Harm Reduction Coalition
22 W. 27th Street, 5th Floor
New York, NY 10001

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

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:

On behalf of the Harm Reduction Coalition, a national organization addressing the intersection of substance use and health, I am writing to comment on regulations regarding federal drug confidentiality protections.

While Harm Reduction Coalition supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

Harm Reduction Coalition works with a broad array of partners and stakeholders, particularly community-based syringe exchange and harm reduction programs which serve marginalized and stigmatized people with substance use histories. We routinely hear concerns from these programs and their participants about their fraught relationship and engagement with the health care system, which they experience as stigmatizing towards people who use drugs. We recognize and support efforts to better integrate substance use screening and treatment into primary care, and appreciate the value of ensuring that patients' substance use treatment needs and histories are recognized and responded to by their health care providers. At the

East Coast Office

22 West 27th Street, 5th Floor
New York, NY 10001
(212) 213-6376
hrc@harmreduction.org

West Coast Office

1440 Broadway, Suite 510
Oakland, CA 94612
(510) 444-6969
hrcwest@harmreduction.org

www.harmreduction.org



same time, we feel strongly that the stigma which persists among health care providers jeopardizes access and quality of care for these vulnerable populations. The privacy protections conferred under 42 C.F.R. Part 2 remain critical for people with substance use histories wishing to retain confidentiality and autonomy in their health care.

To take one example, many people with chronic hepatitis C struggle to obtain effective treatment from clinicians who actively discourage, dissuade, or refuse to treat their hepatitis C due to the patient's substance use history. Moreover, with newer and more effective hepatitis C treatments now available, a number of payers are restricting reimbursement for hepatitis C treatment through prior authorization requirements to people with substance use disorders, in some cases requiring drug testing. These restrictions are not based on evidence or sound clinical care, and indeed are just one manifestation of the overwhelming biases across all parts of the health care system towards people with substance use histories.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), Harm Reduction Coalition supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.

East Coast Office

22 West 27th Street, 5th Floor
New York, NY 10001
(212) 213-6376
hrc@harmreduction.org

West Coast Office

1440 Broadway, Suite 510
Oakland, CA 94612
(510) 444-6969
hrcwest@harmreduction.org

www.harmreduction.org



- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

Daniel Raymond
Policy Director

East Coast Office

22 West 27th Street, 5th Floor
New York, NY 10001
(212) 213-6376
hrc@harmreduction.org

West Coast Office

1440 Broadway, Suite 510
Oakland, CA 94612
(510) 444-6969
hrcwest@harmreduction.org

www.harmreduction.org

Central East Alcoholism & Drug Council

A NOT-FOR-PROFIT CORPORATION

SINCE 1972

SERVING CENTRAL ILLINOIS

ADMINISTRATIVE OFFICES • 635 Division St., P.O. Box 532 • Charleston, Illinois 61920

Telephone: (217) 348-8108 • Fax (217) 345-6794

TDD: (217) 348-8116

June 25, 2014

U.S. Substance Abuse and Mental Health Services Administration

1 Choke Cherry Road

Room 5-1011

Rockville, MD 20857

Submitted via email: PrivacyRegulations@SAMHSA.hhs.gov

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:

Central East Alcoholism and Drug Council (CEAD) Council is a community based, not-for-profit Corporation offering a full array of services for alcohol and drug abuse and dependency across a large rural area of central Illinois. As a “stand-alone” provider of prevention, intervention, treatment, and recovery support services since 1972, we have repeatedly found the provisions within 42 CFR Part 2 to be foundational in our ability to successfully provide services. Especially in the rural areas where “everyone knows everyone” the protections afforded to patients via 42 CFR are extremely important to both existing and potential patients. It is because of the protections that exist in the regulations that clients are willing to enter treatment and to openly participate in the treatment process with confidence that their privacy will be protected. Though obtaining written consent for disclosure of information may present some problems in the current environment of unlimited electronic exchange of data, it is of utmost importance to continue the protections afforded to patients that requiring written consent maintains. Effective integration of care can readily occur while maintaining 42 CFR’s privacy protections. Effective treatment of substance abuse cannot occur without the protections that currently exist in 42 CFR.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA’s May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), Central East Alcoholism and Drug Council supports the following principles:

- Addiction treatment should be integrated with mental and physical health care when determined to be clinically indicated in individual cases and communication among those

Hour House
635 Division St.
Charleston, IL
61920
(217) 348-8108
(217) 348-0154

1501½ 18th St.
Charleston, IL
61920
(217) 348-5444

726 4th St.
Charleston, IL
61920
(217) 348-8118
(217) 348-8591

720 4th St.
Charleston, IL
61920
(217) 348-8651

8500 E. Co. Rd. 150N
Lerna, IL
62440
(217) 235-1303

513 N. 13th St.
Mattoon, IL
61938
(217) 258-6018

521 N. 13th St.
Mattoon, IL
61938
(217) 258-6137

416 N. 19th St.
Mattoon, IL
61938
(217) 258-2968

155 South Morgan
Shelbyville, IL
62565
(217) 774-5566

individually relevant health care providers should be encouraged as applies to the current circumstances of the patient and with the patient's full informed consent. That can readily occur within the existing regulations.

- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place. Even if people seeking and receiving substance use disorder treatment perceive that the confidentiality restrictions have been relaxed, their fear of unwanted release of information may create barriers to treatment access and acceptance.
- Central East Alcoholism and Drug Council continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for disclosures, together with a strong prohibition on re-disclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management and significant testing of those solutions prior to premature and unnecessary changes in the regulations.
- The nature of substance abuse treatment requires that patients discuss and disclose the very-most intimate details of their thoughts, emotions, lifestyle, past behaviors, family issues, and more. The patient record contains information that was shared with a counselor with the understanding that such information would remain confidential within the treatment team and/or program. Effective substance abuse treatment requires a practitioner/patient relationship that has a foundation in honesty and transparency that will only occur in a setting that promotes patient control of the limits of disclosure of that information. Unlike medical records that more readily record only pieces of "data," the content of substance abuse treatment records was never written from the perspective that it would someday be thrown into a public electronic exchange where it would await the next access by some entity unknown to the patient and without the patient's full informed consent.
- The substance abuse treatment field has also experienced extensive workforce issues since inception that continue to this day. Retaining qualified clinical staff is an ongoing

issue. The confidentiality protections afforded via 42 CFR have been instrumental in fostering excellent clinical practice that is extremely important to clinicians working in the substance abuse field and that they want to retain. I would predict a significant exodus of experienced clinical staff away from the substance abuse field if the core protections in 42 CFR cease to exist.

-] Additionally, many organizations in the substance abuse field, including CEAD Council, have strong connections with the self-help fellowships of Alcoholics Anonymous and Narcotics Anonymous. Similar philosophical approaches support our mutual efforts to encourage long-term recovery. The protections of 42 CFR foster our mutual efforts and beliefs regarding anonymity, privacy, personal choice, and informed consent.

It appears that the primary entities who might advocate for changes to 42 CFR Part 2, i.e., computer programmers, health information exchanges, CCO's, ACO's, etc., are not from the substance abuse treatment field. I have worked in the substance abuse treatment field for over 37 years in an organization that has served over 22,000 individuals. I do not know of a single professional or patient in the substance abuse field that has expressed a desire for these regulations to be relaxed. I know of thousands of "stories" wherein these regulations have been of benefit.

Thank you for your consideration.

Sincerely,



Pamela P. Irwin, Ph.D., CADC
Executive Director
Central East Alcoholism and Drug Council
635 Division Street
P.O. Box 532
Charleston, IL 61920
217-348-8108

BOARD OF DIRECTORS

OFFICERS

President

Albert M. Senella

Tarzana Treatment Centers, Inc.
Kern, Los Angeles, Orange,
Ventura Counties

Vice President

Trisha Stanionis

Family Service Agency
Yolo County

Secretary

Shawn Jenkins

WestCare California
Fresno, El Dorado, Kern,
Sacramento Counties

Treasurer

Norman Sprunck

Western Pacific Med Corp
Los Angeles, Orange, Ventura Counties

BOARD MEMBERS

Jack Bernstein

CRI-HELP, Inc.
Los Angeles County

Christine Bierdrager-Salley, Ph.D.

Inland Behavioral & Health Services, Inc.
Riverside and San Bernardino Counties

Kimberly Bond

Mental Health Systems
San Diego, San Bernardino,
Imperial, Riverside, Santa Barbara,
San Luis Obispo, Kern,
Stanislaus, Fresno and Orange Counties

Vitka Eisen, MSW, Ed.D.

HealthRIGHT 360
Kings, Los Angeles, Madera,
Riverside, San Francisco,
and Sutter Counties

Mark Faucette

Amity Foundation
Los Angeles, Madera, San Bernardino
and San Diego Counties

Cassandra Loch

Prototypes
Los Angeles, Orange,
Ventura Counties

RuthAnn Markusen,

Didi Hirsch Community Mental Health
Center
Los Angeles County

Stephen Maulhardt

Aegis Medical Systems
Butte, Fresno, Kern, Los Angeles
Merced, Placer, San Bernardino,
San Joaquin, San Luis Obispo,
Santa Barbara, Stanislaus, Sutter,
Ventura, Yuba Counties

Luis Montes

Narcotics Prevention Association Inc.
Los Angeles County

Patrick Gauthier

Volunteers of America
Los Angeles County

Elvia Torres

SPIRITT Family Services
Los Angeles County

Elizabeth Stanley-Salazar

Phoenix Houses of California, Inc.
Kings, Los Angeles, Madera, Orange,
San Bernardino, San Diego,
Ventura Counties

Shirley Summers

Behavioral Health Services, Inc.
Los Angeles, Orange Counties

Sushma Taylor, Ph.D.

Center Point, Inc.
Contra Costa, Marin, Riverside,
Sacramento, San Diego, San Joaquin,
Solano, Tuolumne Counties

Brenda Wiewel

Los Angeles Centers for Alcohol & Drug Abuse
Los Angeles County

In memoriam
Dale Shimizu

June 25, 2014

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

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:

The California Association of Alcohol and Drug Program Executives, Inc. (CAADPE) is a statewide association of community-based nonprofit substance use disorder treatment agencies. Its members provide substance use disorder services, including co-occurring disorder services, at over 300 sites throughout the state and constitute the infrastructure of the state's publicly funded substance use disorder treatment network. It is the only statewide association representing all modalities of substance disorder use treatment programs

While CAADPE supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, 42 C.F.R. Part 2's core privacy protections MUST be maintained.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), CAADPE supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy

- Standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

Albert Senella
President



Colonial Management Group, LP

SUBMITTED VIA EMAIL

June 25, 2014

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

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 support 63 opiate treatment programs in 18 states.

While Colonial Management Group, LP supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

We strongly believe that fear on the part of potential patients that their involvement with an opiate treatment program will be disclosed to others is a strong deterrent that prevents many from seeking treatment.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), Colonial Management Group, LP supports the following principles:

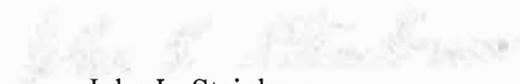
- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.

- @42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute a patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- @LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- @It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- @Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center. Thank you for your consideration.

Sincerely,

Colonial Management Group, LP


John L. Steinbrun
CEO

From: Chip Roberts [<mailto:croberts@cmglp.com>]
Sent: Wednesday, June 25, 2014 9:44 PM
To: Privacy Regulations (SAMHSA)
Subject:

June 25, 2014

Colonial Management Group
8529 South Park Circle
Suite 270
Orlando, FL 32819

U.S. Substance Abuse and Mental Health Services Administration

1 Choke Cherry Road

Room 5-1011

Rockville, MD 20857

RE: Confidentiality of Alcohol & Drug Abuse Patient Records Regulations, 42 C.F.R. Part 2. 79 Fed. Reg. 26929; Docket No. 2014-10913.

While Colonial Management Group (CMG) supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

Many patients are afraid to even tell their treating physicians about being prescribed methadone for fear of being dropped as a patient. To somehow lower the threshold that protects their information would only serve to be another deterrent for patients wanting to enter in treatment.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), CMG supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. I support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally

investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.

- LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

Paul Roberts, DO
Program Sponsor
Colonial Management Group

Illinois Association for Medication Assisted Addiction Treatment

June 25, 2014

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

RE: 42 C.F.R. Part 2
Confidentiality of Alcohol & Drug Abuse
Patient Records Regulations
Docket No. 2014-10913

Dear Colleagues:

As the president of the Illinois Association for Medication Assisted Addiction Treatment (IAMAAT), I am writing on behalf of the nearly 12,000 patients that are currently enrolled in Opioid Treatment Programs in more than 60 different OTPs throughout our state. Our patients and providers have been following much of the discussion about potential changes to the law which protects the privacy of addiction treatment records. We are quite concerned that SAMHSA might be pressured to eliminate some of the essential privacy protections that are critical to patients currently enrolled in treatment as well as for individuals struggling with addiction who might be contemplating accessing treatment at some point in the future.

As a statewide provider association, we have been in touch not only with our members and patients currently enrolled in Illinois OTPs, but also with treatment advocates from across the country. We have yet to meet a treatment provider who does not have a host of examples of external systems attempting to access protected health information of patients in OTPs and patients who have experienced discrimination in healthcare, legal systems, employment arenas, the child welfare system and other aspects of our society. It is incumbent upon us as treatment advocates to be the champions of both current and future patients.

While IAMAAT understands your interest in updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in this electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.** SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929) proposed modifications to 42 C.F.R. Part 2. Regarding those proposed modifications, IAMAAT supports the following principles:

- ❖ 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute a patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will fear entering treatment at all.
- ❖ Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- ❖ We agree with the Legal Action Center (LAC) that patients in addiction treatment programs should 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 healthcare system, HIEs, health homes, ACOs, and CCOs. **The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on re-disclosure.**

- ❖ We recognize the benefits in terms of patient care and cost savings of using electronic health record systems. It is both necessary and technologically possible to integrate addiction and other healthcare and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. **The Illinois Association for Medication Assisted Addiction Treatment strongly urges the continued development of technical solutions for consent management.**

- ❖ Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist. However, **we strongly believe that 42 C.F.R. Part 2 and the specific privacy protections it provides must continue to exist.**

IAMAAT supports the very comprehensive comments submitted by both the Legal Action Center and the American Association for the Treatment of Opioid Dependence.

Thank you for your consideration.

Sincerely,

Kate Mahoney, LCSW
President

Illinois Association for Medication Assisted Addiction Treatment

Marsha Weissman, Ph.D.
EXECUTIVE DIRECTOR

Christine Abaté
DEPUTY DIRECTOR

Josefina Bastidas, Esq.
DEPUTY DIRECTOR

Alan Rosenthal, Esq.
CO-DIRECTOR OF JUSTICE STRATEGIES
AND COUNSEL

Patricia Warth, Esq.
CO-DIRECTOR OF JUSTICE STRATEGIES

Joseph G. Scro
CONTROLLER

BOARD OF DIRECTORS

Bonnie Catone
PRESIDENT

Steven Belenko, Ph.D.

Leonard Berman

Carole Eady

Paula Freedman

Deborah Greebon

Michelle A. Henry

Susan R. Horn, Esq.

Kwame Johnson

Gretchen Purser

Sheila Rule

June 12, 2014

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

Re: SAMHSA Notice of Public Listening Session
Rule Change to 42 CFR Part 2, FR Doc. 2014-10913

Dear SAMHSA:

Please accept these comments submitted on behalf of the Center for
Community Alternatives (CCA).

While we support updating the mechanics of the federal alcohol and
drug confidentiality regulations to facilitate more effective integration of care
and needed communication in the electronic age, 42 C.F.R. Part 2's core privacy
protections must be maintained.

CCA's recommendations to SAMHSA regarding changes to 42 C.F.R. Part 2
are based on the following principles:

- Addiction treatment should be integrated with mental and physical
health care, and communication among health care providers should be
encouraged.
- At the same time, 42 C.F.R. Part 2's heightened privacy protections are
as critical today as they were when they were enacted more than 40 years
ago, and a move toward HIPAA's looser privacy standards would not
sufficiently protect people seeking and receiving substance use disorder
treatment. If patient records can be easily accessed in order to criminally
investigate or prosecute or patient, or deny them insurance or a job, or be
used against them in a divorce or child custody proceeding, many
patients will be afraid to enter treatment in the first place.
- CCA believes that patients in alcohol and drug programs should 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

- 115 East Jefferson Street, Suite 300, Syracuse, NY 13202 T. 315.122.3638 E. 313.171.1921
 - 25 Chapel Street, 7th Floor, Brooklyn, NY 11201 T. 718.838.9638 E. 718.838.9670
 - 100 Pennsylvania Avenue, 2nd Floor, Brooklyn, NY, 11207 T. 929.231.3636 E. 929.231.3613
 - 228 South Plymouth Avenue, Rochester, NY 14608 T. 383.328.8230 E. 383.328.8232
- www.communityalternatives.org | A United Way Agency

health care system, HIEs, health homes, ACOs, and CCOs. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.

- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2.

CCA's Recommendations:

- We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining privacy protections that are as essential today as they were when enacted in the 1970s. People with substance use disorders still face loss of employment, housing, and child custody; insurance and health care discrimination; criminal arrest, prosecution and incarceration; and a host of other negative consequences. 42 C.F.R Part 2's privacy protections greatly minimize the possibilities that a patient's own treatment records could be used against them in all those situations. In order to encourage people with SUDs to seek treatment, 42 C.F.R. Part 2's more stringent privacy protections must be maintained rather than accede to HIPAA standards which would allow many more disclosures that could lead to those harmful consequences for patients.
- We support the goals set out in the request for comments and many of the specific suggestions for tweaking how the regulations currently operate. LAC believes that the current regulations, together with existing plus additional guidance from SAMHSA, can accomplish many (if not all) of the intended goals of integrating substance use disorder and other health care and improving communication between them more effectively. Since HIPAA requires compliance with state and federal laws that mandate greater

privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

- We urge the continued development of technical solutions for consent management.

Very truly yours,

Marsha R. Weissman, Ph.D.
Executive Director



June 30, 2014

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

RE: Confidentiality of Alcohol & Drug Abuse Patient Records Regulations, 42 C.F.R. Part 2. 79 Fed. Reg. 26929; Docket No. 2014-10913.

**FY 2014
Board of Directors**

President

Deborah Megaro, MS, MBA

Vice President

Manuel Guantez, PsyD, LCADC

Treasurer

David Lazarus, Esq

Secretary

Anthony DiFabio, PsyD

At-Large Members

Robert Budsock, LCADC
Robert N. Davison, MA, LPC
Alan DeStefano, MSW
Deborah Hartel, MSW, ACSW
Christopher O. Kosseff, ACSW
Linda Leyhane, CDA
Harry J. Marmorstein, MA, MBA
Harry Postel, MSW, LSW
Paula Sabreen, ACSW, LCSW
Pete Scerbo, MSW, LCSW
Greg Speed, MSW, LCSW
Cheryl Marks Young
Mary Gay Abbott-Young, MEd, LCADC

Past Presidents

J. Michael Armstrong, MA, MBA
James M. Cooney, MSW, LCSW
Daniel Martin, EdD
Joseph Masciandaro, MA
John Monahan, ACSW, LCSW
Robert L. Parker, MPA
Victoria Sidrow, MPA

Chief Executive Officer

Debra L. Wentz, PhD

Associate Executive Director

Shauna L. Moses

**Chief Operating Officer
Director, IT Project**

June A. Noto

To Whom It May Concern:

The New Jersey Association of Mental Health and Addiction Agencies, Inc. (NJAMHAA) is a statewide trade association representing 180 hospital-based and freestanding providers of mental health and substance use treatment services throughout New Jersey. NJAMHAA's mission is to promote the value of its member organizations by providing advocacy, visibility and professional development to facilitate their economic viability, which is essential to ensure their ongoing capacity to deliver quality, cost-effective healthcare and social services and supports to those they serve. NJAMHAA is committed to recovery and wellness for all individuals.

While NJAMHAA supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, 42 C.F.R. Part 2's core privacy protections MUST be maintained.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's June 11, Public Listening Session (79 Fed. Reg. 26929), NJAMHAA supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward the Health Insurance Portability and Accountability Act's (HIPAA's) looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute a patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.



Individuals in alcohol and drug treatment programs should 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 and Accountable Care Organizations. The best way for individuals to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on re-disclosure.

- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, EHRs must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

Debra L. Wentz, PhD
Chief Executive Officer



National Advocates
for Pregnant Women

N A P W

SUBMITTED VIA EMAIL

June 25, 2014

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

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:

National Advocates for Pregnant Women (NAPW) is a nonprofit dedicated to ensuring the human and civil rights and dignity of pregnant and parenting women, particularly those who are most vulnerable, like low-income women, women of color, and drug using women.

While NAPW supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago because, very unfortunately, there has not been a significant reduction in drug-related stigma or discrimination in this country.

We specifically want to bring to your attention punitive and counterproductive child welfare proceedings across the United States in which pregnant women and parents are threatened or charged with civil child abuse and neglect for receiving medication-assisted treatment (MAT). Despite the fact that child welfare proceedings are generally confidential and do not come to public attention, NAPW has identified numerous cases in which state authorities have sought to punish pregnant women because they obtained medically approved methadone treatment.

15 West 36th Street, Suite 901, New York, New York 10018

phone: 212-255-9252 | fax 212-255-9253

 NationalAdvocatesforPregnantWomen |  @NAPW

www.advocatesforpregnantwomen.org

In Tennessee, in the past 10 months, two women contacted NAPW because judges overseeing child welfare cases demanded that mothers “detox from methadone” if they wanted to maintain or regain custody of their children. In both cases, the mothers were receiving therapeutic methadone maintenance treatment as prescribed by their physicians.¹

In Arizona, a mother who had been participating in a methadone maintenance program for nearly six months, and who had been fully compliant with child protective services, contacted NAPW to explain her dilemma:

I am required to partake in substance abuse treatment and CPS ok'd the clinic I go to and simply asked for monthly reports, which I've submitted. They knew I was being medically treated for opioid addiction, however, they must have just realized it was methadone maintenance. Now, just two weeks prior to court, [CPS is] trying to discredit the treatment I'm undergoing and they are saying my drug screens that are positive for methadone are being counted as dirty even though I have a prescription.²

In Ohio, a woman reached out to NAPW because she was charged with civil child abuse and neglect because she received prescribed subutex during the course of her pregnancy. Her story was recently featured on NBC.com in the article, [Pregnant on Opiates: When Following Doctors' Orders Breaks the Law](#).

In New Jersey, the appellate court in *N.J. Div. of Youth & Family Servs. v. Y.N.*, A-5880-11T2, 66 A.3d 237 (App. Div. 2013), upheld a lower court ruling that a newborn was abused and neglected because, after birth, he experienced NAS. The child's mother, while pregnant, obtained federally recommended, medically approved, and supervised methadone treatment from a methadone treatment program. The ruling, if not overturned by the New Jersey Supreme Court, will effectively ban pregnant women from receiving methadone treatment in the state. The mother is currently seeking review by the state supreme court, supported by 48 national and international experts and organizations in an amicus brief.³

NAPW has also identified or been contacted about numerous other cases in Alabama, Florida, Kentucky, Michigan, New York, Pennsylvania, South Carolina, and Texas, where pregnant women and parents have been threatened with loss of custody of their children or have actually lost custody of their children because they have been receiving some form of MAT. These are just a few of the many cases that have come to NAPW's attention that demonstrate the ways in which pregnant women and parents who seek drug

¹ Email from A.F. to NAPW (Aug. 8, 2013) (on file with NAPW); Email from R.N. to NAPW (Sept. 27, 2013) (on file with NAPW).

² Email from V.L. to NAPW (Jan. 15, 2013) (on file with NAPW).

³ Brief of *Amici Curiae* in Support of Defendant-Petitioner's Petition for Certification, *N.J. Div. of Youth & Family Servs. v. Y.N.*, A-5880-11T2, 66 A.3d 237 (App. Div. 2013) (Aug. 1, 2013), available at http://www.advocatesforpregnantwomen.org/main/publications/brief_bank/.

treatment are not provided the full protections that 42 C.F.R. Part 2 requires. And as a result, one of the primary purposes of the regulations—to encourage people to seek treatment for substance addiction—is undermined.

Moreover, in the 2013 study, “[Arrests of and Forced Interventions on Pregnant Women in United States, 1973-2005: Implications for Women's Legal Status and Public Health](#),” Lynn Paltrow and Jeanne Flavin identified more than 400 cases (while acknowledging that this is a substantial undercount) in which a woman’s pregnancy was a necessary factor leading to attempted and actual deprivations of liberty by state authorities. In 276 (about two-thirds) of those 413 cases, they were able to identify the mechanism by which the case came to the attention of police, prosecutors, and courts. And of those 276 cases in which they identified the disclosure of information that led to the arrest or detention, 112 of those disclosures were made by health care providers.

The study confirms that gross violations of these regulations are happening, but unfortunately, the women who suffer as a result of these violations have no private right of action to redress these violations. In fact, far from protecting patient privacy and confidentiality, the study found that health care and other professionals are sometimes the very people gathering information about drug treatment from pregnant women and new mothers and disclosing it to police, prosecutors, and court officials.⁴

Until these types of routine violations cease, NAPW insists that 42 C.F.R. Part 2’s core privacy protections must not only be maintained, but also enforced. With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA’s May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), NAPW supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder records in electronic health record systems and health information exchanges while maintaining 42 C.F.R. Part 2’s core privacy protections.
- 42 C.F.R. Part 2’s heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA’s lesser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute a patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.

⁴ See *Ferguson v. City of Charleston*, 532 U.S. 67 (2001).

- Patients in alcohol and drug programs should 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, health information exchanges, health homes, and accountable care organizations. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- SAMHSA should strengthen protections for people receiving treatment, not lessen them, including revisiting and rescinding the exception for suspected abuse and neglect to child welfare authorities.⁵ It is clear that there is just as much need today, if not more than when the regulations were first enacted, to protect the privacy of people receiving drug treatment.

Thank you for your consideration.

Sincerely,

Lynn M. Paltrow, Executive Director

Kylee Sunderlin, Soros Justice Fellow

⁵ 42 C.F.R. § 2.12 (c) (6) *Reports of suspected child abuse and neglect*. The restrictions on disclosure and use in these regulations do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities. However, the restrictions continue to apply to the original alcohol or drug abuse patient records maintained by the program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.



Center Point, Inc.

CORPORATE OFFICE
135 PAUL DRIVE
SAN RAFAEL, CA 94903
P 415 492 4444 F 415 492 8844
WWW.CPINC.ORG

June 23, 2014

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

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:

Center Point is a health and social services provider with facilities and programs in the states of California, Oklahoma and Texas. Center Point is a not-for-profit corporation providing social and human services to at-risk individuals and families. Center Point mission is “To provide comprehensive social, educational, vocational, medical, psychological, housing, and rehabilitation services to combat social problems such as substance abuse, poverty, unemployment, and homelessness.”

As a national organization and as a member of Therapeutic Communities of America we support updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2’s core privacy protections MUST be maintained.**

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA’s May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), Center Point, Inc. supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. Center Point supports maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2’s core privacy protections.
- 42 C.F.R. Part 2’s heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA’s looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against

them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.

- Center Point, Inc., continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. Center Point's urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

Center Point also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

Sushma D. Taylor, PH.D
President and Chief Executive Officer

**NJATOD****NEW JERSEY ASSOCIATION
FOR THE TREATMENT OF
OPIOID DEPENDENCE**

808 Market Street
Camden, NJ 08102
Phone (856) 225-0505
Mobile (973) 769-5828
Fax (856) 225-0317

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

June 25, 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:

The New Jersey Association For The Treatment of Opioid Dependence (NJATOD) is the provider association which represents all opioid treatment providers in the State of New Jersey. Our mission is to enhance the quality of patient care in treatment programs by promoting the growth and development of comprehensive opioid treatment services through the State of New Jersey.

While NJATOD supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), NJATOD supports the following principles:

- **Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.**
- **42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or**

**NJATOD**

**NEW JERSEY
ASSOCIATION FOR THE
TREATMENT OF
OPIOID DEPENDENCE**

808 Market Street

**Camden, NJ 08102
Phone (856) 225-0505
Mobile (973) 769-5828
Fax (856) 225-0317**

be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.

- LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,
Linda Voorhis,
President



URBAN TREATMENT ASSOCIATES, INC.

**808 Market Street
Camden, NJ 08102
Telephone (856) 225-0505
Fax (856) 225-0317**

June 25, 2014

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

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:

Urban Treatment Associates, Inc. (UTA) is a private, non-profit opioid treatment agency licensed in the State of New Jersey. We provide OTP services to individuals residing in Camden, New Jersey and its environs. Our mission is to provide comprehensive, professional care that recognizes the dignity of all persons struggling against opiate dependence.

We believe that successful change is achieved through the use of medical, behavioral, pharmacological, and socially-focused treatment in an integrated setting. We further believe that abstinence from illicit substance use is the safest choice, but acknowledge that even the person not ready to stop using can be significantly helped.

While UTA supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), UTA supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record

(EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.

- TM42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- TMLAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- TMIt is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- TMSince HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV /AIDS, reproductive health domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIP AA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

Linda Voorhis, Executive Director / Program Administrator



**Middletown Medical, LLC.
600 Route 35
Red Bank, NJ 07701
Telephone (732) 706-1300
Fax (732) 706-1313**

June 25, 2014

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

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:

Middletown Medical, LLC is a private opioid treatment agency licensed in the State of New Jersey. We provide OTP services to individuals residing in Monmouth, Middlesex and Ocean counties of New Jersey. Our mission is to provide comprehensive, professional care that recognizes the dignity of all persons struggling against opiate dependence.

We believe that successful change is achieved through the use of medical, behavioral, pharmacological, and motivational treatment in an integrated setting. We further believe that abstinence from illicit substance use is the safest choice, but acknowledge that even the person not ready to stop using can be significantly helped.

While we support updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), Middletown Medical, LLC supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.

- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- The Legal Action Center continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

Erin McCabe, LCSW, LCADC
Executive Director

Morris County After Care Center

1574 Sussex Turnpike • Randolph, New Jersey 07869 • Tel. #(973) 927-6641 • Fax #(973) 927-6644

June 25, 2014

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

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:

Resource Center for the Chemically Dependent, Inc., DBA Morris County After Care Center, Inc., located at 1574 Sussex Turnpike, Randolph, NJ 07869, is a 30-year old, private, non-profit outpatient opioid treatment agency licensed in the State of New Jersey. Medical doctors, including a psychiatrist, nurses, and licensed clinicians, provide comprehensive treatment services to all persons who are struggling with opiate dependence. Primary health care and co-occurring services, are also provided on site. The agency serves clients from North Jersey, Pennsylvania, and New York in compliance with the rules and regulations of the New Jersey Division of Mental Health and Addiction Services.

We believe that successful change is achieved through the use of medical, behavioral, pharmacological, and socially-focused treatment in an integrated setting. We further believe that abstinence from illicit substance use is the safest choice, but acknowledge that even the person not ready to stop using can be significantly helped.

While UTA supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), UTA supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.

- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute a patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on re-disclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively share addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center.

Thank you for your kind consideration.

Sincerely,

Lorna R. Tangara, MPH
Executive Director



Kansas Association of Addiction Professionals

Kansas Association of Addiction Professionals

**700 SW Jackson, Suite 1101
Topeka, KS 66603
785-235-2400**

June 23, 2014

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

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:

My name is Dulcinea Rakestraw, and I am the Chair of the Kansas Association of Addiction Professionals (KAAP). KAAP is the only trade organization representing substance use disorder treatment and prevention professionals across the state of Kansas.

While KAAP supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, 42 C.F.R. Part 2's core privacy protections MUST be maintained.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), PFH supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. [I/We] support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections:
- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain

Since 1974

KAAP



Kansas Association of Addiction Professionals

**700 SW Jackson, Suite 1101
Topeka, KS 66603
785-235-2400**

Kansas Association of Addiction Professionals

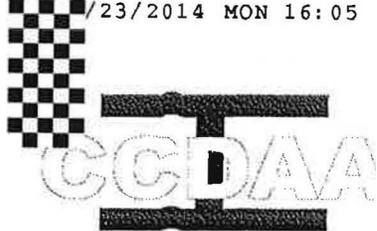
that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.

- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. [I/We] urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Dulcinea Rakestraw
Chair



Inter County Council on Drug and Alcohol Abuse, Inc.

Outpatient Counseling
480 Kearny Avenue
Kearny, NJ 07032
(201) 998-7422
Fax (201) 998-1136

Medication Assisted Therapy
482 Kearny Avenue
Kearny, NJ 07032
(201) 997-4000
Fax (201) 998-1136

Amy Amadeo, MA, LCADC
Director

OFFICERS

Courtney McShane
President

Catherine Santangelo
Treasurer

Jordan Savage
Secretary

BOARD OF DIRECTORS

Paul Aiello
Andrew J. Burch
Earl Crowell
Jack Elsmore
Steve Way
Konstantino Zicopoulos

LEGAL ACTION CENTER TEMPLATE FOR SAMHSA COMMENTS

[SUBMITTED VIA FACSIMILE]

6/23/14

Inter-County Council on Drug and Alcohol Abuse
480-482 Kearny Ave. Y
Kearny, NJ 07032

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

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:

While I support updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, 42 C.F.R. Part 2's core privacy protections MUST be maintained.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), I support the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.

- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward



HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.

- LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on re-disclosure.

- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. [I/We] urge the continued development of technical solutions for consent management.

- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

I also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,
Amy Amadeo, MA, LCADC

ICCDAA Executive Director



Preferred Family Healthcare

830 S. Hillside, Wichita, KS 67211
Phone 316-613-2222 Fax 316-613-2220

June 23, 2014

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

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:

My name is Dulcinea Rakestraw, and I am the Vice President of Treatment Services for Preferred Family Healthcare, Inc (PFH). We are a behavioral healthcare agency that serves around 10,000 consumers annually.

While PFH supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, 42 C.F.R. Part 2's core privacy protections MUST be maintained.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), PFH supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. [I/We] support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.

"Supporting Healthy Lifestyles"

- LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. [I/We] urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely, E
Dulcinea Rakestraw E
Vice President, Treatment Services E



ECD PROGRAM
808 Downtowner Loop West
Mobile, AL. 36609
Phone: (251) 341-9504
Fax: (251) 341-9509

<u>SEND TO:</u> SAMHSA	<u>FROM:</u> ECD Program Inc.
<u>ATTN:</u>	<u>DATE:</u> 6/26/14
<u>RECIPIENTS FAX:</u>	<u>TOTAL PAGES:</u>

Comments:

Confidentiality Notice
This information has been disclosed to you from records protected by Federal Confidentiality Statute (42 CFR Part 2). The federal rules prohibit you from making any further disclosures unless 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 this information to criminally investigate or prosecute any alcohol or drug abuse patient.

June 25, 2014

ECD Program, Inc
808 Downtowner Loop W
Mobile, Al 36609

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

**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:

ECD Program, Inc. is an opiate replacement treatment facility with 230 clients.

While ECD Program, Inc. supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

Although 42 CFR, Part 2 seems very intense and sometimes awkward and complicated, it has been helpful in keeping very important records out of the wrong hands. This organization has had estranged friends and family attempt to obtain records to use against client's and fortunately 42 CFR, Part 2 was in place and the friends and family were not able to obtain ammunition against a client. In this setting, often arguments occur amongst clients or custody battles occur. These are the most common incidents when documents are attempted to be obtained with a subpoena or invalid release.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), ECD Program, Inc. supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. Urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

Susan Case, LPC
Executive Director
ECD Program, Inc.



June 24, 2014

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

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

To Whom It May Concern:

North Charles institute for the Addictions, an Opioid Treatment Program under North Charles Mental Health, Research and Training Foundation, Inc. has been providing opioid treatment services to individual in the greater Cambridge/Somerville and Boston area for over forty years. While North Charles, Inc. supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

We have had extensive experience with the burden that stigma and discrimination place on our patients every day seeking emergency and general medical care services, obtaining and maintaining employment, accessing housing, child custody, and safety and protection during the criminal arrest and prosecution to name a few. Despite the scientific evidence demonstrating the effectiveness of methadone treatment, addicted patients remain misunderstood. We have patients who are denied housing, have lost child custody battles and visitation rights. Many have been denied timely emergency care, adequate pain management for chronic debilitating illness, liver transplantation, and jobs and promotions for which they are well qualified because of their addictive disorders. We had attorneys request details of a patient's history and current treatment that unnecessarily expose them to sanctions by the courts. 42 CFR Part Two allowed for providing information that is deemed necessary without compromising patient privacy and stability. Many are on the judgment that the protections afforded to patients under HIPAA are sufficient. That is no the case. HIPAA protections are not equally strong. We believe that there will be tragic consequences if 42 CFR Part Two is not reserved and patients will be deterred from entering addictions treatment or destabilized in treatment that helps them maintain a sober lifestyle.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929, North Charles supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny their insurance or a job, or be used against them in a divorce or child custody proceeding, or any patients will be afraid to enter treatment in the first place.
- North Charles continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We have reviewed and support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

Janice F. Kauffman R.N., M.P.H., C.A.S., L.A.D.C.1

Vice President, Addition Treatment Services

North Charles Mental Health research and Training Foundation, Inc. (aka North Charles, Inc.)

Assistant Professor of Psychiatry

Harvard Medical School



June 25, 2014

Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road
Room 5-101
Rockville, MD 20857

Re: Docket # 2014-10913

Dear SAMHSA:

I am writing on behalf of the patients of our non-profit addiction prevention and treatment organization. Located in the Chicago metro area, PEER Services is dedicated to strengthening individuals, families and local communities by delivering high quality addiction prevention and treatment services. We have followed with interest, and to be honest a great deal of trepidation, the recent discussions on potentially reducing the privacy provisions contained in 42 CFR Part 2. We strongly urge you to maintain all current privacy protections contained in this key federal law which is a cornerstone in the delivery of substance abuse treatment to individuals who are struggling with substance use disorders.

At SAMHSA you are well aware of the many ways in which individuals whose lives are impacted by addiction have experienced discrimination in a wide range of arenas including employment, healthcare, insurance, the child welfare system, the criminal justice system and housing. The Legal Action Center has tracked many of these cases over recent decades.

Many individuals fear that their privacy will be breached if they seek addiction treatment. This impacts not only that individual, but also their family and extended community. Our agency has been providing community-based substance abuse treatment services for nearly forty years. Protecting the privacy of our patients has been a top priority of ours since our inception. Please do not take any action that will dilute that protection. We are in the midst of a heroin and other opioid epidemic not only in Illinois but across the country. As advocates strive to increase access to treatment, changes to the privacy laws could completely undermine the treatment community's efforts to make treatment accessible to those most in need. Patients need to feel safe entering treatment. Loosening or removing privacy protections could prove disastrous!

While we are excited about the many benefits of implementing electronic health records systems in healthcare settings throughout our country, it is essential that these systems be designed to maintain the granularity of specific data such as addiction treatment information, HIV status and other private health information that individuals may fear will be broadly disseminated without adequate consideration of the potential consequences to the individual to whom the private information belongs. As part of the discussion of 42 CFR Part 2, some individuals have suggested that the protections it provides are also included under HIPAA. The protections are NOT equal. HIPAA allows for the re-disclosure of private information without patient consent. This very distinction is perhaps the most compelling reason to keep 42 CFR Part 2 intact. We are very concerned about the unintended consequences of such re-disclosure on the lives of current patients and as a factor that may discourage new patients from entering treatment.

Please exercise great caution in responding to pressures to erode the privacy protections which have been at the cornerstone of the publically funded addiction treatment system for the past 40 years.

Sincerely,

Gretchen Iglor, LCSW
Program Coordinator



236 Massachusetts Ave. NE STE 505
Washington, DC 20002
202.546.4600

Becky D. Vaughn
Chief Executive Officer

**COMMENTS OF THE STATE ASSOCIATIONS OF ADDICTION SERVICES (SAAS)
IN RESPONSE TO
U.S. DEPT. OF HEALTH & HUMAN SERVICES,
SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMINISTRATION,
NOTICE OF PUBLIC LISTENING SESSION,
79 FED. REG. 26929 (MAY 12, 2014)
DOCKET NO. FR DOC. 2014-10913
(SUBMITTED JUNE 25, 2014)**

I. Introduction to SAAS Comments

SAAS was founded in 1987 as a 501(c)(3) nonprofit organization with a mission of *ensuring quality addiction services nationwide*. The membership consists of state associations of addiction prevention, treatment, and recovery support providers. These associations represent programs of all sizes and treatment and prevention approaches. SAAS is the only national organization of state alcohol and drug addiction treatment and prevention provider associations. Through our member associations, SAAS has a direct link to thousands of programs that are the core of the publicly-supported addiction services system. SAAS serves as an information broker and advocate, linking state associations with national developments such as evidence-based practices and providing input to federal organizations on the needs of community-based services providers and their clients. We support providers with training and technical assistance.

SAAS service provider members believe that behavioral health care should be integrated with physical health care, and that communication between health care providers should be encouraged. At the same time, SAAS believes that 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and that a move toward the looser privacy standards of the Health Insurance Portability and Accountability Act (HIPAA) would not sufficiently protect people seeking and receiving substance use disorder (SUD) treatment. SAAS providers, through first-hand experience recognize that patients seeking and receiving SUD treatment should retain the right to control how their records are disclosed, even for health and payment purposes, given the continued prevalence of prejudice and discrimination in our society. SAAS believes that it is both necessary and technologically possible to integrate SUD and other health care and to effectively exchange SUD treatment data while maintaining the core protections of 42 C.F.R. Part 2.

As you consider these and other comments from stakeholders, we urge you to give the greatest weight to the comments made by patients and consumers, as it is their rights and access to their sensitive health information that will be affected by any changes to 42 C.F.R. Part 2.

SAAS partners with the Legal Action Center (LAC) on many policy issues--particularly SUD confidentiality. SAAS recognizes them as the experts in the field and appreciates and credits LAC for their help and support in putting these comments together. Please find our recommendations concerning the critical issues SAMHSA poses as follows:

- SAAS supports maximizing inclusion of SUD records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining privacy protections that are as essential today as they were when enacted in the 1970s. People with SUDs still face loss of employment, housing, and child custody; insurance and health care discrimination; criminal arrest, prosecution and incarceration; and a host of other negative consequences. 42 C.F.R Part 2's privacy protections greatly minimize the possibility that a patient's own treatment records could be used against them in all those situations. In order to encourage people with SUDs to seek treatment, 42 C.F.R. Part 2's more stringent privacy protections must be maintained rather than accede to HIPAA standards, which many have criticized for their insufficient protection of patient privacy, and which would allow many more disclosures that would lead to those harmful consequences for patients.
- SAAS supports the goals set out in the request for comments and many of the specific suggestions for adjusting how the regulations currently operate. SAAS believes that the current regulations, together with existing plus additional guidance from SAMHSA, can accomplish many (if not all) of the intended goals of integrating substance use disorder and other health care and improving communication between them more effectively.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, EHRs must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. In addition, EHRs must also be designed to comply with the HITECH Act, which provides that individuals have a right to restrict the disclosure of health information in electronic or any other form when they pay out of pocket for services provided.¹ It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA and HITECH-compliant even if 42 C.F.R. Part 2 did not exist.

II. Why the HIPAA Standard is Insufficient to Protect Patient Privacy

Before we answer the specific questions posed by SAMHSA in its May 12, 2014 Notice of Public Listening Session ("Notice"), we would like to address the suggestion by some stakeholders that a potential solution to the challenges posed by 42 C.F.R. Part 2 (hereinafter referred to as "Part 2") to initiatives such as new models of integrated care and electronic health information exchange is to do away with Part 2's heightened privacy protections in favor of a HIPAA standard.

¹ 45 C.F.R. § 164.522(a)(1)(vi).

Acceding to a HIPAA standard for SUD patient information would eviscerate the core protections of Part 2 – in particular the requirements for patient consent, the prohibition on redisclosure, and the heightened standards for disclosure to law enforcement and judicial and administrative bodies – and would likely lead to dire consequences for Part 2 patients and their families. While Part 2 requires patient consent for most disclosures, thus allowing patients to control the flow of information that holds the potential to do them great harm in the wrong hands, HIPAA does not require consent for disclosures made for the purposes of treatment, payment, and health care operations (TPO). HIPAA’s definition of TPO is so broad as to allow virtually unfettered access to patient’s health information by those in the health care system; such an exception would be a death knell for Part 2’s patient consent requirement and prohibition on redisclosure. Furthermore, where Part 2 requires a special court order for disclosures to law enforcement and to judicial or administrative bodies (such as divorce and child custody proceedings)² with heightened review standards, HIPAA permits such disclosures in whatever manner is required by state law, meaning as soon as a health care provider receives a subpoena, judicial or administrative order, or even a discovery request. Given the disastrous consequences patients often face when their SUD histories are disclosed to law enforcement or judicial or administrative bodies, adopting this standard for SUD patient records would do great harm to patients and their families.

While allowing all SUD patient information to flow to all parts of the health care system without restriction may seem benign or even desirable at first blush, we believe it is likely that such a change would backfire, resulting in disclosures that damage the lives of patients and their families more often than improve their care. Allowing virtually unfettered disclosure of SUD patient records without consent to the full range of individuals and organizations involved in health care (including payment and operations) and law enforcement, and allowing those entities to redisclose those records without restriction, as HIPAA does, would result in many people not obtaining the care they need for fear of being arrested and prosecuted, losing custody of their children, and suffering employment, insurance and other discrimination.

In its 40 years serving SUD treatment providers and SUD patients, SAAS has seen these consequences first-hand time and again. Although we hope to see the day when prejudice and discrimination are no longer the reality for people with SUDs, that day has unfortunately not yet arrived. In just the past several months SAAS has received numerous requests for assistance from people facing SUD-based prejudice and discrimination. For example, we have heard from:

- a young father in recovery who was being denied visitation with his children because he was in methadone treatment, despite the fact that he was not using any illegal substances;
- a mother in recovery who had her 2-month-old infant removed from her custody after the hospital where she gave birth reported her for having legally prescribed methadone in her system;
- a young mother who was being threatened with eviction from a shelter because she was taking prescribed methadone for her opioid addiction (another young mother had already

² For example, under 42 C.F.R. Part 2, a court ordinarily may not even order disclosure of treatment records for the purpose of prosecuting a patient. *See* 42 C.F.R. §§ 2.61-2.65.

been evicted from the same facility for the same reason, and had become homeless; neither woman was using illegal substances); and

- a young man whose employer refused to allow him to return to work after he successfully completed treatment for alcoholism, saying that he was a safety threat even though his physician had cleared him to return to work with no restrictions.

In addition, since January 1, 2012, SAAS has received 93 requests for assistance from SUD treatment programs whose patient records were being sought by law enforcement or a court without obtaining appropriate court orders as required by Part 2. This represents requests from only the 10 states to which we provide hotline assistance.

SAAS is not alone in recognizing the importance of patient privacy protections. When the U.S. Department of Health and Human Services (HHS) issued the HIPAA Privacy Rule in 2000, it stated, “While privacy is one of the key values on which our society is built, it is more than an end in itself. It is also necessary for the effective delivery of health care, both to individuals and to populations.”³ HHS also said that, “Unless public fears are allayed, we will be unable to obtain the full benefits of electronic technologies.”⁴

Yet the issuance of the HIPAA Privacy Rule has done little to allay fears of sharing health information through electronic health systems, and in fact those concerns are growing. A 2010 study in the *Journal of the American Medical Informatics Association*⁵ found that of the outpatient mental health clinicians surveyed:

- 83% disagreed with including their own psychiatric records among routinely accessed EHR systems;
- 80% said that if they were a patient, they would not want health care providers to have the ability to routinely access their mental health records; and
- 63% said they are less willing to record highly confidential information in EHRs compared with paper records.

According to a report issued by the American National Standards Institute in 2012, an online poll of 2,000 adults revealed that 97% of the public believe that health care providers and insurers should not be able to share their health information without their consent.⁶ A 2013 study found that that about two-thirds of U.S. adults were concerned about a breach in the security of their protected health information (PHI) during transfer between health care professionals by fax or electronically, and concerns over the safety of PHI was associated with higher likelihood of withholding medical information from a health care professional.⁷

³ 65 Fed. Reg. 82462, 82467 (Dec. 28, 2000).

⁴ 65 Fed. Reg. 82462, 82466 (Dec. 28, 2000).

⁵ See Ronald M. Salomon et al., “Openness of patients' reporting with use of electronic records: psychiatric clinicians' views,” *J. of Am. Med. Informatics Ass'n* (2010);17:54-60, doi:10.1197/jamia.M3341, available at <http://jamia.bmj.com/content/17/1/54.full>.

⁶ Am. Nat'l Standards Inst. et al., *The Financial Impact of Breached Protected Health Information* (Mar. 2012), p. 23.

⁷ I. Agaku, et al., *Concern About Security and Privacy, and Perceived Control Over Collection and Use of Health Information Are Related to Withholding Health Information from Healthcare Providers*, *J. of Am. Med. Informatics Ass'n* (Aug. 2013).

The fears that these professionals and adults have regarding electronic health information privacy breaches are unfortunately well founded. According to HHS, more than 1,000 medical record breaches involving 500 or more people have been reported to HHS since federal reporting requirements took effect nearly five years ago.⁸ In total, large health data breaches reported by health care providers and their business associates have affected the medical records of about one in ten U.S. residents, or 31.7 million people.⁹

The very real risks to and breaches of individuals' privacy resulting from adoption of the HIPAA standard and the development of interoperable EHR systems have led many to call for the adoption of broader protections for *all* health information, giving it protections like those afforded by Part 2. The reports and recommendations issued by the National Committee on Vital Health Statistics in its consensus-driven *Recommendations on Privacy and Confidentiality, 2006-2008* advocate for this type of change, as do numerous other stakeholders.¹⁰

HHS seemed to recognize the risks that could come when health care payers are given access to health information when, in the final rule implementing the HITECH Act (which amended HIPAA in 2009), it provided that individuals have the right to restrict the disclosure of health information in electronic or any other form when they pay out of pocket for services provided. This right should not be limited to people who have the financial means to pay for health care out of pocket, but should be afforded to all individual, regardless of the means of payment.

Below are the SAAS comments on the specific questions posed by SAMHSA in its May 12, 2014 Notice.

III. SAAS Comments

a. Applicability of 42 C.F.R. Part 2

SAAS agrees with SAMHSA that the current definition of which providers fall under Part 2 has been the source of some confusion. It makes no sense for the application of Part 2 to depend on whether entities “hold themselves out” as providing substance abuse services, rather than on what substance abuse treatment services they are providing. Thus we welcome a new definition of the applicability of Part 2 that clarifies which providers and what information is covered by Part 2. Such clarification would help HIEs, HIT vendors, etc. to understand what information is covered by Part 2 and requires heightened protection.

⁸ Joseph Conn, “Major medical records breaches pass 1,000 milestone as enforcement ramps up,” *Modern Healthcare* (June 13, 2014), available at <http://www.modernhealthcare.com/article/20140613/BLOG/306139996/major-medical-records-breaches-pass-1000-milestone-as-enforcement#src=serp>.

⁹ “One in 10 U.S. Residents Affected by Large Health Data Breaches,” *iHealthBeat* (June 16, 2014), available at <http://www.ihealthbeat.org/articles/2014/6/16/one-in-10-us-residents-affected-by-large-health-data-breaches>.

¹⁰ U.S. Dep’t of Health & Human Svcs, Nat’l Comm. on Vital & Health Statistics, *Privacy Report: Recommendations on Privacy & Confidentiality, 2006-2008* (May 2009), available at <http://www.ncvhs.hhs.gov/privacyreport0608.pdf>.

The definition suggested by SAMHSA, that Part 2 would apply to any federally assisted health care provider that provides a patient with “specialty substance abuse treatment services,” removes the “holds itself out” language and is a step in the right direction. However, this proposed definition raises new questions. What is the difference between a “specialty substance abuse treatment service” and a “non-specialty substance abuse treatment service”? Is the provision of buprenorphine a “specialty substance abuse service”? It would certainly seem so, and in fact we cannot see how the provision of buprenorphine could be considered otherwise. If that is the case, then would all physicians who prescribe buprenorphine be covered by Part 2?

The definition suggested by SAMHSA also states that “providers would not be covered [by Part 2] if they provided only substance abuse screening, brief intervention, or other similar pre-treatment substance abuse services.” This makes clear that providers who only provide SBIRT services “would not be covered by Part 2.” However, in order to for this provision not to run afoul of Part 2’s authorizing statute, which explicitly extends confidentiality protections to SUD prevention,¹¹ “screening, brief intervention, or other similar pre-treatment substance abuse services” would have to be differentiated from other types of prevention services. We think an attempt at such differentiation would be difficult to impossible, and would create a large amount of confusion. It is important to maintain the statute’s protection of SUD prevention records, as prevention programs around the country depend on these protections to reassure their program participants that information shared will be held in confidence.

b. Consent Requirements

Before we address SAMHSA’s specific suggestion for possible changes to Part 2’s consent requirement, we note that we are very gratified that SAMHSA continues to support and appreciate the importance of obtaining patient consent for the release of patient information. Based on our nearly 40 years of experience advising SUD programs and their patients, SAAS continues to believe that patients in SUD programs should retain the power to decide when and to whom their records are disclosed, including disclosures to the general health care system, HIEs, health homes, ACOs, and CCOs, and that the best way for patients to retain that power, and to ensure that care is, in fact, patient centered, is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.

Like SAMHSA, we also believe that there are ways to resolve some concerns that have been raised about Part 2’s consent requirements in order to facilitate “the flow of information within the health care context while ensuring the patient is fully informed and the necessary protections are in pSAASe.” In addition, we agree with SAMHSA’s assessment that “technical solutions for managing consent collection are possible” – in fact, such solutions are already under development. As such, we urge the continued development of technical solutions for consent management as well as the development of organizational policies and procedures that provide patients with meaningful consent options.

¹¹ See 42 U.S.C. § 290dd-2(a) (“Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity related 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 shall, except as provided in subsection (e) of this section, be confidential....” (emphasis added)).

Comments on First and Second Suggested Consent Changes:

SAMHSA's first suggested change is, "Allow the consent to include a more general description of the individual, organization, or health care entity to which disclosure is to be made." Its second suggested change is, "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."

With respect to the first suggested change, we believe that there is a simple way to address concerns raised by some stakeholders that Part 2's current "to whom" provision is too narrow. Part 2 currently requires that a consent form must list the "name or title of the individual or the name of the organization to which disclosure is to be made."¹² We believe that "title of the individual" to whom disclosure is to be made could be interpreted as allowing "treating provider" to be listed as the title of the individual to whom disclosure is to be made.

In addition, patients could consent to the disclosure of their alcohol and drug information to their *future* treating providers, in addition to their current treating providers. With respect to the second suggested change, in order for consent to disclosure to future providers (such as providers that join an HIE or ACO after the date consent is signed) to be informed and meaningful, we suggest that a consent that permits disclosure to future providers should be accompanied by:

- a limitation on disclosures only to future providers to with a treating relationship with the patient;
- effective notification of the patient when any new provider is added to an entity to which they have provided such consent;
- an easy opt-out mechanism that is always available but is also reiterated each time patients are notified that a provider has been added.

We believe implementation of this interpretation of the "to whom" requirement could be accomplished by a change to the regulations or by sub-regulatory guidance.

We believe our recommendation permitting patients to consent to the disclosure of their alcohol and drug information to their treating providers, including future treating providers, appropriately balances the concerns of HIEs, ACOs, and other health care entities with the need to provide patients with meaningful consent options. Permitting disclosure to treating providers and future treating providers maintains the core protections of 42 C.F.R. Part 2 – the prohibition on disclosing, and redisclosing, patients' SUD records without their consent – while at the same time making it easier for patients who choose to consent to such disclosures to participate in integrated care models and HIT, including HIEs. Such an interpretation is consistent with both Part 2 and statutory language.

A potential additional benefit of this change is that fewer health care providers will need to access patient information by "breaking the glass" (accessing a patient's SUD information without consent in a medical emergency, as permitted by Part 2), since most providers treating a

¹² 42 C.F.R. § 2.31.

patient in a medical emergency will be covered by a treating provider (including future treating providers) consent. Currently, when Part 2-protected records are accessed without consent in a medical emergency, they lose the protections of Part 2. An expanded consent interpretation that allows providers to access SUD records in a medical emergency by consent, rather than by “breaking the glass,” will ensure that more alcohol/drug records remain protected by Part 2.

To the extent that SAMHSA is considering allowing an HIE or ACO together with all of its affiliated/member providers to be listed as an “organization” in the consent form’s “to whom” field, we strongly urge against such a change. Allowing an HIE, ACO, or other new health care model to call itself an “organization” would have broad implications, namely the proliferation of disclosures of SUD records without meaningful patient consent. Depending on the size of the HIE or ACO, potentially vast networks of health care providers (and other personnel) would have access to patients’ alcohol and drug records after the patient signs a single consent form. In the ACO context, member providers and personnel would be free to redisclose the SUD records amongst themselves without patient consent; in the HIE context, any provider affiliated with the HIE would be able to redisclose SUD records with any other affiliated provider without patient consent. This is particularly worrisome given widespread SAASk of knowledge of Part 2’s protections – and the reasons for those protections – among non-Part 2 providers, and the risks associated with freely flowing electronic health information, including breaches.

Another possible consequence of defining or reinterpreting the meaning of “organization” in the context of Part 2 consent is that the expanded meaning of “organization” may apply elsewhere in the regulations, such as in reference to Qualified Service Organizations (QSOs). If, for example, an HIE along with all of its affiliated providers could be considered a QSO, then patients’ SUD records could be disclosed without consent by a Part 2-covered program to the HIE as well as all of its affiliated providers, as long as a QSO Agreement (QSOA) was in pSAASE. Because Part 2 contains no requirement that patients be notified of a Part 2 program’s QSOAs, patients would not even be aware that these consent-less disclosures were occurring. The implications of this type of re-interpretation of QSOs and QSOAs would be a virtual gutting of Part 2’s consent-based patient protections.

Comments on Third and Fourth Suggested Consent Changes:

With regard to SAMHSA’s proposals regarding changes to the “by whom” consent requirements, we are not familiar with a current challenge that such a change would address, and would have concerns that such changes may only serve to make the consent process more onerous. We believe that the current language regarding the description of the programs or people permitted to make disclosures is sufficiently clear.

Comments on Fifth Suggested Consent Change:

We are unclear about what is meant by “explicitly describe the substance abuse treatment information that may be disclosed,” and what concern this suggestion is meant to address. The current regulations require written patient consent to describe the amount and type of information to be disclosed, and the purpose of the disclosure.¹³ In addition, current regulations

¹³ 42 C.F.R. § 2.31.

require that “any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.”¹⁴ We believe the current regulations provide sufficient specificity with regard to what information will be disclosed and for what purpose.

c. Redisdisclosure

SAMHSA is considering revising the redisdisclosure provision (42 C.F.R. § 2.32) “to clarify that the prohibition on redisdisclosure only applies to information that would identify an individual as a substance abuser, and allows other health-related information shared by the Part 2 program to be redisdisclosed, if legally permissible.” SAMHSA gives as the reason for such a revision that “most EHRs do not support data segmentation,” and that such a revision will “allow HIT systems to more easily identify information that is subject to the prohibition on redisdisclosure enabling them to utilize other technological approaches to manage redisdisclosure.” We support further clarification that Part 2’s Prohibition on Redisdisclosure does not apply to information that does not identify an individual as having an SUD or being in SUD treatment, including how that relates to and can facilitate communications between substance use treatment providers and HIT systems.

The possible revision SAMHSA is suggesting would restate exactly what the current regulations allow. The current prohibition on redisdisclosure states that information cannot be redisdisclosed unless it is permitted by written consent “*or as otherwise permitted by 42 CFR Part 2* [emphasis added].”¹⁵ Part 2’s restrictions on disclosure only apply to information that “would identify a patient as an alcohol or drug abuser...”¹⁶ Thus, currently under Part 2, information that does not identify a patient as a “substance abuser” is not protected and can be redisdisclosed. Therefore, no revision to Part 2’s redisdisclosure provision is necessary. SAMHSA can clarify any confusion about the applicability of Part 2’s redisdisclosure provision through the issuance of sub-regulatory guidance.

Moreover, adoption of SAMHSA’s proposed revision would not ease the technological challenge of data implementation. Data segmentation would still be necessary to ensure proper implementation and adherence to the prohibition against redisdisclosing information that would identify an individual as a substance abuser. Thus we do not see any reason why Part 2’s prohibition on redisdisclosure should be revised.

d. Medical Emergency

We do not see the need to change Part 2’s definition of medical emergency, and worry that broadening that definition to encompass situations that are not emergencies would create an impermissible end-run around Part 2’s requirement to obtain consent from the patient. At the same time, we strongly support further guidance making clear that health care providers can

¹⁴ 42 C.F.R. § 2.13(a).

¹⁵ 42 C.F.R. §2.32.

¹⁶ 42 C.F.R. §2.12(a)(i)

“break the glass” and disclose information in situations where a patient is not able to give consent and information in a patient’s medical records is needed to treat a medical emergency, including medications s/he is taking that could dangerously cross-react with a medication that might be prescribed to treat the emergency.

SAAS does not believe there should be a changes to Part 2’s current medical emergency exception that states that information may be disclosed without consent “for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention,” and opposes any revision that would allow providers to use the medical emergency provision to prevent emergencies.

As SAMHSA noted, the statute only allows disclosure, without a patient’s written consent, “to medical personnel to the extent necessary to meet a bona fide medical emergency.”¹⁷ A speculative concern that an emergency might happen in the future does not and should constitute a bona fide medical emergency that allows for an unconsented-to disclosure. Invoking the medical emergency exception and accessing a patient’s protected SUD records without consent should be allowable only when: (1) there is an actual emergency in which a patient’s prior consent cannot be obtained by the provider treating the emergency – because the individual is actually unconscious or incapacitated/unable to give consent; and (2) there is need for immediate action requiring immediate access to the person’s records.

The current rule already gives providers the discretion they need to interpret it appropriately in fact-specific situations. We do not believe that there should be any attempt to try to write into regulatory language specific scenarios (such as the example SAMHSA offers of changing the existing standard in order to “prevent emergencies or to share information when a patient is unable to provide informed consent due to their level of intoxication”), because attempting to anticipate and spell out all of the potential scenarios that *might* conceivably arise would be an exercise in futility, and would rob those faced with such a list of the crucially important discretion the current standard must continue to afford them.

e. Qualified Service Organization (QSO)

In its May 12 Notice, SAMHSA states that it has “heard concerns from payers and health management organizations related to disclosing information that is subject to 42 C.F.R. Part 2 to health care entities (ACOs/CCOs) for the purpose of care coordination and population health management; helping them to identify patients with chronic conditions in need of more intensive outreach” (emphasis added). SAMHSA proposes expanding the definition of a QSO to allow for Qualified Service Organization Agreements (QSOAs) for the purposes of care coordination and population health management.

SAMHSA has always taken the position that a QSOA is a two-way agreement between two parties – one a Part 2 program and the other a Qualified Service Organization (QSO) that is providing a service to that Part 2 program. We strongly support that position and urge SAMHSA not to open up the QSOA exception so as to allow Part 2 information to flow between multiple entities. To do so would be a complete evisceration of Part 2’s consent requirements.

¹⁷ 42 U.S.C. § 290dd-2 (b)(2)(A)

To the extent that, for the purpose of care coordination and population health management, there might be one entity that is gathering data from different data sources, a QSOA would be an acceptable tool for a Part 2 program to disclose protected information to that information gathering entity. If, however, Part 2 information would need to flow to all entities involved in care coordination and population health management, then a QSOA should not be allowed for such a purpose, and SAMHSA should remain staunch in its position that patient consent would be needed. Indeed it is quite simple for a consent to be drafted that allows communication among multiple parties.

Should SAMHSA also be proposing that a QSOA can be used for payment purposes, Part 2 currently requires that a consent be used for such a purpose, and we strongly agree that consent should remain the only option for disclosing information for payment purposes. This interpretation is the only one that is consistent with Part 2's authorizing statute.

Finally, we are not sure if, when SAMHSA proposed that "One potential solution includes ... to allow a ... QSOA to be executed between an entity that stores Part 2 information, such as a payer or an ACO that is not itself a Part 2 program, and a service provider," SAMHSA meant the term "service provider" to refer to a program covered by Part 2, or to another type of entity. We strongly believe that a QSOA should remain an agreement only between a Part 2 program and an entity that provides a service to that program.

In sum, to the extent that SAMHSA may be suggesting any significant broadening of the rules surrounding QSOAs, we believe this would not only run afoul of Part 2's authorizing statute, but it would also create an end-run around Part 2's core protections – namely the requirement that patient consent be obtained before making a disclosure of SUD information, and the prohibition on redisclosure. Allowing QSOs to disclose Part 2 information to one another would eviscerate Part 2's consent and redisclosure protections and damage patient trust.

f. Research

If SAMHSA is suggesting that third party payers, HIEs, etc., should be able to disclose Part 2 information already in their possession to researchers, we support the underlying rationale for this suggested change, i.e., that researchers should have the ability to get access to information for research purposes. However, we are concerned that the protections contained in Part 2's research exception (found at 42 C.F.R. §2.52) will not be enforceable if entities other than Part 2 treatment providers have the authority to release Part 2 information in their possession to researchers. How will HIEs, third party payers, etc., be able to determine that a researcher will maintain the Part 2 information in accordance with the security requirements set out in §2.52(a)(2)? How will they be able to assess whether the potential benefits of the research outweighs any risks to confidentiality as required by §2.52(a)(3)? Who at these organizations will be the equivalent of a "program director" and have the authority to make these decisions? Will they know enough about §2.52 to inform the researchers about the limitation about how the Part 2 information can be redisclosed under §2.52(b)?

In sum, we would support qualified researchers gaining access to Part 2 information for scientific research purposes, from sources other than Part 2 programs, if there is a way to ensure that all of Part 2's research protections in §2.52 will be complied with.

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

SAAS understands, and finds both justifiable and necessary in light of the current regulation, SAMHSA's current interpretation requiring Part 2 programs to obtain patients' proper written consent before disclosing patients' electronic prescription information to a pharmacy, requiring the pharmacy to obtain proper patient consent before disclosing the Part 2-protected information to a PDMP, and requiring the PDMP to obtain proper patient consent before re-disclosing Part 2-protected information to others. As stated earlier in these comments, it is critical that SUD patients retain control over who has access to their records in light of ongoing prejudice and discrimination, and the potential unintended consequences of permitting widespread disclosure of those records.

According to the National Alliance for Model State Drug Laws, as of December 2013, 18 states allow law enforcement to access their PDMPs with a search warrant, subpoena, court order, or other judicial process. Furthermore, 13 states allow law enforcement to be registered users of their PDMPs.¹⁸ Law enforcement attempts to access SUD patient records, and the deterrent impact of law enforcement access against people seeking SUD treatment, was a primary reason for creating Part 2's protections in the first pSAASE. Any change to Part 2 that would allow law enforcement to access patients' SUD information without their consent would directly contravene the most basic purposes of Part 2, and would violate Part 2's authorizing statute.¹⁹

Furthermore, discrimination by non-Part 2 health care providers and insurers continue to cause real concern among SUD patients. Any change to Part 2 that would allow patients' SUD information to flow without their consent to pharmacies, PDMPs, and all those with access to PDMPs would not only violate Part 2's authorizing statute but could also cause damage to patients, including discrimination by health care providers, insurers, and others. We support SAMHSA's continued interpretation of Part 2 as requiring patient consent for disclosure of their SUD prescription information to pharmacies, PDMPs, and those with access to PDMPs, and for redisclosure by any of those entities.

¹⁸ Nat'l Alliance of Model State Drug Laws, *Law Enforcement Access to State PMP Data* (2013), available at <http://www.namsdl.org/library/C4AA9EA3-65BE-F4BB-AAFBAB1F5736F070/>.

¹⁹ 42 C.F.R. Part 2's authorizing statute states: "Except as authorized by a [Part 2] court order ... no [Part 2] record ... may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient." 42 U.S.C. § 290dd-2(c).

IV. Conclusion

The health care environment is changing rapidly, moving toward more integrated care and the electronic exchange of health information. It is important for behavioral health to be included in integrated care and HIE in order to provide the best care for the millions of individuals in the U.S. who suffer from substance use disorders, and also to reduce costs associated with those disorders. At the same time, the privacy protections afforded to SUD information by Part 2 remain as critical today as they were when enacted in the 1970s. People with substance use disorders still face loss of employment, housing, and child custody; insurance discrimination; criminal arrest, prosecution, and incarceration; and a host of other negative consequences. In order to encourage people with substance use disorders to seek treatment, we strongly urge that Part 2's privacy protections be maintained. We also urge that, where possible, the issues identified by SAMHSA as causing confusion be addressed through additional and revised sub-regulatory guidance by SAMHSA, without the need for regulatory change.

SAAS also encourages the continued development of technology, along with corresponding policies and procedures, that will enable patients with SUD records – and other types of sensitive health records – to maintain control and choice regarding disclosures of their health information. We believe granular control in health information technology (HIT) is possible and imminent. We also hope that incentives for the adoption of HIT will be extended to behavioral health providers, and that SAMHSA and other departments of HHS will continue to pilot cutting-edge behavioral health HIT initiatives. Finally, we agree with stakeholders who stressed at the June 11, 2014 Listening Session the importance of educating health care providers, Part 2 programs, and Part 2 patients about consent, Part 2, and substance use disorders generally.

CODAC BEHAVIORAL HEALTHCARE

June 23, 2014

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

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:

CODAC, Inc. (dba CODAC Behavioral Healthcare) is a not-for-profit organization that has been providing substance abuse/disorder treatment services in Rhode Island since 1971.

For most of those years the information obtained, developed, and maintained for every patient has been protected by 42 C.F.R. Part 2 and its core privacy protections.

A significant number of those served by CODAC are engaged in Medication Assisted Treatment (MAT) and receive methadone to treat and sustain their recovery. There remains little doubt, that stigma and discrimination continues to be a part of this population's day-day life. This is evident in housing, employment, criminal justice, social services, and health care. In spite of continuous efforts by providers to educate other members of the "care community", our patients are often denied housing, employment, and custody of their children if they remain in treatment. Likewise, physicians and other healthcare providers refuse to either initiate or continue treatment.

It is our concern that any "weakening" of the core privacy protections will expose our patients to new levels of discrimination.

While CODAC supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, we believe that **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), CODAC supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.

- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- We continue to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

CODAC also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Michael Rizzi
President/CEO

June 23, 2014

Discovery House
66 Pavilion Ave.
Providence, RI 02905

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

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:

Discovery House is a national network of Medication Assisted Treatment Programs maintaining 18 separate locations in 4 States. We have been providing services for over 25 years.

While Discovery House supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

Our organization has experienced first hand the stigma our patients face when we have attempted to open new facilities or even move an existing facility.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), Discovery House supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support

maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.

- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center and the American Association for the Treatment of Opioid Dependence.

Thank you for your consideration.

Sincerely,

Richard Froncillo
Patient Ombudsman

LOCATIONS:

- Inland Empire
- Los Angeles
- San Fernando Valley
- West Los Angeles



Administrative Office
1850 Sawtelle Blvd., Suite 470, West Los Angeles, CA 90025
Tel: (310) 478-6006 Fax: (310) 478-6117
www.matrixinstitute.org

June 23, 2014

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

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:

The Matrix Institute on Addictions has been delivering treatment services for substance use disorders for the past 30 years to thousands of patients.

While Matrix Institute supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

I personally have had dozens of experiences over the years in which the current protections kept patient records and treatment information from being acquired by individuals who were not acting in the best interests of the patient. When there is a valid reason for providing information, patient's have the discretion to exercise a release of information and waive protection for a specific purpose.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), Matrix Institute supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.

- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- We continue to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

Michael McCann, M.A.
Associate Director



New Hampshire Alcohol & Drug Abuse Counselors Association
New Hampshire Training Institute on Addictive Disorders

130 Pembroke Road, Suite 100
Concord, NH 03301
www.nhadaca.org

(603) 225-7060 phone
(603) 225-7062 fax
nhtiad@myfairpoint.net

June 23, 2014

NH Alcohol & Drug Abuse Counselors Association
130 Pembroke Road, Suite 100
Concord, NH 03301

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

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:

The NH Alcohol & Drug Abuse Counselors Association (NHADACA) is a non-profit membership organization of approximately 220 members. Since 1986, NHADACA has worked to advance the addiction profession in New Hampshire. We accomplish our mission through education and advocacy. By providing relevant, quality training on substance abuse treatment, intervention and prevention NHADACA has improved the skills of working addiction professionals and those preparing to enter the profession. NHADACA is an affiliate of NAADAC, the National Association of Addiction Professionals, a national leader in setting standards for the treatment and prevention of addictive disorders and for the training and qualifications of professionals.

While NHADACA supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

We provide ethics and confidentiality trainings for persons working within the substance abuse professions as well as other professions that have involvement with alcohol and drug-impacted or addicted persons. The frustration that some people experience when they cannot get the information they want immediately or without a release of information is minor in comparison to the security and protection the regulations afford alcohol and drug abuse patients. It is vital to keep these legal regulations in or to best assure clients that their privacy concerns are respected.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), the NH Alcohol & Drug Abuse Counselors Association supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- We agree with the Legal Action Center in the belief that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

Thank you for your consideration.

Sincerely,

Dianne Pepin, MEd., MLADC
Executive Director

Peter DalPra, LADC, LCS
President



June 22, 2014
(Via Email)

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

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:

Aegis Treatment Centers, LLC (Aegis) operates 25 Narcotic Treatment Programs in the state of California and treats approximately 6,000 patients per day, primarily using Methadone replacement therapy together with counseling and other services.

While Aegis supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, Aegis believes that 42 C.F.R. Part 2's core privacy protections MUST be maintained.

Over the 15 years that Aegis has operated, we have treated tens of thousands of unduplicated patients and have a current census of over 6,000 patients. Over the years, we have been made aware of hundreds and perhaps more than a thousand of instances where prejudice, NIMBY, ignorance and stigma have adversely impacted patients under our care. These instances involve uninformed social workers, parole and probation officers, judges, family and specialty physicians, county officials, state legislators, etc. Many of these examples resulted in threats of stopping treatment, losing children to the foster care system, being directed to "get off that stuff or else ..." and some in difficulty in maintaining employment, family relationships and social friendships. We have found that the confidentiality protections in 42 C.F.R. Part 2 are critically important to our patients and we are encouraging you to protect and maintain them.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), Aegis supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.



- Aegis continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on re-disclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA together with provisions in the Health Information Technology for Economic and Clinical Health Act (HITECH Act), and in California the Confidentiality of Medical Information Act (CMIA), and others require compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center and the American Association for the Treatment of Opioid Dependence.

Thank you for your consideration.

Sincerely yours,

Stephen J. Maulhardt,
Executive Vice President

CC: Legal Action Center (LAC)

American Association for the Treatment of Opioid Dependence (AATOD)

2013-2014

CHAIR

Kathleen Scully-Hayes
Baldwin, MD
(410) 207-5028
khayes9933@comcast.net

CHAIR-ELECT

Michael E. Clark
Houston, TX
(713) 402-3905
meclark@duanemorris.com

VICE-CHAIR

William W. Horton
Birmingham, AL
(204) 244-5221
whorton@joneswalker.com

SECRETARY

C. Joyce Hall
Jackson, MS
(601) 965-1982
jhall@watkinseager.com

BUDGET OFFICER

Alexandria Hien McCombs
Addison, TX
(972) 364-8241
alexandria_mccombs@concentra.com

IMMEDIATE PAST CHAIR

David L. Douglass
Washington, DC
(202) 469-4909
ddouglass@sheppardmullin.com

SECTION DELEGATES

TO THE HOUSE OF DELEGATES

J.A. (Tony) Patterson, Jr.
Kalspell, MT

Gregory L. Pemberton
Indianapolis, IN

COUNCIL MEMBERS

Eugene Holmes (2014)
Washington, DC

Robyn Shapiro (2014)
Milwaukee, WI

Hilary H. Young (2014)
Austin, TX

Michelle Apodaca (2015)
Austin, TX

Adrienne Dresevic (2015)
Southfield, MI

Denise Webb Glass (2015)
Dallas, TX

John H. McEniry (2016)
Foley, AL

Shannon Hartsfield Salimone (2016)
Tallahassee, FL

W. Thomas Smith (2016)
Gainesville, FL

BOARD OF GOVERNORS LIAISON

William T. Coplin, Jr.
Demopolis, AL

YOUNG LAWYERS DIVISION LIAISON

Matthew R. Fisher
Worcester, MA

LAW STUDENT DIVISION LIAISON

Arian C. Hull
Opa Locka, FL

DIRECTOR

Wanda Workman
(312) 988-5548
wanda.workman@americanbar.org

ASSOCIATE DIRECTOR

Simeon Carson
(312) 988-5824
simeon.carson@americanbar.org

SENIOR MEETING PLANNER

Nancy Voegtle
(312) 988-5146
nancy.voegtle@americanbar.org

ADMINISTRATIVE ASSISTANT

Jason Billups
(312) 988-5532
jason.billups@americanbar.org

AMERICAN BAR ASSOCIATION

American Bar Association
June 23, 2014

HEALTH LAW SECTION

Mail Stop 18.1
321 N. Clark Street
Chicago, IL 60654
(312) 988-5532
FAX: (312) 988-5814
www.americanbar.org/health

Sylvia Mathews Burwell, Secretary
U.S. Department of Health & Human Services
200 Independence Ave SW
Washington, D.C. 20201

RE: 42 C.F.R. Part 2's Confidentiality Protections

Dear Secretary Burwell:

This letter is submitted by the Health Law Section of the American Bar Association to provide comments to the Department of Health and Human Services Substance Abuse and Mental Health Services Administration in response to a call for comments on the federal regulations governing Confidentiality of Alcohol and Drug Patient Records (42 C.F.R. Part 2).

The views expressed herein are presented on behalf of the Section¹. No government attorneys or government professionals participated in the drafting or submission of these comments. These comments have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and, accordingly, should not be construed as representing the position of the American Bar Association. The views expressed in these comments should not be construed as representing the policy or views of any government employee who is a member of the Section, its Council, or the Task Force on Substance Use Disorders.

The American Bar Association is the largest voluntary professional association in the world. The Section, with nearly 10,000 attorney members, is the voice of the organized health care bar within the ABA. Its members represent clients in all aspects of the health care industry, including physicians, institutional providers, teaching and research organizations, managed care organizations and other third-party payors, governmental health care programs and regulatory bodies, pharmaceutical companies and device manufacturers.

¹ The comments were prepared by a working group of the Health Law Section's Substance Use Disorders Task Force. The contributors to these comments from the working group are Beth Ann Middlebrook, Myer Cohen, Lou Presenza, Richard Roisman, and Robert Fiebach. The final comments were approved by the Section's Council on June 17, 2014. Although members of the Section who participated in the preparation and review of these comments have clients that the initiative affects, no such member has been engaged by a client to participate in the drafting or submission of these comments.

While the ABA Health Law Section supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, 42 C.F.R. Part 2's core privacy protections must be maintained. These recommendations to SAMHSA on the future of 42 C.F.R. Part 2 are based on the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged.
- At the same time, 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect individuals seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute a patient, or deny them insurance or employment, or be used against them in a divorce or child custody proceeding, many individuals will be afraid to enter treatment in the first place.
- Patients participating in alcohol and drug programs should retain the right to decide when and to whom their records are disclosed, even for treatment and payment purposes, given the unfortunate though continued prevalence of discrimination in our society. This includes disclosures to the general health care system, health information exchanges, health homes, accountable care organizations and coordinated care organizations. The best way for patients to retain that right is by continuing to require patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care services and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2.

Recommendations:

- The ABA Health Law Section supports maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining privacy protections that are as essential today as they were when 42 C.F.R. Part 2 was enacted in the 1970s. Individuals with the disease of addiction still face loss of employment, housing, and child custody; insurance and health care discrimination; criminal arrest, prosecution and incarceration; and a host of other negative consequences. 42 C.F.R Part 2's privacy protections greatly minimize the possibilities that a patient's own treatment records could be used against them in these situations. In

order to encourage people with SUDs to access treatment services, 42 C.F.R. Part 2's more stringent privacy protections must be maintained rather than accede to HIPAA standards which would allow far more disclosures, and redisclosures, that could lead to harmful consequences for patients.

- The ABA Health Law Section supports the goals set out in SAMHSA's request for comments and believes that the current regulations, together with additional guidance from SAMHSA, can accomplish many (if not all) of the intended goals of integrating SUD and other health care and improving communication between them more effectively.
- HIPAA requires compliance with state and federal laws that mandate greater privacy protections. Thus, electronic health record systems (EHRs) must be designed to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It therefore is important to bear in mind that EHRs would be required to comply with enhanced protections for the medical records of certain illnesses in order to be HIPAA compliant, even if 42 C.F.R. Part 2 did not exist.
- The ABA Health Law Section urges the continued development of technical solutions for patient consent management.

The ABA appreciates this opportunity to comment to HHS and SAMHSA on potential changes to 42 C.F.R. Part 2 regulations.

Sincerely,

Michael E. Clark, Chair-Elect
ABA Health Law Section

From: Amy Kelly [<mailto:amykelly@gmail.com>]
Sent: Tuesday, June 24, 2014 11:53 AM
To: Privacy Regulations (SAMHSA)
Subject: Comments regarding proposed changes to 42 CFR Part 2

June 24, 2014

Amy Kelly, LICSW, MLADC
195 McGregor Street; Suite 110
Manchester, NH 03102

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

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:

I have worked as a licensed social worker and substance abuse counselor for (19) years. One of the reasons that people feel comfortable talking openly about their issues with substance abuse is the protection offered by 42 CFR Part 2. I agree that collaboration is imperative in treatment, but clients need the right to limit their information as deemed appropriate to protect them from those who do not understand the disease of addiction. In a perfect world, everyone would accept this fact and show compassion for those struggling with the disease. Unfortunately, as a nation, we are not there yet and need to maintain the current confidentiality regulations so individuals feel comfortable getting the help they need.

While I support updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), I supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. I support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy

standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.

- LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. I urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

I also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

Amy Kelly, LICSW, MLADC

Consultant to NH DCYF



June 24, 2014

SUBMITTED VIA EMAIL

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

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:

As a person in long-term recovery with over 26 years of experience in the field of addiction and recovery I am concerned about the proposed changes to the *Confidentiality of Alcohol & Drug Abuse Patient Records Regulations*.

While I support updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), I support the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. I support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.

- A 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- ALAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- A It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. I urge the continued development of technical solutions for consent management.
- A Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

I also support the comments submitted by the Legal Action Center.

Thank you for your consideration.



**State Delegate
to AATOD**

Jennifer Minthorn, MA
LADC CCS
President of MEATOD
Assistant Vice President of
Merrimack River Medical
Services
jennifer.minthorn@csachelp.com
207-590-3263

Members

CAP Quality Care
1 Delta Drive
Westbrook, ME 04092
207-856-7227

Discovery House
74 Dowd Road
Bangor, ME 04401
207-947-6800

Discovery House
13 Beech Street
Calais, ME 04619
207-454-1300

Discovery House
400 Western Ave
S. Portland, ME 04106
207-774-7111

Discovery House
21 Airport Road
Waterville, ME 04901
207-872-7272

**Merrimack River
Medical Services**
18 Mollison Way
Lewiston, ME 04240
207-312-6860

**Merrimack River
Medical Services**
2300 Congress Street
Portland, ME 04102
207-221-2292

Penobscot Metro
659 Hogan Road
Bangor, ME 04401
207-973-0400

Spectrum Health Systems
69 Eagle Drive
Sanford, ME 04073
207-324-2007

June 24, 2014

The Maine Association for the Treatment of Opioid Dependence (MEATOD)
2300 Congress Street
Portland, Maine 04102

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

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:

As the President of the Maine Association for the Treatment of Opioid Dependence (MEATOD) and the State's delegate to the American Association for the Treatment of Opioid Dependence (AATOD), I would like to submit comments on behalf of the opioid treatment providers in Maine.

While MEATOD supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

The patients in our programs continue to experience discrimination and stigma from employers, the medical community, and the criminal justice system due to their participation in a modality of treatment that is not seen as a legitimate form of treatment even though there is 50 years of research demonstrating the effectiveness of methadone maintenance treatment in treating opioid addiction. Without these protections, there will be greater chances for these patients to endure negative life changing experiences.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), MEATOD supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's lesser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute a patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

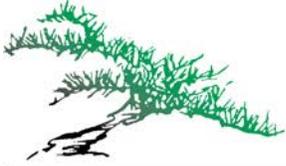
We also support the comments submitted by the American Association for the Treatment of Opioid Dependence and the Legal Action Center.

Thank you for your consideration.

Sincerely,

Jennifer Minthorn, MA, LADC, CCS

MEATOD President, AATOD State Delegate, and AATOD Board Secretary



Evergreen Treatment Services

Transforming the lives of individuals and their communities through innovative and effective addiction and social services.

COLLABORATION

COMPASSION

DIVERSITY

EMPOWERMENT

HOLISTIC

INNOVATION

INTEGRITY

SUBMITTED VIA EMAIL

June 23, 2014

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

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:

Evergreen Treatment Services specializes in medication assisted treatment for adults with opioid dependence. We operate three clinics in the Puget Sound area in western Washington and serve over 1500 patients. We employ more than 140 people who work with our population as medical providers, counselors, nurses and support staff.

While Evergreen Treatment Services supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

For our treatment population, the stigma and misunderstanding about our patients is nothing less than profound. Our patients frequently report interactions with the medical community that shames them regarding their treatment with us, that implores them to discontinue their medication under the false idea that this will propel the patient toward 'true' recovery, that hesitates to appropriately treat them with short acting opioids when an acute pain problem arises, and that the patient reports treats them differently than other patients they can clearly see receiving similar care in the same office. This is not an insignificant problem; our patients often neglect receiving primary care precisely because of these issues. Their health suffers as a direct result of this. Should our patient records become more widely available to the medical community, my entire staff and I have grave concerns about the consequences of this on our patients. 42 CFR Part 2 represents an absolutely critical component of assisting our patients towards our mutual goals of recover.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), Evergreen Treatment Services supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center in this matter.

Thank you for your consideration.

Sincerely,

Molly Carney, Ph.D., M.B.A.
Executive Director

From: Lindsey Downing [<mailto:ldowning@adsyes.org>]

Sent: Tuesday, June 24, 2014 2:23 PM

To: Privacy Regulations (SAMHSA)

Subject: Confidentiality of Alcohol & Drug Abuse Patient Records Regulations, 42 C.F.R. Part 2. 79 Fed. Reg. 26929; Docket No. 2014-10913.

June 24, 2014

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

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:

Alcohol and Drug Services (ADS) is a private non-profit organization in North Carolina. Our Mission is to promote health and wellness through providing high quality substance abuse prevention and treatment services that transform lives.

While ADS supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), ADS supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- LAC continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.

- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

Lindsey Downing
Director of Quality & Compliance



Alcohol & Drug Services
301 E. Washington St. Suite 101
Greensboro, NC 27401
Office: (336) 333-6860 Ext. 265
Mobile: (336) 601-9452
Fax: (336) 275-1187
www.adsyes.org

CONFIDENTIALITY NOTICE: This message and any attachments included are from Alcohol & Drug Services and are for sole use by the intended recipient(s). The information contained herein may include confidential or privileged information. Unauthorized review, forwarding, printing, copying, distributing, or using such information is strictly prohibited and may be unlawful. If you received this message in error, or have reason to believe you are not authorized to receive it, please contact the sender by reply email and destroy all copies of the original message.

CONFIDENTIALITY NOTICE: This e-mail and any files transmitted with it are confidential and intended solely for the use of the individual or entity to which they are addressed. Unauthorized review, forwarding, printing, copying, distributing, or using such information is strictly prohibited and may be unlawful. If you received this message in error please contact the sender by reply e-mail and destroy all copies of the original message. Please note that any views or opinions presented in this e-mail are solely those of the author and do not necessarily represent those of ADS. Check this e-mail and any attachments for the presence of viruses as ADS accepts no liability for any damage caused by any virus transmitted by this e-mail. Thank you! Alcohol & Drug Services (ADS), www.adsyes.org

June 23, 2014

Mr. Jeffrey Reed, CRS
2028 Ridge Road
Sunbury, PA 17801

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

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:

As a person in recovery, I support updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, 42 C.F.R. Part 2's core privacy protections **MUST** be maintained.

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), [PERSON/ORGANIZATION] supports the following principles:

- Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. [I/We] support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.
- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.

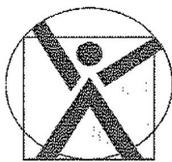
- LAC continues to believe that patients in alcohol and drug programs should retain the power to decide when and to whom their records are disclosed, even for treatment and payment purposes, given the continued prevalence of discrimination in our society. This includes disclosures to the general health care system, HIEs, health homes, ACOs, and CCOs. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. [I/We] urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

I also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

Jeffrey William Reed
Certified Recovery Specialist



BAART

BAY AREA ADDICTION RESEARCH AND TREATMENT, INC.

Administrative Office
1111 Market Street, Fourth Floor
San Francisco, CA 94103

Telephone (415) 552-7914

www.baartprograms.com

Fax (415) 552-3455

June 23, 2014

Bay Area Addiction Research and Treatment, Inc.
1111 Market St.
San Francisco, CA 94103

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

RE: Confidentiality of Alcohol & Drug Abuse Patient Records Regulations, 42 C.F.R. Part 2. 679 Fed. Reg. 26929; Docket No. 2014-10913.

To Whom It May Concern:

BAART Programs began providing drug treatment services to several hundred heroin addicts in San Francisco in 1977. Today, BAART Programs is a multi-service organization providing drug treatment and rehabilitation for patients across the country. We offer treatment for addiction to prescription medications such as oxycontin, hydrocodone and other opioids. Through a number of clinically proven methods, including methadone and buprenorphine (Suboxone) treatment, we have used evidence-based methods to bring the most effective results possible to our patient population. In combining medical treatment with the behavioral services, BAART offers the most successful option for many of our patients.

While BAART supports updating the mechanics of the federal alcohol and drug confidentiality regulations to facilitate more effective integration of care and needed communication in the electronic age, **42 C.F.R. Part 2's core privacy protections MUST be maintained.**

With regard to the modifications to 42 C.F.R. Part 2 proposed in SAMHSA's May 12, 2014 Notice of Public Listening Session (79 Fed. Reg. 26929), BAART supports the following principles:

- **B** Addiction treatment should be integrated with mental and physical health care, and communication among health care providers should be encouraged. We support maximizing inclusion of substance use disorder (SUD) records in electronic health record (EHR) systems and health information exchanges (HIEs) while maintaining 42 C.F.R. Part 2's core privacy protections.

Outpatient Substance Abuse Treatment Services

- 42 C.F.R. Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago, and a move toward HIPAA's looser privacy standards would not sufficiently protect people seeking and receiving substance use disorder treatment. If patient records can be easily accessed in order to criminally investigate or prosecute or patient, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, many patients will be afraid to enter treatment in the first place.
- BAART continues to believe that patients in alcohol and drug programs should 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. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure.
- It is both necessary and technologically possible to integrate addiction and other health care and effectively exchange addiction treatment data while maintaining the core protections of 42 C.F.R. Part 2. We urge the continued development of technical solutions for consent management.
- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, electronic health record systems (EHRs) must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA-compliant even if 42 C.F.R. Part 2 did not exist.

We also support the comments submitted by the Legal Action Center.

Thank you for your consideration.

Sincerely,

Jason Kletter, Ph.D
President