

June 25, 2014

The Substance Abuse and Mental Health Services Administration
Attention: Public Listening Session Comments
1 Choke Cherry Road
Room 5-1011
Rockville, Maryland 20857
PrivacyRegulations@SAMHSA.hhs.gov

Docket Number: 2014-10913

Dear Sir or Madam:

Lincoln Land Health Information Exchange (LLHIE) and Illinois Health Exchange Partners (ILHEP) are pleased to provide comments pertaining to the Public Listening Session regarding the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2 ("Part 2 Regulations"). Lincoln Land Health Information Exchange, LLC (LLHIE, founded 2011) and Illinois Health Exchange Partners, LLC (ILHEP, founded 2012) together provide HIE services across more than 35 counties in central and southern Illinois.

Multiple regional acute care hospitals, critical access and rural community hospitals, rural health clinics, Federally Qualified Health Centers, substance abuse and mental and behavioral health providers, long term care facilities, home health providers, and several primary care and multi-specialty clinics in the region participated in the planning process to establish these provider-led HIEs. Across these organizations, more than 75 clinical departments and 200 individuals participated to help determine how to improve the efficiency, effectiveness, and reliability of healthcare information exchange. LLHIE and ILHEP have separate governance structures to reflect the unique markets they serve, but share technology, infrastructure, and staffing resources.

LLHIE and ILHEP started with a transaction delivery model for clinical information exchange, and is currently operational for EMR-integrated results delivery, referrals, and transitions of care and are in the process of implementing population health management tools and a federated community health record, which will be live early next year.

We would like to thank SAMHSA for its willingness to consider revisions to the Part 2 Regulations. We share SAMHSA's commitment to protecting the privacy and security of information related to an individual's substance abuse treatment. We know firsthand the challenges of trying to comply with the Part 2 Regulations while also promoting the availability of health information electronically via a Health Information Exchange ("HIE"). Our comments to the proposed regulatory changes are grounded in our own experience with developing and operating an HIE in which all parties are committed, through a common trust framework, to exchange health information electronically in a safe and secure manner that protects the confidentiality of all patients. We believe that our experience makes us well situated to offer comments to SAMHSA as it considers changes to the Part 2 Regulations.

In the enclosed document, we offer our comments and recommendations regarding five of the seven topics addressed in the Public Listening Session held on June 11, 2014. While we think that many of the proposed changes could help to address the impediments to the electronic exchange of substance abuse information, we do not think that these changes are sufficient. We respectfully suggest that SAMHSA consider, and recommend to Congress, that the Part 2 Regulations and the enabling legislation be repealed. The public

policy drivers which led to the creation of the Part 2 confidentiality protections in the 1970's have been met through other, more comprehensive, legislative initiatives. The legislative history of the underlying statute and SAMHSA's own 2010 FAQs make it clear that the Part 2 Regulations were enacted due to the need to protect the confidentiality of substance abuse treatment information so that patients would not be deterred from seeking treatment and would not be the subject of discrimination based on their substance abuse history. When Congress enacted the statutory protections for substance abuse records in 1972 and directed the Secretary to promulgate the Part 2 Regulations, there was no comprehensive federal legal framework for the protection of health information. The statute and the Part 2 Regulations appropriately filled this gap and provided patients of federally assisted substance abuse treatment facilities with assurance that their records were protected from improper disclosure. Today there is a robust set of laws and regulations, at the federal and the state level, that are specifically focused on protecting the privacy and security of health information. Congress, in 1996, passed the Health Insurance Portability and Accountability Act ("HIPAA"), which created a comprehensive federal statutory framework for the privacy and security of all individually identifiable health information related to past, present or future medical conditions. The Department of Health and Human Services ("HHS") promulgated the HIPAA Privacy Rule in 2000, which imposed very specific requirements on HIPAA covered entities to protect the privacy of all Protected Health Information, including substance abuse treatment information. HHS promulgated the HIPAA Security Rule in 2003 which defined an extensive set of technical, physical and administrative safeguards for covered entities and their business associates to follow to assure that PHI is secure. HIPAA was expanded in 2009 by the HITECH Act to cover many non-healthcare providers, like HIEs, and make them subject to both the Privacy and the Security requirements of HIPAA. HHS also adopted the Breach Notification Rule in 2009 which imposed specific requirements on the content and timing of reporting suspected data breaches under HIPAA. The HIPAA Omnibus Rule, promulgated in 2013, further strengthened HIPAA protections including an expansion of the breach reporting requirements. We respectfully submit that the legitimate confidentiality interests of persons who obtain treatment of substance abuse issues are adequately protected by HIPAA and the Privacy Rule, as amended by HITECH and the HIPAA Omnibus Rule. We believe that the Part 2 statute and regulations simply create unnecessary confusion and actually deprive substance abuse patients of the benefits of electronic health information exchange.

Thank you for your consideration.

Respectfully submitted,

Stephen J. Lawrence, Executive Director
Lincoln Land Health Information Exchange
Illinois Health Exchange Partners

David Graham, M.D., Board Chair Lincoln Land Health Information Exchange and
Senior Vice President/Chief Information Officer/Chief Medical Information Officer, Memorial Health
System

Tom Mikkelsen, M.D., Board Chair Illinois Health Exchange Partners and
Chief Operating Officer, Touchette Regional Hospital

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APPLICABILITY OF 42 CFR PART 2

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

FR Citation: 79 FR 26930

Questions:

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

Public Comment Field:

As discussed in our transmittal letter, we believe the Part 2 Regulations are no longer needed to adequately protect the confidentiality of substance abuse records. When Congress enacted the statutory protections for substance abuse records in 1972 and directed the Secretary to promulgate the Part 2 Regulations, there was no comprehensive federal legal framework for the protection of health information. The statute and the Part 2 Regulations appropriately filled this gap and provided patients of federally assisted substance abuse treatment facilities with assurance that their records were protected from improper disclosure.

In 1996, Congress passed HIPAA which created a comprehensive federal statutory framework for the privacy and security of all individually identifiable health information related to past, present or future medical conditions. The U.S. Department of Health and Human Services ("HHS") promulgated the HIPAA Privacy Rule in 2000 which imposed very specific requirements on HIPAA covered entities to protect the privacy of all Protected Health Information ("PHI"), including substance abuse treatment information. HHS promulgated the HIPAA Security Rule in 2003 which defined an extensive set of technical, physical and administrative safeguards that covered entities and their business associates should follow to assure that PHI is secure. HIPAA was expanded in 2009 by the HITECH Act to cover many non-healthcare providers, like HIEs, and make them subject to both the Privacy and the Security requirements of HIPAA. HHS also adopted the Breach Notification Rule in 2009 which imposed specific requirements on the content and timing of reporting suspected data breaches under HIPAA. The HIPAA Omnibus Rule, promulgated in 2013, further strengthened HIPAA protections including an expansion of the breach reporting requirements. Together these laws and regulations provide a comprehensive set of protections for all forms of PHI, including substance abuse information. We respectfully submit that the legitimate confidentiality interests of persons who obtain treatment of substance abuse issues are adequately protected by HIPAA and the Privacy Rule, as amended by HITECH and the HIPAA Omnibus Rule. Clearly, the legal and regulatory environment is very different today than it was in 1972. Maintaining a separate, and different, legal standard for substance abuse records is no longer necessary.

Today, HIPAA covered entities and their business associates must comply with both HIPAA and the

APPLICABILITY OF 42 CFR PART 2

Part 2 Rules if they maintain any substance abuse records that are governed by Part 2. The requirement to comply with both sets of rules creates confusion about which rules apply to which records. Despite the various educational documents and FAQs published by SAMHSA which try to clarify the scope of the Part 2 Rules, there is still a lot of confusion about the applicability of the Part 2 Rules. We know that many health care providers err on the side of caution and segregate all records that might contain any substance abuse information about a patient for fear of violating the Part 2 Rules. This ultra-conservative approach is understandable from a compliance perspective but is detrimental to effective patient care. It results in relevant clinical information about substance abuse not being available to those who treat patients even though that information is not covered by the Part 2 Rules. Timely access to complete and accurate clinical information is one of the key reasons the federal government has invested so heavily in promoting the widespread adoption and use of certified Electronic Health Record ("EHR") technology. The success of ACOs, medical homes, population health programs and other important national priorities depend upon health care providers, payers and care coordinators having access to complete clinical information about a patient. While this was never the intent, the fact is that the Part 2 Rules have resulted in important clinical information related to patients' substance abuse conditions and treatment being kept away from those who legitimately need it. Therefore, we urge SAMHSA to recommend that Congress repeal the statute.

We understand that this decision rests with Congress and not the agency. Therefore, in the interim, we suggest that the Part 2 Regulations be modified to narrow the scope to apply only to inpatient substance abuse treatment provided in a dedicated substance abuse facility or unit that is federally funded. Today, there can be some Part 2 information in the inpatient record, the outpatient record and the physician office record. Even though the Part 2 information is only a small part of the total information in the record, the entire record is often withheld from being exchanged through an HIE due to the inability to detect and remove only the Part 2 information. Based on our experience, we know that most EHRs can identify records that come from a specific location, like an inpatient substance abuse facility, and can prevent those records from being disclosed while allowing other records to be made available. Most EHRs do not currently have the ability to segregate records with substance abuse data without a specific identifier, such as the location of service. Narrowing the applicability of the Part 2 Rules to inpatient substance abuse facilities will result in more health care providers being comfortable participating in HIEs and actually sharing their data since there will be less risk of an improper disclosure of Part 2 information. This will enable more exchange of health information for these patients which will result in greater continuity of care and a higher quality of patient care. We stress that this is an interim solution only since a lot of important clinical information would still be excluded from electronic sharing. However, we think that this is an implementable interim step while Congress considers the repeal of the law.

It is very important that SAMHSA clarify that any revisions to the regulations do not result in the applicability of the regulations actually being broader than it is today. We are very concerned that any revision which ties the applicability of the Part 2 Regulations to substance abuse services rather than the facility where the services are provided could result in the regulations being applicable to a much broader range of providers than are currently included under the Part 2 Regulations. We do not believe it is SAMHSA's intent to broaden the scope of Part 2 Regulations, but are concerned that it may be an unintended consequence should the applicability be redefined to services rather than the type of facility. SAMHSA has asked three specific questions about redefining the applicability of the Part 2 Regulations from a facility-based framework to a services-based framework. We have addressed those questions in our narrative above, but to avoid any confusion we can summarize our

APPLICABILITY OF 42 CFR PART 2

comments as follows:

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

If the Part 2 Regulations are not repealed, they should be narrowed as much as possible in order to allow health care provider organizations, HIEs, CCOs, and others that have a legitimate HIPAA-compliant reason to use and disclose substance abuse records to do so using electronic exchange technology. We suggest that the Part 2 Regulations be narrowed to inpatient care only, since records from those facilities can be identified and segregated using current EHR technology. While this is not an optimal solution, it is substantial progress that would be immediately beneficial to health care providers and others.

- *Would this change address stakeholder concerns?*

Narrowing the applicability of Part 2 to inpatient only does address the concern of those stakeholders that insist that substance abuse records must be treated differently than other types of “sensitive health information” such as HIV information and behavioral health information. While we do not agree that this is correct, we understand that these stakeholders sincerely believe that this is necessary.

- *Would this change raise any new concerns?*

Changing the applicability requirement to a services-based framework creates a significant risk of unintentionally expanding the scope of the Part 2 Regulations to cover more substance abuse records than the law currently covers. As discussed above, we are concerned that this will lead to more confusion about the applicability of the Part 2 Regulations and will further restrict access to substance abuse records by those who have a legitimate and HIPAA-compliant need to use and disclose them.

CONSENT REQUIREMENTS

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

1. ... Allow the consent to include a more general description of the individual, organization, or health care entity to which disclosure is to be made.
2. ... Require the patient be provided with a list of providers or organizations that may access their information, and be notified regularly of changes to the list.
3. ... Require the consent to name the individual or health care entity permitted to make the disclosure.
4. ... Require that if the health care entity permitted to make the disclosure is made up of multiple independent units or organizations that the unit, organization, or provider releasing substance abuse related information be specifically named.
5. ... Require that the consent form explicitly describe the substance abuse treatment information that may be disclosed.

FR Citation: 79 FR 26931

Questions:

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

Public Comment Field:

We agree that the consent requirements in the Part 2 Regulations must be substantially revised in order for Part 2 records to be exchanged using HIEs and other electronic health networks. Today, most HIEs require that their data sources exclude any records from Part 2 providers in order to avoid the possibility of accidentally disclosing substance abuse records without a Part 2 compliant consent. We also know that many health care providers treat all substance abuse records as if they are covered by the Part 2 Regulations because of widespread confusion about the applicability of Part 2 and because it is simply too complicated to maintain one consent management process for Part 2 records and another consent management process for other substance abuse records. This means that health care providers are being denied access to important information about a patient's substance abuse treatment. This does not benefit patients, providers, or the healthcare system as a whole.

The requirements of a Part 2 compliant consent are simply incompatible with participants in an HIE being able to query for patient records. We believe that SAMHSA understands this. While we appreciate SAMHSA's efforts to address this problem, we believe the alternatives which SAMHSA has identified are not sufficient because they are still based on a "point to point" model of information

Consent Requirements Ó

exchange. Let's consider each of the suggested revisions to the Part 2 consent requirements to see why they do not address the problem.

1. ? *Allow the consent to include a more general description of the individual, organization, or health care entity to which disclosure is to be made.*

Modifying the Part 2 consent requirement to only require a "general description" of the person or organization to whom the disclosure is being made does not address one of the core problems that HIEs face today. When a Part 2 provider makes its records available through an HIE to be queried by the HIE Participants (who have all signed an HIE trust agreement and are bound by the privacy and security requirements of the HIE), the Part 2 provider does not know which of those participants is going to submit a query for the records. Simply allowing a more general description of the individual, organization or health care provider to which the disclosure is made is not going to resolve this problem.

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

This suggested revision is certainly a step in the right direction. HIEs can make available a list of their participants that health care providers can give to patients. The problem with this approach is that most HIEs have agreements with other HIEs (sometimes referred to as "Partner Networks") that expand the number of data sources available to the HIE's participants thereby increasing the value of the HIE participation. HIEs will not be able to make participant lists for all of its Partner Networks available without incurring substantial costs that the HIEs cannot afford.

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

This requirement will prevent Part 2 records from being made available by Part 2 providers for exchange through HIEs. When a health care provider obtains a patient's consent for records, the provider may not know that there are Part 2 records or will almost certainly not know where those records are located. This is one of the primary drivers behind the "query" based exchange model of electronic health information exchange; to allow those who are treating a patient to discover relevant records about the patient from multiple sources without having to establish individual point to point data sharing agreements. HIEs are not based on point to point exchange relationships in which both the party requesting the record and the party disclosing the record are known.

One of the primary reasons we are involved in HIE activity is because it is not possible to develop and support the large number of "point to point" exchanges that we need. This is not a new conclusion; the federal government realized this many years ago when it embarked on developing the Nationwide Health Information Exchange, now called the eHealth Exchange. If the Part 2 compliant consent continues to require the identity of each discloser and recipient and a patient consent for each exchange, then most HIEs will continue to not support the exchange of substance abuse records. It would be possible for HIEs to provide a list all of its HIE participants, which would serve to identify who might be asked to disclose Part 2 records of hey

CONSENT REQUIREMENTS

have them

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

The model that nearly all HIEs follow is that the HIE enters into a trust agreement with health care providers or other organizations that serve as participants in the HIE. Health care provider organizations made up of multiple units or organizations will decide which of these is the proper party to become an HIE participant. In some cases this is the ultimate parent organization while in other cases it is one, or more, of the subsidiaries. HIEs should be able to provide a list of all participants, but this is not necessarily going to list every source of information within complex health care provider organizations. Therefore, we believe that this requirement will deter the ability of HIEs to exchange substance abuse records.

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

We do not know what is meant by “explicitly describe” and would like to better understand what SAMHSA means by this. However, one of the great benefits of HIEs is that they allow participants to seek information about their patients without knowing exactly what information exists or who has the information. This allows the treating health care provider to obtain a more complete picture of a patient’s medical information which improves the quality of care the provider can deliver. If SAMHSA retains the requirement that the Part 2 compliant consent identify the information being sought, this will defeat one of the key benefits of an HIE.

We appreciate that SAMHSA is exploring ways in which to revise the requirements of a Part 2 compliant consent while retaining the basic model. As we have already discussed, we recommend that the Part 2 Regulations be repealed. If that does not occur, we recommend that the Part 2 consent requirements be revised to incorporate a tiered approach to patient consent. If the purpose of the disclosure is for treatment, payment or health care operations (as defined by HIPAA, “TPO”) then a HIPAA-like general consent would be sufficient to support disclosure of Part 2 records. For those disclosures that are not for TPO purposes, we believe a higher level of documentation should be required. For these situations, we would support maintaining the current requirements for a Part 2 compliant consent. We believe that this is a reasonable approach because it leverages the extensive legal framework that HIPAA has created. This legal framework has been in place for 14 years and has effectively protected PHI from improper use and disclosure. It is familiar to those who hold and use PHI since they are either HIPAA covered entities or business associates of covered entities. Most HIEs have trust agreements with their participants that require the participant to comply with the HIE’s policies and procedures on privacy and security. Most HIEs require a treatment relationship with the patient before a query for information can be initiated by an HIE participant. All of this assures that records are not being queried for improper purposes.

Redisclosure p

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

FR Citation: 79 FR 26931

Questions:

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

Public Comment Field:

We appreciate SAMHSA's willingness to consider revising the Part 2 redisclosure prohibition in order to limit it only to information that would identify the patient as a substance abuser. Based on our experience, we do not think that this approach is supported today by health information technology and it might take some time for that to occur. The technology that drives the exchange of health information today is very sophisticated when compared to what existed only 20 years ago. The ability to create software interfaces that allow discrete systems to communicate (i.e., interoperability) has opened the door for HIEs and other information sharing models. The development of patient matching algorithms, such as Master Patient Indexes ("MPIs"), and the ability to use Record Locator Services to quickly search through vast amounts of data to find relevant information has truly revolutionized health IT.

Even with these amazing advances, however, we still struggle with identifying and isolating specific data elements within a patient record. While "discrete" data, such as a lab result, that has its own unique digital label can be identified and isolated, this is not yet widely possible with "non-discrete" or "free text" data. This means that text which identifies a patient as a substance abuser cannot be identified and removed from key clinical documents such as History and Physical, Discharge Summaries, Procedure Notes, or narrative imaging reports. These records might contain information that identifies the patient as a substance abuser and could not be redisclosed under SAMHSA's suggested revision. We do know that several companies are working very hard to develop software that will scan free text documents for key terms and then redact them. This work has been spurred on by the Part 2 Regulations but it has proven to be more difficult than many expected. We do not think that revising the redisclosure rule will accelerate the technical solution.

Part 2 providers have largely chosen to not participate in HIEs due to the requirement of the Part 2 compliant consent. This means that their records are not available to other HIE participants to query,

Redisclosure

even in a treatment situation. This means that patients are suffering because their health care providers do not have access to important clinical information that would be useful to the provider in the treatment of the patient. We are very concerned that the suggested revision to the rule will serve only to continue forcing Part 2 providers, and others that maintain records which contain substance abuse information, to withhold those records for fear that they will be improperly redisclosed. This is not beneficial to the patient.

Our recommendation is to remove the redisclosure prohibition for any recipient who is required to comply with HIPAA. This would include all covered entities, all business associates, and those who are contractually required to comply with HIPAA that are not already either covered entities or business associates. As a discloser, I know that the recipient is subject to HIPAA and that they will not redisclose this information except as permitted by HIPAA. For requestors of information that are not subject to HIPAA, either by virtue of being a covered entity or a business associate or by contract, we are comfortable with retaining the Part 2 redisclosure prohibition. Covered entities and business associates, including HIEs, are already familiar with the HIPAA rules related to redisclosure and have incorporated these rules into their daily operations. It is already difficult for them to comply with the stringent Part 2 Regulations today with paper records. It is virtually impossible for them to do so with electronic records.

MEDICAL EMERGENCY

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

FR Citation: 79 FR 26931

Questions:

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

Public Comment Field:

We support SAMHSA's recommendation that the emergency exception be revised to match the statutory language of a "bona fide medical emergency." This will give providers the flexibility to seek substance abuse records when they are truly needed to treat the patient or to prevent harm to the patient. We do not believe that this should be limited to specific use cases since this will create more confusion about which rule applies when.

Medical Emergency

We also urge SAMHSA to substantially lessen the documentation requirement on the Part 2 provider when it releases records for an emergency. The Part 2 Regulation requires the Part 2 provider to document the following:

- The name and affiliation of the medical personnel to whom the disclosure was made;
- The name of the individual making the disclosure;
- The date and time of the disclosure; and
- The nature of the emergency.

In a traditional point to point model, where the requester of the data is in direct contact with the Part 2 provider, it might be feasible to obtain this information. However, in a medical emergency time is of the essence and delays in obtaining potentially critical information could mean the difference between life and death for the patient. An HIE allows the emergency provider to send a query seeking all relevant records for the patient that are available from other HIE participants and any partner networks. This information can be returned immediately. The documentation requirements of the Part 2 Regulation will interrupt the response to a query by Part 2 providers. The risk to the patient is clear, that important medical information might not be available in a timely fashion, not because of barriers in technology but because of policy barriers. This should not be allowed to be the case, especially since there are alternatives that allow for timely access to clinical information without compromising the patient's privacy. Unlike paper records, EMRs allow us to track every time records are viewed which provides even more protection to the patient. While the documentation requirements in medical emergencies certainly served a purpose decades ago, we firmly believe that it no longer does. Therefore, we urge SAMHSA to eliminate these requirements.

Qualified Service Organization (QSO)

SAMHSA is analyzing the regulations to identify options for allowing Part 2 data to flow to health care entities for the purpose of care coordination and population management while maintaining patient protections. One potential solution includes expanding the definition of a qualified service organization (QSO; § 2.11) to explicitly include care coordination services and to allow a QSO Agreement (QSOA) to be executed between an entity that stores Part 2 information, such as a payer or an ACO that is not itself a Part 2 program, and a service provider.

FR Citation: 79 FR 26931

Questions:

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

Public Comment Field:

We certainly support the expansion of the types of organizations that are included as QSOs. However, we believe that the entire construct of the QSO and the QSOA has been superseded by HIPAA and the business associate rule. When the Part 2 Regulations were promulgated, the concept of a trusted partner for sharing clinical information was a new concept. That is no longer the case. We have 14 years of experience with the HIPAA Privacy Rule's business associate provisions. The definition of who is a business associate, and their obligations, has been expanded over time, most recently by the HIPAA Omnibus Final Rule that was finalized in 2013. SAMHSA has made it clear that Part 2 providers are required to comply with both the HIPAA business associate requirements and the Part 2 QSO requirements. We do not believe there is any reason to maintain this parallel structure any longer. The Privacy Rule's requirements for Business Associate Agreements are very extensive and are actually broader than the Part 2 QSO requirements. Therefore, we see no reason to continue to require HIPAA covered entities to maintain both BAAs and QSOAs.

If SAMHSA decides to continue the QSO framework, then we strongly support expanding the definition of a QSO to include those involved in care coordination. We recommend a broadly worded definition of "care coordination" to allow flexibility to include medical home, ACOs, population health initiatives, and other innovative models.

RESEARCH

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

FR Citation: 79 FR 26932

Questions:

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

Public Comment Field:

No comments

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

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

FR Citation: 79 FR 26932

Questions:

- How do pharmacy information system vendors anticipate addressing this issue? Are there specific technology barriers SAMHSA should take into consideration?
- Are there other concerns regarding 42 CFR Part 2 and PDMPs? Please describe relevant use cases and provide recommendations on how to address the concerns.
- Are there patient concerns about the impact of e-prescribing and PDMPs on their privacy?

Public Comment Field:

No comments

June 25, 2014

The Substance Abuse and Mental Health Services Administration
Attention: Public Listening Session Comments
1 Choke Cherry Road
Room 5-1011
Rockville, Maryland 20857
PrivacyRegulations@SAMHSA.hhs.gov

Dear Sir or Madam:

Mary Washington Hospital Snowden at Fredericksburg is pleased to provide comments pertaining to the Public Listening Session regarding the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2 ("Part 2 Regulations"). Mary Washington Hospital has a long history of providing psychiatric services to the Fredericksburg region, dating back more than 115 years. Snowden at Fredericksburg, developed in 1991, is a 40 bed inpatient and outpatient behavioral health facility supporting adult and adolescent patients with psychiatric and chemical dependency. As a not-for-profit, premier mental health resource, Snowden at Fredericksburg has an unwavering commitment to the community. Our experienced behavioral health care providers serve our patients with the utmost confidentiality and discretion in a secure and caring environment.

We would like to thank SAMHSA for its willingness to consider revisions to the Part 2 Regulations. We share SAMHSA's commitment to protecting the privacy and security of information related to an individual's substance abuse treatment. We know firsthand the challenges of trying to comply with the Part 2 Regulations while also promoting the availability of health information electronically via a Health Information Exchange ("HIE"). Our comments to the proposed regulatory changes are grounded in our own experience with developing and operating an HIE in which all parties are committed, through a common trust framework, to exchange health information electronically in a safe and secure manner that protects the confidentiality of all patients. We believe that our experience makes us well situated to offer comments to SAMHSA as it considers changes to the Part 2 Regulations.

In the enclosed document, we offer our comments and recommendations regarding five of the seven topics addressed in the Public Listening Session held on June 11, 2014. While we think that many of the proposed changes could help to address the impediments to the electronic exchange of substance abuse information, we do not think that these changes are sufficient. We respectfully suggest that SAMHSA consider, and recommend to Congress, that the Part 2 Regulations and the enabling legislation be repealed. The public policy drivers which led to the creation of the Part 2 confidentiality protections in the 1970's have been met through other, more comprehensive, legislative initiatives. The legislative history of the underlying statute and SAMHSA's own 2010 FAQs make it clear that the Part 2 Regulations were enacted due to the need to protect the confidentiality of substance abuse treatment information so that patients would not be deterred from seeking treatment and would not be the subject of discrimination based on their substance abuse history. When Congress enacted the statutory protections for substance abuse records in 1972 and directed the Secretary to promulgate the Part 2 Regulations, there was no comprehensive federal legal framework for the protection of health information. The statute and the Part 2 Regulations appropriately filled this gap and provided patients of federally assisted substance abuse treatment facilities with assurance that their records were protected from improper disclosure. Today there is a robust set of laws and regulations, at the federal and the state level, that are specifically focused on protecting the privacy and security of health information. Congress, in 1996, passed the Health Insurance Portability and Accountability

Mary Washington Healthcare

June 25, 2014

Mary Washington Healthcare

Comments on Public Listening Session re: Confidentiality of Part 2 Records

Act (“HIPAA”), which created a comprehensive federal statutory framework for the privacy and security of all individually identifiable health information related to past, present or future medical conditions. The Department of Health and Human Services (“HHS”) promulgated the HIPAA Privacy Rule in 2000, which imposed very specific requirements on HIPAA covered entities to protect the privacy of all Protected Health Information, including substance abuse treatment information. HHS promulgated the HIPAA Security Rule in 2003 which defined an extensive set of technical, physical and administrative safeguards for covered entities and their business associates to follow to assure that PHI is secure. HIPAA was expanded in 2009 by the HITECH Act to cover many non-healthcare providers, like HIEs, and make them subject to both the Privacy and the Security requirements of HIPAA. HHS also adopted the Breach Notification Rule in 2009 which imposed specific requirements on the content and timing of reporting suspected data breaches under HIPAA. The HIPAA Omnibus Rule, promulgated in 2013, further strengthened HIPAA protections including an expansion of the breach reporting requirements. We respectfully submit that the legitimate confidentiality interests of persons who obtain treatment of substance abuse issues are adequately protected by HIPAA and the Privacy Rule, as amended by HITECH and the HIPAA Omnibus Rule. We believe that the Part 2 statute and regulations simply create unnecessary confusion and actually deprive substance abuse patients of the benefits of electronic health information exchange.

Thank you for your consideration.

With appreciation,

Joyce Hanscome
SVP/CIO

APPLICABILITY OF 42 CFR PART 2

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

FR Citation: 79 FR 26930

Questions:

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

Public Comment Field:

As discussed in our transmittal letter, we believe the Part 2 Regulations are no longer needed to adequately protect the confidentiality of substance abuse records. When Congress enacted the statutory protections for substance abuse records in 1972 and directed the Secretary to promulgate the Part 2 Regulations, there was no comprehensive federal legal framework for the protection of health information. The statute and the Part 2 Regulations appropriately filled this gap and provided patients of federally assisted substance abuse treatment facilities with assurance that their records were protected from improper disclosure.

In 1996, Congress passed HIPAA which created a comprehensive federal statutory framework for the privacy and security of all individually identifiable health information related to past, present or future medical conditions. The U.S. Department of Health and Human Services ("HHS") promulgated the HIPAA Privacy Rule in 2000 which imposed very specific requirements on HIPAA covered entities to protect the privacy of all Protected Health Information ("PHI"), including substance abuse treatment information. HHS promulgated the HIPAA Security Rule in 2003 which defined an extensive set of technical, physical and administrative safeguards that covered entities and their business associates should follow to assure that PHI is secure. HIPAA was expanded in 2009 by the HITECH Act to cover many non-healthcare providers, like HIEs, and make them subject to both the Privacy and the Security requirements of HIPAA. HHS also adopted the Breach Notification Rule in 2009 which imposed specific requirements on the content and timing of reporting suspected data breaches under HIPAA. The HIPAA Omnibus Rule, promulgated in 2013, further strengthened HIPAA protections including an expansion of the breach reporting requirements. Together these laws and regulations provide a comprehensive set of protections for all forms of PHI, including substance abuse information. We respectfully submit that the legitimate confidentiality interests of persons who obtain treatment of substance abuse issues are adequately protected by HIPAA and the Privacy Rule, as amended by HITECH and the HIPAA Omnibus Rule. Clearly, the legal and regulatory environment is very different today than it was in 1972. Maintaining a separate, and different, legal standard for substance abuse records is no longer necessary.

Today, HIPAA covered entities and their business associates must comply with both HIPAA and the Part 2 Rules if they maintain any substance abuse records that are governed by Part 2. The

APPLICABILITY OF 42 CFR PART 2

requirement to comply with both sets of rules creates confusion about which rules apply to which records. Despite the various educational documents and FAQs published by SAMHSA which try to clarify the scope of the Part 2 Rules, there is still a lot of confusion about the applicability of the Part 2 Rules. We know that many health care providers err on the side of caution and segregate all records that might contain any substance abuse information about a patient for fear of violating the Part 2 Rules. This ultra-conservative approach is understandable from a compliance perspective but is detrimental to effective patient care. It results in relevant clinical information about substance abuse not being available to those who treat patients even though that information is not covered by the Part 2 Rules. Timely access to complete and accurate clinical information is one of the key reasons the federal government has invested so heavily in promoting the widespread adoption and use of certified Electronic Health Record ("EHR") technology. The success of ACOs, medical homes, population health programs and other important national priorities depend upon health care providers, payers and care coordinators having access to complete clinical information about a patient. While this was never the intent, the fact is that the Part 2 Rules have resulted in important clinical information related to patients' substance abuse conditions and treatment being kept away from those who legitimately need it. Therefore, we urge SAMHSA to recommend that Congress repeal the statute.

We understand that this decision rests with Congress and not the agency. Therefore, in the interim, we suggest that the Part 2 Regulations be modified to narrow the scope to apply only to inpatient substance abuse treatment provided in a dedicated substance abuse facility or unit that is federally funded. Today, there can be some Part 2 information in the inpatient record, the outpatient record and the physician office record. Even though the Part 2 information is only a small part of the total information in the record, the entire record is often withheld from being exchanged through an HIE due to the inability to detect and remove only the Part 2 information. Based on our experience, we know that most EHRs can identify records that come from a specific location, like an inpatient substance abuse facility, and can prevent those records from being disclosed while allowing other records to be made available. Most EHRs do not currently have the ability to segregate records with substance abuse data without a specific identifier, such as the location of service. Narrowing the applicability of the Part 2 Rules to inpatient substance abuse facilities will result in more health care providers being comfortable participating in HIEs and actually sharing their data since there will be less risk of an improper disclosure of Part 2 information. This will enable more exchange of health information for these patients which will result in greater continuity of care and a higher quality of patient care. We stress that this is an interim solution only since a lot of important clinical information would still be excluded from electronic sharing. However, we think that this is an implementable interim step while Congress considers the repeal of the law.

It is very important that SAMHSA clarify that any revisions to the regulations do not result in the applicability of the regulations actually being broader than it is today. We are very concerned that any revision which ties the applicability of the Part 2 Regulations to substance abuse services rather than the facility where the services are provided could result in the regulations being applicable to a much broader range of providers than are currently included under the Part 2 Regulations. We do not believe it is SAMHSA's intent to broaden the scope of Part 2 Regulations, but are concerned that it may be an unintended consequence should the applicability be redefined to services rather than the type of facility. SAMHSA has asked three specific questions about redefining the applicability of the Part 2 Regulations from a facility-based framework to a services-based framework. We have addressed those questions in our narrative above, but to avoid any confusion we can summarize our

APPLICABILITY OF 42 CFR PART 2

comments as follows:

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

If the Part 2 Regulations are not repealed, they should be narrowed as much as possible in order to allow health care provider organizations, HIEs, CCOs, and others that have a legitimate HIPAA-compliant reason to use and disclose substance abuse records to do so using electronic exchange technology. We suggest that the Part 2 Regulations be narrowed to inpatient care only, since records from those facilities can be identified and segregated using current EHR technology. While this is not an optimal solution, it is substantial progress that would be immediately beneficial to health care providers and others.

- *Would this change address stakeholder concerns?*

Narrowing the applicability of Part 2 to inpatient only does address the concern of those stakeholders that insist that substance abuse records must be treated differently than other types of “sensitive health information” such as HIV information and behavioral health information. While we do not agree that this is correct, we understand that these stakeholders sincerely believe that this is necessary.

- *Would this change raise any new concerns?*

Changing the applicability requirement to a services-based framework creates a significant risk of unintentionally expanding the scope of the Part 2 Regulations to cover more substance abuse records than the law currently covers. As discussed above, we are concerned that this will lead to more confusion about the applicability of the Part 2 Regulations and will further restrict access to substance abuse records by those who have a legitimate and HIPAA-compliant need to use and disclose them.

<p>CONSENT REQUIREMENTS</p>
<p>While technical solutions for managing consent collection are possible, SAMHSA is examining the consent requirements in § 2.31 to explore options for facilitating the flow of information within the health care context while ensuring the patient is fully informed and the necessary protections are in place. Specifically, we are analyzing the current requirements and considering the impact of adapting them to:</p> <ol style="list-style-type: none"> 1. Allow the consent to include a more general description of the individual, organization, or health care entity to which disclosure is to be made. 2. Require the patient be provided with a list of providers or organizations that may access their information, and be notified regularly of changes to the list. 3. Require the consent to name the individual or health care entity permitted to make the disclosure. 4. Require that if the health care entity permitted to make the disclosure is made up of multiple independent units or organizations that the unit, organization, or provider releasing substance abuse related information be specifically named. 5. Require that the consent form explicitly describe the substance abuse treatment information that may be disclosed.
<p>FR Citation: 79 FR 26931</p>
<p>Questions:</p> <ul style="list-style-type: none"> • Would these changes maintain the privacy protections for patients? • Would these changes address the concerns of HIEs, health homes, ACOs, and CCOs? • Would these changes raise any new concerns?
<p>Public Comment Field:</p> <p>We agree that the consent requirements in the Part 2 Regulations must be substantially revised in order for Part 2 records to be exchanged using HIEs and other electronic health networks. Today, most HIEs require that their data sources exclude any records from Part 2 providers in order to avoid the possibility of accidentally disclosing substance abuse records without a Part 2 compliant consent. We also know that many health care providers treat all substance abuse records as if they are covered by the Part 2 Regulations because of widespread confusion about the applicability of Part 2 and because it is simply too complicated to maintain one consent management process for Part 2 records and another consent management process for other substance abuse records. This means that health care providers are being denied access to important information about a patient's substance abuse treatment. This does not benefit patients, providers, or the healthcare system as a whole.</p> <p>The requirements of a Part 2 compliant consent are simply incompatible with participants in an HIE being able to query for patient records. We believe that SAMHSA understands this. While we appreciate SAMHSA's efforts to address this problem, we believe the alternatives which SAMHSA has identified are not sufficient because they are still based on a "point to point" model of information exchange. Let's consider each of the suggested revisions to the Part 2 consent requirements to see</p>

CONSENT REQUIREMENTS

why they do not address the problem.

1. *Allow the consent to include a more general description of the individual, organization, or health care entity to which disclosure is to be made.*

Modifying the Part 2 consent requirement to only require a “general description” of the person or organization to whom the disclosure is being made does not address one of the core problems that HIEs face today. When a Part 2 provider makes its records available through an HIE to be queried by the HIE Participants (who have all signed an HIE trust agreement and are bound by the privacy and security requirements of the HIE), the Part 2 provider does not know which of those participants is going to submit a query for the records. Simply allowing a more general description of the individual, organization or health care provider to which the disclosure is made is not going to resolve this problem.

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

This suggested revision is certainly a step in the right direction. HIEs can make available a list of their participants that health care providers can give to patients. The problem with this approach is that most HIEs have agreements with other HIEs (sometimes referred to as “Partner Networks”) that expand the number of data sources available to the HIE’s participants thereby increasing the value of the HIE participation. HIEs will not be able to make participant lists for all of its Partner Networks available without incurring substantial costs that the HIEs cannot afford.

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

This requirement will prevent Part 2 records from being made available by Part 2 providers for exchange through HIEs. When a health care provider obtains a patient’s consent for records, the provider may not know that there are Part 2 records or will almost certainly not know where those records are located. This is one of the primary drivers behind the “query” based exchange model of electronic health information exchange; to allow those who are treating a patient to discover relevant records about the patient from multiple sources without having to establish individual point to point data sharing agreements. HIEs are not based on point to point exchange relationships in which both the party requesting the record and the party disclosing the record are known.

One of the primary reasons we are involved in HIE activity is because it is not possible to develop and support the large number of “point to point” exchanges that we need. This is not a new conclusion; the federal government realized this many years ago when it embarked on developing the Nationwide Health Information Exchange, now called the eHealth Exchange. If the Part 2 compliant consent continues to require the identity of each discloser and recipient and a patient consent for each exchange, then most HIEs will continue to not support the exchange of substance abuse records. It would be possible for HIEs to provide a list all of its HIE participants, which would serve to identify who might be asked to disclose Part 2 records of hey have them

CONSENT REQUIREMENTS

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

The model that nearly all HIEs follow is that the HIE enters into a trust agreement with health care providers or other organizations that serve as participants in the HIE. Health care provider organizations made up of multiple units or organizations will decide which of these is the proper party to become an HIE participant. In some cases this is the ultimate parent organization while in other cases it is one, or more, of the subsidiaries. HIEs should be able to provide a list of all participants, but this is not necessarily going to list every source of information within complex health care provider organizations. Therefore, we believe that this requirement will deter the ability of HIEs to exchange substance abuse records.

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

We do not know what is meant by “explicitly describe” and would like to better understand what SAMHSA means by this. However, one of the great benefits of HIEs is that they allow participants to seek information about their patients without knowing exactly what information exists or who has the information. This allows the treating health care provider to obtain a more complete picture of a patient’s medical information which improves the quality of care the provider can deliver. If SAMHSA retains the requirement that the Part 2 compliant consent identify the information being sought, this will defeat one of the key benefits of an HIE.

We appreciate that SAMHSA is exploring ways in which to revise the requirements of a Part 2 compliant consent while retaining the basic model. As we have already discussed, we recommend that the Part 2 Regulations be repealed. If that does not occur, we recommend that the Part 2 consent requirements be revised to incorporate a tiered approach to patient consent. If the purpose of the disclosure is for treatment, payment or health care operations (as defined by HIPAA, “TPO”) then a HIPAA-like general consent would be sufficient to support disclosure of Part 2 records. For those disclosures that are not for TPO purposes, we believe a higher level of documentation should be required. For these situations, we would support maintaining the current requirements for a Part 2 compliant consent. We believe that this is a reasonable approach because it leverages the extensive legal framework that HIPAA has created. This legal framework has been in place for 14 years and has effectively protected PHI from improper use and disclosure. It is familiar to those who hold and use PHI since they are either HIPAA covered entities or business associates of covered entities. Most HIEs have trust agreements with their participants that require the participant to comply with the HIE’s policies and procedures on privacy and security. Most HIEs require a treatment relationship with the patient before a query for information can be initiated by an HIE participant. All of this assures that records are not being queried for improper purposes.

REDISCLASURE

<p style="text-align: center;">REDISCLASURE</p>
<p>SAMHSA is considering revising the redisclosure provision to clarify that the prohibition on redisclosure only applies to information that would identify an individual as a substance abuser, and allows other health-related information shared by the Part 2 program to be redisclosed, if legally permissible. This would allow HIT systems to more easily identify information that is subject to the prohibition on redisclosure enabling them to utilize other technological approaches to manage redisclosure. If data are associated with information about where the data were collected (data provenance) which reveals that the data were collected by a practice that exclusively treats addiction, the data would still be protected under the proposed change.</p>
<p>FR Citation: 79 FR 26931</p>
<p>Questions:</p> <ul style="list-style-type: none"> • Would this type of change facilitate technical solutions for complying with 42 CFR Part 2 in an EHR or HIE environment? • Would these changes maintain the privacy protections for patients?
<p>Public Comment Field:</p> <p>We appreciate SAMHSA’s willingness to consider revising the Part 2 redisclosure prohibition in order to limit it only to information that would identify the patient as a substance abuser. Based on our experience, we do not think that this approach is supported today by health information technology and it might take some time for that to occur. The technology that drives the exchange of health information today is very sophisticated when compared to what existed only 20 years ago. The ability to create software interfaces that allow discrete systems to communicate (i.e., interoperability) has opened the door for HIEs and other information sharing models. The development of patient matching algorithms, such as Master Patient Indexes (“MPIs”), and the ability to use Record Locator Services to quickly search through vast amounts of data to find relevant information has truly revolutionized health IT.</p> <p>Even with these amazing advances, however, we still struggle with identifying and isolating specific data elements within a patient record. While “discrete” data, such as a lab result, that has its own unique digital label can be identified and isolated, this is not yet widely possible with “non-discrete” or “free text” data. This means that text which identifies a patient as a substance abuser cannot be identified and removed from key clinical documents such as History and Physical, Discharge Summaries, Procedure Notes, or narrative imaging reports. These records might contain information that identifies the patient as a substance abuser and could not be redisclosed under SAMHSA’s suggested revision. We do know that several companies are working very hard to develop software that will scan free text documents for key terms and then redact them. This work has been spurred on by the Part 2 Regulations but it has proven to be more difficult than many expected. We do not think that revising the redisclosure rule will accelerate the technical solution.</p> <p>Part 2 providers have largely chosen to not participate in HIEs due to the requirement of the Part 2 compliant consent. This means that their records are not available to other HIE participants to query,</p>

REDISCLASURE

even in a treatment situation. This means that patients are suffering because their health care providers do not have access to important clinical information that would be useful to the provider in the treatment of the patient. We are very concerned that the suggested revision to the rule will serve only to continue forcing Part 2 providers, and others that maintain records which contain substance abuse information, to withhold those records for fear that they will be improperly redisclosed. This is not beneficial to the patient.

Our recommendation is to remove the redisclosure prohibition for any recipient who is required to comply with HIPAA. This would include all covered entities, all business associates, and those who are contractually required to comply with HIPAA that are not already either covered entities or business associates. As a discloser, I know that the recipient is subject to HIPAA and that they will not redisclose this information except as permitted by HIPAA. For requestors of information that are not subject to HIPAA, either by virtue of being a covered entity or a business associate or by contract, we are comfortable with retaining the Part 2 redisclosure prohibition. Covered entities and business associates, including HIEs, are already familiar with the HIPAA rules related to redisclosure and have incorporated these rules into their daily operations. It is already difficult for them to comply with the stringent Part 2 Regulations today with paper records. It is virtually impossible for them to do so with electronic records.

MEDICAL EMERGENCY

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

FR Citation: 79 FR 26931

Questions:

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

Public Comment Field:

We support SAMHSA's recommendation that the emergency exception be revised to match the statutory language of a "bona fide medical emergency." This will give providers the flexibility to seek substance abuse records when they are truly needed to treat the patient or to prevent harm to the patient. We do not believe that this should be limited to specific use cases since this will create more

MEDICAL EMERGENCY

confusion about which rule applies when.

We also urge SAMHSA to substantially lessen the documentation requirement on the Part 2 provider when it releases records for an emergency. The Part 2 Regulation requires the Part 2 provider to document the following:

- The name and affiliation of the medical personnel to whom the disclosure was made;
- The name of the individual making the disclosure;
- The date and time of the disclosure; and
- The nature of the emergency.

In a traditional point to point model, where the requester of the data is in direct contact with the Part 2 provider, it might be feasible to obtain this information. However, in a medical emergency time is of the essence and delays in obtaining potentially critical information could mean the difference between life and death for the patient. An HIE allows the emergency provider to send a query seeking all relevant records for the patient that are available from other HIE participants and any partner networks. This information can be returned immediately. The documentation requirements of the Part 2 Regulation will interrupt the response to a query by Part 2 providers. The risk to the patient is clear, that important medical information might not be available in a timely fashion, not because of barriers in technology but because of policy barriers. This should not be allowed to be the case, especially since there are alternatives that allow for timely access to clinical information without compromising the patient's privacy. Unlike paper records, EMRs allow us to track every time records are viewed which provides even more protection to the patient. While the documentation requirements in medical emergencies certainly served a purpose decades ago, we firmly believe that it no longer does. Therefore, we urge SAMHSA to eliminate these requirements.

QUALIFIED SERVICE ORGANIZATION (QSO)
<p>SAMHSA is analyzing the regulations to identify options for allowing Part 2 data to flow to health care entities for the purpose of care coordination and population management while maintaining patient protections. One potential solution includes expanding the definition of a qualified service organization (QSO; § 2.11) to explicitly include care coordination services and to allow a QSO Agreement (QSOA) to be executed between an entity that stores Part 2 information, such as a payer or an ACO that is not itself a Part 2 program, and a service provider.</p>
<p>FR Citation: 79 FR 26931</p>
<p>Questions:</p> <ul style="list-style-type: none"> • Are there other use cases we should be taking into consideration? • Are there specific patient concerns about the impact of this change on their privacy?
<p>Public Comment Field:</p> <p>We certainly support the expansion of the types of organizations that are included as QSOs. However, we believe that the entire construct of the QSO and the QSOA has been superseded by HIPAA and the business associate rule. When the Part 2 Regulations were promulgated, the concept of a trusted partner for sharing clinical information was a new concept. That is no longer the case. We have 14 years of experience with the HIPAA Privacy Rule’s business associate provisions. The definition of who is a business associate, and their obligations, has been expanded over time, most recently by the HIPAA Omnibus Final Rule that was finalized in 2013. SAMHSA has made it clear that Part 2 providers are required to comply with both the HIPAA business associate requirements and the Part 2 QSO requirements. We do not believe there is any reason to maintain this parallel structure any longer. The Privacy Rule’s requirements for Business Associate Agreements are very extensive and are actually broader than the Part 2 QSO requirements. Therefore, we see no reason to continue to require HIPAA covered entities to maintain both BAAs and QSOAs.</p> <p>If SAMHSA decides to continue the QSO framework, then we strongly support expanding the definition of a QSO to include those involved in care coordination. We recommend a broadly worded definition of “care coordination” to allow flexibility to include medical home, ACOs, population health initiatives, and other innovative models.</p>

RESEARCH
SAMHSA is considering expanding the authority for releasing data to qualified researchers/research organizations to health care entities that receive and store Part 2 data, including third-party payers, health management organizations, HIEs, and care coordination organizations.
FR Citation: 79 FR 26932
<p>Questions:</p> <ul style="list-style-type: none">• Are there factors that should be considered related to how current health care entities are organized, how they function or how legal duties and responsibilities attach to entities that make up an umbrella organization?• Would this change address concerns related to research?• Are there specific privacy concerns associated with expanding the authority or releasing data to qualified researchers/research organizations in this way?• Are there additional use cases that should be considered in the research context?
<p>Public Comment Field:</p> <p>No comments</p>

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

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

FR Citation: 79 FR 26932

Questions:

- How do pharmacy information system vendors anticipate addressing this issue? Are there specific technology barriers SAMHSA should take into consideration?
- Are there other concerns regarding 42 CFR Part 2 and PDMPs? Please describe relevant use cases and provide recommendations on how to address the concerns.
- Are there patient concerns about the impact of e-prescribing and PDMPs on their privacy?

Public Comment Field:

No comments

OTHER COMMENTS

Topic:

Public Comment Field:

Please take our feedback into consideration when making your decisions.

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

Document Number: 2014-10913, Notice of Public Listening Session: Confidentiality of Alcohol and Drug Abuse Patient Records

Comments on proposed changes to regulations submitted on behalf of Allegheny County Department of Human Services, Allegheny County, Pennsylvania.

Commenter Background: The Allegheny County Department of Human Services (DHS) provides and administers publicly-funded human services to approximately 220,000 county residents each year. DHS provides drug and alcohol services through direct service to clients as well as through contracted providers. The wide range of other services DHS provides includes services for older adults; child protective services; at-risk child development and education; hunger services; emergency shelters and housing for the homeless; non-emergency medical transportation; job training and placement for public assistance recipients and older adults; and services for individuals with a diagnosis of intellectual disability. Our mission is “to create an accessible, culturally competent, integrated and comprehensive human services system that ensures individually tailored, seamless and holistic services to Allegheny County residents, in particular, the county’s vulnerable populations.” Unnecessarily restrictive rules around patient records hinder DHS’ ability to provide integrated services. We offer the following comments on the proposed changes to 42 CFR Part 2, under topic headings matching the Federal Register notice.

Consent Requirements:

We support allowing the consent to include a more general description of the individual, organization, or health care entity to which disclosure is to be made. The name of the program or entity to receive the information should be sufficient to allow informed consent. Besides federal and/or state regulations, individuals working for these organizations are also governed by codes of professional ethics, and we support an environment of trust among providers. Broadening the description from an individual’s name or title will prevent barriers to communication due to personnel changes.

It is our position that the proposed requirement that patients be provided with a list of providers or organizations that may access their information, and be notified regularly of changes to the list is unnecessary. Maintaining and distributing such a list is impractical and inefficient for organizations like ours, and regularly receiving copies of the list is not an effective way for an individual client to exercise control over his or her information.

We also believe that the requirement that if the health care entity permitted to make the disclosure is made up of multiple independent units or organizations that the unit, organization, or provider releasing substance abuse related information be specifically named is counterproductive to the goal of integration of services. DHS strives to provide individualized and holistic treatment, and being able to share information across service areas is a necessary part of achieving that goal.

Redisclosure

We support the proposed clarification that prohibition on redisclosure applies only to information that would identify the individual as a substance abuser. Such a clarification would facilitate broader sharing of information among providers and programs in support of integrated service provision.

Medical Emergency

We support amending this standard to allow, for example, providers to use the medical emergency provision to prevent emergencies or to share information with a detoxification center when a patient is unable to provide informed consent due to their level of intoxication. It is crucial that providers have the discretion to interpret the definition of emergency to include prevention of a condition that would pose threat of immediate harm. Again, providers are governed by codes of ethics beyond these regulations, and entrusting them with greater freedom to act in patients' best interests will allow them to more effectively serve our clients.

Qualified Service Organization (QSO)

Again, we support expanded sharing of information. We favor monitoring employees' access/use at the organization level rather than at the federal regulation level. Providers should be free to use discretion and enter into agreements with organizations that will maximize the quality of care they are able to provide to patients.

Research

We fully support expanding the authority for releasing data to qualified researchers. We see research as essential to our mission, and the inability to use person-based data or to share data with certain types of organizations ties our hands. This is another area where we support greater freedom for organizations to work according to their guiding principles and professional ethics.

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

We agree that the current model of requiring a pharmacy to obtain consent to put information in a PDMP and further consent to re-disclose that information to those with access to the PDMP is needlessly cumbersome, and such barriers to access to information will prevent the programs from operating effectively.

Other Comments

We would like to reiterate that providers and administrators of services are not bound only by regulations, but also by codes of professional ethics. Broadening the regulations to allow providers and administrators greater discretion would allow organizations like ours to work within our governing principles to achieve our mission of providing holistic, integrated services.

We would also suggest that SAMHSA and DHHS consider urging states to update their regulations, considering the same issues that SAMHSA is examining here. Pennsylvania's regulations, for example, are particularly restrictive and even if there is sweeping change to the regulations at the federal level our organization would not be able to significantly change how we provide services in Allegheny County.



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Agency of Human Services

VIA EMAIL

June 25, 2014

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

**Re: Comments on Possible Changes to 42 C.F.R. Part 2 [79 FR 26929;
Document Number 2014-10913]**

The Vermont Departments of Health and Health Access¹ appreciate the opportunity to offer comments to SAMHSA on its suggestions for updating 42 CFR Part 2. First, we want to emphasize that we fully support updating the regulation. As SAMHSA states the new models of integrated care and the electronic infrastructure for managing and coordinating that care were not envisioned when this regulation was enacted in the 1970's or when it was last updated 25 years ago. Unfortunately, to date integration of addiction treatment has been severely hampered by 42 C.F.R. Part 2 despite efforts to clarify the regulation by SAMHSA in its two sets of Frequently Asked Questions. Unless the regulation is updated addiction treatment will continue to be left out of coordinated systems of care to the detriment of the system as a whole and especially to those patients in addiction treatment.

Our comments below address several of the specific issue areas on which SAMHSA requested feedback.

A. Applicability of 42 CFR Part 2

Covered information could be defined based on what substance abuse treatment services are provided instead of being defined by the type of facility providing the services. For example, the regulations could be applied to any federally assisted health care provider that provides a patient with specialty substance abuse treatment services. In this scenario, providers would not be covered if they provided only substance abuse screening, brief intervention, or other similar pre-treatment substance abuse services

¹ The state office of alcohol and drug abuse programs operates within the Vermont Department of Health (VDH), Vermont's Blueprint for Health operates within the Department of Vermont Health Access (DVHA). Together these programs jointly developed five (5) regional hubs that are or will provide specialty health homes and medication assisted therapy services.

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

Any change to the regulation that provides more clarity for patients and providers, while promoting healthcare integration is positive, however we would encourage SAMHSA to make more substantial revisions. Changes to the regulation should make the privacy protections as consistent with HIPAA as is allowable by the authorizing statute with the exception of access to records by law enforcement and the courts which should remain more protective. Separate treatment of substance abuse treatment records compromises patient safety, frustrates coordination of care, and drives higher costs and results in inefficiencies. We support many of the recommendations proposed in a recently published White Paper: PART 2: EVOLUTION A Vision for Integrated Care and Enhanced Rights by Renee M. Popovits, Laura Ashpole & Kelly T. Whelan (April 2014). The authors offer concrete recommendations on how to modernize Part 2 to facilitate effective participation in HIEs, CCOs, ACOs and health homes. At the same time they also provide concrete recommendations on strengthening the protections in the regulation on excluding information protected by Part 2 from being introduced in evidence in any criminal or civil proceedings.

We support amending the regulation to clearly carve out the provision of screening, brief intervention, or other similar pre-treatment substance abuse services. Such a change will encourage screening, brief counseling, and referral to become integrated in regular primary care by removing any concern on the part of primary care providers that providing such care could make them subject to 42 CFR Part 2. In addition this change would mean that such information would be included in the health information transmitted to HIE, ACO, CCO environments.

It is unclear that modifying the regulation, to cover only federally assisted health care providers that provide patients with specialty substance abuse treatment services, would be of benefit. The current explanation of applicability of coverage in the regulation is too open to interpretation resulting in a great deal of uncertainty for providers and patients as to whether their practice or their substance abuse treatment information is covered by the regulation or not. If SAMHSA was to take a type of information-based approach “specialty substance abuse treatment services” would need to be defined with as much clarity as possible. Coverage based on facility-type is easier to segregate in EHRs and HIEs, but pure facility-based coverage is problematic for integrated providers such as FQHCs. Irrespective of whether coverage by the regulation is determined by services or by facility pre-treatment services, and SBIRT only services, should be excluded from the regulation.

- Would this change address stakeholder concerns?

Clarifying the regulation’s reach will be helpful, however such changes won’t address the overarching problem that the regulation presents to healthcare integration because as currently written the regulation cannot, in any straightforward manner, be complied with in an electronic health information sharing environment.

- Would this change raise any new concerns?

This proposed change could raise new concerns if it is not carefully crafted and thereby creates new ambiguity as to when the regulation applies. The changes to the language should clearly define what is meant by “specialty substance abuse treatment services” to prevent such confusion.

The change may be as difficult or more difficult to implement in an electronic environment since segmenting data based on information type remains challenging.

B. Consent Requirements

Specifically, we are analyzing the current requirements and considering the impact of adapting them to:

1. Allow the consent to include a more general description of the individual, organization, or health care entity to which disclosure is to be made.

This proposed change would be extremely helpful in facilitating the inclusion of covered substance abuse treatment information into HIEs, health homes, ACOs, and CCOs. The current requirement for such organizations to provide patients with continuing evolving lists of providers is unworkable. The regulation should permit patients to consent to disclosure to any and all providers involved in their care since that is what most patients want and is best for optimal healthcare. Patients of covered programs should not continue to be denied this option.

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

We object to this requirement because it is unworkable in the electronic health information sharing environment. This requirement has proven to present a significant barrier to the inclusion of substance abuse treatment information in HIEs, ACOs, and CCOs. There is little justification for the requirement since, if allowed, most patients choose to share their health information with anyone involved in their care. Patient confidentiality can still be carefully protected by requiring providers to certify, prior to accessing a patient's records, that they have a bona fide treatment relationship with the patient and by requiring good quality control and auditing functions for HIEs, ACOs, and CCOs.

If the regulation continues to require that every provider and organization be named then SAMHSA should permit organizations to provide such lists on their websites and allow for the lists to be updated on a monthly basis.

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

We object to this proposal since it would further narrow what is permitted by the regulation as well as further complicate inclusion of patient records into electronic record environments.

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

We object to this proposal for the same reasons cited above and because of the increased difficulty health care entities would face in segmenting the patient information.

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

We object to this proposal because it both further narrows what would constitute valid consent, and does not describe what would constitute a sufficiently explicit description of information.

- Would these changes maintain the privacy protections for patients?

Patient choice and privacy could still be protected and better coordination and integration achieved by permitting a "more general description of the individual, organization, or health care entity to which disclosure is to be made."

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

Allowing a more general description of the individual, organization or health care entity, to which disclosure can be made would help to address concerns of HIEs, health homes, ACOs, and CCOs.

- Would these changes raise any new concerns?

The changes suggested by items 2-5 would create additional barriers for HIEs, health homes, ACOs, and CCOs. Such modifications would further sideline the inclusion of information from covered programs into electronic environments and frustrate the goals of the Affordable Care Act (ACA).

C. Redisclosure

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

collected by a practice that exclusively treats addiction, the data would still be protected under the proposed change.

- Would this type of change facilitate technical solutions for complying with [42 CFR Part 2](#) in an EHR or HIE environment?

It seems unlikely that this proposed change would facilitate EHR/HIE solutions since complex data segmentation abilities would still be needed.

The regulation should be amended to permit redisclosure of covered records between provider members of HIEs, ACOs, CCOs who have a bona-fide treatment relationship with the patient. Patients should be allowed to consent to such redisclosures without necessitating additional consent; this recommendation is discussed in the white paper cited above. Allowing redisclosure in this context would facilitate inclusion of substance abuse treatment records into electronic environments as well as enhance treatment and care coordination.

- Would these changes maintain the privacy protections for patients?

Yes.

d. Medical Emergency

SAMHSA has heard concerns regarding the medical emergency exception of [42 CFR Part 2](#) (§ 2.51). The current regulations state 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.” The statute, however, states that records may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency. SAMHSA is considering adapting the medical emergency exception to make it more in-line with the statutory language and to give providers more discretion as to when a bona fide emergency exists. For example, amending this standard to allow providers to use the medical emergency provision to prevent emergencies or to share information with a detoxification center when a patient is unable to provide informed consent due to their level of intoxication.

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

We agree that it would be helpful to amend the regulation to allow providers to use the emergency provision to prevent emergencies, or to share information with a detoxification center when informed consent is not possible. Providers should be required to have a good faith belief that, in their professional opinion, a bona fide emergency exists.

In addition, we would recommend amending the regulation to add a duty to warn provision. Providers should be permitted to disclose information to law

enforcement officials, family members, or others who may reasonably be able to prevent or lessen a serious and imminent threat to the health or safety of a person or the public as is permitted by HIPAA.

E. Qualified Service Organization (QSO)

SAMHSA is analyzing the regulations to identify options for allowing Part 2 data to flow to health care entities for the purpose of care coordination and population management while maintaining patient protections. One potential solution includes expanding the definition of a qualified service organization (QSO; § 2.11) to explicitly include care coordination services and to allow a QSO Agreement (QSOA) to be executed between an entity that stores Part 2 information, such as a payer or an ACO that is not itself a Part 2 program, and a service provider.

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

This change should also permit the range of functions and activities that are permitted of business associates under HIPAA.

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

The regulation could model the responsibilities of QSOs on the responsibilities placed on business associates in HIPAA. QSOs should only be able to use and maintain the information for the reason(s) specified in the QSOA and should have the same obligations and face the same penalties as a covered program.

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

If a patient does not consent to sharing their data via e-prescribing, their only option for filling their prescription is to bring a paper prescription to the pharmacy. In this instance, since the information is given by the patient, it is not protected by [42 CFR Part 2](#). They, therefore, cannot prevent the information from reaching the PDMP which in some states is accessible by law enforcement and has the potential to lead to investigation/arrest and other forms of discrimination.

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

Unknown.

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

SAMHSA's September 2011 letter to OTPs provides that OTPs may access PDMPs as a resource to assist in treating their patients. The letter cites a case study where an OTP physician found that 23% of the facility's patients were being prescribed

significant quantities of opiates, benzodiazepines, and other controlled substances by physicians outside their practice. Yet, because of the regulation's prohibition on redisclosure SAMHSA advises such programs to not disclose controlled substances used to treat opioid addiction to PDMPs. This prohibition reduces the reliability of the PDMP and significantly compromises patient safety given that other treatment providers may prescribe the patient opioids while being unaware of the opioid addiction treatment the patient receives at the OTP or OBOT.

At the very least patients should be able to sign a consent to have their prescription information included in the PDMP which acknowledges that the information could be redisclosed in accordance with the law and regulations governing the PDMP.

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

It is likely that some patients would be concerned that information from the PDMP could be accessed by law enforcement.

Conclusion

The Vermont Departments of Health and Health Access fully support SAMHSA's efforts to clarify and reduce the burdens associated with the specific consent requirements of the regulation while continuing to protect patient privacy. The most critical areas in need of change are consent and redisclosure. Patients should be able to consent to share their substance abuse treatment information to any provider or organization involved in their treatment, and substance abuse treatment information should be allowed to be redisclosed between members of HIEs, ACOs, and CCOs that have a treatment relationship with the patient. These modifications will foster the integration of substance abuse treatment into the treatment models necessary to effectuate healthcare reform.

Sincerely,

Barbara Cimaglio, Deputy Commissioner
Alcohol and Drug Abuse Programs



June 25, 2014

Pamela Hyde
Administrator
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
1 Choke Cherry Road
Rockville, MD 20857

RE: Netsmart Comments to 42 CFR Part 2 Listening Session

Dear Administrator Hyde:

The SAMHSA Public Listening Session on the Confidentiality of Alcohol and Drug Abuse Patient Records held on June 11, 2014 provided a good forum for discussion of important issues related to 42 CFR Part 2 consent requirements.

I appreciate the opportunity to provide comments on this topic from the perspective of the largest provider of technology to behavioral health organizations. Netsmart serves more than 20,000 private behavioral health practices, 40 state-operated hospital systems, and approximately one third of all community mental health centers in the country, many of which offer substance use treatment services. We are also engaged in the creation of care coordination systems and the associated health information exchanges (HIEs) needed to connect behavioral health to physical health for some of the nation's largest health homes.

The confidentiality of substance use treatment records is important, but much has changed in the last 42 years – in fact, much has changed in the past four years. In this digital era, the act in its current form is threatening patient safety by forcing healthcare providers to work in proverbial silos.

Health homes, Accountable Care Organizations (ACOs) and HIEs will not succeed until behavioral health organizations are able to share data with their physical health care partners in care coordination programs. However, due to SAMHSA's interpretation of the privacy laws, behavioral health and substance use providers are all but eliminated from participating fully these entities.

HIE Example

For example, if an adult with Alzheimer's disease and diabetes consents to sharing his or her records on an HIE, they can receive the superior care that can be delivered by coordinating care and reducing the risk of medication interactions associated with their multiple medications. A second person, one with diabetes and a substance use issue who has part of his or her treatment provided by a substance use treatment provider, cannot consent to share their records on an HIE without enormous administrative burden on themselves and their provider. In fact, in most cases, this is impossible to do because of the current technologies in use in HIEs. As was indicated in the Listening Session, most HIEs currently refuse to accept substance use EHRs.

In essence, providers cannot effectively participate in HIEs because when a patient wishes to consent to the release of his or her records to an HIE, he or she must specifically identify every member of that HIE. The HIE members/providers change over time, and maintaining the list as well as updated consents for redisclosure is challenging, which diminishes the ability coordinate care. Current regulations restrict providers from being able to send their substance abuse data up to the HIE, but only query down the longitudinal record comprised of physical health providers. This model does not serve the larger continuum because emergency departments and other physical health providers do not have access to the critical patient data represented during their substance abuse or behavioral health treatment.

This unintended consequence is a result of SAMHSA's interpretation of "informed consent." On the surface, this appears to be discriminatory to a consumer with substance use issues and against the intent of Mental Health Parity and Affordable Care Act legislation.

We strongly urge HHS and SAMHSA to issue sub-regulatory guidance that allows a patient to identify "current and future providers in the HIE involved in my care" as an appropriate title under the "To Whom" requirement of a Part 2 consent.

ACO Impact

Similarly, the Accountable Care Workgroup of the Office of the National Coordinator for Health Information Technology (ONC) noted the same problem in the context of Medicare ACOs (also applicable to Medicaid ACOs) – the inability to share addiction and mental health EHRs because of HHS privacy interpretations. In fact, the CMS Center for Medicare and Medicaid Innovation (CMMI) acknowledges that in sharing Medicare claims data with Pioneer ACOs nationwide, it must redact all addiction medical records due to Part 2 consent requirements.

Consent Requirements

Netsmart strongly urges a new 42 CFR Part 2 regulation to allow consent forms to include more general descriptions of the individual, organization or health care entity to which disclosure is to be made. This important change would ease the multiple consent requirements discussed above, thereby facilitating the interchange of substance abuse treatment information across HIEs, Medicare ACOs, Medicaid Health Homes and state-based Coordinated Care Organizations (CCOs). In conjunction with this proposal, it is important to note that substance use EHRs would be covered under existing HIPAA privacy standards, which protect the confidentiality of sensitive medical information associated with stigmatized medical conditions including HIV/AIDS and Sexually Transmitted Disease (STDs).

Qualified Service Organizations

We also urge SAMHSA to issue a Part 2 regulation that expands the definition of qualified service organization (QSO) to explicitly include care coordination services, and to allow a QSO Agreement (QSOA) to be executed between an entity that stores Part 2 information (such as a payer or an ACO that is not itself a Part 2 program), and a service provider.

The ability to share information with appropriate but updated privacy safeguards is key to treatment and recovery for patients with substance use issues. It will also improve the quality and breadth of substance

use treatment, mitigate the negative impact of co-occurring conditions and significantly enhance patient safety.

In addition, the timely, efficient sharing of authorized medical information via the fastest and most complete methods possible reduces risk of medication errors and increases the ability of emergency room clinicians to provide appropriate treatment in that setting.

The overwhelming feedback at the June 11 Listening Session was in favor of updating the rules. **Overall, we suggest a larger scale change: Exempt care coordination and population health management from Part 2 requirements to align with similar exemptions in HIPAA.**

Sincerely,

Kevin Scalia
Executive Vice President
Netsmart

June 25, 2014

The Substance Abuse and Mental Health Service Administration
1 Choke Cherry Road
Rockville, MD 20857

Room 5-1011

Email: PrivacyRegulations@SAMHSA.hhs.gov

RE: Substance Abuse and Mental Health Services Administration, HHS
FR Doc No: 2014-10913

Applicability of 42 CFR Part 2

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

FR Citation: 79 FR 26930

Questions:

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

Public Comment Field:

Recommendation: Application of the definition of “Covered Information” should not be based on the type of “services” but must be limited to information created or obtained by designated substance abuse treatment facilities or designated substance abuse treatment units within the larger facility.

Rationale: Unless application of the rule and definition of “Covered Information” is limited to designated substance abuse treatment facilities or specifically designated substance abuse treatment units within a larger facility, or there is a substance abuse diagnosis code listed, there is no way to identify information that could identify a patient as a substance abuser without manually reading all the records.

Even if a substance abuse diagnostic code is listed in connection with a general medical or surgical patient, and is identified by the EHR, the EHR is not able to parse that information from the non-substance abuse information and therefore, would require the entire PHI to be treated as substance abuse treatment records.

If a patient comes to the hospital or physician’s office for general medical treatment or pre-surgical treatment, and the physician’s history and physical address the patient’s substance abuse treatment, there is no way for an EHR or HIE to identify that note in the history to be a substance abuse record.

Recommendation: A Program should not be considered to include an emergency department of a hospital if the entire facility or the emergency department itself does not hold itself out as providing substance abuse treatment. Substance abuse screenings done in the emergency department and referral for substance abuse treatment by the emergency department should not be considered Covered Information.

Rationale:

Electronic health records are not built to identify and parse this information from other protected health information and in order to isolate information that could identify the patient as a substance abuser, the record must be reviewed manually which is not feasible.

Recommendation: Whether or not SAMHSA chooses to apply a definition of “Covered Information” to types of “services”, SAMHSA must provide a list of what it considers to be substance abuse treatment medications to assist pharmacies and providers to identify redisclosure issues.

Rationale: Other providers and pharmacies have no way of knowing, with certainty, whether a provider falls within the definition of a Program in order to avoid redisclosure violations. If the type of “Services” determines the application of the definition of “Covered Information” and a substance abuse treatment medication finds its way into a medication reconciliation list upon hospital discharge, a family practitioner or surgeon would then have unwittingly created Covered Information.

Consent Requirements

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

1. Allow the consent to include a more general description of the individual, organization, or health care entity to which disclosure is to be made.
2. Require the patient be provided with a list of providers or organizations that may access their information, and be notified regularly of changes to the list.
3. Require the consent to name the individual or health care entity permitted to make the disclosure.
4. Require that if the health care entity permitted to make the disclosure is made up of multiple independent units or organizations that the unit, organization, or provider releasing substance abuse related information be specifically named.
5. Require that the consent form explicitly describe the substance abuse treatment information that may be disclosed. X

FR Citation: 79 FR 26931 X

Questions:

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

Public Comment Field:

Answer to #1. Recommendation: Allow the consent to provide a more general description of the health care provider or entity to which a disclosure may be made for treatment, payment or health care operations (as defined by HIPAA). The consent would need to be valid for past, current, and

future treatment unless the patient provides notice to the provider to revoke consent.

Rationale: This would allow patients to choose to participate in an HIE so that all treating providers can be knowledgeable of all treatment information of the patient.

Answer to #2. This would be difficult to operationalize as providers can change daily; e.g., hospitalists.

5. An electronic health record cannot parse or segregate data even if the consent explicitly describes the substance abuse information that may be disclosed. Additionally, requiring an explicit description of information to be disclosed on the consent form itself would cause Covered Information to be disclosed to entity personnel who otherwise would have no need to know.

Redisclosure

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

FR Citation: 79 FR 26931

Questions:

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

Public Comment Field: “

If “Covered Information” is defined by “services” and EHRs and HIEs cannot parse substance abuse information from non-substance abuse health information, all healthcare information would have to be blocked from release or carry redisclosure notice. Whereas, if “Covered Information” is defined by facility or unit, at least only those designated facilities’ or units’ disclosure would have to be blocked or carry redisclosure.

The substance abuse treatment cannot be identified by services; it needs to be by Program facility or designated Program unit. Even if one could identify by services, the PHI cannot be separated in the electronic health record. So in order to protect the substance abuse information that may exist, all recipients of PHI from a HIE would have to receive the redisclosure notice on every patient's information – even if the patient didn't have substance abuse treatment. Within a physician group practice that includes physicians who hold themselves out as providing substance abuse treatment, the electronic medical record is not able to segregate the substance abuse treatment records. Therefore, all of the physician group's medical records would have to be blocked from the HIE whether the other providers in the group are treating the patient SAMHSA is trying to protect or any substance abuse patients or not.

Medical Emergency

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

FR Citation: 79 FR 26931

Questions:

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

Public Comment Field: **Recommendation:** Allow emergency department providers to use professional judgment to determine that an illness or injury is acute and poses an immediate risk to a person's life or long-term health so that the provider can review the substance abuse treatment Covered Information to immediately treat the patient and potentially prevent further harm.

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

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

Preamble FR Citation: 79 FR 26932

Questions:

- How do pharmacy information system vendors anticipate addressing this issue? Are there specific technology barriers SAMHSA should take into consideration?
- Are there other concerns regarding 42 CFR Part 2 and PDMPs? Please describe relevant use cases and provide recommendations on how to address the concerns.
- Are there patient concerns about the impact of e-prescribing and PDMPs on their privacy?

Public Comment Field:

Recommendation: SAMHSA must publish a list of drugs which would be considered to be prescribed by a Program which require consent for redisclosure. Example: A pharmacy receiving electronic prescriptions from a family practice physician would not know if the physician holds himself out as a substance abuse treatment provider or not. It would not be possible to rely on the practice name either. For pharmacy uses, this would need to be addressed by drug rather than by facility. A pharmacy in Tennessee may not be familiar with a provider in California.

Comment number 2. The questions appear to address only electronic prescription information and do not address getting hand-written prescription to PDMPs.

Other Comments

Topic:

Public Comment Field: Providers feel a very real need to be able to notify state authorities when the

substance abuse patient poses a risk to the health or safety of another person or the public in general. For instance, while we realize that allowing reporting could have a chilling effect on patients seeking

treatment, public safety is a major concern with patients who detox but are not in recovery and continue to drive while under the influence. This is especially concerning for drivers of public transportation.

Respectfully,

June Gerson
Director/Privacy Officer

June 25, 2014

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

Docket Number: 2014-10913

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

We, representatives from State Innovation Models Testing (SIM) states, are pleased to submit comments to SAMHSA on behalf of three SIM states. The State Innovation Models Initiative is providing support to states for the development and testing of state-based models for multi-payer payment and health care delivery system transformation with the aim of improving health system performance for residents of participating states. The SIM states offer a unique perspective on the challenges to better coordination of behavioral and physical health care posed by the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (hereinafter, “42 C.F.R. Part 2” or the “Part 2 regulations”).

The SIM states are testing new models of integrated care that are built on a foundation of information sharing to support coordination of patient care, the development of an electronic infrastructure for managing and exchanging patient data, and a new focus on performance measurement within the health care system. When the Part 2 regulations were written, these new models of care had not yet been developed. With their strict disclosure and redisclosure requirements, the Part 2 regulations make it difficult for health care providers seeking to better coordinate behavioral and physical health care to exchange substance abuse treatment information. It has been the experience of the SIM states that organizations across the country are excluding substance abuse treatment data from care coordination initiatives due to the difficulty and expense of implementing the functionality and the workflow changes necessary to comply with the Part 2 regulations as currently structured.

The SIM states agree that there continues to be a need for confidentiality protections that encourage patients to seek substance abuse treatment without fear of compromising their privacy. Indeed, the goal of the SIM states is to facilitate information exchange while respecting the legitimate privacy concerns of patients. The SIM states hope to assist SAMHSA in clarifying the Part 2 requirements associated with information exchange in the new and innovative care coordination models they are testing.

These comments address several of the specific issue areas on which SAMHSA requested feedback.

Issue: Applicability of 42 C.F.R. Part 2

SAMHSA is considering options for defining what information is covered under 42 C.F.R. Part 2. According to SAMHSA, covered information could be defined based on what substance abuse treatment services are provided instead of by the type of facility providing the services.

The SIM states appreciate that the U.S. health care system is changing and more substance abuse treatment is occurring in general health care and integrated care settings, which are typically not covered under the current regulations. They also appreciate that this has posed difficulties for identifying which providers are covered by the Part 2 regulations since whether a provider or organization is covered by Part 2 can change depending on whether they advertise their substance abuse treatment services (i.e. “hold themselves out”), which can change over time.

However, the SIM states do not support defining covered information based on what substance abuse treatment services are provided instead of the type of facility providing the services. According to SAMHSA, the regulations could be applied to any federally assisted health care provider that provides a patient with specialty substance abuse treatment services. In this scenario, providers would not be covered if they provided only substance abuse screening, brief intervention, or other similar pre-treatment substance abuse services.

The SIM states believe that this proposed change would have a negative effect on the type of care coordination initiatives they are testing because it would necessitate that providers seeking to share information about patients who have received substance abuse treatment services be able to tag and separate records about such treatment from other records about the patient, and to treat the substance abuse treatment records differently (i.e., to subject them to Part 2’s more stringent consent requirements). Most electronic health record systems (“EHR”) and electronic health information exchanges (“HIEs”) do not have the technical capability to perform this type of data segmentation. Even in cases where data segmentation is possible, building and maintaining an effective process is extremely costly. If SAMHSA adopts this proposal, the associated financial and reporting requirements would fall on a greater number of providers, many of whom have not had to previously bear this financial and operational burden. Thus, if the applicability of Part 2 is expanded as proposed, it would serve only to prevent more providers, indeed, vast numbers of providers of all types, from engaging in health information exchange, which is exactly the opposite of SAMHSA’s goal.

The SIM states request that SAMHSA consider how this proposed change would be operationalized in light of the current limitations on EHR and HIE data segmentation. For example, how will SAMHSA identify substance abuse treatment information (i.e., by use of billing codes)?

Currently, 42 C.F.R. Part 2 applies to federally funded individuals or entities that “hold themselves out as providing, and provide, alcohol or drug abuse diagnosis, treatment or treatment referral” including units within a general medical facility that hold themselves out as providing

diagnosis, treatment or treatment referral. While not ideal, this model, which makes Part 2 applicable to a certain type of provider rather than to a certain class of information, is more conducive to health information exchange because it allows HIEs to identify information that needs to be subject to greater privacy protections by identifying the providers from which it came, which is an easier proposition than identifying substance abuse treatment information in the records of any provider that happens to have provided such treatment.

Issue: Consent Requirements

SAMHSA is examining the consent requirements in the Part 2 regulations to explore options for facilitating the flow of information within the health care context while ensuring the patient is fully informed and the necessary protections are in place.

The SIM states support SAMHSA's proposal to liberalize Part 2's consent requirement to allow the consent to include a more general description of the individuals, organizations, or health care entities to which disclosure is to be made. This would enable the SIM states to implement a universal consent form/process that would support community-wide care coordination activities. Having to include the name or title of the individual or the name of the organization to which the disclosure is to be made is a challenge for care coordination initiatives like HIEs, health homes, accountable care organizations ("ACOs") and care coordination organizations ("CCOs"), which have large and constantly evolving numbers of participants and which do not have the resources to update consent forms whenever new providers join these organizations. If the proposal is not effectuated, the SIM states suggest that SAMHSA should provide greater flexibility by explicitly allowing organizations to maintain and update on a monthly basis on their websites a list of providers to whom disclosure may be made under a care coordination initiative. The SIM states also support broadening the consent requirement to allow consent to be made to "any provider involved in the patient's care."

The SIM states do not support the requirement that the consent form explicitly describe the substance abuse treatment information that may be disclosed since the substance abuse information available through the care coordination initiatives that the SIM states are testing may change as time goes on.

Finally, while liberalizing the consent requirement would reduce barriers to information-sharing, it will only go so far in states where state consent laws are not aligned with Health Insurance Portability and Accountability Act (HIPAA).

Issue: Redisclosure

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

SAMHSA suggests that this change would allow HIT systems to more easily identify information that is subject to the prohibition on redisclosure, enabling them to utilize other

technological approaches to manage redisclosure. If data associated with information about where the data were collected (data provenance) reveals that the data were collected by a practice that exclusively treats addiction, the data would still be protected under the proposed change.

The SIM states support SAMHSA's proposal to allow for health-related information that would not identify an individual as a substance abuser to be redisclosed. Given the high prevalence of comorbidity between substance abuse and mental health and/or physical health conditions, treatment records frequently contain other health information – such as treatment plans and medication lists – that would be of value to other providers. For example, the majority of Vermont's community mental health centers are designated substance abuse facilities covered under Part 2. Fifty to seventy five percent of patients in these centers have comorbid mental health and substance abuse issues. Would SAMHSA's proposal enable these community mental health centers to redisclose information that does not identify a patient as a substance abuse treatment recipient if the information was received from the Part 2 program? If so, the SIM States would support this change, but they would appreciate clarification from SAMHSA about exactly how this would be operationalized.

Issue: Medical Emergency

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

The current regulations state 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.” The statute, however, states that records may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency.

The SIM states support SAMHSA's interest in adapting the medical emergency exception to make it more in-line with the statutory language and to give providers more discretion as to when a bona fide emergency exists. However, the SIM states note that this change, in the absence of the other changes above, will do little to increase the exchange of information between behavioral and physical health care providers. The goal of the care coordination initiatives in which the SIM states are participating is for providers to share information on an ongoing basis in order to prevent emergencies from happening. While SAMHSA's proposal to broaden the definition of medical emergencies in which Part 2 records may be disclosed without patient consent would provide some needed relief in emergency situations, it will do nothing to help providers share information to prevent emergencies from happening in the first place.

Another proposal for SAMHSA's consideration that relates to emergency services is amendment of the current requirement under the Part 2 regulations that Part 2 programs be notified when their records are accessed without consent in an emergency. This is a cumbersome

requirement when considered in the context of electronic HIE, since notification of a Part 2 program by an HIE initiative or participants in an HIE initiative necessitates implementation of a new and separate workflow than is otherwise required under the HIE initiative. It would be more efficient if the Part 2 requirement of notification could be considered satisfied if the Part 2 program has the option of learning from the HIE or its participants who has accessed its records by requesting an audit trail of such access.

Issue: Qualified Service Organization (QSO)

SAMHSA is analyzing the regulations to identify options for allowing Part 2 data to flow to health care entities for the purpose of care coordination and population management while maintaining patient protections. One potential solution includes expanding the definition of a qualified service organization to explicitly include care coordination services and to allow a QSO Agreement (QSOA) to be executed between an entity that stores Part 2 information, such as a payer or an ACO that is not itself a Part 2 program, and a service provider.

Under the current regulations, substance abuse information may not be shared without consent with health care entities such as ACOs and CCOs for the purposes of care coordination and population health management (e.g., to help them to identify patients with chronic conditions in need of more intensive outreach).

The SIM states strongly support SAMHSA's proposal to expand the definition of a qualified service organization to explicitly include care coordination services and 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, so long as that information is used for treatment or quality improvement or similar purposes. This change would better reflect the various entities responsible for patient treatment and coordinated care.

However, the SIM states would argue that SAMHSA's proposal does not go far enough and would not permit networked care coordination initiatives and organizations to further share information they receive from a Part 2 program with other providers in their networks. For example, Oregon has developed Care Coordination Organizations, which are networks of all types of health care providers (physical health care, addictions and mental health care and sometimes dental care providers) who have agreed to work together in their local communities to serve people who receive health care coverage under the Oregon Health Plan (Medicaid). CCOs have the flexibility to support new models of care that are patient-centered and team-focused, and reduce health disparities. CCOs are also local and have one budget that grows at a fixed rate for mental, physical and ultimately dental care. They are accountable for the health outcomes of the population they serve and are governed by a partnership among health care providers, community members, and stakeholders in the health systems that have financial responsibility and risk. Today, there are 16 CCOs operating in communities around Oregon.

While, under SAMHSA's proposal to expand the definition of QSO, Oregon's CCOs would be able to receive Part 2 data from their Part 2 program participants without consent, they would not be able to further disclose the Part 2 data to other participants within each CCO and between other CCOs without consent, meaning SAMHSA's proposal, while helpful, does not go

far enough. Although CCOs are directed to work collaboratively to improve population health within specific regions, they are compromised in their ability to do so without the authority to effectively exchange data for individuals living in those communities. Therefore, the SIM states request that SAMHSA consider creating a new exception to the Part 2 consent requirements that permits providers that are participating in an organized integrated care network like a CCO or ACO to share information with one another and allow the Part 2 program to share information with other providers within the network. The rationale is that the providers participating in the ACO or CCO are acting as a unified collaborative provider organization, a circumstance that warrants a new consent exception to the Part 2 rules.

Issue: Research

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

Under the current regulations, the Part 2 “program director” has to authorize the release of information for scientific research purposes. Under the current regulatory framework, absent consent, organizations that store patient health data, including data that are subject to Part 2, which may be used for research (e.g. health management organizations) do not have the authority to disclose Part 2 data for scientific research purposes to qualified researchers or research organizations. SAMHSA is proposing to address this issue by expanding the authority for releasing data to qualified researchers/research organizations to other health care entities that receive and store Part 2 data, including third-party payers, HIEs, and CCOs for the purposes of research, audit, or evaluation.

Several states are in the process of developing All Payer Claims Databases (APCDs), which collect health care claims information and allow health care entities and researchers to access the data to gain a more comprehensive view of health care system performance. Select states are further along in development, such that their APCDs have the ability to integrate claims and clinical information. Given the constraints on disclosures of Part 2 records, substance abuse information is often not included in these new APCDs, thus limiting their utility in measuring health system quality and performing other health services research.

Oregon’s APCD provides an algorithm to data submitters that enables them to filter out Part 2 records by use of billing code before they submit their data to the APCD’s warehouse. Because this algorithm uses various codes as the means to identify Part 2 records, the algorithm serves to keep out of the APCD any substance abuse treatment services provided by any type of provider – not just those providers that are subject to Part 2. This leaves a very large gap in the APCD’s data; Oregon is limited in its ability to perform research that relates to the coordination of behavioral and physical health care and research related to total health care expenditures because the data are incomplete. Limiting the ability to generate and disseminate evidence on the impacts of Oregon’s coordinated care model may constrain the model’s impact over time.

SAMHSA's proposal to authorize disclosure of Part 2 data for research purposes could alleviate this problem and ensure the contribution of Part 2 data by health plans to emerging APCDs.

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

Part 2 protections include a prohibition on the redisclosure of information received directly from a Part 2 program. A pharmacy that receives electronic prescription information directly from a Part 2 program must obtain patient consent to send that information to a PDMP, and patient consent is also required for the PDMP to redisclose that information to those with access to the PDMP. Several SIM states are in the process of implementing PDMPs through regulatory and operational action and they support SAMHSA's proposal to broaden the information available through these programs.

Conclusion

Having been last updated in 1987, Part 2 is ripe for changes that will ensure that it no longer stands as a barrier to the exchange of substance abuse treatment information and more integrated delivery of behavioral and primary health care. We appreciate SAMHSA's dedication to this issue and the opportunity to submit comments as the Agency moves down this important path.

Sincerely,

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June 25, 2014

U.S. Substance Abuse and Mental Health Services Administration
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Re: Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2
Docket No. 2014-10913
Federal Register, Volume 79, No. 91, Pages 26929 – 26932

To Whom It May Concern:

I am writing to provide comment on the changes being considered by the SAMHSA to 42 CFR. Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records. I currently am the Director of Human Services for the County of Chester, Pennsylvania. The human services include the Departments of Drug and Alcohol; Aging; Mental Health, Intellectual and Developmental Disabilities; Children Youth and Families; Youth Center (juvenile detention and dependency shelter); Military and Veteran's Affairs; and our Health Choices behavioral health Medicaid managed care program. I have also served at the state and county in leadership positions in the single county and single state agencies.

The changes being considered should not be enacted. The federal confidentiality rules play a key role in ensuring safe access to essential drug and alcohol treatment services. Unfortunately, the stigma associated with addiction continues and the need for the confidentiality protection is as, if not more, necessary today as when these rules were established. This is particularly true in an era of electronic data that can easily be widely disseminated - requiring us to be more cautious, not less.

Our nation has example after example of advanced technology capabilities. To not utilize this capability to protect patient privacy is not acceptable. We know that alcohol and other drug problems result in tremendous financial and human costs. We need to ensure that we do not create any disincentives to seeking care – especially those that are entirely preventable such as protecting privacy.

The changes proposed are designed to minimize the need for the healthcare system to design patient centered records. This should not be the case. We need to maintain the strong confidentiality protections currently in place in 42 CFR. Following are responses to the specific questions posed:

- a. Applicability: Screening and brief intervention should continue to be covered under the law and this provision should not be weakened. The term "other similar pre-treatment substance abuse services" is nebulous at best and – what are these services?

- b. v Consent requirements: Individuals should retain the power to specifically decide who may receive information about their diagnosis and care. The proposed adaptations discussed in the Background are too general and would result in little real protection. This is even more concerning given the discussion of the lack of "sophisticated consent management capabilities" of the organizations and member providers. Consents should continue to require identification of the specific name, title or organization to whom the information can be released. It should also continue to specify what information can be released and for what purpose. Modifications under consideration: 1. General consents; 2. Simply requiring the provision of a list of who may access their information to the individual or; 3. Changing to only requiring consent for who may release information, are all completely insufficient protections. Therefore, modifications 1, 2, and 4 should be rejected. The inclusion of 3 as a potential modification is confusing as the current regulations require that the consent identifies who is permitted to make the disclosure. If this is intended to be the sole requirement, then it should be rejected. The entity permitted to release information should be maintained as one required component of a consent in addition to specifically identifying to whom the information may be released. The changes proposed would compromise and not maintain privacy protections.
- c. v Redisclosure: Limitations on redisclosure is a key element of the drug and alcohol privacy protections and must be maintained. The revision being considered is unclear. How would this information be differentiated? This seems to add complexity.
- d. v Medical Emergency: It is unclear why change is being proposed.
- e. v Qualified Service Organizations: The proposed revision discussed would remove an important patient confidentiality protection and should be rejected. Under current rules, patients can decide not only who receives their information, but also what information they can receive. This change would eliminate an individual's right to decide not only who gets their information, but also the extent of information that can be provided. This would essentially provide insurers/managed care organizations carte blanche access to a person's information without the person knowing or consenting not just to the release, but also the extent of the release. A payer or an Accountable Care Organization is just that - they are not providing a service to a provider and the individual should have a right to determine not only if they can receive information, but also how much information they receive.
- f. v Research: If these changes were enacted, who would be responsible for ensuring the protection of the data? There is typically some oversight of programs' compliance with confidentiality regulations, e.g. through state licensing. Who would be responsible for oversight if the authority for release is expanded? Without a clear oversight mechanism, this should not be contemplated.

The need for the protections afforded by 42 CFR has not diminished and, in fact, with the potential reach of electronic data sets, they are even more important today. We have the technological capability to do it right and we should not, nor do we need to, sacrifice these important privacy rights and protections. Weakening these protections would result in fewer people accessing care which we know will only drive up our health care, societal and human costs.

Sincerely,
Kim P. Bowman v

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Substance Abuse and Mental Health Services Administration
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RE: 79 Fed. Reg. 26929 (May 12, 2014) FR Doc. 2014-10913
Substance Abuse and Mental Health Services Administration

To Whom It May Concern:

Thank you for the opportunity to provide comments on potential revisions to the federal Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2 (Part 2 regulations). The Drug Policy and Public Health Strategies Clinic, University of Maryland Carey School of Law, (Clinic) is very interested in ensuring that consumers with substance use disorders retain their right to determine who receives information that identifies them as a substance use patient and that redisclosure of that information is limited to authorized individuals and entities. The Clinic has had extensive experience in implementing the Part 2 regulations as health delivery systems have evolved. Specifically, the Clinic has assisted treatment providers in Maryland apply and enforce the Part 2 regulations on behalf of their patients and has worked to implement the Affordable Care Act (ACA) in Maryland with a specific focus on ensuring that individuals with substance use disorders gain the full benefit of expanded insurance coverage for prevention and treatment services. The Clinic has also actively participated in Maryland's efforts to implement its Health Information Exchange (HIE) by addressing the Part 2 standards in the State's regulatory framework for HIEs. Finally, the Clinic has represented individuals who face discrimination based on their histories of drug dependence and participation in treatment and is familiar with the overt and subtle ways in which health information can be obtained and used to discriminate against individuals. Despite advances in medical care and aspirations to coordinate patient care, stigma and inequitable treatment of persons with substance use disorders persist. The need to protect the health information of persons with substance use disorders is as critical today as it was in the mid-1970s. Thus, the Clinic urges SAMHSA to not dilute the bedrock Part 2 standards as it seeks to ensure that these individuals have access to effective and coordinated care and to respond to stakeholders that seek a singular health privacy standard aligned with HIPAA standards.

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The Clinic shares SAMHSA's goal of ensuring that persons with substance use disorders gain the full benefit of integrated health care delivery systems and real-time coordination of care. Persons with substance use and mental health disorders have complex chronic health care needs that cross many provider settings and can impose significant costs on the health care delivery system. Coordinated care and access to up-to-date health care information is essential to reduce system-wide health costs and ensure that persons with substance use problems receive the best health services available. While the Clinic recognizes that some health care systems and HIEs have chosen to not invest in the development of IT systems that would allow for the inclusion of Part 2 information based on patient consent, we strongly endorse the implementation of technology solutions that would allow for the segmentation of health data and the segregation of protected health information so that consent-based disclosures of patient identifying information can be carried out. We would also support the adoption of monetary remedies to incentivize general medical facilities and other entities that receive Part 2 information to adhere to Part 2 disclosure standards. Our experience has revealed that hospitals, for example, routinely use and redisclose Part 2 information without adherence to consent standards. Real penalties may encourage such entities to implement procedures to prevent unauthorized disclosures (which would not constitute a HIPAA violation) and to implement technology solutions that would allow patients to share their health information through consent.

The Clinic provides the following responses to SAMHSA's questions.

A. Applicability of Part 2: Type of Information v. Provider

As primary care and other non-specialty care health providers are increasingly involved in the identification of problematic alcohol and drug use, it is important to provide clear regulatory guidance to identify both the providers that are subject to Part 2 and substance use activities (screening and brief interventions, diagnosis, treatment or referral to treatment) that trigger Part 2 protections. The Clinic believes that the current Part 2 "program" definition is sufficiently clear to allow health practitioners in general medical practices to determine whether the provision of substance use services is his/her primary function and, accordingly, subject to Part 2. It would be difficult to envision a health care practitioner who provides screening and brief counseling services as one of his/her preventive health services would satisfy the definition of "program;" the provision of substance use services would not constitute his/her primary function. The current standard, importantly, gives the general medical practice or practitioner the latitude to make this determination and to adjust to any changes in practice that may occur over time. Thus, the current standard seems to adequately address the stated concerns and appropriately limits Part 2 standards to those situations in which a practitioner who specializes in substance use services provides such services.

The Clinic is concerned that the proposal does not define "specialty substance abuse treatment services" and suggests that the definition of "program" would be revised without providing guidance on the proposed standard. While the proposal makes clear that screening and brief intervention information would not fall within the definition of "specialty substance abuse treatment services," additional guidance is needed to evaluate the scope of information that would be covered. Indeed, an argument could be made that screening and brief intervention information would be the type of information that consumers seek to protect as much as a diagnosis.

The proposal notes that Part 2 would still apply to “federally assisted” health care providers, but it does not indicate whether the current standards for programs or staff in general medical facilities would be amended. The Clinic would oppose the revision of the “program” definition to exclude from Part 2 coverage specialized units or designated staff within general medical practices. With the expansion of substance use services under the ACA, individuals will need to access care in settings beyond traditional treatment settings, such as federally qualified health centers and ACOs. Expanded access to services is, in fact, the goal of health care reform. The protection of this sensitive health information should **not** be based on setting in which the patient receives care.

It is unclear how the proposed modification would simplify coverage determinations. Although the proposal does not define “specialty substance abuse treatment services,” that designation is essentially coterminous with the current program definition for coverage of health care providers in general medical facilities; i.e. only those units or health care personnel that provide diagnosis, treatment or referral for treatment are subject to the regulations. Depending upon whether the “program” definition for general medical facilities is revised to delete this qualifier, the proposed standard could arguably cover more non-specialty practitioners, as the provision of “specialty services” would trigger coverage regardless of whether the delivery of those services constitutes the primary function of the practitioner or is provided by a designated unit.

The proposed revision would not, in our view, address the concerns of stakeholders that do not want to invest in strategies that allow for the integration of substance used disorder information. Basing coverage on the type of information gathered does not facilitate the incorporation of information in HIEs or simplify the work of HIT vendors, as the program and HIE would still have to address the segmentation/separation of information that pertains to specialized treatment services (however defined). General medical facilities that create or receive information relating to specialty substance abuse treatment services would still need to separate this information to ensure consent is provided for disclosure either through traditional or HIE modes of information sharing.

B. Consent Requirements

The Clinic recognizes the limitations and administrative challenges that are associated with a consent standard that requires specificity in the identification of the recipient(s) of Part 2 information.¹ At the same time, any modification of the consent standards must carefully consider the consequences of expanding consent to allow multi-partner entities to gain access to Part 2 information without the patient having an opportunity to authorize such disclosure. Many multi-partner entities will have no association with a particular patient and no need for his or her substance use treatment information, but would nonetheless gain access to Part 2 information if the consent requirement were to allow for more generalized identification of the recipient entity. Under such circumstances, unnecessary disclosure of Part 2 patient information would increase and the monitoring of redisclosure would be impossible. In our view, the importance of protecting patient confidentiality in this context overrides the administrative inconvenience to

¹ It is important to note the HIPAA contains this same level of specificity for disclosures subject to consent. 45 C.F.R. § 164.508(c)(1)(ii).

programs, health homes, ACOs and CCOs that must update consent forms and seek consent for disclosure to identified organizations as they enter the partnership.

The five-part proposal raises several questions regarding the ability of patients to control the disclosure of their information. First, when presented with a list of providers or organizations that may access their information, would the patient have the right to authorize disclosure to some but not all of the partners? Second, how frequently would the updated list of recipients be provided to the patient? Depending upon the frequency of updates, a patient's information will likely have been disclosed to an entity that the patient had no knowledge of and could have significant objections to. The proposal suggests that the patient would not be given the authority to select the partners with whom information is shared either before or after the effect. While we recognize the importance of sharing information to facilitate coordinated care, we also trust that most patients will consent to the disclosure of information when practitioners communicate the need for and value associated with disclosure of information. The proposed process eliminates the need for that practitioner-patient conversation and could result in the patient simply denying consent for the release of any patient information. Moreover, the subsequent revelation that patient information has been disclosed to an entity that the patient was not aware of and which has no need for the information could undermine trust in the provider and disrupt the therapeutic relationship.

Finally, we are most concerned with the application of the proposed standard to HIEs. The number of health care providers and payors that would have access to patient identifying substance use information via an HIE would be significant, and any participating entity could access and use the information for population health management and consumer outreach purposes. The current standards provide patients with substance use disorders greater protection of their health information in these contexts and should not be weakened at this time. Technology can and should be developed that will allow for consent-based disclosures.

C. Redisclosure

The Clinic supports the retention of the current Part 2 redisclosure provision, which seems to accomplish the goal of the proposal. From our reading of § 2.32, the current standard already allows for the redisclosure of patient health information as long as the information does not disclose the individual's status as a substance use patient; i.e., patient information may be redisclosed pursuant to consent or "as otherwise permitted" by Part 2. The identification of a person's status as a substance use disorder patient arises most frequently through the identification of the source of the data – an identified substance use disorder treatment program. Indeed, the proposal recognizes this and would not alter the current standard that information/data cannot be redisclosed if the data provenance would reveal that the person is a substance use patient.

We are also confused by the proposal which, on the one hand, is premised on the lack of data segmentation by HIEs, but which also suggests that an HIE could segment data sufficiently to separate information that identifies a patient as a substance use patient from all other health information. Such technology should be applied broadly. The Clinic supports all efforts to expedite the implementation of uniform standards and technology that would allow for the

segmentation of substance use disorder and other sensitive information and allow for consented disclosures of protected health information.

D. Medical Emergency

The Clinic would have no objection to SAMHSA conforming the regulatory standard for medical emergencies to the statutory standard, which authorizes the disclosure of patient information to meet a bona fide medical emergency. 42 U.S.C. § 290dd-2. We recommend that treatment providers, individuals in treatment and health practitioners identify factors that should be considered in making this determination and identify medical situations that meet the definition of a “bona fide medical emergency.”

That said, we would not interpret the statutory provision to authorize unconsented disclosures of information to medical personnel to “prevent an emergency.” We interpret the statute to require the existence of an actual “medical emergency.” While medical personnel should be given discretion to determine what constitutes a medical emergency, they should not be given latitude to access treatment records simply because a patient fails or refuses to disclose participation in medication assisted treatment or the use of prescription medications and hinders the practitioner’s ability to provide care or prescribe other medications. Prescription drug monitoring programs, which have been implemented in most states, will allow health providers to identify certain medications that have been prescribed to patients when providing health care services. To the extent a patient shares information about other drug use to a treatment provider, we are concerned that disclosure of such information without the patient’s consent will undermine the therapeutic relationship and should be avoided unless a medical emergency exists.

E. Qualified Service Organization

The Clinic agrees that care coordination is a function that is consistent with the types of services that are currently defined as services that may be provided to the treatment program via a qualified service organization/business associates agreement. We do not envision consumer privacy concerns if an ACO uses information in its possession to identify program patients with chronic conditions who are in need of additional health services or care coordination. Accordingly, we would support the revision of the definition of QSO, 42 C.F.R. § 2.11, to identify care coordination as among the services that may be available to the program’s patients, provided all other requirements governing QSO/business associates remain in effect. See 42 C.F.R. §2.12(c)(4).

We are also in support of the disclosure of patient information to facilitate population health management to the extent that service is limited to the assistance of patients being treated by the program. The term “population health management” can encompass many different services, including outreach to individuals who may not currently participate in treatment. We recommend that any revision to the regulations define that term so that it relates to the assistance of a program’s patients for purposes of care coordination.

We have greater reservations about allowing a payor to enter a QSOA for purposes of care coordination as this could allow the payor to access health information that is otherwise subject

to Part 2 disclosure requirements. Although the payor would be subject to Part 2 rules regarding disclosure of patient information, we have general concerns about whether payors would be inclined to overstep and use patient information in an unauthorized manner. In such circumstances, patients would have little recourse against the payor.

F. Research

The Clinic has not studied this issue sufficiently to offer comments.

G. Electronic Prescribing and Prescription Drug Monitoring Programs

Although the Clinic has not studied this issue sufficiently to address SAMHSA's request for guidance, we recommend that standards be developed to ensure that patient information is not disclosed or redisclosed to law enforcement personnel absent compliance with Part 2 requirements for criminal investigations of a program's patients. Additionally, it is important to develop privacy rules related to e-prescribing that afford all patients comparable protection for the use and disclosure of their prescription drug information if used to treat a substance use disorder, regardless of whether a Part 2 program discloses the information to a pharmacy, a physician who is not a "program" under Part 2 submits the prescription, or the patient effectively discloses his/her participation in treatment by filling a prescription at the pharmacy. In all of these situations, a patient has no choice but to disclose his or her status as a substance use patient in order to get treatment and should not be subject to potential criminal investigations by virtue of compliance with care.

Thank you for considering our comments and please contact me at the email identified below if you have any questions. We look forward to reviewing any formal proposal to revise Part 2.

Sincerely,

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Comments on SAMHSA Proposed Rule on

Confidentiality of Alcohol and Drug Abuse Patient Records

Submitted by: New York eHealth Collaborative in Collaboration with the NY State Qualified Entities (RHIOs)

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Southern Tier Health Link (STHL)
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HEALTHeCONNECTIONS
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INTERBORO RHIO
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Introduction

The NY eHealth Collaborative is a public/private partnership founded in 2006 by healthcare leaders in partnership with the NY State Department of Health. NYeC receives funding from state and federal grants to serve as the focal point for health IT in NY State. NYeC works to develop policies and standards to assist healthcare providers in making the shift to electronic health records, and to coordinate the creation of a network to connect healthcare providers statewide. The goal of NYeC is that no patient, wherever they may need treatment within the State of New York, is ever without fast, secure, accurate, and accessible information.

Currently there are 9 Qualified Entities (formerly known as RHIOs) in NY State. NY State has established a governance model that is built on a statewide collaborative process. Through that process the state has established privacy and security policy standards and technical requirements for all certified QEs and their Participants.

General Statement

In NYS sharing of SAMHSA covered data has been inhibited through the health information exchanges throughout the state based on current interpretations of the SAMSHA regulations. This is to the detriment of a whole class of patients who use such services and who are also in need of improved care coordination. It also creates a 2-tier system. In many integrated delivery networks (IDN), where SAMHSA covered data is documented in the same repositories as other health care services, the Part 2 data is available within the medical record and without additional limitations within the IDN. This is one tier. Then, for patients who receive their Part 2 services in a separate organization from other care received, the data is not shared. This is the second, and in practice, lesser, tier. HIEs offer the ability to share data across organizations so that a single organizational EMR is not the requirement for coordinated care.

- 1. Applicability of the Part 2 Regulations:** To whom and to what data should the Part 2 Regulations apply?

Applicability based on a location is possible. Applying the regulation based on the nature of the services offered is not possible at this time and will always be difficult. If SAMHSA feels compelled to maintain this extra level of restriction, beyond that of all other sensitive health information, then we strongly recommend it be facility/location based. The best solution, however, would be to acknowledge that this data is critical to good patient care and that existing HIPAA and other statutory controls protect patients adequately. Stronger enforcement and more aggressive provider education requirements (including attestations at licensure renewal) would go a long way toward reminding the health care community of its responsibilities.

2. **Consent Requirements:** Do the consent requirements under the Part 2 Regulations need to be changed to allow for substance abuse records to be exchanged through an HIE?

A simplified process is essential and should not require the patient to go back to the disclosing entity for each disclosure. In NYS, consent to access is required, thereby ensuring that the provider has received the patient's approval to use the HIE to access data. That consent is very clear about the types of data included when such an access is made so the patient has the knowledge and the right to deny access if he or she so chooses. The patient is also provided with a list of all data sources participating in the HIE and how to reference any up-to-date versions of the list.

We recommend that SAMHSA re-write the consent policy to be more in line with HIPAA requirements and to minimize the differences with standard procedures in use for all other areas of health information sharing today. Consent to access vs consent to disclosure gives the patient a powerful tool to control who sees their information.

3. **Redisclosure Prohibitions:** How can the re-disclosure prohibitions be modified to allow providers to be able to technically comply with them?

In NYS we believe we can meet the existing re-disclosure requirement by including the re-disclosure warning before any access of a patient record and/or in the "front matter" of any CCD. We suggest that a more effective approach would be regular education and training of providers and the requirement of an attestation at re-licensure that they understand the re-disclosure requirements. The greatest risk to inappropriate re-disclosure comes as more EMRs actively consume externally generated clinical information but do not tag it in such a way as to control re-disclosure. Limiting the restriction to only some data, i.e., identifying the individual as a substance abuser, sets the bar on data segmentation too high for the state of technology today. While such approaches will almost certainly work in the future, the need for data exchange *today* argues for very realistic implementation design. It is imperative that we increase efforts to improve EMR functionality and Health Information Management (HIM) policy so that future solutions can be developed.

4. **Medical Emergency Exception:** Does the medical emergency exception to the consent requirement need to be broadened or modified?

The current requirement that the Part 2 facility be notified of any break the glass event so that they can add this event to their log is an artifact of old, manual processes. Given the availability of audit trails at a health information exchange, and the ease with which the participating Part 2 provider can access those audit trails when required for any reason, including the request of a patient for a full accounting, this should suffice. Requiring the HIE to notify the Part 2 facility and for the Part 2 facility to integrate that information with the audit trails they keep is onerous and inefficient. NYS policies require that all emergency departments notify their patients of the use of break the glass access so patients are aware of such activity.

We request that the requirement for notification to the Part 2 facility be dropped.

5. **Requirements related to Qualified Service Organizations:** Do the categories of Qualified Services Organizations need to be broadened to allow for care coordination services to be performed by a QSO?

Broadening the categories of QSOs to include those who provide services to the Part 2 organization and/or those who provide services *to the patient* who has received services from the Part 2 organization would allow care coordination programs who are serving the needs of the patient to be aware of care provided by the Part 2 organization. The challenge is that we cannot expect each care coordination organization to sign a separate QSOA with each provider of services. This is an area where the HIE can be helpful by including a QSOA as part of its over-riding participation agreement with each member of the

exchange. All organizations participating in the exchange can then have a level of trust that all other members have signed and do abide by the QSOA.

6. **Ability to conduct research using data that is subject to the Part 2 Regulations:** Should the ability to use Part 2 data for research be expanded to include health care entities that receive and store Part 2 data?

Research criteria that hold for all PHI should be applied to use of Part 2 data for research. If the data is de-identified and has IRB approval consent would not be required and the data can be used for health services research by the health care entities that receive and store Part 2 data. With use of any identified data (PHI or Part 2) the patient's consent should be required unless waived by an IRB.

We are available to discuss any of these comments at any point in the process. Please contact Cynthia Sutliff, Director of Policy at csutliff@nyehealth.org if you have any questions.

patientprivacyrights

Ensuring you control who sees your sensitive health information

June 24, 2014

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RE: Comments on a Proposed Rule concerning the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, [42 CFR Part 2](#) by the [Substance Abuse and Mental Health Services Administration](#)

ATTN: PrivacyRegulations@SAMHSA.hhs.gov.

Dear Sir or Madam:

Patient Privacy Rights Foundation (PPR), a 501c3 non-profit organization is pleased to submit comments on the proposed changes to 42 CFR Part 2.

PPR is the world's leading consumer health privacy advocacy organization, with over 12,000 members in all 50 states. Our mission is to restore personal control over the most sensitive information, data about our minds and bodies, in electronic systems. With that mission in mind, PPR also founded and leads the bipartisan Coalition for Patient Privacy, representing 10.3 million US citizens who want to control the use of personal health data in electronic systems. In 2007-2008, PPR developed a Privacy Trust Framework, [75+ auditable criteria](#) that measure how effectively technology systems protect data privacy. The Framework can be used for research about privacy and to certify HIT systems. In 2011, PPR created the first annual [International Summit on the Future of Health Privacy](#), co-hosted by Georgetown Law Center.

I have been a practicing boarded adult psychiatrist for 40 years, was the Chair of the Department of Psychiatry at Brackenridge Hospital in Austin, Texas for 11 years, am a former President of the Texas Society of Psychiatric Physicians, and am the Founder and Chair of Patient Privacy Rights.

The elimination of our human and civil rights to health information privacy, i.e., the elimination of our rights to give consent and control the use of sensitive personal health information by the Amendments to the HIPAA Privacy Rule in 2002 led me to found PPR in 2004.

During the ten years of our work at PPR, the strong federal privacy protections in 42 CFR Part 2, and in the federal regs known as "7332" that grant members of the military the right to segment certain sensitive data and prevent it from being shared outside the military health system, have been critical bulwarks and powerful federal precedents for health privacy rights.

In the face of ever-increasing pressure from industry and the federal government to eliminate privacy rights and create a health data surveillance system, the preservation of privacy protections in 42 CFR Part 2 stand as a shining example of the data privacy protections patients need to trust healthcare institutions and physicians. In fact, privacy is essential for quality treatment and for patients' willingness to participate in electronic records systems.

Despite strong privacy-protective laws in all 50 states for genetic information, mental health and substance abuse information, and information about STDs; despite Constitutional protections for health information privacy; despite strong privacy protections in tort law, common law, and medical ethics; and despite patients' universal expectations to control the use of personal health information, the US has ended up with health technology systems designed to serve the massive hidden US health data broker industry.

The "world's largest information, technology, and service company" states "We have one of the largest and most comprehensive collections of healthcare information in the world, spanning sales, prescription and promotional data, medical claims, electronic medical records and social media. Our scaled and growing data set, containing over 10 petabytes of unique data, includes over 85% of the world's prescriptions by sales revenue and approximately 400 million comprehensive, longitudinal, anonymous patient records." The company buys "proprietary data sourced from over 100,000 data suppliers covering over 780,000 data feeds globally." The company sells health data to "5,000 clients," including the US Government. See:

<http://www.sec.gov/Archives/edgar/data/1595262/000119312514000659/d628679ds1.htm>

Clearly existing strong US laws like 42 CFR Part 2 must not be weakened, but strengthened and extended to cover all health data.

Many commenters on June 11th claimed that HIPAA protects privacy. If that is so, how could the vast US health data broker industry even exist? Clearly data privacy protections in US law and medical ethics were not built into current health technology systems.

Alan Westin's research showed that 35-40% of the United States public has been health privacy intense for at least 20 years, see: <http://patientprivacyrights.org/wp-content/uploads/2013/08/Westins-Slides-from-2011-Summit.pdf>.

The consequence having of no health privacy in the US is that 37.5 million people a year take action and hide health information, which in turn causes bad health outcomes and bad, incomplete data for research. And many millions more people – 5 to 6 million a year – delay or avoid treatment entirely, including for mental illness, cancer, and sexually transmitted diseases. The leaky, leaky US health IT system causes 40-50 million people every year to risk their health and lives.

The US electronic healthcare system was built for data mining and data theft, not to serve patients' urgent needs.

We need to retain all our strong laws, and fight to restore the privacy patients require. SANHSA should stand firm and continue its long history of protecting patients with substance abuse and mental health diseases.

Sincerely,

Deborah C. Peel, MD
Founder and Chair, Patient Privacy Rights

**The Substance Abuse and Mental Health Services Administration Public Listening Session
Comments**

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

A Proposed Rule by the Substance Abuse and Mental Health Services Administration, U.S.
Department of Health and Human Services

Document Citation:

79 FR 26929

Document Number:

2014-10913

Applicability of 42 CFR Part 2

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

FR Citation: 79 FR 26930

Questions:

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

Public Comment Field:

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

ANSWER: All health care provider organizations, HIEs, CCOs, HIT vendors, and integrated care organizations will handle sensitive substance abuse data, regardless of whether they advertise substances abuse services or not. That information needs to be protected the same way everywhere. **The privacy protections for sensitive substance abuse treatment records/information should be expanded to follow the data everywhere it is used or disclosed, in every kind of health facility, and the protections should apply to all substance abuse treatment services, not just certain specified services.**

Patient Privacy Rights (PPR) strongly supports defining “covered information” as any and all information about substance abuse, wherever it is held or used. The very broad requirements in 42 CFR Part 2 protect all information about substance abuse. 42 CFR Part 2 does not allow any exceptions to protecting substance abuse data/information based on the services provided, or on type of provider or institution.

All substance abuse data must be protected, whether the data is collected for screening, for brief intervention, or for any other pre-treatment or other services. It is impossible to draw a line based on where services for substance abuse treatment are performed or what the services are, because people with substance abuse disorders are treated in every type of medical and/or healthcare facility. Therefore, **the information about substance abuse must have privacy protections (privacy meta-tagging and data segmentation functionality) everywhere it is used or held.**

This means every EHR must also have the capacity to handle and protect substance abuse information as required by 42 CFR Part 2, because every health facility that treats patients will have patients with substance abuse disorders. The ability to meta-tag data for privacy enables sensitive substance abuse data to be segmented from other medical data. This functionality is

also essential to ensure that patient consent before re-disclosure is enforced. For EHRs to function effectively, they must all have the capacity to handle and segment sensitive data, as required by HITECH, and as required long before HITECH by strong state and federal laws including 42 CFR Part 2, and medical ethics—since people with substance abuse disorders are treated in every kind of healthcare setting.

EHRs fail if data cannot be segmented. It's astonishing that most EHR vendors ignored US law and medical ethics when designing their products. Not only do EHRs need to be able to segment sensitive data, this same functionality is also required for handling erroneous data. **Technology to segment patient data is essential both for patient safety and for privacy.** It's obvious that EHRs must have the functionality to segment data; otherwise an EHR would endlessly disclose erroneous data, which could harm patients.

The HIT industry continues to pretend that no EHRs or technology comply with the requirements of 42 CFR Part 2, or that it would be too expensive or difficult to comply. But industry has also long ignored the robust open source behavioral health EHR built by the NDIIC, which has very detailed consent and segmentation technologies that enable patients to choose which parts of their PHI to disclose to whom and for how long (and the EHR fulfills all the other requirements of 42 CFR Part 2). Over 4 million electronic health records have been exchanged in 22 jurisdictions and 8-9 states. HHS held a Consumer Choices Technology Hearing in June 2010, and the NDIIC technology was one of the 7 privacy-enabling technologies that were demonstrated.

However, EHR and HIT vendors continue to lobby to oppose longstanding patient privacy rights and oppose building the capacity for data segmentation and meta-tagging data into their products. The lack of these crucial functions forces physicians and health professionals to create dangerous “work-arounds” outside the EHR to be able to deal with sensitive or erroneous data, introducing more complexity, creating more opportunities for errors, jeopardizing patient safety, and even creating a need to go back and keep some records on paper.

Privacy protections must follow the data so that patients can give consent to selected health professionals to see and use selected parts of their health data, and prevent access by those who do not need to see or use certain data. Every person on the patient's care team does not require or want the same level of access to all aspects of the patient's health. If everyone on the team has access to the entire patient record, then everyone on the team is also liable for the entire record and the patient's treatment, regardless of whether they have knowledge and expertise about each diagnosis and treatment.

The patient's ability to choose which health professionals can see and use substance abuse data is essential for integrated care settings and ACOs because some team members will have negative reactions to people with substance abuse disorders.

In addition, most of the team that is treating the patient's other diseases has no need to know every detail of the patient's substance abuse treatment. Patients simply do not trust every health professional to the same degree. Today 1/8 patients hide or omit information to keep certain information private, when they know they can't control access to their records. If integrated care settings do not permit patients to control access to their substance abuse data, the result will be the same. And when patients hide or omit data, they put their lives and health at risk. The lack of patient control over access to PHI causes 37.5 million people every year to

hide information. Trust and personal control over access to PHI is particularly critical for effective treatment of substance abuse integrated settings.

Decisions about who should have access to substance abuse data should be made by the patient in consultation with the admitting physician and/or with the health professional responsible for the substance abuse treatment, which is the same way treatment teams worked using paper records systems. Access to sensitive information is shared with consent when necessary and appropriate, only with selected individuals on the treatment team.

2) Would this change address stakeholder concerns?

ANSWER: No, but stakeholders don't have rights to obtain information about substance abuse without patient consent.

Patient Privacy Rights strongly supports the rights of patients to control the use and disclosure of substance abuse information. 42 CFR part 2 privacy protections should not be weakened for the convenience of stakeholders, HIEs, or integrated care teams; or be weakened because most EHR vendors have long ignored US laws that require health record holders to protect substance abuse data in very specific ways. It's time for the EHR vendors to step up and build products that comply with the law and patients' rights.

3) Would this change raise any new concerns?

ANSWER: Yes, if SAMHSA weakens the 42 CFR Part2 privacy protections as proposed by narrowing the broad directive to protect sensitive information about substance abuse information (wherever it is held) so that the protections only apply to certain facilities or to certain services, then even more people with substance abuse disorders will delay or avoid treatment and/or hide information, causing bad data and bad health outcomes.

Currently 40-50 million people every year hide information or delay or avoid treatment for cancer, mental illness or STDs because they know that their sensitive health data is not private. Surely SAMHSA should not weaken the 42 CFR Part 2 regulations, knowing that the consequence will be to increase the number of people with substance abuse disorders who act to protect their privacy by hiding information, or delaying or avoiding substance abuse treatment. See: <http://patientprivacyrights.org/wp-content/uploads/2010/08/The-Case-for-Informed-Consent.pdf> for statistics.

EHRs should not drive even more people to act in ways that put their health and lives at risk. When EHRs are built to ensure patients' privacy rights, then patients will be willing to disclose the right sensitive information to the right persons on their integrated care team at the right time.

Consent Requirements

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

1. Allow the consent to include a more general description of the individual, organization, or

health care entity to which disclosure is to be made. **NO**

2. Require the patient be provided with a list of providers or organizations that may access their information, and be notified regularly of changes to the list. **NO**

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

4. Require that if the health care entity permitted to make the disclosure is made up of multiple independent units or organizations that the unit, organization, or provider releasing substance abuse related information be specifically named. **NO**

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

FR Citation: 79 FR 26931

Questions:

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

Public Comment Field:

1) Would these changes maintain the privacy protections for patients? **NO**

ANSWERS: No to 1, 2, and 4. Yes to 3 and 5.

It is critical for patients to know exactly who is in charge of their treatment, who is part of their treatment team, and who discloses their PHI. The name of a data discloser should be easily available.

Part of the problem is that health data holders prefer to use written, paper consents:

According to SAMHSA, "These organizations have a large and growing number of member providers and they generally do not have sophisticated consent management capabilities. Currently, a Part 2 compliant consent cannot include future un-named providers which require the collection of updated consent forms whenever new providers join these organizations."

SAMHSA could mandate the use of robust independent electronic consent tools. Patients need one place to set their own rules for the use of their PHI, so anyone who wants the data could automatically/electronically check with our consent management system and either is granted access or ping us for any exceptions to our data use rules. It is essential to create technology to improve patients' experiences with healthcare systems.

If the name of the person who will be responsible for the patient's treatment at a new facility or organization is not yet available, the name of the entity may be temporarily used instead to receive the disclosed records. Once the patient arrives at the entity, the name of the specific person responsible for treatment should be given to the patient and designated in the EHR as the admitting physician or health professional.

All technology systems authenticate all users, so there is no need to provide lists of possible users or organizations that may or may not access patient data when audit trails of every access are logged and easy to provide automatically in real-time using patient portals. This is a right that HITECH granted to patients and is known as an "Accounting for Disclosures" (A4D), that industry has blocked since 2009. **SAMHSA could mandate that all entities that hold or use substance abuse data make all disclosures open, transparent, and accountable to patients by offering patients electronic consent tools and giving patients access to real-time lists of A4Ds as HITECH required, enabling substance abuse data to be protected and disclosures to be**

automated.

It is also critical for patients to know exactly who has accessed their information and specifically which information was accessed. All staff must be authenticated by EHR systems in order to use the system and an accounting of all users and which PHI they accessed can be provided to patients easily and automatically.

Being “fully informed” of lists of possible data users means not being accurately informed and violates the privacy protections 42 CFR Part 2. First, patients have the right to control the use and disclosure of PHI about substance abuse; and current technology systems are required to authenticate users, log all access, and audit logs show exactly which data was used or disclosed by whom. Second, technology makes it easy to automate electronic real-time patient access to an Accounting for Disclosures, ie to the list of users and what data they used.

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

ANSWER: No, but 42 CFR part 2 privacy protections should not be weakened for the convenience of stakeholders, HIEs, health homes, ACOs, CCOs, or integrated care teams; or be weakened because most EHR vendors have long ignored US laws that require health record holders to protect substance abuse data in very specific ways. It’s time for the EHR vendors to build products that comply with the law and patients’ rights.

3) Would these changes raise any new concerns?

ANSWER: Yes. SAMHSA accepts at face value industry assertions that obtaining paper consent is laborious and that they “generally do not have sophisticated consent management capabilities”. Industry is simply asking SAMHSA and the public to accommodate using poorly-designed EHR and HIT systems that deprive patients of their rights to protect PHI, rather than build or use existing open source technologies for consent, patient portals, BB+, Direct Secure email so we can email our physicians, A4D, or data segmentation. Technology should serve patients’ needs, not industry’s needs.

Redisclosure

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

FR Citation: 79 FR 26931

Questions:

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

Public Comment Field:

I found this section hard to understand.

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

ANSWER: If SAMHSA's intent is to enable PHI--- such as certain specific lab results, other tests, treatments, or information from a physical exam or history that isn't related to a patient's substance abuse disorder---to be **redisclosed** without patient consent, if the data provenance was not from a substance abuse treatment facility, PPR supports that intent. If SAMHSA's intent is also to separate substance abuse-related PHI from non-substance abuse-related PHI, PPR agrees that could be done by meta-tagging the substance abuse-related data and data provenance for privacy.

SAMHSA seems to expect that meta-tagging both data and documents for privacy will make compliance with 42 CFR Part 2 and re-disclosure of some PHI simpler and clearer for industry and patients to understand when using EHRs and HIEs. If that is the intent, it builds on both the PCAST Report of December 2010 and also on the recently proposed certification standard for meta-tagging PHI in behavioral health EHRs for privacy to comply with Stage 3 Meaningful Use voluntary criteria, slated to go into effect in 2017. If we correctly understand SAMHSA's intents about re-disclosure of data, then PPR agrees with the proposals for technical solutions, which also require the ability to segment data.

2) Would these changes maintain the privacy protections for patients?

ANSWER: If we correctly understood what SAMHSA proposed, then PPR agrees these methods are one way to maintain data privacy protections for patients.

Medical Emergency

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

FR Citation: 79 FR 26931

Questions:

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

Public Comment Field:

Patient Privacy Rights agrees that the critical piece is to rely on the expertise of the health professional who handles the emergency. That person should be given wide latitude to decide what poses an "immediate threat" to self or others and what requires "immediate intervention". The idea that emergencies can be prevented may be another way of saying the same thing, but that is not clear. "Immediacy of threat and immediate need for intervention" seems a much clearer way to characterize the decision.

The situation about what constitutes an immediate threat to life and the immediate need for

intervention with someone who is intoxicated also should depend on the discretion and judgment of the health professional. Intoxication can be life-threatening or may not be, and a physician can figure that out with lab tests and physical exam. Not being able to give consent does not necessarily mean that intoxication is an immediate threat to life or requires immediate intervention.

Use cases that are cut and dried are easy, such as coma. But most decisions must be made based on the status of a particular individual.

PPR recommends not mandating a list of situations that constitute immediate threats and must be acted upon; i.e., do not create a 'duty to act'.

Qualified Service

SAMHSA is analyzing the regulations to identify options for allowing Part 2 data to flow to health care entities for the purpose of care coordination and population management while maintaining patient protections. One potential solution includes expanding the definition of a qualified service organization (QSO; § 2.11) to explicitly include care coordination services and to allow a QSO Agreement (QSOA) to be executed between an entity that stores Part 2 information, such as a payer or an ACO that is not itself a Part 2 program, and a service provider.

FR Citation: 79 FR 26931

Questions:

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

Public Comment Field:

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

PPR already explained in detail why allowing the use of Part 2 data for care coordination, whether it is designated a QSO or not, is a very bad idea. Because Part 2 data is extremely sensitive, violating patients' rights to selectively share that information will drive patients with substance abuse disorders away from treatment in ACOs, integrated care settings, and every other setting where data is shared for population health management without consent. See our extensive comments in the section on Applicability of 42 CFR Part 2.

Although the first HIPAA Privacy allows broad disclosure of PHI without consent for population health, research, public health, and law enforcement uses, these broad disclosures were never debated by the public at large. The public regards all use of PHI to answer questions about health as "research," which they believe should only take place if they consent. The US public strongly opposes the use of PHI for 'research' of any kind without consent. See Alan Westin's study for the IOM about public attitudes about research use of personal health information without consent at: <http://patientprivacyrights.org/wp-content/uploads/2010/01/WestinIOMSrvyRept.pdf>

Some key statistics from Westin's study for the IOM: Only 1% of people would agree to unfettered research use of their health data without consent. Even with IRB approval and the use of de-identified health data, still only 19% of people would agree to use of their health data without consent.

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

Please see our detailed comments in the section on Applicability of 42 CFR Part 2.

97% of patients believe their health data belongs to them and they should control its use. AHRQ convened 20 focus groups across the US in 2009 and found that the majority of people agreed that there is no need for one-size-fits-all policies to control the use and disclosure of PHI; they expected to be able to make individual decisions. A majority believes their medical data is “no one else’s business” and should not be shared without their permission. This belief was expressed not necessarily because they want to prevent some specific use of data but as a matter of principle. Participants overwhelmingly wanted to be able to communicate directly with their providers with respect to how their PHI (protected health information) is handled, including with whom it may be shared and for what purposes. See study at:

<http://healthit.ahrq.gov/sites/default/files/docs/citation/09-0081-EF.pdf>

Research

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

FR Citation: 79 FR 26932

Questions:

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

Public Comment Field:

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

ANSWERS:

This proposal violates the strong rights patient have to control the use of sensitive Part 2 data. All the entities that SAMHSA proposes to release data to are not organizations that patients know or trust with sensitive personal data about substance abuse diagnoses and treatment. Many vulnerable populations have long memories of abuse at the hands of researchers, including African Americans (Tuskegee), mentally ill people, prisoners, and those with low IQs.

No matter what legal duties or responsibilities or other arrangements are made so healthcare entities can release data for research to third parties, HIEs, HMOs, care coordination organizations or umbrella organizations, US patients will never support this kind of hidden,

coerced, deceptive use of their Part 2 data without consent. The qualifications of the research organizations and researchers do not outweigh the public's needs and expectations for privacy, autonomy, and respect. The only way the majority of US patients are willing to participate in research is if they are asked openly for consent about a particular project or projects and are informed about the results of the research. The US public simply does not trust researchers or organizations that steal, take, or use their data without consent.

Addressing Potential Programs (PDMPs)

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

Preamble FR Citation: 79 FR 26932

Questions:

- How do pharmacy information system vendors anticipate addressing this issue? Are there specific technology barriers SAMHSA should take into consideration?
- Are there other concerns regarding 42 CFR Part 2 and PDMPs? Please describe relevant use cases and provide recommendations on how to address the concerns.
- Are there patient concerns about the impact of e-prescribing and PDMPs on their privacy?

Public Comment Field:

KEY ANSWER: **Yes, patients are very concerned about the lack of privacy of e-prescribing and of prescriptions in PDMPs.** Many patients simply refuse to take effective, needed medications knowing that it is impossible to keep any prescription private in the US, even if you pay cash. Every prescription in the nation has been sold every night for over 25 years. IMS Health Holdings is the largest health data prescription broker in the world.

I am not aware of barriers in 42 CFR Part 2 that prevent prescriptions from being tracked in state PDMPs.

GENERAL ANSWERS:

I don't think that SAMHSA has all the correct facts about how PDMPs obtain prescriptions. I am not aware of any states where pharmacies have to get consent from patients to send controlled substance prescriptions to the state's PDMP. Patients apparently have no choice about their controlled substances prescriptions being tracked via state PDMPs.

I am most familiar with how the Oregon PDMP works. The state of Oregon requires all controlled substance prescriptions to be directly entered into the state's PDMP; patient consent is not required for pharmacies to add controlled substance prescriptions to the data base. Do state or federal laws preempt 42 CFR Part 2 redisclosure prohibitions? Clearly 42 CFR Part 2 alone does not prevent state law enforcement access to state PDMPs either.

I was a legal expert for the ACLU in a battle over law enforcement access to the Oregon PDMP. <https://www.aclu.org/technology-and-liberty/oregon-prescription-drug-monitoring-program-v-drug-enforcement-administration>

Oregon passed a state law requiring stronger data privacy protections than federal law requires for access to the data. The case is called OREGON PRESCRIPTION DRUG MONITORING PROGRAM, an agency of the STATE OF OREGON, Plaintiff, v. UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, an agency of the UNITED STATES DEPARTMENT OF JUSTICE, Defendant, in US District Court, District of Oregon, Portland Division, Case No.: 3:12-cv-02023-HA.

Many state Prescription Drug Monitoring Programs (PDMPs), *not* including Oregon's PDMP, currently allow access to access identifiable patient prescriptions for controlled substances by law enforcement, the Drug Enforcement Agency (DEA), and other government agencies. This case showed the DEA's intent to have full access to all prescriptions for controlled substances in all state PDMPs, despite Americans' broad rights to health information privacy^{1,2} and despite specific privacy rights that law enforcement requests for information in Oregon PDMP must be pursuant to a valid court order.³

Physicians' ethical and professional duty of confidentiality exists precisely to protect the kind of sensitive medical information at issue in this case. Easy law enforcement access to confidential and sensitive prescription records has adverse effects for both patients and doctors, and violates the privacy that most patients and practitioners expect for protected health information. State PDMPs, including the Oregon PDMP potentially could contain sensitive information on a large percentage of residents, risking the exposure of their sensitive prescription records via data breach, theft, misuse, fraudulent use, and harms such as extortion or reputation harm. Data bases that contain sensitive personal health information are extremely attractive targets because health information is the most valuable personal information in the Digital Age. Social Security numbers and other types of personal information sell online for far less.⁴

Moreover, the website of the Oregon Prescription Drug Monitoring Program makes strong representations about the privacy and security of prescription records and explicitly assures patients that law enforcement can only access those records with a court order based on probable cause.

A district court judge ruled in February 2014 that Oregon patients have a reasonable expectation of privacy in their prescription records and that law enforcement must obtain a warrant in order to search such information. Most states do not require warrants for access to their PDMPs like Oregon does.

Since controlled substance prescriptions are now tracked in almost every state in the US, the treatment of addiction, chronic pain, ADHD, and the use of steroids for hormone replacement

¹ "The right to be let alone is the most comprehensive of rights and the right most valued by civilized men. To protect that right, every unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation of the [Constitution]." *Olmstead v. United States*, 277 U.S. 438, 478, 48 S.Ct. 564, 572 (1928) (Brandeis dissenting)

² "In fact, the constitutionally protected right to privacy of highly personal information is so well established that no reasonable person could be unaware of it." *Sterling v. Borough of Minersville*, 232 F.3d 190, 198 (3rd Cir. 2000).

³ Oregon [prescription Drug Monitoring Program, see:

http://www.orpdmp.com/orpdmpfiles/PDF_Files/PDMP_FactSheet_2012_v1.1.pdf

⁴ ABC TV story

therapies have been “criminalized,” i. e., instead of that information being dealt with by treating health professionals, law enforcement has access to all data in most states.

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June 25, 2014

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

**Re: Comments on the Confidentiality of Alcohol and Drug Abuse Patient
Records Regulations, 42 CFR Part 2. FR Doc. 2014-10913.**

Dear Ms. Tipping,

I write on behalf of the Tanana Chiefs Conference (TCC) to comment on the Substance Abuse and Mental Health Services Administration's (SAMHSA) Notice of Public Listening Session concerning the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 C.F.R. Part 2 (the Notice).¹ Thank you for the opportunity to respond to the Notice.

¹ 79 Fed. Reg. 26,929 (May 12, 2014).

TCC provides health care services to Alaska Natives and other eligible individuals pursuant to a compact and funding agreement with the United States Indian Health Service. We provide care to approximately 12,000 patients in the TCC region and operate a large clinic in Fairbanks (Chief Andrew Isaac Health Center), a crisis respite house for the chronically mentally ill, an alcohol/substance abuse recovery camp, a patient hostel, and 23 smaller village clinics.

Chief Andrew Isaac Health Center is a primary care facility providing health care services on an out-patient basis to eligible beneficiaries of the Indian Health Service. Clinic staff includes physicians, physician assistants, family nurse practitioners, nurses, and pharmacists committed to comprehensive quality health care, including both acute and chronic services, health education, and wellness promotion. TCC provides limited outpatient counseling services to address child, adolescent, and family community mental health problems; information and referral to other outpatient and inpatient programs; and outpatient psychiatric services to beneficiaries in the TCC area. In addition, TCC provides mental health and substance abuse counseling for rural communities throughout the TCC region through a network of professional providers.

TCC provides prevention activities to address substance abuse and associated problems through prevention/education, outreach, continuing development of local aftercare support services, and community capacity. TCC provides services and support to the Recovery Camp program for residential treatment to individuals and families for substance abuse treatment. TCC also provides outpatient substance abuse services to the Upper Tanana Region.

I. Discussion.

TCC supports the proposed changes discussed on the June 11, 2014, listening session and identified in the Notice, particularly those that will make it easier for providers to share patient information for legitimate medical purposes within a patient's medical support network. At the time the Part 2 regulations were promulgated, substance abuse treatment was often provided within a single health practice or facility: a treating emergency room physician, a detox or rehabilitation center, a psychiatric or other mental health office, etc. But as SAMSHA correctly notes, "new models of integrated care . . . are built on a foundation of information sharing to support coordination of patient care, the development of an electronic infrastructure for managing and exchanging patient data, the development of prescription drug monitoring programs and a new focus on performance measurement within the health care system."²

Like many other providers nationwide, TCC falls within these latter categories, having moved towards a holistic, patient-centered treatment approach that coordinates treatment of acute conditions with enhanced preventive and wellness services, behavioral health care, and overall lifestyle changes designed to promote good health. This is

² *Id.* at 26,929.

particularly important in the case of patients with substance abuse issues, whose drug or alcohol problems can lead to medical emergencies (drunk driving accidents or overdoses), treatment for long-term health problems (hepatitis or cirrhosis), and a need for behavioral health care (cessation services or rehabilitation). Although TCC fully appreciates the necessity of protecting patient privacy and health information, the Part 2 requirements as currently drafted make it difficult for provider types to share necessary medical information within these expanded networks and provider associations. TCC therefore supports the following proposals in the Notice that address these concerns.

1. Relaxing Consent Requirements.

Part 2 currently requires providers to draft patient disclosure consent forms with a very high level of specificity, despite the fact that the consents may well change depending upon the patient's specific condition. However, patients with significant substance abuse issues often have complex medical needs that make it difficult to pinpoint the specific providers or facilities they will need to visit for a given condition. They are also comparatively more likely to present in need of emergency (or other) services in conditions where they cannot provide an informed consent due to intoxication or unconsciousness. TCC therefore agrees with SAMHSA's proposal to authorize providers to proactively present patients with lists of the staff and organizations that might eventually need to access the patient's Part 2-covered information and to regularly notify TCC of changes to the list.³ This will ensure that patients remain aware of where their information might be sent and have an opportunity to object or ask questions accordingly while also giving providers the flexibility to disseminate medically-relevant information as necessary to best provide care in various circumstances.

2. Clarifying Redislosure Rules.

As SAMHSA correctly identifies, many provider electronic health record (EHR) systems do not support data segmentation. Providers are often required to choose between keeping alcohol- and drug-abuse patient records separate from the rest of the patient's medical record or apply Part 2 protections to the entirety of any patient records containing information subject to Part 2.⁴ This is not only administratively burdensome, but it can lead to delays in the disclosure of relevant, non-substance abuse related medical information, such as medication allergies or current drug treatments. TCC therefore supports SAMHSA's proposed clarification that the prohibition on redislosure only applies to information that would identify an individual as a substance abuser, while still allowing other health-related information shared by the Part 2 program to be redislosed, if legally permissible.⁵

³ *Id.* at 26,931.

⁴ *Id.*

⁵ *Id.*

3. Expanding the Definition of a Qualified Service Organization

SAMHSA is analyzing the regulations to identify options for allowing Part 2 data to flow to health care entities for the purpose of care coordination and population management while maintaining patient protections. One potential solution SAMHSA has identified includes expanding the definition of a qualified service organization to explicitly include care coordination services and to allow a QSO Agreement to be executed between an entity that stores Part 2 information and a service provider. TCC strongly supports this proposed change. It would be extremely beneficial to TCC's patient population if substance abuse providers and other providers could more easily coordinate patient services. Many of TCC patients believe this should be occurring, and many times TCC must explain to its patients the barriers in the law that require consent even for care coordination.

4. Medical Emergencies.

The current Part 2 medical emergency exception at 42 C.F.R. § 2.51 states that covered information may be disclosed without patient 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." As SAMHSA notes, though, the actual statute says that records may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency.⁶ SAMHSA therefore proposes to redraft the exception to make it closer to the statutory language and to give providers more discretion as to when a bona fide emergency exists (such as instances where the provider seeks to *prevent* a medical emergency or to share information with a detoxification center when a patient is unable to provide informed consent due to their level of intoxication). SAMHSA additionally seeks comment concerning the definition of "medical emergency."⁷

TCC strongly supports additional flexibility in this area. The current regulatory standards focus entirely on imminent medical status, essentially limiting information disclosure to immediate emergencies such as a patient in cardiac arrest. But as SAMHSA identifies in the Notice, there are other instances where such disclosure may be necessary to proactively prevent emergencies or, as is often the case with substance abusers, the patient cannot provide coherent consent. TCC would go so far as to support a general treatment exception similar to the HIPAA treatment exception. However, short of that we suggest that SAMHSA promulgate emergency disclosure language along the lines of the following:

Medical Emergency. A provider may disclose information covered by Part 2 when, in the opinion of the attending or treating provider, disclosure

⁷ *Id.*

is medically necessary to prevent a potential bona fide medical emergency or treat an existing medical emergency. In such situations, patient consent shall not be necessary if the provider determines that obtaining consent would endanger the health of the patient or that the patient is intoxicated or otherwise incapable of providing informed consent. For the purposes of this provision, a "medical emergency" is defined as an event that would require emergency room treatment or which could otherwise result in death, disability, or other permanent injury to the patient.

We believe that this will maintain patient privacy while offering providers the flexibility to share necessary information with one another in emergency circumstances.

II. Conclusion.

The Part 2 regulations are essential to ameliorate the stigma associated with substance abuse and ensure that the fear of prosecution does not deter people from entering treatment. We therefore commend SAMHSA's recognition of the fact that innovations in health care delivery require a reevaluation of certain aspects of Part 2 that might be outdated or which, in practice, do not address these goals. Adopting the suggestions discussed above will help adapt the Part 2 regulations to meet new modes of patient care.

We appreciate the opportunity to comment on the Notice and looks forward to a continued open dialogue with SAMHSA on issues related to Part 2.

Sincerely,

SONOSKY, CHAMBERS, SACHSE,
MILLER & MUNSON, LLP

By: Marissa K. Flannery Æ



June 25, 2014

Pamela Hyde
Administrator
U.S. Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
42 CFR Part 2
Docket Number 2014-10913

Dear Ms. Pamela Hyde,

I am submitting comments on behalf of the members of Medicaid Health Plans of America (MHPA). MHPA is the leading national trade association solely representing Medicaid managed care plans, ranging from multi-state, for-profit plans to small, non-profit plans. MHPA's 117 health plan members serve the nation's poorest, most vulnerable population across 33 states and D.C. MHPA plans proudly manage the care of over 18 million Medicaid enrollees, through the use of innovative programs that keep individuals and families healthy, manage chronic diseases, and avoid expensive hospital stays.

We appreciate the opportunity to respond to the Substance Abuse and Mental Health Services Administration (SAMHSA) request for public comment through the Federal Register notice on whether the Agency should make changes to the current rules at 42 CFR Part 2 regarding Confidentiality of Alcohol and Drug Abuse Patient Records. Section 42 CFR Part 2 currently applies to federally-funded programs or entities that "hold themselves out as providing, and provide, alcohol or drug abuse diagnosis, treatment or treatment referral." SAMHSA is considering options for defining what information is covered under this rule. These regulations were last updated in 1987, and SAMHSA acknowledges that the rules do not account for significant changes in the U.S. health care system. MHPA recommends 42 CFR Part 2 be defined in a way that mirrors HIPAA's existing regulations and laws as it relates to substance abuse treatment to establish consistency and help reduce any barriers or confusion when plans and providers are trying to effectively coordinate care. Some points that should be considered:

- The current 42 CFR Part 2 rules do allow communication between providers but they mandate that written consent must include the name of the individual or the organization to whom information can be disclosed, along with a lot of additional information, making it challenging to obtain this consent and creating barriers to member centric, integrated approaches to care, which are part of our current health care framework.
- The 42 CFR Part 2 increases administrative burdens on the substance abuse treatment providers since the privacy requirements are not consistent with other existing health information privacy rules and there are anti-discriminatory rules that address this issue.
- The population that falls under the current regulations often has comorbidities of medical diagnoses with mental health and substance abuse and would benefit the most from

coordination of care that is available to all other populations. However, the current consent requirements in 42 CFR Part 2 make these goals very challenging and at times impossible.

- For example, when members need emergency substance abuse treatment, it can be difficult to obtain consent, but these same members could be medically harmed if the provider caring for an acute emergency does not have access to the information that the patient has received treatment for substance abuse.
- Members with severe and persistent mental illness are known to die 25 years younger than their peers without SPMI, and 42 CFR Part 2 rules make it likely that someone who is hospitalized for behavioral illness could be treated without the provider's knowledge of the member's physical health problems or medications.

Given these considerations, MHPA provides the following recommendations on how 42 CFR Part can be aligned with HIPAA.

Recommendations:

- HIPAA allows disclosures among providers for the treatment of a patient, and 42 CFR Part 2 should be updated to align with HIPAA and allow similar disclosures for the treatment of substance abuse.
- 42 CFR Part 2 should also be revised to include a consent exception for payment as HIPAA does. Under current rules, payment may be delayed or denied because the provider or the insurer cannot get the necessary signed consent from the member. Health plans have strict policies regarding HIPAA compliance and security of protected health information (PHI). The information needed to process a claim, whether medical or behavioral is available only to those in the plan with a need to know and only to ensure proper adjudication and payment of claims. Members could lose access to providers if the plans cannot pay the providers correctly and in a timely manner.
- 42 CFR Part 2 should be changed to mirror the HIPAA provisions that allow disclosures for healthcare operations under limited circumstances. This would particularly allow for better coordination of care between separate entities, such as when a state awards a physical health MCO contract to one entity and a behavioral health MCO contract to another. This also allows sharing of information related to quality of care, population health, and at times evidence of fraud and abuse.
- The emergency exception that currently states that 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" should be broadened. Emergencies could be prevented, for example, if a hospital provider treating a patient with a severe injury had access to information that the patient also had been receiving substance abuse treatment.

If it is not possible to have 42 CFR Part 2 regulations mirror existing HIPAA regulations, MHPA recommends that in its current form, the rules should allow only program and substance abuse treatment providers who are licensed, credentialed and accredited for a substance abuse specialty to be recognized as a covered entity. Individuals who are licensed, credentialed and accredited in providing these specialty services would not qualify a larger organization within which they participate as this would be discouraging for the integration of services at healthcare organizations providing comprehensive services. Additionally, MHPA would encourage the regulation to maintain its current

standard that allows treatment providers who are known to the public as substance abuse specialty treatment providers to determine whether or not they are considered a covered entity. Again, we thank you for the opportunity to provide comments and hope that the Agency will consider the issues expressed in this letter given the challenges that plans and providers are currently facing within the arena of treating mental health and substance abuse disorders.

Sincerely,

Jeff Myers
President and CEO

Greetings,

Privacy issues are important to all Americans, but none more so than for methadone patients because of the stigma involved.

Many people who would otherwise get the help they so desperately need, will not receive it if they know their primary care physician will know about their methadone treatment.

Common sense tell us that drug treatment is a very private matter, and if it does not remain a private matter, some people will not seek the treatment that might save their life,

This is also a matter of our constitutional rights as citizens, please don't take away, or allow others to take our rights away.

Tuesday 6/24/14

Dear Sirs & Madams,

I am writing this in Reference to the proposal to connect methadone maintenance programs to the Health Information Technology or (HIT) System. The first thing I would like to say is, Don't --- Please, Please don't do this, --- Let me tell you why not! ----- There are simply too many people who do not understand the true reasons for addiction. These people also do not understand the need for confidentiality during treatment. I've met many, many people who think that drug addiction & alcoholism is a moral issue. Morals have nothing whatsoever to do with addiction. But many people don't understand this! They think addicts are a bunch of low lifes who have no morals and who can not or will not live by the rules & expectations of society as a whole.

I personally have never met a 10 year old child who said their highest ambition in life was to be a drug addict. Nobody wants to be a drug addict or an alcoholic!

So that begs the questions, why are there so many of them? There are many reasons for this, none of which have anything to do with anybody's morality.

I do not want every Tom, Dick or Harry to know I'm a drug addict. My own personal physician doesn't know! Most people who find out try to talk you into getting off the methadone. Most addicts that do this, go right back to their drug of choice. I do not want to do this. I'm doing fine on the methadone.

Please leave it confidential!

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

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

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

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

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

Applicability of 42 CFR Part 2

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

FR Citation: 79 FR 26930

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Public Comment Field:

- It will reduce the confusion about what information requires consent to be shared.
- The protected information will be easier to identify.
- It will however prevent over reach (removing anything vaguely associated with SA) and increase entities sense that they are compliant with the law.
- It will however still require the SA date be treated differently for other diagnosis.
- Until SA data is treated in accordance with HIPAA, I anticipate that entities will continue to remove the all SA data as consents are too costly and time consuming to manage in a population health environment that is utilizing big data sets.

Consent Requirements

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

1. Allow the consent to include a more general description of the individual, organization, or health care entity to which disclosure is to be made.
2. Require the patient be provided with a list of providers or organizations that may access their information, and be notified regularly of changes to the list.
3. Require the consent to name the individual or health care entity permitted to make the disclosure.
4. Require that if the health care entity permitted to make the disclosure is made up of multiple independent units or organizations that the unit, organization, or provider releasing substance abuse related information be specifically named.
5. Require that the consent form explicitly describe the substance abuse treatment information that may be disclosed.

FR Citation: 79 FR 26931

Questions:

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

Public Comment Field:

- **Separate and costly modifications will not happen to systems for a single medical condition to be managed through any consent.**
- **SA needs to be exchanged in accordance with HIPPA**
- **Laws need to be passed, enforced, strengthened so that all patients have privacy protections. Patients with cancer, HIV, anxiety.... do not want to be discriminated against for employment, insurance.....**

Redisclosure

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

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

Public Comment Field:

- Yet another layer of complexity requiring additional financial and workforce investments
- It will not address that the data was isolated and never sent to the HIE.
- It could reinforce that that any data pertaining to the identified SA data be isolated at the source

Medical Emergency

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

FR Citation: 79 FR 26931

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Public Comment Field:

- If the Health Care Administrative entity isolates the identified SA information before sending to a vender (say for a provider portal) or the HIE
- The information is not available in the case of an emergency therefore:
- Patient concern should be that I am unconscious from a car accident and because my diagnosis is SA my provider will be potentially providing me with a lower standard of care which in some case could be life threatening.
- If information is truly used to provide high quality care it has been my experience that few patients object

Qualified Service Organization (QSO)

SAMHSA is analyzing the regulations to identify options for allowing Part 2 data to flow to health care entities for the purpose of care coordination and population management while maintaining patient protections. One potential solution includes expanding the definition of a qualified service organization (QSO; § 2.11) to explicitly include care coordination

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Questions:

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

Public Comment Field:

- Treatment
- Care coordination agencies may use software products for risk stratification, care alerts and other tools to identify high risk individuals that would benefit from an intervention.
- Data warehouses (such as APCD) may be used for care coordination, quality improvement, provider benchmarks on quality, geo mapping for “hot spots” provider portals for improved treatment.....

Research

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

FR Citation: 79 FR 26932

Questions:

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

Public Comment Field:

- Any efforts to align 42CFR with HIPAA is to be applauded
- Patients with SA desire the same level of treatment, care coordination, quality bench marking and research.
- The current environment is highly discriminatory to patient's with SA

Addressing Potential Issues With Electronic Prescribing and Prescription Drug Monitoring Programs (PDMPs)	
P p to t	
Preamble FR Citation: 79 FR 26932	
Q • • •	
Public Comment Field:	

Other Comments	
Topic:	
Public Comment Field:	

Dear SAMHSA,

It has recently come to my attention that possible changes could be made to confidentiality regulations 42 CFR Part 2. This is very concerning to me as a MMT patient. Confidentiality is crucial for MMT patients nationwide, being that many stigmas surround methadone in and out of the medical field.

I myself have first hand experience as to how unacceptable methadone is to society. In a phone call regarding my treatment facility an investigator for the OSBI Prescription Enforcement Division told me that “drug addicts go there to take drugs.”

There is very much work to be done in making MMI socially acceptable before any changes should be made to current confidentiality regulations. I’m pretty much begging to keep my rights in a hope you can understand how detrimental it would be to all MMT patients if any changes are made to 42 CFR pt. 2.

- Concerned Citizen -

Dear SAMHSA,

I am a methadone patient and I understand that you are thinking about changing the confidentiality regulations for the treatment of methadone. This greatly concerns me with what could potentially happen if my status as a methadone patient were known. Medically as well as professionally this could have major effects on a lot. Trying to get a job, getting medical care, etc would become more difficult because of people not understanding methadone and deeming every user an “addict”. Please don’t change the regulations and continue to let the Human Beings that need methadone lead a normal life as possible.

Sincerely,

Concerned Patient

Jerry Brown
Governor



State Of California OFFICE OF HEALTH INFORMATION INTEGRITY (CalOHII)



June 25, 2014

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

Dear Sir or Madam:

The California Health and Human Services (CHHS) Agency is pleased to have the opportunity to provide public comments to the Substance Abuse and Mental Health Services Administration (SAMHSA) on its public listening session notice published in the Federal Register on May 12, 2014.

The California Office of Health Information Integrity has the statutory authority and responsibility to provide leadership, policy formulation, coordination, and direction for the implementation and ongoing oversight of the Health Insurance Portability and Accountability Act (HIPAA) compliance for state departments in California, as well as previously overseeing the State Health Information Exchange (HIE) Cooperative Agreement Grant under the American Recovery and Reinvestment Act (ARRA). Comments have been collected from state and county departments that are impacted by this public listening session.

The County Issues Work Group (CIWG) and California Privacy and Security Compliance Officers (CaPSCO) represent California counties. CHHS, CIWG, and CaPSCO applaud SAMHSA's efforts to make thoughtful and incremental changes to the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2. The following comments are presented to SAMHSA:

- The changes will facilitate needed communication and coordination in patient/client care;
- Consent would provide standardization between entities in the exchange of information in the care of the patient/client;
- It will reduce the administrative and technical encumbrances when exchanging information that is currently redacted but is medically necessary;
- Recommend continued protection of identity for research, as one would have with any research involving human subjects;
- The Qualified Service Organization (QSO) will facilitate in needed exchange of patient/client relevant information to treat the client/patient as a whole;
- With regards to the Medical Emergency release, who makes the determination of a "Medical Emergency" and under what circumstances?

We again thank you for allowing us to comment on these important issues. We are available to discuss any questions you or your staff have about our comments. We look forward to working with you on these important matters.

Sincerely,

Pamela Lane, MS, RHIA, CPHIMS
Deputy Secretary, HIE
CA Health and Human Services

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

From: Richardson, Maria [<mailto:maria.richardson@topaztx.org>]

Sent: Wednesday, June 25, 2014 5:55 PM

To: Privacy Regulations (SAMHSA)

Subject: Public Comment: Submit Your Comments on Patient Confidentiality

The privacy provisions in 42 CFR Part 2 enacted over three decades ago -an era of little awareness or acceptance and motivated by thoughts that stigma and fear might dissuade persons with substance use disorders from seeking treatment. Three decades later, society has matured, realizing that these individuals deal with a wretched disease that knows no boundaries. If we are to treat the wellbeing of these individuals in a holistic manner, then the privacy provisions should be updated and brought in line with current healthcare initiatives; as well as making provisions to protect entities that sever this population for the betterment of their overall health. As we continue to grow and improve healthcare, technology (HIE) is key to saving lives in the treatment of this disease. Healthcare professions will need to have the ability to share information across all necessary providers. The barriers of three decades ago should not be the barriers that prevent the saving of life today. Provisions for sharing information through HIEs should be made to be inclusive of programs or entities whose services target these populations.

Regards,

Maria Richardson
Director of TOPAZ Software Authority
713-970-7196 office
832-367-0471 cell

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Kaiser Foundation Health Plan
Program Offices

June 25, 2014

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

Submitted via email to: *PrivacyRegulations@SAMHSA.hhs.gov*

RE: *Confidentiality of Alcohol and Drug Abuse Patient Records; 42 CFR Part 2* [Docket 2014-10913]

Dear Sir or Madam:

Kaiser Permanente offers the following comments to the Substance Abuse and Mental health Services Agency ("SAMHSA") on proposed updates to existing regulations in 42 CFR Part 2 regarding *Confidentiality of Alcohol and Drug Abuse Patient Records*, published in the Federal Register on May 12, 2014.¹

The Kaiser Permanente Medical Care Program is the largest private integrated healthcare delivery system in the U.S., delivering health care to over 9 million members in eight states and the District of Columbia.² Kaiser Permanente is committed to providing the highest quality health care; as part of this commitment, we have made a significant investment in developing our secure Electronic Health Record ("EHR") system, KP HealthConnect®, to support the delivery of healthcare services to our members and to enhance communications among the medical professionals who serve them, consistent with the highest standards of medical privacy.

Kaiser Permanente is actively engaged in numerous public health initiatives and also conducts and supports a broad agenda of health research through its various research entities.³ In our

¹ 79 Fed.Reg. 26929

² Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 37 hospitals and over 600 other clinical facilities; and the Permanente Medical Groups, independent physician group practices that contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente's members.

³ Research has long been a hallmark of Kaiser Permanente, which conducts research in all of its eight regions, both within research centers as well as in medical centers and other health care delivery venues. In addition to health services research, Kaiser Permanente also conducts many studies involving FDA-regulated drugs, devices, and biologics.

research and public health efforts as well as in our delivery of health care, we provide protections to safeguard member/patient health information against unauthorized use and disclosure.

General Comments

Kaiser Permanente supports efforts by SAMHSA to ensure that its regulatory approach will help to foster coordinated care and improve patient safety, while also addressing patient privacy concerns. Within our integrated model of care delivery, we have developed robust and secure tools, including a comprehensive EHR system that enables communication among treating providers, including primary care and specialty providers. As stewards of our patients' information, we support regulatory changes designed to ensure confidentiality, reduce confusion and promote consumers' trust in the privacy and security of their health information, including substance abuse information.

We offer the following feedback on specific proposed changes to 42 CFR Part 2 regulations ("Part 2").

The Federal Legal Framework for Protecting Identifiable Health Information

Part 2 predates by more than two decades the comprehensive federal legal framework for protecting health information afforded by the Health Insurance Portability and Accountability Act (HIPAA) of 1996. The HIPAA Privacy Rule (2000), modified in 2002, was followed by the HIPAA Security Rule in 2003, which defined an extensive set of technical, physical and administrative safeguards designed to ensure that covered entities and their business associates keep protected health information ("PHI") secure.

HIPAA has evolved to keep pace with technological innovations, such as the adoption of EHRs and greater use of health information exchange ("HIE") to allow access to patient information at the point of care. In 2009, the HITECH Act expanded HIPAA to cover many non-healthcare providers, like health information organizations ("HIO"), and the Breach Notification Rule imposed specific requirements on the content and timing of reporting suspected data breaches under HIPAA. Most recently, the HIPAA Omnibus Rule (2013) further strengthened HIPAA protections.

The confidentiality of individuals treated for substance abuse issues are adequately protected by HIPAA and the Privacy Rule, as amended by HITECH and the HIPAA Omnibus Rule. Part 2 has long created unnecessary confusion about how information regarding patients with substance abuse disorders can be shared, which has had the effect of suppressing communications among treating health care providers and preventing other communications that are vital to facilitate treatment, such as enabling coverage and payment for treatment. Most of Part 2's current requirements act as administrative burdens that do not meaningfully afford patients greater rights than HIPAA for protecting the privacy of substance abuse information, but deprive substance abuse patients of the benefits of electronic HIE and other care coordination mechanisms.

Part 2 also precludes providers in many cases from sharing medically critical information (such as lab test results or diagnosis that would alert a provider not to prescribe a particular drug or

treatment to a patient), even where doing so is necessary to act in the best interests of their patients in combating their addiction or preserving their safety. We believe that the Part 2 regulations could be repealed in order to address these barriers to care without diminishing substance abuse patients' privacy rights.

If Part 2 is kept, then its restrictions should be modified substantially to bring Part 2 into conformance with HIPAA's minimum necessary standard. This would allow health care providers, HIEs, and other organizations to use and disclose substance abuse records using electronic exchange technology under appropriate privacy safeguards and consistent with other medical care.

Specifically, SAMHSA should give careful consideration to harmonizing Part 2 with HIPAA by instituting exceptions similar to HIPAA's treatment, payment, and health care operations ("TPO") exceptions. This could involve expanding Sec. 2.12(c) on Exceptions to Applicability. Such alignment would lead to much greater clarity in privacy and security policies and practices as well as meet expectations of patients regarding the use and disclosure of PHI, including PHI associated with substance abuse treatment; under HIPAA patients can request restrictions to uses and disclosures of specified PHI.

Recommendation

We recommend aligning Part 2 with HIPAA, specifically by adopting exceptions for TPO disclosures.

Applicability

Services versus Programs as the Basis for Applying Part 2

To address the difficulty in determining which types of providers and organizations are considered "programs," under current Part 2 definitions, SAMHSA is considering revising Part 2 to cover certain types of specialty substance abuse treatment services.

While the current definition of a "program" is somewhat ambiguous, it would be disruptive to redefine the applicability of rules based on service type as opposed to provider type. Many organizations, including Kaiser Permanente, identify these programs based upon provider department (e.g., Behavioral Health/Addiction Medicine) and design data protections accordingly. The "firewalled" portion of a patient medical record, as well as authentication and access rules for individual providers, in many EHRs were designed and implemented to reflect a department-based definition of a "program."

A service-based classification may actually make it more difficult to distinguish Part 2 regulated information from other information. Each record of a service would need to be characterized as a service regulated under Part 2 or not. The ability to distinguish Part-2 covered information would depend on the health care industry developing, adopting and implementing a data classification system that would be comprehensive, reliable and maintainable – presenting administrative, technical and operational challenges, especially within existing EHR systems.

Given the difficulty of implementing and maintaining a service classification taxonomy that is consistent across the industry, it is highly likely that such a change to the scope of Part 2 would have the unintended consequence of extending its application, introducing new barriers to access by and data sharing among treating providers.

Recommendation

Kaiser Permanente recommends that SAMHSA retain the program-based definition rather than move to a service-based definition to determine whether Part 2 applies.

Definition Revisions to Clarify Applicability

SAMHSA acknowledges the potential to apply these rules too broadly and therefore proposes to exempt some primary care services – and thus primary care providers – from Part 2 provisions. However, SAMHSA’s proposed exemption for screening, early intervention or other pre-treatment services could be addressed more simply and clearly by revising definitions of “patient,” “patient-identifying information,” “record,” or Sec. 2.12 on Applicability; or by revising SAMHSA FAQs to clarify that records of pre-diagnosis services (e.g., screenings, counseling on the harms of substance abuse etc.) are not subject to Part 2 restrictions because such records do not definitively identify a patient as a substance abuser.

SAMHSA could also consider redefining “program” to mean an entity (including health care professionals and staff identified by that entity as being part of the program) that provides in-patient or residential treatment services for drug or alcohol abuse to patients with a primary diagnosis of a substance abuse disorder.

Another rule change that could improve clarity and increase regulatory certainty about the application of Part 2 would be a “de-identification” safe harbor that describes which data could be removed so a record no longer identifies an individual as a substance abuser.

Recommendation

We recommend more revising key definitions of Part 2 to clarify the rules’ applicability as opposed to an approach that broadens the scope of the rules. This approach will establish a consistent framework for providers and patients. We also recommend creating a de-identification standard, similar to HIPAA’s, that would act as a safe harbor in determining whether any data set/record contains information covered by Part 2.

Consent Requirements

SAMHSA seeks feedback on how to make the consent process more manageable. We advocate for a reasonable approach – consistent with our earlier recommendation for HIPAA alignment – that would help eliminate unnecessary barriers to appropriate data access and use. SAMHSA should permit Part 2-regulated entities/providers to seek a patient’s general authorization to disclose information for TPO (as defined by HIPAA) to recipients who need the information to perform these functions.

Absent such a general authorization, at a minimum, Part 2 authorizations should specify only roles or functions of recipients, i.e., identifying authorized recipients generically, rather than identifying individual recipients by name. This approach would still honor patients' intent to control the types of persons able to receive their information and the purposes of disclosures, but would reduce the need to obtain multiple consents from patients or to delay care in order to get a new consent. Such a change would eliminate one administrative impediment to inclusion of substance abuse information in HIEs – the impossibility of identifying in advance every individual or entity that will need the patient's information for a designated purpose.

We advise against SAMHSA's suggestion to require programs to periodically notify patients of the actual identities of authorized recipients, simply because such after-the-fact accounting imposes a substantial burden without increasing patient privacy protections. This proposal to name entities and individuals is more restrictive than current rules and runs counter to SAMHSA's intent to broaden access and foster integrated care.

SAMHSA has also suggested that consent forms identify the discloser by specific unit or organization if the disclosing entity comprises multiple units/organizations and to explicitly describe information to be disclosed. These changes are inadvisable because increasing the complexity of consent documentation is likely to create substantial confusion among disclosing entities about how to interpret and comply, without enhancing patient privacy. More complicated forms also have greater potential to confuse patients.

We also urge SAMHSA to consider revisions designed to allow Part 2 records to be exchanged using HIEs and other electronic networks. Because of the current onerous Part 2 restriction, the technology constraints on segregating records, and the inability to automate verification of the adequacy of consents, HIEs usually exclude records from Part 2 providers. Many health care providers also treat all substance abuse records as covered by Part 2 because of confusion about applicability, as well as the complexities of consent management. This substantially limits legitimate access to information about substance abuse treatment, to the detriment of patients, providers, and the healthcare system as a whole.

Recommendation

Kaiser Permanente recommends that SAMHSA adopt a general authorization that allows Part 2 programs to disclose PHI for TPO, as permitted under HIPAA. We strongly discourage consent that requires more specific information, such as names of individual recipients, names and departments of disclosers, etc. In addition, we recommend that consent forms be considered sufficient if they identify recipients by function or role rather than by name.

Redisclosure

SAMHSA proposes to clarify that the redisclosure prohibition only applies to information that would identify an individual as a substance abuser. Such clarification is unnecessary; it does not afford greater flexibility or facilitate technical solutions for sharing among HIE users.

The redisclosure prohibition and notice labeling requirements, combined with Part 2's requirement for recipient-specific consents, are barriers to inclusion of substance abuse records

in HIEs. Although technology solutions for data segmentation are being developed, they are currently experimental, costly and not yet fully operational. There are also inherent limitations to technologies' ability to parse, select and segregate information within a patient record by content type. While structured data can be identified and isolated, free-text data, like provider notes, that identifies a patient as a substance abuser (either alone or in combination with other data fields in the record) may be difficult to find and redact from key clinical documents.

Given these challenges, we believe the best way to facilitate integrated medical records and foster communication among HIE users and other persons who need substance abuse information for TPO purposes would be to limit application of the blanket redisclosure prohibition, to allow Part 2-covered information to be combined (and subsequently shared) with other individually identifiable health information for uses consistent with the purposes of Part 2.

The redisclosure prohibition could be revised in one of two ways. First the redisclosure provision could apply only to disclosures to persons who do not fall into specified categories, such as persons who are not already required to comply with HIPAA. Such a change would permit redisclosure to covered entities, their business associates, and public health authorities or other types of recipients that have a legal obligation to use PHI for narrowly defined purposes and otherwise safeguard confidentiality by following strict privacy and security standards. Or, SAMHSA could prohibit specific uses, meaning that the obligation of the recipient (and the corresponding restriction notice to be appended) would be to not use the disclosed information for specified uses, such as for civil litigation or criminal investigation or prosecution.

Recommendation

Kaiser Permanente recommends revising the blanket redisclosure prohibition to apply narrowly only to recipients not already covered by HIPAA obligations, which would ensure that redisclosures for TPO purposes would not be hindered. We would also support replacing the redisclosure prohibition with a use prohibition applicable to recipients, so as to permit disclosure but forbid specified improper uses of the disclosed information.

Medical Emergency

SAMHSA proposes to align the medical emergency exception with the statutory definition – “to medical personnel to the extent necessary to meet a bona fide medical emergency” – and to give providers discretion to decide when a bona fide emergency exists, including amending Part 2 to allow providers to use this provision to disclose information to prevent emergencies or where a patient is unable to consent because of intoxication.

Recommendation

Kaiser Permanente supports the proposed regulatory revisions, and recommends that emergency prevention disclosures include information about medications to prevent overdose or possible harm from contraindicated drugs. We also recommend removing post-disclosure documentation requirements for disclosures in emergencies, which are not statutorily required and serve little purpose.

QSOs

SAMHSA is considering how to expand the definition of a Qualified Service Organization (“QSO”) to explicitly include care coordination services and to allow a QSO between an entity that stores Part 2 information (e.g., a payer or ACO) and a service provider.

It is important that the QSO concept cover disclosures to entities that perform care coordination, population management and quality assessment/improvement activities. We believe such disclosures are already permitted under the current QSO provisions, when these entities are performing such activities as services for the program. Thus, revising the regulatory text is unnecessary to achieve this objective.

However, we strongly recommend expanding the QSO concept to be more consistent with the business associate concept under HIPAA. One way would be to revise the definition of a QSO to allow disclosures under the QSO concept to entities that perform care coordination, population management or QA/QI activities for the program (which may not necessarily qualify as services to the program). Additionally, we suggest that, if SAMHSA declines to create a TPO exception consistent with HIPAA (as recommended above), the agency explicitly allow a payer to qualify as a QSO and a QSOA to cover disclosures to third party “payers.” Such disclosures are necessary for programs to be financially able to furnish substance abuse services, so payment disclosures are effectively disclosures for the benefit of the program. Many programs today simply refuse to provide treatment where a Part 2 conforming consent for payment disclosures is absent.

SAMHSA should consider other changes to the QSO provisions to extend the availability of the QSO concept, with the goal of allowing substance abuse information to be used, like other health information, for public health improvements and patient safety.

First, Part 2 could be revised to allow a QSO to provide services to perform activities for multiple programs or programs generally (e.g., quality improvement studies or administrative activities to benefit more than one program). Second, the QSO concept could allow a QSOA to be any organization that provides services to or for the program or the patient. That would also facilitate exchanges of information to payers (because a patient has an interest in the coverage and reimbursement of his/her services and care coordination entities). Additionally, SAMHSA could limit Part 2 restrictions on subsequent uses and disclosure by QSOs. Limited restrictions would still address the core concerns of Part 2 – information may not be used to prosecute or discriminate against individuals.

Recommendation

We recommend that a QSO be defined as an organization that “provides services to *or for* a program *or performs activities on behalf of or for the benefit of the program, for multiple programs, or for program patients*, such as . . . , *payers and companies performing care coordination, population management or quality assessment activities*” Similar changes could be made to 2.12(c) “the restrictions on disclosure in these regulations do not apply to communications between a program and a qualified service organization of information needed by the organization to.... “

We also recommend that SAMHSA clarify (through FAQs or otherwise) that two programs may, under the auspices of a QSOA, disclose information to each other for treatment purposes. The rationale is that each program needs the services of the other to provide total treatment of the patient. For example, the referring program may provide outpatient treatment and the referral recipient program may provide inpatient treatment. We believe that prior SAMHSA FAQs support this conclusion and that current regulations allow such QSO arrangements, but think clarification would be beneficial for providers and other in the health care industry serving this population.

Finally, SAMHSA should rescind its prior FAQ that forbade multi-party QSOAs allowing communication among all QSO parties.

Research

SAMHSA proposes to expand the authority to release data for research purposes when the recipients are qualified researchers. Currently, only program directors have that authority, which can limit Part 2 data that is available for research.

Research into substance abuse treatment and outcomes has the potential to benefit patients, improve understanding of substance abuse and confounding or concomitant behavioral health problems, and ultimately reduce the stigma associated with these health conditions. At the same time, we acknowledge the privacy concerns of individuals who should be able to trust that their information will remain confidential, and the ability to maintain such information in confidence is central to promoting voluntary uptake and continuation of substance abuse services.

Currently, Part 2 assigns the program director sole authority to weigh the benefits of the research against the risks of disclosure, including review of the research protocol, assessment of research data security, and determination about the qualifications of the researchers. However, current federal requirements for the protection of human research subjects establish a framework for the conduct of research that requires oversight by an institutional review board (“IRB”) to evaluate any risks to participant safety and privacy.

IRB review and approval of research provides an equal or possibly greater level of oversight and trust for research involving Part 2 data, including continuing review and the authority to put certain processes in place to enhance data security.

Recommendation

Kaiser Permanente supports expanding the authority to release data for research purposes when an IRB has reviewed and approved the release of information.

PDMPs

SAMHSA’s request for comments raises questions about state prescription drug monitoring programs (“PDMPs”). Recently, SAMHSA has demonstrated support for PDMPs, including by sponsoring a project with ONC to expand provider access to PDMPs and data exchange with

EHRs. We note also that SAMHSA has in the past stated in public presentations that once a prescription is issued and either sent by electronic means or given to a patient to be filled at a pharmacy, it is no longer protected by Part 2,⁴ presumably because the patient is considered to have self-disclosed that information to the pharmacy (whether the actual information is transmitted by or on behalf of the patient).

Prescription drugs are one tool for treating substance abuse disorders and underlying or collateral pathologies, such as depression or pain, although in most cases, information included on a prescription is not alone enough to clearly identify an individual as having a substance abuse disorder, since most drugs prescribed to substance abuse patients can be used to treat other conditions.

Currently, in most states pharmacies and health care providers who dispense controlled substances are legally required to report to state PDMPs and subject to penalties for not reporting. SAMHSA should identify, address and resolve any conflicts between Part 2 disclosure restrictions and state PDMP reporting laws, either through preemption rules at the federal level or in guidance from SAMHSA, identifying the circumstances under which PDMP reporting would not violate Part 2 restrictions.

SAMHSA could accomplish the latter in one of two ways. First, through regulations or FAQs that explain that prescriptions submitted to a pharmacy by a patient or transmitted to a pharmacy by the program on behalf of the patient (via e-prescribing, fax or other telecommunication) are not disclosures by the program.⁵ Second, SAMHSA could create a safe harbor for datasets that are deemed not to include information identifying a patient as a substance abuser (therefore records not subject to Part 2).

CONCLUSION

Kaiser Permanente looks forward to working with SAMHSA to improve access, care integration and confidentiality of patient information. We appreciate your willingness to consider our comments. Please feel free to contact me (510-271-6835; email: anthony.barrueta@kp.org) or Lori Potter (510-271-6621; email: lori.potter@kp.org) with any questions or concerns.

Sincerely,

Anthony A. Barrueta
SVP, Government Relations
Kaiser Foundation Health Plan, Inc.

⁴ See SAMHSA 2012 Presentation at the USPHS Scientific and Training Symposium, *What You Need to Know about Prescription Drug Monitoring Programs*

⁵ As stated by SAMHSA in its 2012 presentation on PDMPs.

I don't think I have to say much, but providing my medical information to all doctors without my permission is bad policy and worst standard.

I should have a choice on who of my doctors should know what.

HAVEN'T YOU HEARD ABOUT HIPPA. Why do not you think HIPPA exist. It was not because medical providers were anonymous. They do not have the right to know what they shouldn't know.

I have a HIPPA complain on a Psychologist Quack who wrote a report that has all of the characteristics of slander and intuition to harm

Tues. 6/24/14

Substance Abuse and Mental Health Services
Administration (SAMHSA.)
1 Choke Cherry Road, Rockville, MD 20785 Room 5-1011

To Whom It May Concern,

On behalf of the project I'm involved with, (Recovery), along with all my peers – and everyone having to do with recovery etc., confidentiality is a must. The regulations (42 CFR Part 2), should be abided by in all respects. I don't think anybody would want anything confidential about one's self to be thrown out there for others to know about etc. So it's best to follow rules and guidelines not only in (42 CFR Part 2), but in all areas. (Life, business, etc.) The bottom is confidentiality is a must.

Thank you.

June 24, 2014

To Whom It May Concern:

I am totally against my confidentially being bought into public knowledge. I feel that my medical information should remain confidential unless I give permission (written consent). As a person receiving Medical Assisted Treatment, I have personally experienced unfair treatment in the care of a Doctor, after telling him of my methadone treatment.

Respectfully yours

Confidentiality is a must!

(42 CFR Part 2)

To Whom It May Concern:

As a patient at the Port Morris Outpatient program, I sincerely feel that no one absolutely no one should make anyone see any one medical chart unless the patient signs and gives them permission to look and I haven't given no one any consent to tell my business. Please keep my charts confidentially. (42 CFR 2)

Keep it private.

Sincerely 42 (CFR) Pt 2

To Whom It May Concern,

As a patient at the Port Morris outpatient program I sincerely feel that no one absolutely no one should make anyone see another patients medical chart unless the patient signs and gives whomever permission to look into their medical history. But confidentiality is a must to any and all (42 CFR – Pt 2. So please keep all of our patient confidentiality regulations private.

Sincerely 42 CFR Pt 2

Dear Sir, Madam

I'm very concern about our confidentiality being open to more agencies and people who don't have to know. Also as a patient for near 40 years I can say I've seen how patients are treated when that person, pro or etc. sees your on methadone for example I've had three bruised ribs and other seeing eye was a patient of a M.M.T.P. he said he can only suggest aspirin or Motrin this was one time one of many, threw my time as a patient not only doctors but other people. I have worked and had been for 20 years now but unless I'm sure about who ever I talk too that I don't tell them I'm on methadone please keep a open mind if its passed to open this information it will cause, job, apt and looked down on as criminals. Please don't take our dignity away.

I also wanted to say why is it that no patients are involved in theses decisions or meeting, (like the one in mid june) I think you would see a better side of methadone treatment if you would talk to the patients who are or trying hard to be in recovery. Some of these patients – clients are worried that their bosses, teachers clients will find out that they are on methadone they don't want to take the chance of being fired and looked down on. I know because I was fired because my confidentiality was violated also no matter how and how much pain I was in through the yrs in E.Rs if they knew (Hosp Staff) I was a methadone patient they were not going to give me anything stronger then aspirin or motrin. It seem's to me that people who are not educated in methadone treatment should talk to the high percentage of patients that work or go to school or trying hard to be in recovery. If you need

June 17, 2014

To whom it may concern:

I am writing to make it clearly certain that by no means am I allowing anyone to share my personal information regarding Morris Port Institution to release any medical information to my private doctors etc. Without my written consent. Thank you. Kindly

X patient of Morris Inst.

Pss I have left out my name due to confidentiality.

6/24/2014

Confidentiality is a must, I have the to my private health and anything else doctors are suppose to get permission to give anyone medical information

6/23/14

To whom it may concern:

As a patient @ the port morris outpatient program, I sincerely feel that no one absolutely no one should make anyone see another patient's medical chart unless the patient signs and gives whom ever permission to look into their medical history! But confidentiality is a must to any and all (42 CFR –Pt2) so please keep all of our patient confidentiality regulations private only a written consent will allow for anyone to look into their private medical charts.

Respectfully,

Confidentiality is a must! (CFR 42)

6-24-14

To whom it may concern:

Please be advised that I would like for not or nobody to look up my medical file

Thank you

6/23/14

To whom it may concern

As a patient of port morris outpatient program I sincerely feel that no one should make anyone see another patient medical records without permission so I feel that confidentiality is a must.

Respectfully

Confidentiality is a must (CFR 42)

June 24, 2014

To whom it may concern:

I [REDACTED] am writing to clearly state that by no shape or form, would I allow any person to address any of my doctors, regarding any medical information nor my records due to patient confidentiality.

I need confidentiality to stay the same at my methadone center. In regulation (42 CFR PART 2). We ask that any information leaving the program, a patient must sign a release that requires the request to be exact.

Thank you for your time.

To whom it may concern

As a patient at O.T.P. I believe that confidentiality is a must. For someone who want to read my medical record it is very important to get a written consent by the patient. My medical charts is for me and program (42 CFR-PT2) should stay in place. It protect the patient and the program.

(CFR 42 – PT 2) confidentiality is a must.



June 25, 2014

Pamela Hyde
Administrator
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
1 Choke Cherry Road
Rockville, MD. 20857

RE: Confidentiality of Alcohol and Drug Abuse Patient Records

Dear Administrator Hyde:

I am writing in response to the 42 CFR Part 2 Discussions Topics document posted in the Federal Register on May 12, 2014 [4162-20-P]. In turn, that document, which outlines alternative regulatory approaches to Part 2, was at the heart of a Listening Session held at SAMHSA on June 11, 2014.

Background -- Substance Use/Mental Health Consumers Are Experiencing A Public Health Crisis: The Kennedy Forum was founded to carry on the work of President John F. Kennedy who signed the Community Mental Health Act in to law more than 50 years ago, weeks before his assassination. The legislation aimed to build mental health centers accessible to all Americans so that those with mental illnesses could be treated while working and living at home, rather than being kept in neglectful and often abusive state institutions, sometimes for years on end – thereby transforming the way people with mental illness are treated and cared for in the United States.

While we have made tremendous progress over the past five decades in improving access to services for people with substance use and mental health disorders, it is not overstatement to claim that these patients/consumers are experiencing an ongoing public health crisis today. Specifically, according to a recent Synthesis Project report published jointly by the Kaiser Family Foundation and the Robert Wood Johnson Foundation, comorbidity between medical and behavioral health conditions “is the rule rather than the exception.” A nationally representative epidemiological survey revealed that more than 68% of adults with mental illnesses reported having at least one general medical condition. The same survey showed that nearly 30% of persons with substance abuse disorders have co-occurring chronic diseases including heart disease, diabetes, cirrhosis, emphysema and COPD.

Because of poor care coordination and lack of access to primary care and specialty medical services, the ultimate outcome is radically shortened life expectancy. Combined research efforts by both SAMHSA and the HHS Assistant Secretary for Planning and Evaluation (ASPE), show that people served in the public mental health system (where the incidence rate for comorbid substance abuse disorders exceeds 70%) die, on average, in their early 50s, a life expectancy similar to that in extremely poor sub-Saharan African nations.

This public health crisis must be an urgent federal priority addressed through aggressive care coordinated efforts, improved integration of behavioral health and medical/surgical services, and expanded access to primary care and specialty medical services.

But none of these policy choices are available without a fundamental re-examination of 42 CFR Part 2. With that background, I will seek to briefly address some of the key issues highlighted in the Discussion Topics document.

Consent Requirements: Recent federal initiatives intended to improve coordination care for patient populations with multiple chronic diseases – including HITECH Act-funded Health Information Exchanges (HIEs), Medicare Accountable Care Organizations (ACOs), Medicaid Health Homes and state-based Coordinated Care Organizations (CCOs) have limited applicability to the needs of people with behavioral health conditions, in part, because of Part 2's stringent consent requirements. Each program experiences different confidentiality challenges. For example, HIEs don't accept mental health and addiction Electronic Health Records (EHRs) because they lack sophisticated consent management capabilities. As a result, people with major mental illnesses and serious addiction disorders are denied the expanding use of HIE data to facilitate early intervention and population-based health. Similarly, the CMS Center for Medicare and Medicaid Innovation (CMMI) must redact all addiction medical records due to the Part 2 "To Whom" consent requirements when it shares Medicare claims data with Pioneer ACOs meaning reduced care coordination opportunities for persons with schizophrenia and bipolar disorder who also have a comorbid substance abuse condition.

What's the end result? Federal information management policies directly contribute to silo-based care, fragmentation of the behavioral health system, and a continuation of poor clinical outcomes. At a minimum, SAMHSA should consider 42 CFR Part 2 policy changes allowing consent forms to include more general descriptions of the individual, organization, or health care entity to which disclosure is to be made.

Re-disclosure: Again, this issue presents a conflict between the very poor overall health status of people with addiction disorders, the emerging capabilities of digital health records, and federal privacy rules little changed since the early 1970's. As indicated earlier, the Kaiser Family Foundation reports that 30% of people with an active substance abuse disorder have comorbid chronic medical/surgical diseases often directly related to substance abuse including emphysema, COPD, cirrhosis, and heart disease. Therefore, I would urge SAMHSA to promulgate a new Part 2 rule revising the re-disclosure provision to clarify that the prohibition on re-disclosure 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 re-disclosed. Such a rule presents

no obvious obstacle to SAMHSA's data segmentation efforts, which, in any case, are four to six years away from broad implementation.

Qualified Service Organization: Against the historical arc of American medicine, Health Information Technology is in its infancy, but the possibilities for improved health outcomes among vulnerable, low-income populations are significant. For instance, enhanced care coordination for patients/consumers with behavioral health conditions could avoid adverse medical events from drug-to-drug interactions, but that clinical outcome requires robust information exchange between behavioral health professionals, physicians, hospitals and medical specialists. Sharing behavioral health EHRs in HIEs could also produce substantial savings for the larger health care system. A recent *Health Affairs* article highlighted the role that HIEs can play both in identifying high users of emergency hospital department beds and facilitating communitywide quality measurement.

These prospects should encourage SAMHSA to take a new approach to the Qualified Service Organization (QSO) question. I believe the agency should issue a Part 2 regulation that expands the definition of qualified service organization (QSO) to explicitly include care coordination services and to allow a QSO Agreement (QSOA) to be executed between an entity that stores Part 2 information, such as a payer or an ACO that is not itself a Part 2 program, and a service provider.

For many years, I fought for mental health parity legislation in the U.S. Congress. Under the banner of the Kennedy Forum, I am now working to help people with mental illnesses and substance abuse disorders to benefit from parity in practice. I am convinced beyond a doubt that an essential building block in this effort is access to the new coordinated, digitally enabled health care system. I urge SAMHSA to do all in its power to ensure those with mental illnesses and substance use disorders have the same access to coordinated care as people with cancer, heart disease, or any other condition.

Thank you for your attention to these important matters.

Sincerely,

Patrick Kennedy