



VIA ELECTRONIC MAIL

April 11, 2016

Kana Enomoto
Acting Administrator
The Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
Attn: SAMHSA-4162-20
5600 Fishers Lane
Room 13N02B
Rockville, Maryland 20857
Submitted electronically to <http://www.regulations.gov>

RIN: 0930-AA21: Confidentiality of Substance Use Disorder Patient Records

Dear Ms. Enomoto:

The New York eHealth Collaborative (NYeC) appreciates the opportunity to submit comments on the “Confidentiality of Substance Use Disorder Patient Records” (the Proposed Rule) published in the Federal Register on February 9, 2016. NYeC is a not-for-profit organization that works to improve the sharing of health information among health care organizations in New York State. As New York’s state designated entity eligible for health information technology grants under the Health Information Technology for Economic and Clinical Health (HITECH) Act, NYeC provides advice to the New York State Department of Health on policies that govern the operations of Health Information Exchanges (HIEs) in New York, which are linked together through the Statewide Health Information Network of New York (SHIN-NY). Many of those policies address the critical need to protect patient privacy regarding the electronic exchange of information. Approximately 8 million New Yorkers have consented to the exchange of their information through HIEs, and more than 50,000 providers are able to access the HIE system across the state. These comments reflect NYeC’s position as well as the comments of a broad range of stakeholders which NYeC has assembled.

NYeC is supportive of SAMHSA’s effort to consider revisions to the regulations at 42 C.F.R. Part 2. As SAMHSA is well aware, the rules date back to 1975 and have not been substantively revised since 1987. Not only do these rules predate the development of electronic health records and efforts to reform delivery systems through improved information sharing, but they also predate the widespread use of personal computers and the internet. The regulations also were issued well before the Health Insurance Portability and Accountability Act of 1996 (HIPAA). As a result, there is a pressing need to reconsider these rules in light of more recent technological, legal, and policy developments.

SAMHSA’s comments in the Proposed Rule demonstrate that SAMHSA is concerned that the Part 2 rules impede HIEs in facilitating the exchange of information that is subject to Part 2 for important clinical purposes. We appreciate SAMHSA’s sensitivity to this issue.

However, we are concerned that the provisions of the Proposed Rule addressing the requirements of a Part 2 compliant consent form do not advance SAMHSA’s goal of fostering the exchange of Part 2 information for legitimate purposes that benefit patients. To the contrary, we fear that the Proposed Rule may have the opposite of its intended effect by causing HIEs to exclude Part 2 information from information exchanges entirely.¹ If this occurs, patients will be denied the option of allowing their information to be exchanged electronically by their providers. Patients will therefore be unable to benefit from the improved quality of care and safety that can result from such exchange.

We set out our comments below according to the relevant section of the Proposed Rule.

Consent Form and Related Provisions

The Need to Obtain Consent

Before we set out our detailed responses to SAMHSA’s specific proposals in regards to the consent form, we think it is important to put our comments in the proper context. We are not advocating that HIEs or other entities be allowed to exchange Part 2 information without obtaining patient consent. We recognize that federal law requires patient consent in order to exchange Part 2 information, subject to limited exceptions.² Moreover, we agree that substance use disorder information can be stigmatizing to patients, and that privacy protections are especially important in this area.

For this reason, we support the principle that patient consent must generally be obtained in order for HIEs to exchange Part 2 information. Our own policies require patient consent for the exchange of all forms of patient information, including Part 2 information, except in limited circumstances such as a medical emergency, and in conjunction with the state we designed our information exchange system around the need to obtain patient consent. Moreover, we agree with SAMHSA’s goal of ensuring that such consent is informed. We think patients are in the best position to know whether or not their own sensitive health information should be shared, and that patients will make choices that are in their best interest if they fully understand their options.

We therefore are in agreement with SAMHSA on the core principles at stake here. Our concerns relate solely to SAMHSA’s rules relating to the specific information that must be included in a consent form. We believe the Proposed Rule imposes consent form requirements that make it nearly impossible for HIEs in New York to exchange Part 2 information, and that these new requirements do little to promote informed consent. We therefore request that SAMHSA reconsider its approach.

¹ Many HIEs across the country in fact already exclude Part 2 information due to the difficulty of complying with Part 2 rules.

² 42 U.S.C. § 290dd-2(b).

From Whom (§ 2.31(a)(2))

In the past, we have expressed concerns to SAMHSA that the Part 2 rules make it difficult for HIEs to exchange information subject to Part 2. Unfortunately, the provisions of the Proposed Rule addressing the manner in which the disclosing party must be identified in the consent form may have the effect of imposing further restrictions on the sharing of health information. In order to understand why the consent form proposal is problematic, we discuss below certain details of how HIEs operate in our state.

In New York State, HIEs operate under a “consent to access” model. Under that model, HIEs sign Qualified Service Organization Agreements (QSOAs) with each Part 2 program that participates in the HIE (Part 2 programs, like other providers that join an HIE, are called “Participants”). In accordance with Part 2 rules and guidance previously issued by SAMHSA, the Part 2 programs are allowed to upload their information to an HIE under a QSOA without obtaining patient consent. However, the HIE may not share the Part 2 information with any other Participants without patient consent, except in extremely limited circumstances, such as if there is a medical emergency. Typically, in order for a Participant to access a patient’s information maintained by the HIE (which includes Part 2 information), that Participant must obtain a consent from the patient. Following the Part 2 rules, the Participant must use a consent form that informs the patient that the patient’s substance use disorder information may be accessed if the patient agrees to sign the form. If the patient does sign the consent, the Participant may access the patient’s information for the purposes specified in the form, such as treatment.

This model is premised on the idea that a Participant only needs to obtain a consent form from a patient once. This is critical to the functioning of the system. Take, for example, a case where a primary care physician (PCP) is providing ongoing care to a patient with a serious mental illness who is frequently in and out of the hospital and takes a wide variety of medications. If the patient gives the PCP consent to access the patient’s information through the HIE, the PCP is not required to obtain a new consent form every time the patient is admitted to a different hospital or every time the patient sees a new physician. Rather, the consent form allows the PCP to continually access the patient’s new information so long as the PCP is seeking to access that information for a legitimate purpose stated on the consent form, such as treatment. Indeed, requiring the PCP to frequently obtain a new consent would render the information in the HIE much less useful to the PCP. If the PCP was meeting with a patient post-hospitalization, the PCP may not even be aware that the patient was hospitalized if the PCP was not allowed to access the patient’s information without obtaining a new consent. In contrast, assuming a new consent form is not required, the PCP could receive an alert from the HIE informing the PCP that the patient had been hospitalized, and the PCP could review the hospital records prior to the patient’s next visit in order to provide optimal care.

The consent-to-access model also offers two other critical benefits. First, it places responsibility for obtaining consent on the party that is most motivated to spend the time seeking consent from the patient: the provider who wants access to the records for treatment purposes. In contrast, a disclosing provider derives no immediate benefit from obtaining consent.

As a result, the consent-to-access model better facilitates data sharing that benefits patients. Second, by uploading data to the HIE pursuant to a QSOA without patient consent, the HIE can make the data available to hospital emergency rooms in the event the patient requires emergency medical services and does not have the capacity to provide consent at that time. If consent had to be obtained first from the disclosing provider, no data would be available in the HIE to assist the hospital at the time of a medical emergency.

SAMHSA’s proposal that § 2.31(a)(2) be revised to require the consent form to disclose “[t]he name of the part 2 program(s) or other lawful holder(s) of the patient identifying information permitted to make the disclosure” threatens the underpinnings of the consent-to-access model. This proposal directly conflicts with the consent-to-access model since the Participant seeking access to the patient’s Part 2 information likely will not know the name of all of the information sources contributing data to the HIE, including all of the Part 2 programs. The only way for the Participant to comply with this requirement would be for the Participant to list the name of every Part 2 program in New York State on the face of the consent form in order to inform the patient that there is a possibility that one of these programs might be the source of the information being accessed. Not only would this require the listing of hundreds of providers on the face of a consent form—effectively transforming the document into a provider directory—but it would also require the listing of Part 2 programs that are not participating in the HIE, which would be misleading and likely draw objections from these programs. Moreover, the identities of Part 2 programs that may be sources of information are constantly changing as new programs are licensed or join the HIE. This would mean that every time a Participant sought to access a patient’s information in an HIE, it would have to provide the patient with a consent form listing all of these new providers, and the Participant would constantly need to print new forms with updated lists of Part 2 programs in the state. This would even apply in the vast majority of cases where no Part 2 information would be exchanged, since a Participant in a consent-to-access model often does not know whether the sought-after information contains Part 2 information and therefore needs to assume that it does. Requiring Participants to print lengthy consent forms with an updated list of Part 2 programs every time a new Part 2 program is licensed in New York State (and developing a system to inform every Participant about such updates) is simply not feasible. Thus, if this requirement were actually implemented, HIEs in New York may have no choice but to exclude all Part 2 programs from HIEs entirely.

Theoretically, it is possible for Part 2 programs to switch to a consent-to-disclose model while all other Participants continue to operate under a consent-to-access model. However, practically speaking such a system is not viable. As noted earlier, Part 2 programs would not be motivated to obtain a consent to disclose because they would see no direct benefit from such a consent, so inevitably many Part 2 programs will fail to present the option to their patients. As a result, less information would be available for other providers treating the patient, which would undermine patient care and discourage use of the HIE. But just as critically, the current state of HIE technology may not allow this solution to be operationalized. This proposal would require the

HIE software to determine both whether a patient had given consent to access his or her data and whether the patient had given consent for the Part 2 facility to disclose his or her data. Since this would be an entirely new system that would require HIEs to operationalize two different consent models at the same time, it is unclear if it is even possible for the HIE software to track both sets of consents. Given this difficulty, the HIEs would most likely prohibit the disclosure of all patient information from Part 2 programs.

We also do not believe that imposing this new requirement helps promote the goal of informed consent. In 1987, SAMHSA's predecessor agency recognized that there was no benefit to a requirement to name all information disclosures in the consent form, and revised § 2.31(a)(2) to allow for a general designation of the parties disclosing information. At the time, the agency wrote that this change would not "diminish[] the potential for a patient's making an informed consent to disclose patient identifying information" because "[t]he patient is in position to be informed of any programs in which he or she was previously enrolled and from which he or she is willing to have information disclosed."³ That remains true today. The fact that the Proposed Rule would allow the form, in some circumstances, to not provide the names of the information recipients does not change this analysis. Patients know which providers have given them treatment: requiring the consent form to list the name of past treating providers does not assist patients in making a decision as to whether to grant consent. If there are concerns about patients who might not recall all of the Part 2 programs from which they have received treatment, SAMHSA could require HIEs to list on their websites all of their Part 2 program information sources, and HIEs could be required to provide this information to patients upon request.

For these reasons, we request that SAMHSA withdraw its proposal to revise § 2.31(a)(2) and continue to allow the consent form to contain a general designation of the information sources.

Amount and Kind (§ 2.31(a)(3))

SAMHSA proposes to require the consent form to include "an explicit description of the substance use disorder information that may be disclosed." We believe this requirement imposes an unnecessary burden on Participants in New York's HIEs without any significant benefit to the patient.

As is the case in most HIEs, New York's HIEs utilize a standard consent form that is not customized on a case-by-case basis, except to indicate which Participants are authorized to access the patient's information. The standard consent form indicates that authorized Participants may access all of the records made available by other Participants through the HIE. This portion of the consent form is standardized for two reasons. First, the HIEs do not have the technical capacity to exclude portions of a Participant's record when making the record available to other Participants. As a result, the HIEs could not comply with customized consent forms that authorize disclosure of part of the available data set. Second, the type of data made available through the HIEs is evolving over time. Thus, a consent form that listed all of the data elements

³ 52 Fed. Reg. 21796, 21799 (June 9, 1987).

currently being made available through the HIE would likely become outdated at some point in the future.

However, in describing its proposal in the preamble, SAMHSA indicated that a consent form that indicates a patient is providing access to “all of my records” would violate this provision. SAMHSA further explained that “the designation of the ‘Amount and Kind’ of information to be disclosed must have sufficient specificity to allow the disclosing program or other entity to comply with the request.” As noted above, though, in an HIE, Part 2 programs are not making individualized determinations about which portions of their records to disclose in each case; indeed, even if made, such determinations could not be technically implemented. As a result, we do not believe a case-by-case specification in the consent form of the “Amount and Kind” of data being disclosed serves the purpose articulated by SAMHSA. The only way for a Part 2 program to participate in an HIE is to disclose all of the data elements exchanged through the HIE in each case and to rely on the clinical judgment of other Participants treating the patient to use only those data elements they need for treatment purposes.

Conceivably, each HIE consent form could list every data element exchanged through the HIE. But listing these data elements would not serve as a guide to Part 2 programs as to which data they may disclose and would unnecessarily complicate the consent form. We do not see why the inclusion of this information is preferable to simply stating that the consent form covers all of the records maintained by the Part 2 program.

For these reasons, we request that SAMHSA withdraw its proposal to modify § 2.31(a)(3) and continue to allow more general descriptions of the type of information being disclosed.

To Whom (§ 2.31(a)(4) and § 2.11)

We appreciate SAMHSA’s efforts to simplify the manner in which recipients of Part 2 information may be identified on the consent form. However, we believe the proposal advanced by SAMHSA requires clarification and improvement.

The Problem with the Current Rule

As discussed above, under the New York consent-to-access model, it is the entity seeking access to a patient’s information, not the information discloser, who is responsible for obtaining a patient’s consent. In most HIEs in New York, each Participant must obtain the patient’s consent to access the patients’ records. Thus, if a patient is treated by a physician group, a hospital, and a home health agency, the patient must sign three consent forms, one for each of these entities.

However, some HIEs in New York have implemented successfully an alternative form of the consent-to-access model called a community-wide consent model. Under that model, a patient can sign a consent form that grants access to multiple – or even all – Participants treating the

patient. HIEs that implement this model have to ensure that the community-wide consent form is only an option, and that patients always have the choice of limiting their consent to one Participant or not providing consent at all. Community-wide consent is not an option selected by all patients. But for patients who want their information shared widely among their treating providers without having to sign multiple consent forms, it is a useful tool. A community-wide consent not only reduces the burden on patients, but also improves the quality of care by enabling health care providers to access information for treatment purposes when the patient is not physically present to give written consent. This model can be beneficial to many types of Participants. For example, a pathologist typically does not meet with patients face-to-face and therefore lacks the opportunity to request that the patient grant that pathologist the right to see the patient's records. Similarly, a care management organization may provide telephone-based support to the patient and also struggle to obtain consent. Even Participants that regularly do meet with patients, such as a primary care practitioner, can benefit from such a model since the model allows that practitioner to review the patient's history in advance of a patient's initial visit.

Unfortunately, the current Part 2 rules conflict with this model. Because SAMHSA guidance interpreting the rules requires providers to list the name of every potential recipient on the consent form and not refer to a list of providers on a website, in order to meet the Part 2 requirements in a community-wide consent model, every provider within an HIE must include the list of all potential recipients on their consent form. As the HIEs in New York become more mature, that list may include hundreds or even thousands of providers. Even more problematic, since the providers participating in an HIE will change from month-to-month, the list of providers on a consent form will almost immediately become out of date. The result is that HIEs in New York currently face a choice: exclude Part 2 data, adopt a model that requires providers to print a list of current Participants when the patient grants community-wide consent (and which only allows Participants on the printed list, not future Participants, to access the patient's records), or forego a community-wide consent model altogether. Moreover, if one HIE decides to adopt a community-wide-consent model without Part 2 data and another adopts a consent model that allows it to include Part 2 data, this can lead to the problematic result of prohibiting the first HIE from accessing any information from the second HIE.⁴

Clarifying the Proposed Rule

We appreciate SAMHSA's efforts in the Proposed Rule to create more flexibility to include a general designation of a class of data recipients in the consent form. Based on SAMHSA's description of the new § 2.31(a)(4), it appears that SAMHSA is attempting to allow data exchange approaches similar to the community-wide consent model. Our understanding of the intent of SAMHSA's proposal is the following: if a consent form states that information may be shared with a particular HIE and all Participants who provide treatment to a patient, then the

⁴ The root of the problem is that HIEs are not always able to identify which information is subject to Part 2 and which is not. If an HIE that has adopted community-wide consent seeks to access information from an HIE with Part 2 information, that second HIE cannot share any patient information at all with the requesting HIE unless it can be sure it can segregate all Part 2 information. This scenario has in fact occurred in the state. In effect, this single Part 2 requirement has led to the scenario where providers in one region in New York cannot share any health information with providers in another region in New York through an HIE.

consent form need not list those Participants and the HIE may share the patient's information with those Participants, so long as the patient can be provided with a list of Participants upon request.

However, we believe the actual language of the proposal is ambiguous in several respects. The proposed language says that the consent form must include the following information:

- (4)(i) The name(s) of the individual(s) to whom a disclosure is to be made; or
 - (ii) If the entity has a treating provider relationship with the patient whose information is being disclosed, such as a hospital, a health care clinic, or a private practice, the name of that entity; or
 - (iii) If the entity does not have a treating provider relationship with the patient whose information is being disclosed and is a third-party payer that requires patient identifying information for the purpose of reimbursement for services rendered to the patient by the part 2 program, the name of the entity; or
 - (iv) If the entity does not have a treating provider relationship with the patient whose information is being disclosed and is not covered by paragraph (a)(4)(iii) of this section, such as an entity that facilitates the exchange of health information or a research institution, the name(s) of the entity(-ies); and
- (A) The name(s) of an individual participant(s); or
 - (B) The name(s) of an entity participant(s) that has a treating provider relationship with the patient whose information is being disclosed; or
 - (C) A general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed.

We suggest the following changes to the above language to provide greater clarity and achieve the intent of the proposal:

- This provision repeatedly uses the term "entity" but does not define which "entity" is being referenced. We assume the intention is to refer to an entity, as opposed to an individual, receiving the patient's information. If so, we suggest that be made clearer. For example, Section 4(ii) could read: "If the disclosure is made to an entity (rather than an individual) and that entity has a treating provider relationship ..." Similar changes could be made in Sections 4(iii) and (iv).
- As currently written, Section 4(iv) applies to two very different categories of entities. The section covers both entities in the health care system that seek to exchange information among their participants – such as HIEs and ACOs – and it also covers entities that do not fit within 4(ii) or 4(iii) and may operate entirely outside the health care system, such as life insurers or a patient's employer. We therefore suggest dividing Section 4(iv) into two sections. The first

would contain special provisions governing disclosures made through HIEs and would retain the references to “individual participants” and “entity participants.” The latter would cover all entities that do not fall into any of the other categories in Section 4; in these cases, the specific entity to which disclosure is made would have to be specified.

- If SAMHSA is seeking to create a special rule that governs disclosure to Participants in an HIE, we believe it is necessary to include a definition of an HIE so that it is clear when the special rule applies. For example, the Health Information Management and Systems Society (HIMSS) defines an HIE as an organization that “provides the capability to electronically move clinical information among disparate healthcare information systems, and maintain the meaning of the information being exchanged, with the goal to facilitate access to, and retrieval of, clinical data to provide safe, timely, efficient, effective, equitable and patient-centered care.”
- If a special provision is included in the regulations to cover disclosures through an HIE, we do not believe it should be necessary for the consent form to name every HIE that may assist in the distribution of the patient’s information. In New York, multiple HIEs are linked through the SHIN-NY. It would be confusing to patients to list all of the State’s HIEs in a consent form. Moreover, SAMHSA has previously provided guidance that HIEs may have access to Part 2 information under a QSOA without patient consent.

Treating Provider Relationship under the Proposed Rule

In addition to these changes aimed at improving the clarity of the proposal, we have concerns about the provision limiting the use of a “general designation” only to Participants in an HIE who have a “treating provider relationship” with the patient. An organization that is not a treating provider may have a legitimate need for accessing the patient’s Part 2 information. For example, the organization may be a Health Home – an organization that helps coordinate the care of individuals with multiple chronic health conditions – or a payor that is engaging in care management activities and is seeking the patient’s Part 2 information in order to better coordinate the patient’s care. Such an organization may not have a “treating provider relationship,” and therefore it would need to obtain a separate consent form from a patient if it could not be included in a general designation. But since these organizations often do not meet face-to-face with a patient, it may be difficult for them to obtain such consent, and therefore in practice a patient may be unable to share Part 2 information with such an organization under the Proposed Rule.

We understand the rationale behind the proposed treating provider limitation: SAMHSA only wants Part 2 information to be shared based on a general designation of recipients if those recipients are responsible for the patients’ health. We agree with this goal, but we believe there are other ways to achieve it. Rather than limiting the class of recipients to treating providers, we think it should be permissible to designate the recipients broadly to include various participants in the health care system that are responsible for the patient’s health: providers, health plans, public health authorities, ACOs and similar organizations, and entities engaging in care management. The permissible uses for such information should also be broadened to include not just treatment but care management and quality improvement. Many of these terms are defined

in the HIPAA regulations, and SAMHSA could incorporate the HIPAA definitions into its rules to the extent appropriate. To ensure that patients understand the implications of granting consent, SAMHSA could require that the consent form spell out all the categories of permissible recipients and permissible uses. For example, if an HIE wanted to allow Part 2 information to be shared with a large category of providers for many different uses, the form could state: “By signing this form, you agree that your information may be shared with providers, health plans, and care management organizations for purposes related to your treatment, care coordination, or quality improvement.”

If SAMHSA is unwilling to eliminate the “treating provider relationship” requirement, we request that SAMHSA at least revise its proposal to allow entities involved in care management to access patient information under a general designation. Care management can include efforts to assist a patient in obtaining appropriate care, coordinating the provision of multiple health care services provided to a patient, or working with a patient to help that patient to follow a plan of medical care. Care managers are central to payment reforms in New York State such as Health Homes and the Delivery System Reform Incentive Payment (DSRIP) Program. Care managers may be employees of providers, but they also may work for other entities such as health plans or an entity dedicated to care management such as a Health Home. Care managers need to have comprehensive information on a patient’s medical care since their primary role is coordinating such care. However, since care managers often do not diagnose, evaluate, or treat a patient, they may not have a “treating provider relationship” as contemplated by the Proposed Rule.

As an alternative to eliminating the “treating provider relationship” requirement, SAMHSA could redefine “treating provider relationship” to include entities that provide care management. For example, the following language could be used: “*Treating provider relationship* means, regardless of whether there has been an actual in-person encounter, a relationship between a patient and an individual or entity under which (1) that individual or entity assesses, diagnoses, counsels or treats the patient, coordinates the patient’s care, or assists with the implementation of the patient’s care plan, and (2) the patient agrees to have such assessment, diagnosis, counseling, treatment, care coordination, or assistance provided by the individual or entity.” Alternatively, if SAMHSA does not think it is appropriate to broaden the definition of a “treating provider relationship,” § 2.31(a)(4) could be revised to allow a general designation to be used whenever there is a “treating provider relationship” or a “care management relationship,” and “care management relationship” could be defined to include the concepts of assistance in obtaining appropriate care, care coordination, and assistance in the implementation of a plan of medical care.

Finally, if SAMHSA retains the “treating provider relationship” requirement, we suggest clarification of Section 4(iv)(C), which limits the use of a “general designation” to “a participant(s) who has a treating provider relationship with the patient whose information is being disclosed.” To make it clear that Participants who develop a treatment relationship with the patient after the date the consent is signed may gain access to the patient’s information, we suggest revising this language to read: “... to a participant(s) who has a treating provider relationship with the patient at the time the disclosure is made.”

Alternative Approach Suggested by SAMHSA

Under an alternative approach, SAMHSA proposes to provide a definition of the term “organization.” Paragraph (c) of that definition would include within that definition “an organization that is not a treating provider of the patient whose information is being disclosed but that serves as an intermediary in implementing the patient’s consent by providing patient identifying information to its members or participants that have a treating provider relationship, as defined in §2.11, or as otherwise specified by the patient.”

It appears that SAMHSA’s intent here is to treat an HIE and its Participants as part of the same “organization” for purposes of the consent form, and therefore require that only the name of the HIE and not its Participants be listed in the consent form. If that is the intention, then we support the alternative approach. That being said, we think it would be clearer if SAMHSA spelled this

out in the text of the regulation by including language such as: “In the case of a health information exchange, the consent form must include the name of the health information exchange receiving the information but need not list the name of all of the health information exchange’s members or participants.”

For the reasons stated above, we disagree with the “treating provider relationship” limitation in the alternative approach. We would recommend instead that the language state “to its members or participants that are health care providers, health plans, entities providing care management, or other entities providing health care services” (again HIPAA definitions could be used to the extent necessary).

In regards to additional protections for patients under the alternative approach, we think it is appropriate for SAMHSA to require the consent form to make clear that by granting consent, the patient is allowing the HIE to share information with its Participants. We also generally support applying the list of disclosures requirement, discussed below, to the alternative approach.

List of Disclosures (§ 2.13(d))

We agree that if an HIE shares a patient’s Part 2 information with a Participant, it is fair to require the HIE to provide information to the patient upon request about which Participants accessed the patient’s information. This allows patients to monitor the sharing of their information to make sure it is being properly shared, and we have the same requirement in our own rules. It is important to give HIEs sufficient time to address such requests, and we appreciate that SAMHSA is proposing to allow HIEs to have up to 30 calendar days to respond.

We emphasize, though, that the “brief description” of the information shared should, indeed, be brief. For example, we think if the information came from a laboratory, we think it is appropriate to describe the information as “laboratory data.” If the rule required more detail, it may pose implementation challenges for HIEs.

Electronic Signatures (§ 2.31(a)(9))

SAMHSA proposes to adopt a rule stating that: “Electronic signatures are permitted to the extent that they are not prohibited by any applicable law.” We agree that in this day and age of electronic media, electronic signatures should be recognized.

Other Aspects of the Proposed Rule

Security of Part 2 Records (§ 2.16)

SAMHSA proposes more detailed security requirements for Part 2 programs. We agree that it is important to keep Part 2 records secure, both in electronic and paper form. However, we note that HIPAA already has a detailed security regime. We ask SAMHSA to clarify whether it is intending to impose any security requirements that go beyond HIPAA. If not, we recommend that SAMHSA insert language into the regulation that states that Part 2 programs can meet these security requirements by following the HIPAA Security Rule.

Definition of Qualified Service Organization (§ 2.11)

SAMHSA proposes to amend the definition of a Qualified Service Organization to make clear that an entity that provides population health management to a Part 2 program may qualify as a Qualified Service Organization. We agree with this change in that it will enable such organizations to better serve Part 2 programs and their patients, and we thank SAMHSA for this proposal.

Notice to Patients of Federal Confidentiality Requirements (§ 2.22)

SAMHSA proposes to allow Part 2 programs to provide notice to patients of the federal confidentiality requirements in electronic form. We agree with this change as well. Since many patients are accustomed to receiving information electronically, it will be helpful for Part 2 programs to have this option.

Conclusion

We again thank SAMHSA for focusing on the issue of the electronic exchange of Part 2 information through HIEs.

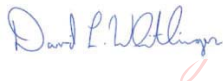
We ask SAMHSA to consider one question: is it ever appropriate for HIEs to share Part 2 patient information with providers and other entities participating in those HIEs? If the answer is yes, then we ask that your agency commit itself to making such information sharing a reality and address restrictions that prevent this from occurring. This means that, for the reasons stated above, substantial revisions need to be made to the Proposed Rule. The practical impact of

SAMHSA's current proposal is that it will likely cause HIEs in New York State to exclude Part 2 information from their exchanges. Doing so will deprive patients of the opportunity to make a choice as to whether their Part 2 information can be exchanged. While the revisions at § 2.31(a)(4) have the potential of making exchange of Part 2 information easier, the proposed changes at § 2.31(a)(2) and (3) effectively erase any benefit that may come from the changes at § 2.31(a)(4).

If SAMHSA ultimately determines that the changes at § 2.31(a)(2) and (3) are appropriate, we at the very least ask that SAMHSA allow HIEs to preserve the status quo. That is, the requirements of § 2.31(a)(2) and (3) should only apply if an HIE decides to make use of the new flexibility under § 2.31(a)(4). That way, HIEs could continue to exchange information under the current system. While the current system makes it very difficult for HIEs to exchange Part 2 information, we unfortunately think the proposed alternative would make such exchange even less practical.

As always, we appreciate your consideration of our comments and look forward to working with SAMHSA.

Sincerely,



Digitally signed by David Whitlinger
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Date: 2016.04.08 11:20:20 -04'00'

David Whitlinger
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