I. Introduction to LAC Comments

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

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

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

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

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

- LAC supports the goals set out in the request for comments and many of the specific suggestions for adjusting how the regulations currently operate. LAC believes that the current regulations, together with existing plus additional guidance from SAMHSA, can accomplish many (if not all) of the intended goals of integrating substance use disorder and other health care and improving communication between them more effectively.

- Since HIPAA requires compliance with state and federal laws that mandate greater privacy protections, EHRs must be designed so as to comply with the many state statutes that require heightened protections for information related to mental health, HIV/AIDS, reproductive health, domestic violence and other types of sensitive health information, as well as with 42 C.F.R. Part 2. In addition, EHRs must also be designed to comply with the HITECH Act, which provides that individuals have a right to restrict the disclosure of health information in electronic or any other form when they pay out of pocket for services provided. It is important to keep in mind, therefore, that EHRs would be required to accommodate enhanced protections for the medical records of some illnesses in order to be HIPAA and HITECH-compliant even if 42 C.F.R. Part 2 did not exist.

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

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

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

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1 45 C.F.R. § 164.522(a)(1)(vi).
payment, and health care operations (TPO). HIPAA’s definition of TPO is so broad as to allow virtually unfettered access to patient’s health information by those in the health care system; such an exception would be a death knell for Part 2’s patient consent requirement and prohibition on redisclosure. Furthermore, where Part 2 requires a special court order for disclosures to law enforcement and to judicial or administrative bodies (such as divorce and child custody proceedings) with heightened review standards, HIPAA permits such disclosures in whatever manner is required by state law, meaning as soon as a health care provider receives a subpoena, judicial or administrative order, or even a discovery request. Given the disastrous consequences patients often face when their SUD histories are disclosed to law enforcement or judicial or administrative bodies, adopting this standard for SUD patient records would do great harm to patients and their families.

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

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

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

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

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2 For example, under 42 C.F.R. Part 2, a court ordinarily may not even order disclosure of treatment records for the purpose of prosecuting a patient. See 42 C.F.R. §§ 2.61-2.65.
without obtaining appropriate court orders as required by Part 2. This represents requests from only the 10 states to which we provide hotline assistance.

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

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

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

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

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

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

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

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

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

**III. LAC Comments**

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

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

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

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

b. Consent Requirements

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

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

Comments on First and Second Suggested Consent Changes:

SAMHSA’s first suggested change is, “Allow the consent to include a more general description of the individual, organization, or health care entity to which disclosure is to be made.” Its second suggested change is, “Require the patient be provided with a list of providers or organizations that may access their information and be notified regularly of changes to the list.”

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11 See 42 U.S.C. § 290dd-2(a) (“Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity related to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United states shall, except as provided in subsection (e) of this section, be confidential….” (emphasis added)).
With respect to the first suggested change, we believe that there is a simple way to address concerns raised by some stakeholders that Part 2’s current “to whom” provision is too narrow. Part 2 currently requires that a consent form must list the “name or title of the individual or the name of the organization to which disclosure is to be made.”\footnote{42 C.F.R. § 2.31.} We believe that “title of the individual” to whom disclosure is to be made could be interpreted as allowing “treating provider” to be listed as the title of the individual to whom disclosure is to be made.

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

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

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

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

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

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

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

Comments on Third and Fourth Suggested Consent Changes:

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

Comments on Fifth Suggested Consent Change:

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

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13 42 C.F.R. § 2.31.
14 42 C.F.R. § 2.13(a).
c. Redislosure

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

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

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

d. Medical Emergency

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

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

15 42 C.F.R. §2.32.
16 42 C.F.R. §2.12(a)(i)
immediate medical intervention,” and opposes any revision that would allow providers to use the medical emergency provision to prevent emergencies.

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

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

e. Qualified Service Organization (QSO)

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

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

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

17 42 U.S.C. § 290dd-2 (b)(2)(A)
be needed. Indeed it is quite simple for a consent to be drafted that allows communication among multiple parties.

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

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

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

f. Research

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

In sum, we would support qualified researchers gaining access to Part 2 information for scientific research purposes, from sources other than Part 2 programs, if there is a way to ensure that all of Part 2’s research protections in §2.52 will be complied with.
g. Addressing Potential Issues With Electronic Prescribing and Prescription Drug Monitoring Programs (PDMPs)

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

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

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

IV. Conclusion

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

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

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