April 6, 2016

The Honorable Kana Enomoto
Acting Administrator
Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
Attention: SAMHSA-4162-20
Submitted electronically to: http://www.regulations.gov

Re: Confidentiality of Substance Use Disorder Patient Records Proposed Rule

Dear Administrator Enomoto:

On behalf of the American Medical Informatics Association (AMIA), thank you for the opportunity to submit comments regarding this Notice of Proposed Rulemaking (NPRM) on the Confidentiality of Substance Use Disorder Patient Records. This NPRM was published by the Substance Abuse and Mental Health Services Administration (SAMHSA) in the February 9, 2016 issue of the *Federal Register*.

AMIA is the professional home for more than 5,000 informatics professionals, representing researchers, front-line clinicians and public health experts who bring meaning to data, manage information and generate new knowledge across the health and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA members play a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

In providing input to this proposed rule, we first offer general comments about SAMHSA's approach to the confidentiality of substance use disorder (SUD) patient records, followed by an attachment where we discuss selected provisions of the proposed rule, and provide recommendations to specific proposals included in the NPRM.

General Comments

AMIA appreciates and supports SAMHSA's motivations for updating 42 CFR Part 2 (Part 2) rules in order to facilitate electronic exchange of SUD information, while ensuring appropriate confidentiality protections are in place. We also agree with the goals explicitly stated by SAMHSA in its NPRM[1] to:

- Increase opportunities for individuals with substance use disorders to participate in new and emerging health and healthcare models and health IT;
- Facilitate the sharing of information within the health care system to support new models of integrated healthcare;

[1] Confidentiality of Substance Use Disorder Records, 81 Fed. Reg. 6990 (Feb. 9, 2016)

- Improve patient safety while maintaining or strengthening privacy protections for individuals seeking treatment for substance use disorders; and
- Decrease burdens associated with several aspects of the rule, including consent requirements.

However, AMIA is concerned the proposed modifications are unlikely to fully accomplish the goals established by SAMHSA. There are systemic obstacles in contemporary workflows, caused in part by 42 CFR Part 2, that make delivering comprehensive care for SUD patients next to impossible. As indicated in Figure 1, Part 2 regulations have had the effect of erecting a "brick wall" that blocks information exchange between Part 2 programs and other health system elements. Technically, Part 2 programs can share information with appropriate patient consent or under narrowly defined circumstances (e.g., life threatening medical emergencies) but on a practical level, information exchange is incomplete and infrequent. Logistical barriers and widespread confusion about the regulatory requirements often paralyze organizations from exchanging data or coordinating care with Part 2 programs.

Furthermore, we now live in a digital era where numerous data types from electronic health records (EHRs) can be searched, indexed, and employed to extrapolate information about SUDs across patient populations. The ability to query large numbers of EHRs, combined with the reality that medications for substance abuse treatment, are already being exchanged through statewide and national databases, underscores the difficulty of segmenting discrete data to maintain privacy and confidentiality.

These trends – the unavailability of important information at the point of care and the ability to triangulate SUDs across populations – render the current 42 CFR Part 2 grossly inadequate for modern medicine. Part 2 rules, through the prohibitions on information sharing, have made delivering care to SUD patients difficult to manage, and they have inhibited the broader movement toward improved care coordination and interoperability. Regrettably, this NPRM largely maintains the status quo, where the benefits afforded to the patient are minimal and the burdens of compliance are extremely high.

AMIA urges SAMHSA to initiate a broad conversation among other Department of Health & Human Services (HHS) agencies to develop a granular data specification standard that enables patients to be in full control of all their health data, not just Part 2 data. The use case of SUD data is emblematic of a much bigger issue that affects reproductive, mental health and other types of sensitive information. Rather than treating Part 2 data as the only kind of information that merits protection, HHS should acknowledge the right of patients to have much more granular control of their entire medical record. While the Office of the National Coordinator for Health Information Technology's Data Segmentation for Privacy (DS4P) demonstrated a technical solution for re-disclosure, it was destined to remain a pilot with limited reach because HHS has neglected to explore comprehensively the scale of sensitivity that exists across data types.

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April 6, 2016

AMIA suggests that regulators reflect on the December 2010 report from the President's Council of Advisors on Science and Technology (PCAST), which emphasized the need for national leadership to develop granular data and metadata standards.

> "There is not yet a recognized standard for health metadata, and healthcare organizations and technology providers considering adoption of a standard face a coordination problem. Even for the healthcare systems that are leaders in using information technology, there is little private incentive to focus on widespread interoperability unless other providers are making the same investment and there is a clear path toward productive data exchange…Federal leadership, therefore, has a clear role to play in coordinating standards for health metadata and in creating economic incentives to adopt the standard."[2]

The 2010 PCAST report also laid the groundwork for several subsequent works, including the influential JASON report, "A Robust Health Data Infrastructure," which also called for a new software architecture that "Represent the data as atomic data," and includes "corresponding metadata, context, and provenance information."[3] Further, evidence suggests patients want the kind of granular control that metadata tagging would provide. In a 2013 study, "Patients expressed sharing preferences consistent with a desire for granular privacy control over which health information should be shared with whom and expressed differences in sharing preferences for sensitive versus less-sensitive EMR data."[4]

As the professional home for informaticians with both technical expertise and clinical experience working with SUD patient populations, AMIA extends an offer to work closely with SAMHSA to revisit solutions to this daunting challenge. We would like to help SAMHSA and HHS think broadly, across the spectrum of sensitive data in healthcare, to develop policy and technical solutions that provide confidentiality to patients and appropriate access to information for treating providers. Only by addressing the full challenge of keeping sensitive information confidential, and by giving patients complete access and total control of all their health data, can SAMHSA fulfill its statutory obligations and realize their stated goals.

Below, we address individual proposals and provide additional context to our general comments. Should you have any questions about these comments or require additional information, please contact Jeffery Smith, Vice President of Public Policy at jsmith@amia.org or (301) 657-1291. We look forward to continuing this dialogue, and we offer our assistance to improve the current landscape of issues.

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[2] Executive Office of the President, President's Council of Advisors on Science and Technology. Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward. https://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf

[3] AHRQ Publication No. 14-0041-EF. Prepared by JASON, MITRE Corporation. A Robust Health Data Infrastructure. http://healthit.gov/sites/default/files/ptp13-700hhs_white.pdf.

[4] Caine K., Hanania R. "Patients want granular privacy control over health information in electronic medical records." Journal of the American Medical Informatics Association. 2013;20:7–15.

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Sincerely,

Douglas B. Fridsma, MD, PhD, FACP, FACMI
President and CEO
AMIA

Thomas H. Payne, MD, FACP
AMIA Board Chair
Medical Director, IT Services, UW Medicine
University of Washington

Enclosed: AMIA Response to SAMHSA Confidentiality of Substance Use Disorder Patient Records Proposed rule Proposed Rule

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Provisions of the Proposed Rule

Applicability
According to the NPRM, "These regulations cover any information (including information on referral and intake) about patients receiving a diagnosis, treatment, or referral for treatment for a substance use disorder obtained by a part 2 program. Coverage includes, but is not limited to, those treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners (other than general medical practices) who hold themselves out as providing, and provide substance use disorder diagnosis, treatment, or referral for treatment."[5]

AMIA Comment
The use of the phrase "holds themselves out" is problematic for two reasons. First, there is organizational complexity in a dynamic market of mergers, acquisitions and partnerships. This complexity has led to variation in interpretation of applicability, absent a clear definition of "hold themselves out." Second, the proposals would permit the regulations to apply to a single provider among a large group, or a single unit in a large general medical facility. These circumstances would substantially increase administrative burdens and increase difficulties with EHR configuration since two distinct approaches would be needed to manage and transmit records.

With a freestanding SUD treatment program, or a clearly designated treatment program that is part of a larger organization, the distinction between these entities and non-part 2 programs is clear. And if a physician prescribes acamprosate or naltrexone to patients in a private practice when indicated as part of general medical care and does not specifically advertise or otherwise "hold out" these services as focused on SUDs, he or she would presumably avoid the regulatory burdens of Part 2 rules (stemming from the emergency department personnel example in the NPRM). However, other delineations may be less clear such as including SUDs with a list of multiple other psychiatric disorders treated as part of a listing of managed care providers.

AMIA Recommendation: AMIA requests SAMHSA specifically define "hold themselves out" or more fully develop a set of examples where entities are "holding themselves out" as providing, and providing substance use disorder services. Further, we request that SAMHSA clarify the applicability of Part 2 Regulations for providers represented medically and legally as a separate entity, but who are in actuality a part of the same health system as a clinic for substance abuse treatment.

Although we support the flexibility to apply Part 2 regulations to individual providers within a larger group, or a single unit in a large general medical facility, we note how this policy will increase total costs and complexity of compliance, and may reduce the number of providers willing to treat substance use disorders at a time when expanded access to treatment is crucial.

[5] Confidentiality of Substance Use Disorder Records, 81 Fed. Reg. 7015-7016 (Feb. 9, 2016)

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Notice to Patients of Federal Confidentiality Requirements
SAMHSA is proposing a number of changes to the contents of the Part 2 consent forms required to exchange substance use disorder information:

- SAMHSA proposes to make the "To Whom" section of the consent form less constrained, allowing for a general designation and making clear that a patient may designate an HIE (plus one of three other kinds of designees) in the "To Whom" section.
- SAMHSA is proposing to move the current "Amount and Kind" and revise the provision to require the consent form to explicitly describe the substance use disorder-related information to be disclosed.
- SAMHSA proposes to add a requirement that, when requested, patients are provided a list of entities to whom their information has been disclosed. This provision would apply to disclosures made in the previous two years, and would be effective two years after the effective date of the final rule.
- SAMHSA is proposing to permit electronic signatures to the extent that they are not prohibited by any applicable law.
- SAMHSA is considering whether to issue guidance at a later date that includes a sample consent form.

AMIA Comments
The primary lever through which SAMHSA proposes to facilitate exchange, enable participation in emerging care models, and decrease administrative burden is through modifications to the Part 2 consent form. Specifically, SAMHSA proposes to allow patients to provide a generic designation in the "To Whom" portion of the form, so that consent is not required each time it is requested by a clinician, a hospital, an HIE or an ACO. This policy, while an improvement to the existing rules, is offset by the constriction of the "From Whom" portion of the consent form. Constraining the "From Whom" portion of the consent form seems logical if the record is sent from one treating physician to another through a protocol like the Direct standard, but the concept breaks down in the networked environment of an HIE query. In this scenario, there is no individual actively "sending data," but rather the data is "pulled" from a system or a database. The proposed policy would require a patient to renew their consent form each time a new provider joined the HIE, unless the "From Whom" could be designated as "from the HIE." Such a model would be very challenging, if not unworkable, in an HIE environment.

The proposed rule also lists examples of the "kind" and "type" of information to be disclosed, but there is ambiguity in what data is included under each example. It is unclear whether multiple patient consents would be required when the contents of a record changes. It is also unclear whether providers would have to manually redact notes that should not be released. Even if a specific description of the amount and kind of information were possible, few (if any) electronic health records have the capability to segment record information in a way that would fully support this requirement, particularly in terms of information that may be present in free text portions of

notes. Were the outputs of the DS4P pilots refined and required under the federal health IT certification program, we would only have a solution for the re-disclosure of SUD information – a solution that addresses a fraction of the problem. Without the universal availability of data segmentation and free text recognition capabilities, manual review and redaction would presumably be needed to comply with the letter of the regulations.

AMIA Recommendation: AMIA supports the broadening of entities that may be listed in the "To Whom" portion of the consent form. We believe this is a sensible policy change, and should improve both the availability of information when and where it's needed, as well as provide patients with control over their Part 2 data. However, we do not support SAMHSA's proposal to constrain the "From Whom" portion of the consent form. We recommend SAMHSA finalize the rule with as much flexibility as possible on both the To Whom and From Whom portions of the consent form.

AMIA Recommendation: We suggest SAMHSA give patients full control of their record by allowing them to consent to sharing the "entire record" as an additional option. If the patient chooses to share only discrete information, we recommend SAMHSA use the required elements of a Summary of Care Record, as defined by Centers for Medicare and Medicaid Services for the EHR Incentive Program,[6] as a foundation for the "kind" and "type" of information able to be disclosed. EHR developers and providers have experience with, and may be able to build Part 2-compliant communications by, using Summary of Care Record data elements.

AMIA Recommendation: AMIA supports this right of patients to receive a list of entities to whom their information has been disclosed in concept. However, we are concerned that similar efforts to develop an "Access Report" by the HHS Office of Civil Rights (OCR) have proven extremely difficult and impractical to implement.[7] We urge SAMHSA to engage with OCR, providers and vendors to fully understand the implications of such a requirement before establishing and implementation date. Should SAMHSA insist on setting an implementation target for this provision, we request a full two-year period, at a minimum, to implement this provision of the proposed rule.

AMIA Recommendation: AMIA supports the use of electronic signatures, unless otherwise prohibited by law, and we believe that guidance on a sample consent form would be helpful for those who must comply with Part 2 rules.

AMIA Recommendation: AMIA supports development of a sample consent form, and we believe it would be helpful for those who must comply with Part 2 rules.

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[6] Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 2, 77 Fed. Reg. 54013 (Sept. 4, 2012)

[7] HIPAA Privacy Rule Accounting of Disclosures, 76 Fed. Reg. 31426 (May 31, 2011).

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April 6, 2016

Prohibition on Re-disclosure
SAMHSA clarified that the prohibition on re-disclosure only applies to information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a SUD, such as indicated through standard medical codes, descriptive language, or both. SAMHSA would allow other health-related information shared by the Part 2 program to be re-disclosed, if permissible under other applicable laws.

AMIA Comment
SAMHSA correctly identified "confusion on the part of some providers as to how much of a patient's record is subject to 42 CFR part 2, which often leads to a decision to protect the entire record,"[8] thus the proposed clarification. AMIA, again, points to a lack of consistent interoperable segmentation of information in the electronic record. The proposed policy is laudable, and we would support it if the technical capabilities to comply with it existed. As mentioned previously the technical capabilities do not exist at this time. We again reiterate our offer to work with SAMHSA to help think through how a holistic approach may accomplish the dual goals of confidentiality and appropriate data availability for clinical care.

We also believe this proposed clarification itself necessitates additional clarity. During our review of the NPRM, the question arose: does the prohibition of "re-disclosure" apply only to the actual record sent from the other facility or does it also prevent disclosing information from the Part 2 compliant record that is now incorporated into physician notes at the receiving institution?

For example, a hypothetical patient at a free-standing substance use program is in treatment for an opioid use disorder and is receiving methadone. The patient makes a suicide attempt by hanging and is brought to the emergency department. Records from the substance use treatment program are sent and reviewed. The emergency physician notes in her evaluation that "Pt. was referred from Center X for a suicide attempt after learning he would be facing criminal charges for drug distribution. He has been treated with methadone for one week with dose titrated to 40 mg daily." If the patient is now transferred to a distinct psychiatric facility for care, would the emergency physician note be precluded from disclosure because it contains Part 2 information, would it be disclosable with Part 2 information redacted or would it be releasable in its entirety because it is a note from a non-part 2 entity? If the note were unable to be disclosed, or if it required redaction, significant compromises in care would result.

AMIA Recommendation: AMIA reiterates its recommendation that HHS engage in a broad discussion about the relative sensitivity patients have regarding their all their health data, not just Part 2 data. We also request additional clarification by way of example of how such data may, or may not, be disclosed after lawful receipt of Part 2 data.

[8] Confidentiality of Substance Use Disorder Records, 81 Fed. Reg. 7003 (Feb. 9, 2016)

April 6, 2016

Research
SAMHSA proposes to expand the availability of Part 2 data for purposes of research, as well as address data linkages to enable researchers holding Part 2 data to link to data sets from federal data repositories.

AMIA Comment
AMIA supports greater availability of Part 2 data for research and we agree with SAMHSA on the value of using data linkages to expand the scope of research. This proposal is particularly relevant as healthcare providers are being asked to address readmissions and behavioral health data, examining rates of chronic diseases in the mental health and SUD population. Expansion to non-federal data repositories is crucial to be able to do research across the lifespan and across individuals of different socioeconomic classes. Limiting linkage possibilities to Medicare, Medicaid or other federal databases would limit (and likely skew) our view of the important health issues being researched. Further, we view non-profit entities, such as academic centers, research-focused foundations, healthcare facilities who engage in research and similar organizations as being distinct from for-profit organizations that may have business motives for attempting re-identification if given access to large linked datasets. For example, even though pre-existing conditions can no longer be used to deny issuance of health insurance, there may be ways in which such information could be used by other types of insurers, or by employers, with clear detriments to the patient if re-identification were to occur.

AMIA Recommendation: AMIA recommends that SAMHSA better align its requirements for disclosure of information for conducting scientific research with existing requirements for research as regulated by the Common Rule. Maintaining a fragmented approach is cumbersome and virtually impossible to maintain with large data sets, particularly when the same data is likely available from a non-Part 2 source and a Part 2 source for a given patient. An alternate approach would be to create a single category of consent for research purposes.

AMIA Recommendation: AMIA supports the ability of researchers holding Part 2 data to be able to link to data sets outside of federal data repositories if the correct security and privacy protections are in place.

AMIA Recommendation: For private, commercial enterprises that request access, there should be a mandatory review of whether potential conflicts of interest exist that should reduce or bar access to the linked data. It may also be appropriate to require filing of conflict of interest statements by the primary investigators and co-investigators.

Costs
SAMHSA has included several estimates of costs to implement proposals related to this NPRM.

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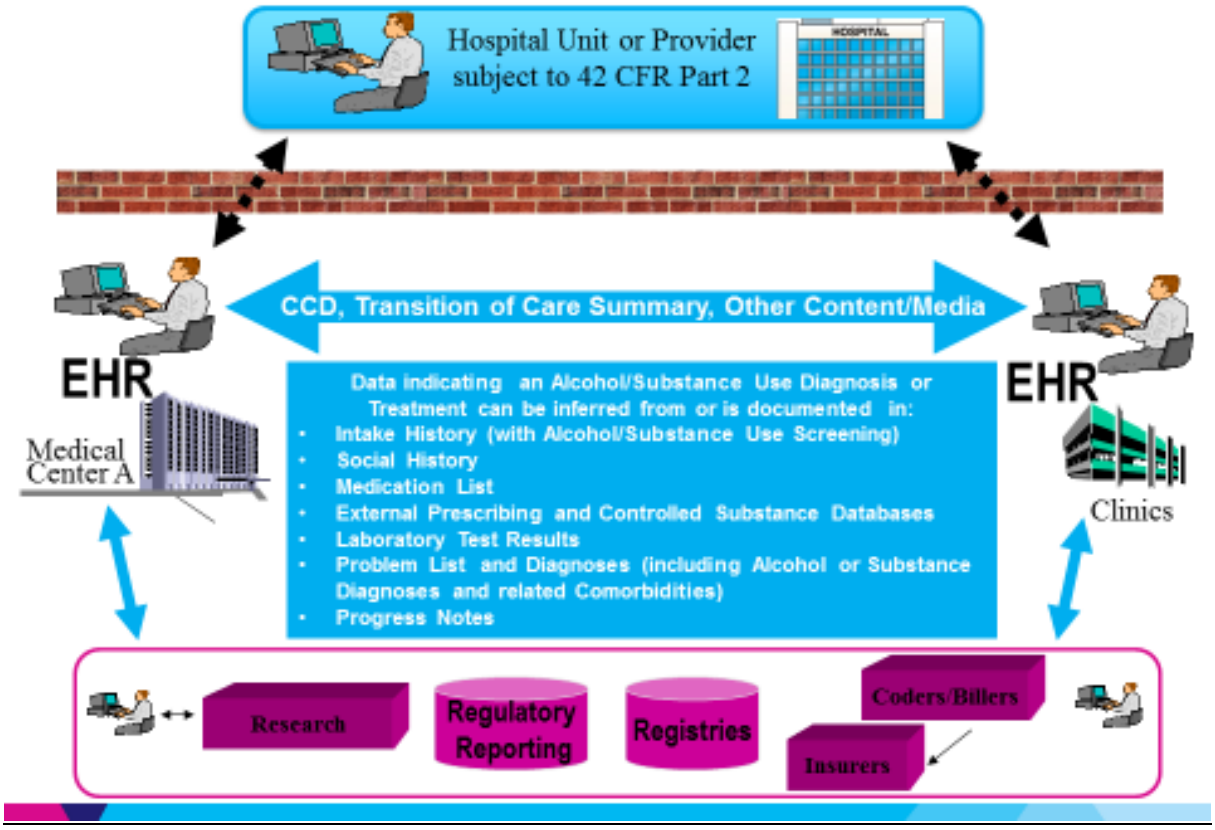
April 6, 2016

AMIA Comment

With the proposals put forth by SAMHSA related to consent form changes and re-disclosure policy, we believe the cost estimates, in terms of EHR customizations, are likely to be a gross underestimate since there is no current interoperability standard within and across EHRs that can address Part 2 information. The larger burdens for complying with Part 2 rules also pertain to non-Part 2 organizations that need to maintain parallel methods for keeping track of information from Part 2 programs vs other programs in terms of re-disclosure prohibitions.

AMIA Recommendation: We suggest SAMHSA better articulate and revisit their cost estimates for compliance.

Figure 1



In the current health care delivery system, diagnosis and treatment of SUDs can occur in multiple settings, some of which are subject to 42 CFR part 2 and many of which are not subject to Part 2. As shown in Figure 1, the Part 2 regulations have had the effect of erecting a "brick wall" that

blocks information exchange between Part 2 programs and other health system elements. Technically, Part 2 programs can share information with appropriate patient consent or under narrowly defined circumstances (e.g., life threatening medical emergencies). On a practical level, however, information exchange is relatively infrequent due to logistical barriers and widespread confusion about the regulatory requirements. Further, many of the same issues are present for behavioral health organizations that treat both mental health and SUDs and are complicated by a set of state laws, rules and guidance for mental health. Figure 1 also shows that goals of 42 CFR Part 2 cannot be met simply by sequestering information and tightly controlling its release from Part 2 programs. Within other elements of the healthcare system, there has always been documentation and exchange of information related to SUDs. However, such data is more readily available with the growth of electronic health records and the increasing emphases on coordination of care and behavioral health integration.