



October 24, 2019

Elinore F. McCance-Katz, MD, PhD  
Assistant Secretary  
Office of the Assistant Secretary for Mental Health and Substance Abuse  
Substance Abuse and Mental Health Services Administration (SAMHSA)  
Department of Health and Human Services (HHS)  
Attention: SAMHSA 4162-20  
5600 Fishers Lane, Room 17E41  
Rockville, MD 20857

Submitted electronically to: <https://www.regulations.gov/>

Re: Confidentiality of Substance Use Disorder Patient Records Proposed Rule  
Attention: SAMHSA 4162-20

Dear Assistant Secretary McCance-Katz:

Health Level Seven (HL7®) International welcomes the opportunity to submit comments on the *Confidentiality of Substance Use Disorder Patient Records* proposed rule.

HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena. The products of our organization provide the underpinnings for connected, patient-centered health care and an information highway for precision medicine. HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related interoperability standards, including the rapidly evolving Fast Healthcare Interoperability Resources (HL7 FHIR®), the Consolidated Clinical Document Architecture (C-CDA®), and the widely used V2 messaging standards. HL7 has more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

HL7 appreciates SAMHSA's efforts to facilitate information exchange for safe and effective substance use disorder (SUD) care while addressing the legitimate privacy concerns of patients seeking treatment for a substance use disorder. HL7 and its standards are a critical piece in successfully achieving SAMHSA's important objectives in this proposed rule. We therefore, provide our brief comments on the applicability and implications of HL7 standards and other issues below. In addition to our leadership and Policy Advisory Committee, HL7 Work Groups contributing to these comments include:

- Community-Based Care and Privacy (CBCP); and
- Security;

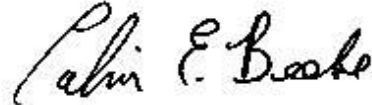
Our organization stands ready to support SAMHSA in addressing America's opioid epidemic and in ensuring better alignment of care for individuals with substance abuse disorder among those involved in the design and execution of that such care, while also ensuring appropriate confidentiality protection for 42 CFR Part 2 (Part 2) programs.

Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at [cjaffe@HL7.org](mailto:cjaffe@HL7.org) or 734-677-7777. We look forward to continuing this discussion and offer our assistance to SAMHSA.

Sincerely,



Charles Jaffe, MD, PhD  
Chief Executive Officer  
Health Level Seven International



Calvin Beebe  
Board of Directors, Chair  
Health Level Seven International

## Select Detailed HL7 Comments on Confidentiality of Substance Use Disorder Patient Records Proposed Rule (SAMHSA 4162-20) October 2019

The SAMHSA proposed rule regarding the confidentiality of information from federally assisted substance use disorder (SUD) treatment programs, which is laudable in its intent, contains important structural, substantive and standards-related challenges and opportunities for enhancement, which HL7 details below.

- **General** - Page 8 of the proposed rule states that:

“SAMHSA proposes several changes to the regulations at 42 CFR part 2 (part 2). First, we propose to amend language throughout the regulation to clarify several aspects of the applicability and disclosure requirements. Specifically, in Section III.B., Applicability, SAMHSA proposes to amend § 2.12 to clearly state in the regulatory text that the recording of information about a SUD and its treatment by a non-part 2 entity does not, by itself, render a medical record subject to the restrictions of 42 CFR part 2, provided that the non-part 2 entity segregates any specific SUD records received from a part 2 program (either directly, or through another lawful holder). SAMHSA believes this proposed language would encourage part 2 programs and non-part 2 providers to deliver better and safer coordinated care, while also protecting the confidentiality of individuals seeking such care.”

HL7 thanks SAMHSA for the clarifications in Section III.B. Specifically, we appreciate that “the recording of information about a SUD and its treatment by a non-part 2 entity does not, by itself, render a medical record subject to the restrictions of 42 CFR part 2, provided that the non-part 2 entity segregates any specific SUD records received from a part 2 program (either directly, or through another lawful holder).” We also applaud the intent behind the statement that “a non-part 2 provider [is able] to receive SUD information about a patient from a part 2 program, and then to engage in a treatment discussion with that patient, informed by that information, and then be able to create her own treatment records including SUD content, without the latter becoming covered by part 2 . . . [i]t is not SAMHSA’s intent to encourage a non-part 2 provider to abuse the rules, by transcribing extensively from a conversation with a part 2 program or from a received part 2 record when creating her own records, without having a clinical purpose for doing so.”

With respect to the first clarification, HL7 remains concerned that continued need for SUD record “segregation” or “segmentation” as outlined could be both burdensome and clinically problematic, particularly where information about a SUD and its treatment will not be further transmitted further by the non-part 2 entity. As detailed below, we also have concerns with the current status of segmentation-related standards, technology, and implementations; the immature state of segregation poses a challenge to the continued need for segregation or segmentation as outlined in the proposed rule. We urge SAMHSA to reconsider its all or nothing approach on this issue in the proposed rule, consistent with flexibility allowed by the applicable statute

With respect to the second clarification, on part 2 data entered into a non-part 2 record via a treatment discussion or transcription, we are concerned that this issue remains ambiguous and subject to multiple interpretations by experts, which presents a number of challenges including opening users of HL7 and other standards to undesirable legal risks that could hinder the completeness of clinical records and clinical care and the ability to further transmit the resulting records using standards with the need for data segmentation. *We respectfully request further guidance on this issue (e.g., on the nature and extent of data that can arise from treatment discussions informed by part 2 data or clinically relevant transcription) and clarification that data segmentation/tagging of such a non-part 2 record is not required. Finally, and urgently, we urge more evaluation and real world implementation testing with respect to the implementation, standards, and technology issues associated with both clarifications.*

- **Data Segmentation for Privacy (DS4P)** - Page 20 of the proposed rule says:

“Alternatively, ‘segregating’ can involve electronic solutions, such as segmenting an electronic SUD patient record received from a Part 2 program by use of a Data Segmentation for Privacy (DS4P) compliant EHR platform, in which segmentation is carried out electronically based on the standards of DS4P architecture. Either of these methods for “segregating” Part 2 covered records is a satisfactory way for the recipient entity to keep track of them, and to distinguish them from all the other records that the entity holds which are not subject to Part 2 protection.”

HL7 notes that DS4P is an American National Standard method for sending health information to facilitate patient and policy driven labeling of information disclosed or re-disclosed to another entity such as a covered entity, a Health Oversight Agency, or a consumer-selected App. DS4P does not, however, provide for “segmentation” within the receiving health information technology (HIT), but rather informs the receiving HIT on how to manage the data in accordance with the policy indicated by the labeling, to which it may be required to comply.

- **Consent2Share** - Page 22 of the proposed rule includes the first mention of “Consent2Share” an approach to automating the handling of signed, patient consents to disclose their identifiable, clinical data to another person or program. Although SAMHSA sponsored and promoted Consent2Share, its process of development did not meet core requirements for openness, balance, consensus, and due process, and therefore it is not an American National Standard Institute (ANSI) accredited standard. In addition, in our May 2019 letter to ONC on the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* proposed rule (NPRM) RIN 0955-AA01, HL7 noted its concern in reference to consent management for APIs that “Consent2Share does not support a consentor’s signature or specification to protect information content data requirements, e.g., the appropriate LOINC code to indicate information is an Opioid Treatment Agreement, which are required elements of a 42 CFR Part 2 compliant consent. Nor does it include the policy under which the information is governed.” Expanding on the need for an accurate Part 2 security label to include the HL7 42CFR Part2 policy code, HL7 notes that there are state behavioral health laws that could be represented with the same label described in Consent2Share but with different compliance requirements.

Another limitation on the use and applicability of Consent2Share is that it limits the purposes of use to which a Part 2 patient may consent for disclosure to “treatment” and “research”. However, as discussed in the proposed rule, patients may consent to other purposes of use such as payment, certain health care operations, and disclosure to Outpatient Treatment Programs and Prescription Drug Monitoring Programs. We note that HL7 has an extensive list of Purpose of Use codes that can be used in security labels to segment data for all the purposes to which a Part 2 patient may consent. Purpose of use codes as a group are defined as “Reasons for performing one or more operations on information, which may be permitted by source system's security policy in accordance with one or more privacy policies and consent directives.”

See <https://www.hl7.org/fhir/v3/PurposeOfUse/vs.html>.

*HL7 recommends, in reference to the Confidentiality of Substance Use Disorder Patient Records final rule, that a new, well-tailored solution should be developed building on SAMHSA-sponsored Consent2Share foundations, using appropriate processes and then balloted as an accredited ANSI standard. Noting that SAMHSA recognizes and encourages the further development of DS4P standards” [p. 21], HL7 stands ready and willing to partner with stakeholders to develop and publish such standards. Noting that some HL7 members have commented on operational complexities in the implementation of security label technologies, we recommend pilot testing and evaluation of such new*

standards. *We recommend broader government participation in developing a balloted Part 2 specific FHIR Consent Directive. We also invite SAMHSA's collaboration on the HL7 FHIR DS4P and Share With Protection Initiatives, which are intended to provide further guidance on the use of security labels to represent privacy policies and consent directives in an interoperable manner, and the technical means for persisting and enforcing those labels.*

- **Care Teams and Patient Identifying Information** - Page 25 of the proposed rule states that SAMHSA wants to ensure that patient identifying information is only disclosed to individuals and entities on the health care team with a “need to know”.

Given the complex, real world dynamics of healthcare environments and care teams, it can be difficult for an EHR and its users to determine “need to know” until after an entry into the EHR is made. This process typically follows examination and treatment (including prescribing) of the patient – all of which might have been beneficially informed by knowledge of the “segregated” Part 2 information. *Existing HL7 standards and new standards under development support access controls to meet a variety of needs relevant to this and similar scenarios. HL7 seeks support and resources for additional pilot testing, implementation and evaluation of these new technologies in scenarios with diverse care teams related to Part 2.*

- **Limitations on Patient Data Consent** - In a number of sections of the proposed rule, including for example on pages 24 and 25, limitations on the characteristics of those to whom a patient consents to have their data sent are discussed. Common entities receiving information in this scenario might be characterized by any of the following: covered by HIPAA; covered by the Common Rule; covered by FDA regulations; identified as capable of doing scientific research; and involving a specifically named person or entity. *HL7 recommends that SAMHSA clarify how the Part 2 EHR system should identify these characteristics in a target system, which could be accomplished by referencing standards that support conveying those characteristics.*

If the consent is electronically encoded with HL7 standards using either CDA or FHIR, then the consent information could indicate the purpose of use, via standard codes, (e.g., HIPAA Authorization for Research Disclosure or Common Rule for FDA) for which a recipient is permitted to access this information either by query or by a pushed transaction. The recipient could declare the same purpose of use code in their requests or in the credentials used to determine that the recipient is authorized (e.g., using SAML or a Smart on FHIR authorization request). For the information to be released, the EHR would compare the purpose of use codes on the information governed by the Part 2 consent with the purpose of use codes asserted or known to apply to the requester, and permit access only where there is a match. *HL7 stands ready to provide more detailed technical information about guidance that SAMHSA could develop for the industry on how to implement this policy goal and on how implementation could be achieved in a manageable timeframe without undue burden.*