SOFTWARE AND TECHNOLOGY
SATVA
VENDORS' ASSOCIATION

September 13, 2011

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: Steven Posnack
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave., SW., Washington, DC 20201

Reference: RIN 0991– AB78

Dear Mr. Posnack:

I am writing on behalf of the Software and Technology Vendors Association (SATVA) to offer comments regarding the advance notice of proposed rulemaking on metadata standards to support nationwide electronic health information exchange. SATVA members provide software and services to support the operation of a large percentage of the country's mental health and addiction treatment programs.

Behavioral health providers share the national interest in coordination of physical health, behavioral health, and social services, and in the use of health information technology to advance the delivery of patient centered care, improve health care quality, and reduce health costs. But their participation in electronic health information exchange is inhibited by concerns about compliance with ethical and legal standards governing disclosure of highly sensitive mental health and substance abuse program records.

Given these concerns, SATVA established a workgroup to examine the legal and technical issues related to electronic health information exchange by behavioral health providers. After considerable effort, the workgroup developed a model form of patient consent to electronic disclosure of sensitive health records, and agreed to a draft standard of a method for linking that consent to health information exchange transactions, based on the HITSP TP-30 consent directive management standards.

The SATVA workgroup specifically addressed the stringent requirements of 42 CFR Part 2, which requires a specific form of patient consent to disclosure of records created by federally assisted substance abuse programs, restricts re-disclosure, and requires specific notice to the substance abuse program of any "break the glass" emergency access to a record. The group met with the Substance Abuse and Mental Health Administration (SAMHSA) in May 2011, shared its

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work, and provided a live demonstration of 42 CFR Part 2 compliant electronic exchange of continuity of care documents.

We bring this background to our review of ONC's proposed metadata standards. SATVA supports establishment of national metadata standards that are supportive of jurisdictional and individual privacy policies. We think that ONC/DHHS should also establish a national standard for a common set of data elements required to record permissions to disclose and re-disclose particularly sensitive health records and national standards for robust consent directive management procedures, so as to ensure NHIN participant compliance with 42 CFR Part 2 and similarly stringent legal requirements.

Our specific comments about the proposed metadata standards are as follows.

1. **Patient Identity Metadata Standards**

- SATVA has no objection to expression of metadata in accordance with the requirements of the HL7 CDA R2 header.

- Q1. We recommend that the metadata element that identifies the patient have as an option the linkage of the patient identification number used by a provider with that provider's National Provider Identifier.

2. **Privacy Metadata Standards**

- Q.6. The privacy metadata standards should include the elements required to associate the tagged data with the legal requirements (jurisdictional policies) including those of 42 CFR Part 2. These data elements should be structured so as to enable the receiving electronic health record or HIE to algorithmically process the information that is received. The privacy metadata should include elements to identify: (i) the purposes of disclosure (usually limited to treatment, payment, or healthcare operations); (ii) any limitations on re-disclosure of the underlying record established by law or by the individual patient; (iii) the expiration date of any patient permission to re-disclose the record; (iv) any notices that must accompany any disclosure of the underlying record. (42 CFR 2.32 requires a specific form of notice to the recipient of a substance abuse program record that the record may not be re-disclosed except as permitted by 42 CFR Part 2.) If these metadata elements are attached to substance abuse program records at the time of disclosure, there would be no need for a privacy policy pointer.

- Q.7. The problem with privacy policy pointers is that there are no recognized authoritative sources of jurisdictional privacy policies. References to state or federal statutes or regulations are insufficient, given the need to reconcile inconsistent requirements of HIPAA and more stringent state/federal laws governing disclosure of health records based on source (substance abuse programs) or content of record (HIV diagnoses, genetic test results). This analysis would have to be continuously updated.

  There is no realistic expectation that the required policy engines will be in place in time for Stage 2 or even Stage 3 of implementation of the Meaningful Use Rule. There is no current mechanism for qualification of a policy "authority" or funding method to maintain jurisdictional policy engines on an ongoing basis.

- Q.7. SATVA developed an approach for the electronic exchange of substance abuse program records based on establishment of a pre-determined common consent policy based on 42 CFR Part 2 and application of the HITSP TP-30 transaction package. Either the requesting or disclosing provider obtained the patient's consent directive. SATVA believes that this approach would be very effective for NHIN-Direct point- to-point communications among providers.

- Q.11. Use of coded values for sensitivity to trigger special handling of tagged data will only be effective if that approach is consistent with the law governing use/disclosure/re-disclosure of the tagged data. In the case of substance abuse program data, the need for special handling is based on the source of the tagged data, not the type of data. Another type of data that requires special handling is health data maintained by schools, which is governed by FERPA.

- Q.12. It seems to be premature to attempt to implement granular controls over disclosure of specific classes of data included within an individual clinical record. Please note the comments about this issue in the August 19, 2010 report of the "Privacy and Security Tiger Team" assembled by the Office of the National Coordinator for Health Information Technology. The Tiger Team reported that while granular consents are desirable, there is no current standard for implementation of such controls in EHR systems, and that the vast majority of individuals who are offered the opportunity to exercise granular consent control refuse the opportunity and give a general consent to disclose the entire health record.

- Q.15. SATVA believes that the "use case" of creation of metadata standards in the context of population of a Personal Health Record is too limited for purposes of reference to jurisdictional and individual privacy policies. We believe that the privacy metadata standards should also be based on the "use

case" of electronic exchange of health information by providers for purposes of coordination of care, especially in light of the interoperability requirements of the Meaningful Use Rule. The Stage 2 Meaningful Use requirements include interoperability with other providers (NHIN-Direct) and with a Health Information Exchange (NHIN-Connect).

- Q.17. Please consider inclusion of metadata elements and implementation specifications to enable a receiving electronic health record to properly administer privacy policies that restrict re-disclosure of tagged records.

In addition to the responses to these questions, SATVA would like to recommend that a request for disclosure transaction be incorporated into Stage 2 Meaningful Use Rule. The form for the transaction should support communication of the required elements of a Part 2 compliant consent. This would support the "meaningful use case" of use of electronic health records to facilitate collaboration between a substance abuse provider and other providers in the care of a chronically ill person.

Thank you for consideration of these comments.

Sincerely,

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