May 7, 2012

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave., SW., Washington, DC 20201

Reference: CMS-0044-P

Dear Sir/Madam:

I am writing on behalf of the Software and Technology Vendors Association (SATVA) to offer comments regarding the advance notice of proposed rulemaking on the Electronic Health Record Incentive Program. 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 disclosures and.

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, prescribes certain rules for notifications contained in disclosures 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 work, and provided a live demonstration of 42 CFR Part 2 compliant electronic exchange of continuity of care documents. The group provided live demonstrations of the linking of the consent information to the disclosure and to carrying the information required by 42 CFR Part 2 in a Continuity of Care Document (CCD) Disclosure at the recent National Council Conference and the California Institute of Mental Health Conference. A recording of the demonstrated capabilities is available at the association's website www.satva.org.

We bring this background to our review of CMS's proposed EHR Incentive Program. SATVA supports establishment of national standards that are supportive of jurisdictional and individual privacy policies. We think that CMS should 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 EHR Incentive Program are as follows.

1. Proposed Objective: The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.

SATVA believes that the restriction that an electronic transmission of a summary of care record will only count towards the numerator of the second measure if the recipient uses a different CEHRT vendor will exclude certain providers of ultra-sensitive treatment - such as substance use providers subject to the restrictions of 42 CFR Part 2 - who would otherwise be eligible for MU funding from meeting Meaningful Use requirements. A large percentage of the customers of SATVA members provide substance use treatment and have EPs eligible for Meaningful Use funding. SATVA believes that the vendors and CMS have an obligation to assure that any EP that is legally eligible for MU funding is not excluded by functionality or by rulemaking from participating.

Part 2 places the legal requirement on all Part 2 disclosures to contain a narrative notice restricting redisclosure absent consent. SATVA proposes that the disclosure also contain the related information needed by the recipient to be able to act on that notice. This includes the notation of whether the disclosed information can be redisclosed and, if so, the disclosure must contain the specific list of providers to which the disclosed information can be further disclosed and the expiration of the right to redisclose. SATVA recommends that, as a best practice, all Part 2 disclosures also document the restrictions (that were required by Part 2 to be documented in the consent) on the purpose(s) that the disclosed information may be used. SATVA has developed and demonstrated a methodology for accomplishing this within a CCD and demonstrated the approach (www.satva.org)

SATVA recognizes that certain HIEs may not be able to support interoperability of Part 2 disclosures given these special requirements and that disclosures may be limited to NwHIN Direct transactions between providers whose EHRs have the ability to recognize and adhere to the special requirements of Part 2 disclosures. Interoperability may then be limited for a certain amount of time to interoperability among EHRs of specialized treatment providers using specialized EHRs. It is also common for certain MH and substance use specialty EHR vendors to have a large market share within certain geographical regions.

This background brings us to the issue that interoperability within that regional set of providers using the same vendor's EHR may be the only legal avenue available to these EPs to support ultra-sensitive interoperability such as for Part 2 disclosures. It would then be the only avenue available for these EPs, who in fact are accomplishing the MU objective of interoperability on transitions of care, to demonstrate this fact.

If the interoperability between two EPs working at two different organizations is accomplished using a standard transaction such as an NwHIN Direct XDR or XDM transaction transported through an NwHIN Direct certified HISP, the fact that the two EPs use the same vendor's EHR is immaterial since the transportation mechanism is agnostic.

SATVA requests that this measure be modified to include in the numerator any disclosure made between two different agencies via an NwHIN Direct HISP or NwHIN Exchange regardless of whether the originator and recipient use the same vendor's EHR.

2. Proposed EP Clinical Quality Measures

The customers of SATVA vendors primarily provide mental health and substance use treatment and would not be able to report EP clinical quality measures for each of the six domains as currently defined measures exist in either Table 6 or Table 8. It is an unnecessary burden and additional cost to mental health and substance use EHR vendors to develop capabilities which will not be used by our members' customers and the cost of doing so must be absorbed in some fashion by those customers.

SATVA therefore recommends that Option 1a be adopted as modified to include reporting of 12 clinical quality measures from Table 8 that apply to the domains of the customers of specialty EHR vendors. The ONC Rules for Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition should be similarly modified.

Thank you for consideration of these comments.

Sincerely,

John Leipold
Chair
Software and Technology Vendors' Association

Contact SATVA:
On the web: http://www.satva.org/
David Jaffe, Executive Director
Email: info@satva.org , Phone: 646-233-0167