**Questions for DS4P pilots (Netsmart and Cerner):**

***Regarding the Behavioral Health Software And Technology Vendors Association (SATVA) Pilot***

Answers provided by Dan Levene, Cerner Behavioral Health and SATVA Pilot Technical Lead

1. How would you describe the status of the pilot - is it still in testing or operational with actual patient data (and if so, for how long)?
   * ***The SATVA Pilot remains in a testing mode.***
2. What motivated you to participate in this pilot?
   * ***SATVA members have long been proponents of the goals of interoperability and look for streamlined ways to accomplish these goals that are attainable by small vendors and small healthcare practice settings in relatively short time frames and at reasonable cost. Predating the DS4P Pilot opportunity, SATVA began work on an Implementation Guide which aimed to describe a means of conveying health information documents that complies with privacy laws such as 42 CFR Part 2 via Direct messaging.***
3. Please describe the scope of the pilot effort. For example: numbers of institutions/providers/patient involved? Numbers/types of health exchange transactions in total, and BH specifically?
   * ***Two SATVA member organizations, Valley Hope Association and Cerner Behavioral Health and the HEALTHeLINK HIE serving Western New York State have signed on for active participation in the pilot. Other SATVA member organizations are in planning stages of joining the pilot effort.***
   * ***Transactions:***
     1. ***Send unsolicited Summary of Care CCD from one provider to another***
     2. ***Request Summary of Care CCD (including remotely executed and carried consent)***
     3. ***Reply with requested Summary of Care CCD***
     4. ***Refuse reply with message that care of patient within a 42 Part 2 covered program cannot be confirmed or denied (due to insufficient or absent consent of patient to do so for the requestor)***
4. Please describe how sensitive behavioral health data are exchanged in the pilot. We are particularly interested in:
   * What is defined as sensitive data?
     1. ***Substance abuse treatment information covered by 42 CFR Part 2, meaning all information originating from 42 CFR Part 2 covered providers.***
   * Understanding changes (if any) to typical workflows needed to operationalize?
   * Parts of the workflow that are automated/manual?
     1. ***Automated:***
        1. ***Recording 42 CFR Part 2-compliant patient consent at sender’s location.***
        2. ***Generating Summary of Care CCD, including SATVA IG implementation of DS4P tagging of all data elements and advice to recipient of statutory notice and recipient handling obligations.***
        3. ***Generating matching XDM metadata and package to carry the CCD.***
        4. ***Transmission of CCD via Direct.***
        5. ***Receipt of CCDs and matching or creation of patient demographic data.***
        6. ***Warning and auditing of access to EHR end users any time they access ultra-sensitive CCDs.***
     2. ***Manual:***
        1. ***Receiving systems are not required to make any updates in order to receive ultra-sensitive CCDs as long as they can display the CCD via an appropriate style sheet to the end user. End user manual processes are required in this case to manage protecting information from unauthorized redisclosure or reuse. The preference is for receiving systems to be updated to handle this protection in more automated fashions, but a great advantage to early adoption of this method is that receiving entities don’t immediately have to update their EHR systems to handle the disclosure if their workflow processes can abide by the handling obligations conveyed in the CCD.***
   * How is sensitive data handled? Blocked, tagged, etc?
     1. ***Ultra-sensitive data (i.e., more sensitive than HIPAA-level privacy) is marked in CCDs with code sets specified in DS4P IG.***
     2. ***Summary Purpose section is added to CCD conveying purpose of use and handling obligations to the recipient.***
   * How patient consent is documented, managed, and shared?
     1. ***Fundamental to the lightweight approach of the SATVA IG and its pilot participation is decoupling of the concepts of consent and disclosure. Consent is documented and managed within sender organization (as it traditionally has been) and the recipient obligations for handling the disclosed information in compliance with the consent are transmitted in the disclosure.***
     2. ***A common electronic consent format is necessary to convey a patient’s consent captured at one location for release of that patient’s information from another location covered by 42 CFR Part 2 or other ultra-sensitive privacy regulation. Future work for the SATVA IG and pilot anticipate adopting the HL7 Consent Directive CDA that was developed under the guidance/sponsorship of SAMHSA.***
     3. ***No reliance upon a remote, third-party hosted consent repository is required by this approach.***
5. Describe what occurs once information has been sent from a behavioral health provider to another provider’s EHR. What measures are in place to assure this information is not re-disclosed without prior patient consent/authorization?
   * ***For process description, consider answers above.***
   * ***Assurance of compliance with non-redisclosure obligation remains as a point of trust between sender and receiver, as it is today in the realm of manual or disconnected EHR systems. Legal advice is recommended, and sharing parties may rely on informal trust, but a more formal contractual or QSOA participant agreement is recommended.***
   * ***42 CFR Part 2 seems to place the burden of compliance on the sender, implying that the recipient is expected to comply but with no provisions holding the recipient to that expectation. Adding an expectation of recipient compliance to a common DURSA agreement, the one in place for DirectTrust.org members, for instance, would greatly ease the burden on 42 CFR Part 2 covered programs to obtain commitment to handling obligations by all recipients. For now, the existing paradigm of manual trust establishment among providers is still required.***
6. Can you comment on the utility of the DS4P standard? How has the standard facilitated the exchange of behavioral health information? Have you received feedback on DS4P from providers? What are their views? What have been the challenges in implementing the DS4P standard?
   * ***The establishment of common code sets and transport implementation standards with the DS4P IG has created a valuable foundation upon which the SATVA IG acts as a more specific recipe for implementing lightweight interchange of ultra-sensitive information via Direct.***
   * ***Cerner Behavioral Health’s customer base of providers has had multiple public displays of the piloted technology and multiple discussions of its usefulness. Behavioral healthcare providers are eager to find ways to share and receive pertinent care information and to coordinate care with primary care and other providers serving their clients/patients while remaining compliant with the important privacy protections afforded under regulations such as 42 CFR Part 2.***
7. What do you see as the major challenges to making this work on a larger scale both with respect to workflow/processes as well as technology? What adjustments have you made or plan to make in your approach as the pilot proceeded?
   * ***Common adoption of specific data meta-tagging strategies such as the method adopted for the SATVA IG. The DS4P IG points the way, but lacks specific instruction for marking CCD entries or an entire CCD as ultra-sensitive.***
   * ***A simple, universally accepted consent directive and common understanding of its use will facilitate automated, on demand requesting of information via Direct for real time provider-to-provider sharing of current information.***
   * ***Common adoption of XD metadata extensions to convey recipient obligations, disclosure purpose of use, and simple message intent external to the clinical payload and in a manner preserving patient anonymity outside of the clinical document would accelerate on demand use of compliant Direct clinical document exchange.***
8. What are next steps for the pilot?
   * ***The SATVA Pilot intends to expand involvement to other SATVA members who are not already participating and ultimately, other non-SATVA, even non-behavioral health provider entities capable of Direct messaging to implement the approach.***
   * ***Cerner Behavioral Health is releasing this month (April 2014) production functionality to create SATVA IG compliant CCDs and transmit them to Direct messaging endpoints. Millennium, Cerner’s large enterprise/hospital EMR system will be updated later this year to recognize and act upon the ultra-sensitive tagged data to import it into the EMR in a way that the obligations to protect it can be enforced for possible redisclosure scenarios.***