May 1, 2015

Karen DeSalvo M.D.
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Ave, S.W., Suite 729D
Washington, DC 20201

Re: ***Comments on the 2015 Interoperability Standards Advisory***

Dear Dr. DeSalvo:

Thank you for the opportunity to comment on the 2015 Interoperability Standards Advisory. We commend you, the staff of the Office of the National Coordinator, and the members of the advisory committees who support your work for your leadership in the effort to strengthen and expand clinical health IT interoperability. We strongly endorse the collaborative approach and the "open draft" concept outlined in the Advisory and we look forward to engaging in dialogue with industry and regulators as the standards continue to develop over the coming year.

Surescripts operates the nation's largest clinical health information network and we have had extensive experience developing and implementing standards. We serve providers and patients in all 50 states and the District of Columbia and deliver over 700,000 clinical health transactions every hour. Every day, more than 70 percent of all office-based providers use our services on behalf of 3 million patients.   We connect to 99 percent of all retail chain pharmacies in the country and we delivered over 1 billion prescriptions and 1 billion medication histories to providers this past year. Our provider directory contains over 900,000 prescribers and our Master Patient Index covers 270 million insured lives.

In the course of building the Surescripts network we learned that interoperability could not be achieved without the use of simple, effective, collaboratively-developed standards. E-prescribing and the related services we deliver would not be possible without them. We believe that the role of standards in accelerating the effective and efficient operation of our national healthcare system is equally critical. We also recognize that standards are necessary but not sufficient to achieve that goal. Issues related to governance, business interests, privacy and security will also drive the effort to achieve clinical interoperability and will play a role in determining whether and how standards are used. In our estimation, utilization is the most effective measure of success for a standard --the best standards are the ones that are used the most.

2800 Crystal Drive
Arlington, VA 22202
T: 703.921.2121   F: 703.921.2191

www.surescripts.com

920 2nd Avenue South
Minneapolis, MN 55402
T: 866.267.9482   F: 651.855.3001

Attached are our responses to questions outlined in the Advisory. We've limited our comments to those items we can address based on the scope of our experience and our role in the health IT ecosystem.   It has been our privilege to collaborate with the Office of the National Coordinator and we look forward to continuing our work with you over the coming years.

_____
David Yakimischak
SVP, Information Systems

_____
Mary Ann Chaffee
SVP, Policy and Federal Affairs

5-1 [General] What other characteristics should be considered for including best available standards and implementation specifications in this list?

> We recommend that pilot or emerging standards should be named and agree that all should include an Implementation Specification, or other supporting documents, such as Implementation Recommendations documents from NCPDP.

5.2 [General] Besides the four standards categories included in this advisory, are there other overall standards categories that should be included?

We recommend adding more columns so that each standard description will include:
- Statute from which regulation is derived
- Link to the regulation
- In the case of a pilot or draft, a link to explanatory information
- Date when new version is likely to be named

5.3 [General] For sections I through IV, what "purposes" are missing? Please identify the standards or implementations specifications you believe should be identified as the best available for each additional purpose(s) suggested and why.

We suggest that authorization should be included under "purposes." We concur with NCPDP's position that electronic prior authorization (ePA) transactions in the NCPDP SCRIPT Standard v2013101 be used and adopted for authorization for pharmacy benefits. We further recommend that Mediation History be added as a "purpose." Medication History allows prescribers, pharmacies and payers to share a list of medications that have been dispensed to a patient over a particular date range. It can include all medication dispensed or a current medication list.

5.4 [General] For sections I through IV, is a standard or implementation specification missing that should either be included alongside another standard or implementation specification already associated with a purpose?

We recommend that electronic prescribing in Section II include all messaging available in the NCPDP SCRIPT Standard v10.6 to include:
- New Rx
- Refill request
- Cancel
- RxFill Notification

We also recommend that *Script Implementation Recommendations* and the Formulary and Benefit Implementation Recommendations documents that were developed to assist implementers be included.

5.5 [General] For sections I through IV, should any of the standards or implementation specifications listed thus far be removed from this list as the best available? If so, why?

Direct is an adequate standard for pushing non-computable human-readable messages and minimally computable CCDA messages. A significant limitation is that it does not define request/response messaging patterns naturally. Further, it is not the simplest transport pattern for point-to-point connections, as contrasted to RESTful operations over HTTP.

The current NwHIN standards are large, complex, and span multiple disjointed technology stacks. Surescripts supports a specific subset of these transactions for record location services—XDR, XDS, PIX, and PDQ. In terms of engineering efforts, it is not possible to implement any NwHIN operation without fully engaging the SOAP, WS-*, WSDL, ebXML, and the full HL7v3, including exposure to the RIM world. This creates substantial barriers to effective adoption and to further evolution of the standards.

In our experience, the most promising standard to emerge in recent times is FHIR, which defines operations over HTTP and includes a basic set of structured, fine-grained data definitions that cover the most commonly-used data structures in clinical care. We recognize that FHIR is still a draft standard but we have been impressed by the level of ease to implement for our trading partners. FHIR is leveraging technologies from the broader commercial web world as well as defining a simpler set of nouns and verbs. While Surescripts will continue to support the older service standards while there is demand, we see FHIR rapidly eclipsing those standards for both fine-grained request/response services and for moving larger–grained structured documents.

General comments on Transport Standards

Section III: Best Available Transport Standards and Implementation Specifications

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
Simple way for participants to "push" health information directly to known, trusted recipients	Simple Mail Transfer Protocol (SMTP) RFC 5321	
	For security, Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751	
Data sharing through Service Oriented Architecture (SOA) - that enables two systems to interoperate together	Hypertext Transfer Protocol (HTTP) 1.1, RFC 723X (to support RESTful transport approaches)	
	Simple Object Access Protocol (SOAP) 1.2	
	For security, Transport Layer Security (TLS) Protocol Version 1.2, RFC 5246	

Although not specifically requested in the question format, we would like to share the following observations on the Transport Standards specifications included in Section III of the proposal.

- Regarding SMTP S/MIME: In our experience building a national network, many participants require specific technical assistance in working through the practical details of certificate management.
- SOAP over HTTP: We support SOAP as part of our support for the XDR, XDS, PIX, and PDQ standards. SOAP and its associated security standards WS-* stacks is a large and complex world that requires significant engineering efforts over time to achieve the competence necessary for reliable interoperability. The degree of complexity is radically reduced with the frameworks we have worked with in this area, e.g., FHIR implementation vs a SOAP NwHIN.
- Our experience with RESTful alternatives to SOAP strongly suggests that new approaches will be far more accessible to a broader range of competencies for successful implementation.

Regarding TLS: TLS is the backbone of transport level security and we support moving to the standard of mutual TLS at this layer.