

October 2, 2015

Mr. Steven Posnack
Director, Office of Standards and Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Rule on Acceptance and Approval of Non-Governmental Developed Test Procedures, Test Tools, and Test Data for Use Under the ONC Health IT Certification Program (45 CFR 170)

Dear Mr. Posnack:

We are writing in response to the request for information on the rule entitled, *Acceptance and Approval of Non-Governmental Developed Test Procedures, Test Tools, and Test Data for Use Under the ONC Health IT Certification Program* (45 CFR 170), published June 9, 2015. Surescripts operates the nation's largest clinical health information network. 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 over the past year. Our provider directory contains over 900,000 prescribers and our Master Patient Index covers 270 million insured lives.

Our certification program significantly overlaps with the specifics and the intent of many of the criteria in the HHS Meaningful Use Program. Surescripts currently certifies for a much broader set of messages and content than ONC currently requires. For example, we require certification on REFREQ (Refill Request) and REFRES (Refill Response), message types that are used millions of times per month to provide electronic renewal authorization messaging between pharmacies and providers. We test for Medication History Formulary and Benefits and Prior Authorization as well. Some of these additional certifications are optional. We also test for the valid use of our directories, which are in effect the routing tables that define all the end points and service levels for different parts of our network. Using our directories is an example of something that a vendor needs to do that is not fully defined and governed by the NCPDP standards. If a product is certified for operation on the Surescripts network, it is fully ready to operate and

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send the e-prescribing messages that ONC is trying to encourage through the Meaningful Use Program.

Beyond certification, Surescripts also runs an industry-leading <u>compliance</u> program, to ensure that certified applications that operate on the network stay in compliance with the certification requirements and continue to operate correctly over time. We found that a robust compliance program is essential to ensure the smooth operation of the network. In other words, certification is necessary, but not sufficient, to ensure that the technology is properly used over time.

In the area of Test Procedures, Surescripts has several test cases established for testing prescribers (as well as pharmacies) and each test case has very specific criteria that are asked of the prescriber to select for the prescription. Some of the test cases include negative testing in which the data requested is not valid. This is done in order to validate any application controls for invalid messages — for example sending controlled substances for those vendors not certifying for EPCS. The testing procedures include gathering screenshots of application workflow, including the building of the prescription and selecting a pharmacy. The data is then manually verified against the content of every field and the prescription in the application, including items such as drug name, NDC, RxNorm codes, and potency unit code values.

In the area of Test Tools, Surescripts has a robust online, web-based test tool that is used by every participant on the network. In it, we have a robust search capability to locate messages – including all messages associated with the primary searched. For example, searching on a NEWRX shows response and renewal messages as applicable. The tool does syntax check at the NCPDP schema validation level and identifies problematic areas in the message as well as with the sending and receiving portal configurations. The tool has pre-determined and programmable response messages that are intended to allow direct editing of the raw data just prior to sending the message through. This allows a vendor to simulate many of the configurations and messages that they will encounter when they actually operate on the network. There are also shortcuts to allow direct selection of pharmacies, prescribers, portals, and medications to pre-populate new data in the pending message – again, allowing infinite editing capability immediately before sending.

In the area of Test Data, Surescripts has two main categories. One is the test data we allow developers to use while they are building their interface. The other is a set of data that we "hold back" until just before the certification test. This is done to prevent the developer from seeing the data in advance which would enable them to hard code their applications to handle the data in the test cases. We have initiated conversations with NIST about the possibility of developing a common set of test data across the industry. We remain optimistic about the possibility, but need to have detailed conversations about how exactly it would work, including updates and changes.

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We would be happy to discuss our program specifics more with in person, or by writing. Please let us know how we can be of assistance.

Sincerely,

Chris Spadoni

Manager, Certification

David Yakimischak

SVP, Information Systems