



November 9, 2020

Submitted electronically via:

<https://www.healthit.gov/isa/standards-version-advancement-process>

Don Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Mary E. Switzer Building
330 C Street SW
Washington, DC 20201

Re: Standards Version Advancement Process

Dear Dr. Rucker:

Surescripts very much appreciates the opportunity to comment on the first iteration of the Standards Version Advancement Process (SVAP). We strongly agree with ONC's assessment that newer versions of standards are becoming available more quickly than HHS can address through notice and comment rulemaking and applaud ONC for creating a pathway for the voluntary adoption of newer versions of standards. We believe that the e-prescribing standard, NCPDP SCRIPT, is a prime candidate for the voluntary adoption of newer standards through the SVAP. Although we do not believe it would be appropriate for ONC to identify a new SCRIPT standard for voluntary adoption through the SVAP *this year*, due to the ongoing transition from SCRIPT version 10.6 to version 2017071, we wish to provide comment on how ONC might work with CMS in the future to advance the SCRIPT standard in a more orderly, coordinated manner using the SVAP.

Surescripts operates the nation's largest clinical health information network. Founded in 2001 by pharmacies and pharmacy benefit managers (PBMs) to enable electronic prescribing (e-prescribing), the company today offers a wide portfolio of clinical messaging services. Surescripts serves providers and patients in all 50 states and the District of Columbia and delivers 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 over 3 million patients.

We connect to over 99 percent of all retail pharmacies and most mail order pharmacies in the country, and we delivered over 1.91 billion prescriptions and 1.77 billion medication histories to providers this past year. Our provider directory contains over 1.61 million prescribers and our Master Patient Index covers 258 million insured lives. Additional information about Surescripts is available at www.surescripts.com, and we particularly call your attention to our National Progress Report available at <https://surescripts.com/news-center/national-progress-report-2019/>.

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In 2003, under the Medicare Modernization Act, Congress gave HHS the authority to promulgate uniform standards for e-prescribing Part D drugs to Part D eligible individuals. CMS’s adopted e-prescribing standard, NCPDP SCRIPT, is developed through a multi-stakeholder consensus process led by the National Council for Prescription Drug Programs (NCPDP) (and includes participation by CMS). Currently, prescribers, Part D prescription drug plans and pharmacies must use the version of NCPDP SCRIPT named by CMS through rulemaking, and may not send prescriptions or other information about Part D prescriptions electronically through any other version of the standard – including newer versions of the standard. As a result, even when the industry has recommended the implementation of a new version of the NCPDP SCRIPT standard through NCPDP’s consensus-driven process, industry has had to wait for CMS to conduct rulemaking before implementing the standard. Each of the three times that CMS has updated the SCRIPT standard through rulemaking in the past 16 years, the agency has not made any substantive changes to NCPDP’s recommendations. Instead, the CMS rulemaking process has simply delayed adoption of the standard recommended by NCPDP.

Most recently, NCPDP requested in early 2016 that CMS adopt the newest NCPDP SCRIPT standard, as CMS had not implemented a new SCRIPT standard through rulemaking since October 2013. CMS, however, did not propose a new SCRIPT standard until November 28, 2017, and then in its final rule pushed adoption of NCPDP SCRIPT 2017071 back from January 1, 2019 to January 1, 2020.

CMS’s multi-year delays in adopting updates to the NCPDP SCRIPT standard prevented industry from timely adopting important new functionality, including the following examples:

Functionality	Date of Adoption by NCPDP	Date of Adoption by CMS
• Ability to share supply information for prescriptions that require supplies, such as insulin (which requires syringes and needles)	October 2014	January 2020
• Ability to prescribe compound and specialty medications electronically	March 2009	January 2020
• Ability to indicate the patient’s primary language so that the pharmacy can print instructions accordingly	June 2010	January 2020
• Ability to send dosage adjustment (titration) information for medications that must be adjusted based on lab results	April 2016	January 2020
• Ability to share substance use disorder history with pharmacy	July 2015	January 2020

Unlike the two previous transitions to a new SCRIPT standard, CMS in this most recent transition declined to issue an interim final rule in advance of the January 1, 2020 adoption date to permit voluntary adoption of version 2017071. According to CMS, this was due to the fact that NCPDP SCRIPT 2017071 was not “backwards compatible” to SCRIPT 10.6. Surescripts, however, was always prepared to translate messages sent using SCRIPT 2017071 to 10.6 and vice-versa as appropriate – thereby facilitating a smooth and orderly

transition from one version of SCRIPT to another. Instead, however, CMS insisted that no transition could occur until January 1, 2020.

CMS neglecting to provide for a transition period for moving to the new standard was a mistake – one that we feel the SVAP could potentially help to correct in the future. We note, however, that under the current regulatory framework ONC would be unable to apply the SVAP to the NCPDP SCRIPT standard unless CMS first issued an interim final rule to recognize a version of the NCPDP SCRIPT standard as backwards compatible, or engaged in notice and comment rulemaking to advance the NCPDP SCRIPT standard. Although the SVAP would still be useful in these scenarios, as it would provide ONC a mechanism to more quickly permit health IT developers to advance the NCPDP SCRIPT standard to the one selected by CMS through its rulemaking, we believe the SVAP would be considerably more effective for e-prescribing if it could be used to allow voluntary adoption of a new version of the NCPDP SCRIPT standard by prescribers, pharmacies and Part D prescription drug plans *without CMS rulemaking*.

NCPDP has continued to develop the SCRIPT standard in the three years following adoption of version 2017071, and the industry will continue to miss out on important new e-prescribing functionalities unless there is change to the current process. In subsequent versions of SCRIPT after SCRIPT 2017071, NCPDP developed and agreed to standards for pharmacies to communicate partial fills of prescriptions such as opioids and correspond with state opioid abuse programs about medication histories. HHS's continued delay in approving new versions of the SCRIPT standard could prevent these important tools in combatting the opioid epidemic from being adopted in a timely manner.

As a result, we recommend that HHS consider re-delegating the authority to name the standard for e-prescribing, medical history and electronic prior authorization transactions for Part D prescription drug plans from CMS to ONC. This would create a paradigm similar to the Promoting Interoperability program, where CMS would be responsible for outlining the required functionality for a Part D e-prescribing program, and ONC would be responsible for identifying the standards and implementation specifications for the required functionality. We feel that as between CMS and ONC, ONC is better situated to evaluate available e-prescribing, medical history and electronic prior authorization standards, and determine the appropriate timing for adoption. Most importantly, such a change would allow industry to fully benefit from ONC's implementation of the SVAP, and receive access to much-needed innovations in e-prescribing that have been held back previously due to the need for notice and comment rulemaking prior to testing and adoption.

If ONC is given the authority to use the SVAP to allow the industry to voluntarily transition to a new SCRIPT standard, we believe the SVAP should only be used to allow the concurrent adoption of two versions of the NCPDP SCRIPT standard – the older version listed in the regulation, and one newer version for voluntary adoption through the SVAP. It would be too difficult for the e-prescribing network to handle transactions made with more than two versions of the standard. We note that without timely notice and comment rulemaking following the use of the SVAP to permit voluntary adoption of a newer SCRIPT standard, industry would again be stuck at the version adopted through SVAP (as adopting yet a third standard through the process would be unworkable without first moving the standards floor forward). We would ultimately prefer a solution that would allow the industry, working through NCPDP, to sunset older versions of the SCRIPT standard without notice and comment rulemaking.

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Finally, we want to note that in addition to the SCRIPT standard, NCPDP is responsible for developing two other important standards for transactions related to e-prescribing – Formulary and Benefit and Real Time Prescription Benefit. Our concerns about timely advancement of the SCRIPT standard would also be relevant to those two standards if ONC elects to adopt them through the Interoperability Standards Advisory (ISA) process in the future,

Thank you for the consideration of our views. Please do not hesitate to contact me with questions or for further information.

Sincerely,

A handwritten signature in cursive script, reading "Mary Ann Chaffee", enclosed in a thin black rectangular border.

Mary Ann Chaffee

Vice President for Policy and Federal Affairs

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