January 16, 2018

Submitted electronically via:
http://www.regulations.gov

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013

**RE: CMS-4182-P; Medicare Program; Contract Year 2019 Policy and Technical Changes
to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare
Prescription Drug Benefit Programs, and the PACE Program; Proposed Rule;
<u>Medicare Part D E-Prescribing Program Standards Sections Only</u>**

Dear Administrator Verma:

Surescripts operates the nation's largest clinical health information network. Founded in 2001
by pharmacies and pharmacy benefit managers (PBMs) to enable e-prescribing, the company has
moved beyond that product and today offers a wide portfolio of clinical messaging services. We
now 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 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 1.6 billion prescriptions and 1 billion medication histories to providers this past year. Our
provider directory contains over 1,000,000 prescribers and our Master Patient Index covers 270
million insured lives. You and your staff can find more information about Surescripts at
www.surescripts.com, and we would particularly call to your attention our National Progress
Report available at http://surescripts.com/news-center/national-progress-report-2016/.

This letter is in response to the proposed rule that the Centers for Medicare and Medicaid
Services (CMS) published in the Federal Register, Volume 82, Number 227, beginning on page
56336 on November 28, 2017. Surescripts appreciates the opportunity to comment on the
provision of this proposed rule that calls for an update to the electronic prescribing standards to
be used by Medicare Part D prescription drug plans as is required by section 1860D-4(e)(4)(D)
of the Social Security Act (the Act). This update is an action that the health information
technology (HIT) industry believes is overdue, and will significantly enhance the utility and
efficiency of the e-prescribing process for millions of Medicare beneficiaries in a multitude of
ways, so we—as well as the electronic health record (EHR) companies, pharmacy software
vendors, and PBMs/payers connected to our network—applaud this action by CMS.

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Surescripts notes that the National Council for Prescription Drug Programs (NCPDP) originally recommended that CMS start the process to update the NCPDP SCRIPT standard in early 2016. As a result of CMS's delay in acting on NCPDP's recommendation, the HIT industry has been unable to implement important functionality found in the newer versions of the SCRIPT standard.

For example, prescriptions for specialty and compounded medications cannot currently be sent electronically, and must instead be communicated by fax machine or traditional written or oral prescriptions. While specialty pharmacy prescriptions accounted for only approximately 2% of all prescriptions in 2016, these prescriptions accounted for approximately 32.5% of all prescription spending.

The newer version of the NCPDP SCRIPT standard will also allow for communication of allergy and substance use history from prescribers to pharmacies, additional essential features of the new standard, which have been ready for adoption since early 2016. We look forward to a future in which NCPDP's recommendations for improvements to the electronic prescribing standards can more swiftly be piloted and implemented. Surescripts would be pleased to work with CMS to achieve this important goal.

<u>Surescripts Responses to CMS Request for Comment on the Proposed Rule</u>

CMS: 8. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards

c. Proposed adoption of NCPDP SCRIPT version 2017071 as the official Part D E- Prescribing Standard for certain specified transactions, retirement of NCPDP SCRIPT 10.6, proposed conforming changes elsewhere in 423.160, and correction of a historic typographical error in the regulatory text which occurred when NCPDP SCRIPT 10.6 was initially adopted.

We seek comment regarding our proposed retirement of NCPDP SCRIPT version 10.6 on December 31, 2018 and adoption of NCPDP SCRIPT Version 2017071 on January 1, 2019 as the official Part D e-prescribing standard for the e-prescribing functions outlined in our proposed § 423.160(b)(1)(v) and (b)(2)(v), and for medication history as outlined in our proposed § 423.160(b)(4), effective January 1, 2019. We are also soliciting comments regarding the impact of these proposed effective dates on industry and other interested stakeholders.

Surescripts Comments:

(1) <u>Timing</u>: We reiterate our strong agreement with CMS's proposal that the healthcare industry be allowed to move to NCPDP SCRIPT Version 2017071 as soon as participants can reasonably be ready to implement such a change. However, it is our experience, which we believe is shared by the hundreds of HIT companies that are connected to our network, that it is not realistic to

expect that such a change can be implemented by January 1, 2019. We base this assertion on our direct involvement as a key participant when the industry moved from NCPDP SCRIPT 5.0 to 8.1 and 8.1 to 10.6, neither instance of which were required by CMS to occur in less than a year. In fact, it generally takes one to two years or more for industry participants to design, develop, test, certify, submit for audit, release and train end users to use new SCRIPT versions. Accordingly, given our expertise in implementing previous versions of NCPDP SCRIPT, as well as guiding hundreds of entities connected to our network through the process, our recommended change in the timing of the adoption of the new version of NCPDP SCRIPT is as follows:

- CMS should adopt NCPDP SCRIPT Version 2017071 no sooner than 24 months from the effective date of the final rule resulting from this proposed rule, which Surescripts assumes will be 60 days after the official publication date of the final rule.

- In the interim, NCPDP SCRIPT Version 10.6 should remain the officially adopted e-prescribing standard for the Medicare Part D program, but NCPDP SCRIPT Version 2017071 should be permitted to be used on a voluntary basis by those industry participants who are ready, willing and interested in doing so. In other words, CMS should allow the industry the benefit of a 24-month transition period during which either NCPDP SCRIPT Version 10.6 or 2017071 can be used.

- Lastly, recognizing that a high percentage of industry participants that will be implementing the new version of the e-prescribing standard are also involved in Part D plan administration or are plan providers, it is recommended that whatever adoption date that CMS chooses for NCPDP SCRIPT Version 2017071 should not occur within the first three calendar months of any year. This is because January 1st is typically the date upon which Part D plan changes become effective, and requiring EHR and pharmacy software vendors as well as PBMs/payers to implement NCPDP SCRIPT Version 2017071 plus annual Part D program changes at the same time would constitute an excessive burden that could be avoided by appropriate regulatory timing.

(2) Standard Transactions: In general, Surescripts agrees with the list of existing NCPDP SCRIPT Version 10.6 transactions plus the additional new NCPDP SCRIPT Version 2017071 transactions identified in the proposed rule. However, for reasons that we will touch upon below, we are (a) recommending the consolidation of medication history transactions with the CMS list of SCRIPT transactions going forward because they are SCRIPT transactions, (b) strongly urging the recognition and inclusion of electronic prior authorization transactions among the new NCPDP SCRIPT Version 2017071 transactions adopted by this proposed rule, (c) encouraging CMS to adopt the current NCPDP naming conventions for all transactions and (d) requesting the addition of the resupply transaction and the deletion of the password change transaction.

Taking these recommendations into consideration yields the following list of standard transactions that would be adopted by this proposed rule to provide for the communication of a prescription or prescription-related information between prescribers, dispensers, Medicare Part D sponsors, and/or other appropriate entities. (To assist CMS in its analysis, the agency's letter codes assigned for NCPDP Version 2017071 standard transactions on page 56513 at §423.160 in the proposed rule are included following these updated names when available):

- GetMessage (A)
- Status (B)
- Error (C)
- NewRx (D)
- RxChangeRequest (E)
- RxChangeResponse (F)
- RxRenewalRequest (G)
- RxRenewalResponse (H)
- Resupply
- Verify (I)
- CancelRx (K)
- CancelRxResponse (L)
- RxFill (M)
- DrugAdministration (N)
- NewRxRequest (O)
- NewRxResponseDenied (P)
- RxTransferRequest (Q; 1 of 3)
- RxTransferResponse (Q; 2 of 3)
- RxTransferConfirm (Q; 3 of 3)
- RxFillIndicatorChange (R)
- Recertification (S)
- REMSInitiationRequest (T)
- REMSInitiationResponse (U)
- REMSRequest (V)
- REMSResponse (W)
- RxHistoryRequest
- RxHistoryResponse
- PAInitiation Request
- PAInitiation Response
- PARequest
- PAResponse
- PAAppealRequest
- PAAppealResponse
- PACancelRequest
- PACancelResponse

Provider access to a patient's medication history is an essential and integral component of the electronic prescribing process, so the inclusion of medication history transactions within the suite of Medicare Part D e-prescribing standard transactions adopted in NCPDP SCRIPT Version 2017071 makes logical, intuitive sense. Moreover, NCPDP does not segregate medication history transactions from its other SCRIPT transactions, so for consistency's sake as well as incorporation by reference purposes, we recommend the inclusion of medication history transactions within the list of CMS-adopted SCRIPT e-prescribing transactions going forward.

With regard to prescription drug prior authorization, Surescripts respectfully urges CMS to include NCPDP SCRIPT 2017101 prior authorization transactions among those it is adopting with this proposed rule. As the enclosed May 15, 2014 NCVHS letter to HHS clearly states, the HIPAA named standard for prior authorizations (X12 278) was not designed for, and is unable to effectively address, prescription drug prior authorizations. X12 278 lacks a central feature of NCPDP SCRIPT electronic prior authorization transactions, which is question-set logic that allows Part D plans to efficiently request information from providers, resulting in near-real-time

adjudication decisions by said plans. It is for this and other reasons that NCVHS has instead recommended the industry adopt and use the NCPDP SCRIPT prior authorization transactions for prescription drugs.

In addition, NCPDP SCRIPT prior authorization transactions have gained broad industry adoption among PBMs/payers and health care providers. This is due to the flexibility the standard provides, ease of use for providers, and efficiencies gained across the healthcare system. Electronic prescription drug prior authorizations are now routinely approved in under a minute, which increases patient adherence, reduces physician pain points, and improves pharmacy workflows. Further, ONC has designated the NCPDP SCRIPT prior authorization transactions in their standards advisory as the transactions to use for prescription drug benefits, and many states have now enacted legislation adopting NCPDP's electronic prior authorization transactions as the preferred or sole standard to be used for prescription drug prior authorizations. CMS naming the NCPDP SCRIPT 2017101 prescription drug prior authorization transactions in this regulation will continue to encourage and accelerate industry-wide adoption, thereby improving patient care and provider efficiencies.

As for the password change transaction, which is included in NCPDP SCRIPT 2017071, this transaction has been superseded by enhanced security authentication processes, so it is now obsolete. Thus, the use of the password change transaction should not be promoted by NCPDP or CMS, which is why we request that it be deleted from this proposed rulemaking.

Finally, we believe that two citations on page 56513 are incorrect and should be corrected as follows:

(1) The citation with respect to the proposed standards effective date currently states: "(v) On or after January 1, 2019, the standards specified in paragraphs (b)(2)(iii) and (b)(3), (b)(4)(ii), (b)(5)(iii), and (b)(6) of this section." The correct citation should be (b)(2)(iv) instead of (b)(2)(iii).

(2) The citation about the incorporation by reference "(iv) The National Council for Prescription Programs SCRIPT standard, Implementation Guide Version 2017071 approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(i) of this section)…" should be (b)(1)(iv) not (c)(1)(i).

<div align="center">Conclusion</div>

Surescripts appreciates the opportunity to continue to provide advice and assistance as CMS works to update the electronic prescribing standards to be used by prescribers, dispensers, Medicare Part D sponsors, and/or other appropriate entities as they meet the healthcare needs of Medicare beneficiaries. We are confident that the myriad improvements that NCPDP SCRIPT Version 2017071 will bring to bear will significantly increase the safety, efficiency, and quality

of healthcare. Indeed, as is mentioned above, Surescripts looks forward to a future in which NCPDP's recommendations for improvements to the electronic prescribing standards can more swiftly be piloted and implemented.   Surescripts would be pleased to work with CMS to achieve this important goal.

Please do not hesitate to have your staff contact us should they have any questions regarding the comments we have offered above in support of the adoption of NCPDP SCRIPT Version 2017071 or if there are any other ways that we can assist them.

Sincerely,

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