August 16, 2019

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-4189-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS-4189-P: Medicare Program; Secure Electronic Prior Authorization for Medicare Part D

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 electronic prescribing (e-prescribing), the company has moved beyond e-prescribing and 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.

In addition to delivering prescriptions and medication histories, the Surescripts network also allows prescribers to engage in electronic Prior Authorization (ePA) transactions with prescription drug plans using the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard. In the past year, Surescripts saw a 128% increase in provider adoption of ePA functionality through electronic health records (EHRs), and a 172% increase in ePA transactions over the Surescripts network. 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-2018/.

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Surescripts very much appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposal to require Part D plan sponsors to support version 2017071 of the NCPDP SCRIPT standard for ePA transactions, and require prescribers to use NCPDP SCRIPT version 2017071 when performing ePA transactions for Part D-covered drugs starting on January 1, 2021 (Proposed Rule).[1] Surescripts applauds CMS's proposed adoption of NCPDP SCRIPT Standard Version 2017071 for ePA transactions for Part D-covered drugs. This proposal recognizes that prescribers and prescription drug plans that engage in ePA transactions have already voluntarily adopted NCPDP SCRIPT as their standard of choice. The industry has been using NCPDP SCRIPT for ePA since 2012, when CVS Caremark, Surescripts and other industry stakeholders launched a pilot process to demonstrate that ePA with the SCRIPT standard was a viable solution. Surescripts has assisted industry stakeholders to engage in ePA transactions using NCPDP SCRIPT for ePA since 2015. Currently, over 77% of prescribers in the United States are served by EHRs that have contracted with Surescripts or its leading competitor to send ePA transactions to prescription drug plans over an ePA network using NCPDP SCRIPT, and over 96% of patients in the United States receive prescription drug benefits from a prescription drug plan that is capable of responding to ePA transactions using NCPDP SCRIPT.

Surescripts believes that CMS's proposal to require prescribers to use NCPDP SCRIPT when engaging in ePA transactions with Part D prescription drug plans, if adopted, would help to further expand the number of EHRs that offer ePA, and increase prescriber use of this valuable functionality. Currently, prescribers that do not engage in ePA transactions (e.g., because their EHR vendor does not offer ePA functionality) must instead fill out lengthy forms by hand and fax them, along with paper records of medical documentation in some cases, to their patients' prescription drug plans. The unnecessary man-hours required by the paper prior authorization process diverts providers and their staff from treating patients and lengthens the amount of time patients must wait to be approved for needed medications. Increased use of ePA transactions would help to cut down on this unnecessary provider burden, and improve the patient experience.

[1] While we know that the January 1, 2021 deadline to adopt technical standards for ePA is mandated by statute, we implore CMS to clarify in the final rule that Part D prescription drug plans may accept and respond to ePA transactions from prescribers using NCPDP SCRIPT version 2017071 *prior* to January 1, 2021. This guidance is necessary to ensure a safe and effective transition (for those who have not yet adopted NCPDP SCRIPT for ePA transactions), and to reflect the reality that many prescription drug plans are already engaging in ePA transactions using NCPDP SCRIPT. We note that when CMS finalized the transition from NCPDP SCRIPT version 10.6 to version 2017071 on April 16, 2018 (CMS-4182-F), CMS required a hard cutover on January 1, 2020 to upgrade to the new standard. Recognizing that a one-day "transition" is infeasible, CMS subsequently issued guidance on May 9, 2018 supportive of thorough software testing; and we are hopeful that CMS and ONC will jointly provide more specific guidance given continued uncertainty around the transition. We ask that CMS make clear in the final rule preamble guidance that Part D plans may engage in ePA transactions prior to January 1, 2021 using actual prescription data in order to ensure a safe and effective transition to required use of the SCRIPT standard.

Surescripts is puzzled and concerned, however, with CMS's preamble guidance to the Proposed Rule suggesting that non-Part D prescription drug plans are prohibited from engaging in EPA transactions using NCPDP SCRIPT because the use is not permitted by the HIPAA Transactions Rule. This guidance jeopardizes a prior assumption of many prescription drug plans and prescribers that they could engage in ePA transactions using the NCPDP SCRIPT standard because HIPAA did not regulate such transactions. The guidance could have the effect of decreasing rather than increasing the use of electronic prior authorization transactions. This is surely not what Congress intended when it passed the bipartisan SUPPORT for Patients and Communities Act, which directed the Secretary of HHS to mandate Part D prescription drug plans to engage in ePA using the NCPDP SCRIPT standard. This provision, and the entire legislation for that matter, was enacted to combat the nation's opioid addiction crisis and is intended to prevent substance use disorder and facilitate opioid recovery and treatment. Leveraging the best technology available is an effective weapon in fighting the opioid epidemic. CMS should not take steps that unnecessarily limit the use of electronic prior authorization for those in non-Part D plans.

Under HIPAA (45 C.F.R. § 162.923), covered entities conducting a covered transaction with another covered entity must "conduct the transaction as a standard transaction." Under 45 C.F.R. § 162.1201, HIPAA defines the "referral certification and authorization transaction" as "a request from a health care provider to a health plan for the review of health care **to obtain an authorization for the health care**." (emphasis added) Under this transaction, HIPAA requires the use of ASC X12 278 for "dental, professional, and institutional request for review and response". Extensive due diligence by the industry has shown that **the ASC X12 278 standard is not sufficient for ePA workflows for prescription drugs**. NCPDP began standards development work to create the NCPDP SCRIPT ePA transactions as a result of an ePA pilot conducted in 2006 that evaluated the efficacy of the ASC X12 278 and ASC X12 275 transactions for ePA. The pilot found that ASC X12 transactions were sub-optimal for the support of ePA for medications, and did not offer improvements in administrative efficiency. It is clear from studies and research that **the ASC X12 prior authorization transactions named under HIPAA are for *medical benefits* and are not effective for the exchange of information related to prior authorizations of products covered under a pharmacy benefit.** WEDI, which has statutory standing under HIPAA to advise the Secretary of HHS on matters related to the use of electronic transactions in health care, stated the following in a white paper produced earlier this year on the prior authorization process:[2]

> "Electronic prior authorization (ePA) transactions for drugs covered under the pharmacy benefit have been developed as part of National Council for Prescription Drug Programs' (NCPDP's) SCRIPT e-prescribing standard. **The NCPDP ePA transactions have achieved significant penetration in the marketplace and have had a meaningful effect on administrative burden placed upon providers by medical**

[2] WEDI Prior Authorization Council, "The WEDI Prior Authorization Council White Paper" (Feb. 5, 2019), *available at* https://www.wedi.org/docs/public-policy/prior-authorization-council-white-paper.pdf.

> **policies developed to ensure the appropriate use of pharmaceutical therapies**." (emphasis added)

WEDI's endorsement of NCPDP SCRIPT for ePA, and WEDI's recognition of NCPDP SCRIPT's significant penetration in the industry should give CMS pause, as the guidance in the Proposed Rule would have the effect of *reversing* the current adoption of the recommended ePA transaction standard outside of Part-D covered prescriptions. The guidance, if finalized by CMS, would also create significant burdens for prescribers and EHR vendors, as they would need to adopt and use two *different* standards depending on whether or not the patient has a Part D prescription drug plan. In the Proposed Rule, CMS notes that EHR vendors would need "approximately 200 developing hours and 800 programming hours to enable the EHRs to utilize two [different] standards" for ePA transactions. Such development time would be wasteful and burdensome to health care providers, who would shoulder much of this cost to implement unnecessary functionality. As the WEDI Prior Authorization Council notes in its recent white paper on electronic prior authorization, only 12% of the industry has currently adopted the ASC X12 standard for *any* prior authorization transactions (for medical services or prescription drugs). The limited adoption of ASC X12 pales in comparison to the current 77% adoption of NCPDP SCRIPT for ePA transactions, and demonstrates a clear industry preference for NCPDP SCRIPT. The suggested use of two different standards for ePA described by CMS in the Proposed Rule would also be confusing for prescribers and their staffs to implement, and would be contrary to the goal of administrative simplification.[3]

Inclusion of this guidance in the Proposed Rule is perplexing, as we do not believe the Office of the Secretary of HHS, which is responsible for administering the HIPAA Transactions Rule, has ever stated in its own HIPAA rulemaking that the HIPAA Referral Certification and Authorization standards apply to ePA transactions for prescription drugs. We certainly do not believe it is appropriate for HHS to use this CMS rulemaking on the Part D program to announce such a sweeping policy decision that would affect all non-Part D prior authorization requests. **We request that CMS/HHS consider either 1) issuing clarifying guidance in the final rule to indicate that HIPAA's Referral Certification and Authorization standards do not apply to electronic prior authorization transactions for prescription drugs, or 2) rescind the guidance from the Proposed Rule, and issue a separate proposed rule from the Office of the Secretary under its HIPAA rulemaking authority to name the clear industry-accepted standard, NCPDP SCRIPT, as the HIPAA standard for ePA transactions for prescription drugs.** We also request that CMS specifically address the transition issue in order to ensure safe and effective movement to NCPDP SCRIPT version 2017071.

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[3] While WEDI notes in its white paper that HL7 is pursuing a FHIR-based solution for ePA, this is likely a response to the lack of ASC X12 use and NOT meant to supersede use of SCRIPT for ePA. CMS should insist on use of the SCRIPT standard and only the SCRIPT standard for ePA transactions for prescription drugs. The market has already spoken and confirmed its efficacy. Consistent implementation of the *same* standard will advance interoperability and spur innovation.

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

Sincerely,

Mary Ann Chaffee
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