August 16, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-4189-P
P.O. Box 8013
Baltimore, MD 21244-8013

http://www.regulations.gov

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

Dear Administrator Verma,

The National Council for Prescription Drug Programs (NCPDP) is grateful for the opportunity to review and submit comments on the proposed rule, *" Medicare Program; Secure Electronic Prior Authorization for Medicare Part D (CMS-4189-P)".*

NCPDP is a not-for-profit, ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,600 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

For over 40 years, NCPDP has been committed to furthering the electronic exchange of information between healthcare stakeholders. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting, and other functions in the pharmacy services industry as named in HIPAA. The NCPDP SCRIPT Standard, Telecommunication Standard, and the Formulary and Benefit Standard are the standards in use in electronic prescribing as named in MMA.

NCPDP appreciates this opportunity to provide the following comments to the provisions and references outlined in CMS-4189-P as they relate to NCPDP standards, guidance and industry practices used to support the Medicare Part D prescription drug program.

Naming of the NCPDP SCRIPT Version 2017071 electronic prior authorization transactions

General Comments

NCPDP applauds the decision to require the use of the NCPDP SCRIPT Standard Version 2017071 electronic prior authorization (ePA) transactions for Part D-covered products prescribed to Part-D eligible individuals.

Currently, the NCPDP SCRIPT ePA transactions have been adopted by more than 60% of pharmacy benefit managers (https://epascorecard.covermymeds.com/). The use of these transactions significantly reduces the determination time of prior authorizations to hours instead of days. This leads to expedited access to therapy for the patient and results in improved outcomes.

Some benefits of adopting the NCPDP SCRIPT Version 2017071 ePA transactions include:

- Supports the proposed measures for the 2021 Star Ratings.
- Supports innovative approaches to improving program quality, accessibility and improvement in the CMS customer experience.
- Reduces the burden for all participants in the CMS Medicare Part D program.
- Supports establishing a framework addressing the opioid epidemic in which plan sponsors may launch a drug management program for beneficiaries at risk for prescription drug abuse or misuse.
- Reduces the burden related to printing and mailing and the number of paper documents that plans have to provide a CMS initiative.
- The ePA transactions harmonize with the other, previously mandated, electronic prescribing transactions within the SCRIPT Standard.

NCPDP Clarification to Statements within the Proposed Rule

28452: Regulation History

a. *… NCPDP SCRIPT ePA Version 2013101 and 2017 transactions are prepopulated with all NDCs and dosage information so the prescriber can choose among appropriate options….*

b. *Another standard that we are aware of is the NCPDP Telecommunications D.0 standard. However, this standard, does not have the ability to look up and convey NDCs and dosages. The NCPDP Telecommunications D.0 standard was designed to be a standard for insurance companies to approve claims, so it does not include content fields that are relevant to ePA, such as clinical fields and beneficiary-specific information nor does it have the ability to transmit information in real time. As such it is not frequently used by prescribers because it cannot collect information needed for satisfying a medication PA*

NCPDP Comment:

NCPDP would like to advise that the content within statement (a) above, as copied from the proposed rulemaking, is inaccurate. The prepopulating of NDCs and dosing information is a function of the prescriber's EHR system and not the SCRIPT Standard.

Additionally, as related to statement (b) above, as copied from the proposed rulemaking, the NCPDP Telecommunication Standard Version D.0 is used to transmit information in real-time. The Standard is used by pharmacies to submit claims for payment and to determine patient's eligibility. NCPDP agrees the Telecommunication Standard Version D.0 is insufficient for prescribers to submit and complete prior authorizations.

NCPDP Comments to the Proposed Rule CMS-4189-P Medicare Program; Secure Electronic Prior Authorization for Medicare Part D

28455: PA for Part D E-Prescribing

Therefore, we propose to add § 423.160(b)(7) which would require that Part D plans be able to support the NCPDP SCRIPT ePA standard transactions included within version 2017071 beginning on January 1, 2021, and that prescribers use that standard when conducting ePA by the same date. The proposed ePA standard applies to the following list of ePA transactions:

- *PAInitiationRequest and PAInitiationResponse*
- *PARequestandPAResponse*
- *PAAppealRequestand PAAppealResponse*
- *PACancelRequest and PACancelResponse*

We welcome comments on the proposed adoption of the NCPDP SCRIPT standard version 2017071 eRx for these ePA transactions for Part D- covered drugs prescribed to Part D eligible individuals.

We are also soliciting comments regarding the impact of these proposed transactions and the proposed effective date on industry and other interested stakeholders, including whether the implementation of a NCPDPSCRIPT standard version 2017071 ePA transaction standard for use by prescribers and plans in the Part D program would impose an additional burden on the industry as a whole. We would also be interested in hearing if implementation of the proposed transactions is a significant change for Part D sponsors which would make a January 1, 2021 implementation date as required by statute not be feasible.

We also seek comment on strategies to mitigate burden in order to support successful adoption of this policy.

Finally, we seek comment on any additional ways CMS can support plans as they transition to the ePA standard by the 2021 deadline.

NCPDP Comment:

NCPDP agrees with CMS regarding the applicability of use of the NCPDP SCRIPT Standard ePA transactions for requesting and responding to medication prior authorization within the Medicare Part D programs; however, the best solution for the industry is to adopt the NCPDP SCRIPT ePA transactions for all products covered under the pharmacy benefit versus the use of the X12N 278 and the NCPDP SCRIPT ePA transactions as outlined in the preamble of the proposed rule. The use of two different standards would be overly burdensome and confusing for prescribers and their staff and is contrary to the goal of administrative simplification. NCPDP and many across the healthcare industry, such as the Workgroup for Electronic Data Interchange (WEDI)[1], the American Medical Association (AMA)[2] as well as the National Committee on Vital and Health Statistics (NCVHS)[3], have repeatedly requested that all prior authorizations for products covered under the pharmacy benefit be conducted using the NCPDP ePA transactions in order to improve efficiency and access to care.

One strategy to eliminate burden would be to create a roadmap to have the NCPDP electronic prior authorization transactions as the ePA mechanism for products covered under the pharmacy benefit for all payers. NCPDP recommends that any willing trading partners be allowed to use the NCPDP electronic prior authorization transactions.

Extensive due diligence has shown the X12N 278 transaction is not sufficient for ePrescribing workflows. NCPDP began work to create the NCPDP SCRIPT ePA transactions as a result of an ePrescribing pilot conducted in 2006 that evaluated the efficacy of the X12N 278 and X12N 275 transactions. The pilot found the X12N transactions were sub-optimal for the support of prior authorizations for medications and did not offer improvements in administrative efficiency. It is clear from studies and research that the X12N 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 the pharmacy benefit.

28458: § 423.160 Standards for electronic prescribing

*(b) * * **

[1] The WEDI Prior Authorization Council

[2] Prior Authorization and Utilization Management Reform

[3] NCVHS 2014 Letter of Recommendation for use of the NCPDP Electronic Prior Authorization Transactions

(7) Electronic prior authorization. Beginning January 1, 2021, Part D sponsors and prescribers must comply with the National Council for Prescription Drug Programs SCRIPT standard, Implementation Guide Version 2017071 approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(vii) of this section), to provide for the communication of a prescription or related prescription-related information between prescribers and dispensers for the following transactions:

(i) PAInitiationRequest and PAInitiationResponse

(ii) PARequest and PAResponse

(iii) PAAppealRequest and PAAppealResponse

(iv)PACancelRequest and PACancelResponse

NCPDP Comment:

Throughout the *Summary*, *Background*, *Regulation History* and *PA for Part D E-Prescribing* sections, prescribers have the option to implement eRX transactions; however, in §423.160 Standards for electronic prescribing, "prescribers **must"** terminology is used. In the current rule, §423.160 (a)(2) states that applicable standards in (b) must be used when communicated using electronic media. NCPDP requests clarification on whether prescribers "must" implement the ePA transactions for all pharmacy benefit prior authorizations or only for pharmacy benefit prior authorizations if communicated using electronic media.

NCPDP Comment regarding Timeline for Adoption of NCPDP SCRIPT ePA transactions

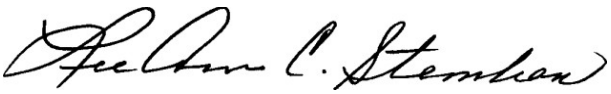
As it relates to the January 1, 2021 timeline for adoption, NCPDP would recommend allowing the industry a 24-month implementation timeframe from the date of final rule publication. This echoes our 2016 written testimony to NCVHS, which is referenced on page 28451 in this CMS proposed rulemaking.

Closing Comments

NCPDP appreciates the opportunity to provide comments to CMS as they relate to NCPDP standards, guidance and industry practices used to support the Medicare Part D prescription drug program.

NCPDP looks forward to working with CMS to ensure a smooth implementation of this rule as we work collaboratively to improve the quality of care of Medicare patients.

Sincerely,



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cc: NCPDP Board of Trustees