October 1, 2020

Submitted electronically at: www.regulations.gov

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Re: CMS-1734-P, Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan

Dear Administrator Verma:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit, American National Standards Institute (ANSI) accredited Standards Developer (ASD) consisting of more than 1,700 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 submits the following comments in response to CMS-1734-P.

***CMS: Section K**. Requirement for EPCS for a Covered Part D drug under a Prescription Drug Plan or an MA-PD Plan*

3. *E-Prescribing Standards – CMS adopted the first set of standards for e-prescribing for Part D, the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Version 5, Release 0 in the Medicare Program; E-Prescribing and the Prescription Drug Program, Final Rule, in 2005. Since then CMS has continued to adopt updated e-prescribing standards with the most recent standard described in a final rule published April 16, 2018 where we finalized an update of the Part D standards to NCPDP SCRIPT standard version 2017071 for e-Rx and medication history, effective January 1, 2020 (83 FR 16440).*

We currently require that Part D plans support the NCPDP SCRIPT standard version 2017071 for certain defined e-prescribing transactions as finalized in the "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" final rule (83 FR 16440). This requirement became effective on January 1, 2020. Under CMS regulations, prescribers are required to use this standard when conducting e-prescribing for covered Part D drugs for Part D eligible individuals.

NCPDP comment: CMS proposes to implement Section 2003 of the SUPPORT Act by requiring providers to use Electronic Prescribing for Controlled Substances (EPCS) for all schedule II-V drugs starting January 1, 2022, by inserting the following text at 42 CFR 423.160(a)(5):

"(5) On or after January 1, 2022, prescribers must, except in circumstances in which the Secretary waives the requirement, conduct all prescribing for all Schedule II, III, IV, and V controlled substances electronically using the applicable standards in paragraph (b) of this section."

CMS also refers to its Request for Information about enforcement and waivers under Section 2003 of the SUPPORT Act currently available for public comment. Based on the proposed regulatory text and CMS' RFI, it is unclear whether the current exemptions at 42 CFR 423.160(a)(3)(iii) will apply for prescriptions of controlled substances "when the prescriber and the dispenser are part of the same legal entity". In addition, CMS should either clarify the exemption will continue to apply when the EPCS requirement takes effect or create a waiver to that effect using its authority under Section 2003 of the SUPPORT Act.

Without a clarification, exemption or waiver, health IT developers that develop integrated systems for entities acting as both the prescriber and the dispensing pharmacy could be required to rush to complete development to change their integrated prescribing and dispensing software to communicate using an NCPDP interface, rather than leveraging the single database to which they both have access today. Requiring a system to "self-interface" rather than leverage its integrated database would have adverse impacts on health IT cost and performance and increase the potential for data corruption and patient matching errors. Meanwhile, such a requirement would not improve the security of the prescribing process since prescribers must adhere to the DEA's expectations for EPCS applications regardless of which electronic prescribing standard or communication method is used.

An exemption from using the NCPDP SCRIPT Standard would align with CMS' existing policy at 42 CFR 423.160(a)(1), because the prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals is not transmitted using electronic media. CMS should align such an exception with CMS' existing policy at 42 CFR 423.160(a)(3)(iii) which allows the use of HL7 messages for transmitting prescriptions and prescription-related information internally by clarifying that exemption's applicability to prescriptions for controlled substances.

5. *Proposed Timeframe for EPCS Adoption— Section 2003 of the SUPPORT Act mandates that EPCS begin on January 1, 2021. Due to this statutory mandate coupled with the aforementioned advantages provided by EPCS, we encourage all prescribers to conduct EPCS as soon as is feasible for them. Based on these considerations, we are proposing to amend § 423.160(a) by adding the requirement that all prescribers conduct electronic prescribing of Schedule II, III, IV, and V controlled substances using the NCPDP SCRIPT 2017071 standard by January 1, 2022, except in circumstances in which the Secretary waives the requirement. We are proposing that prescribers must use the NCPDP SCRIPT 2017071*

standard because they are already required to use this standard when conducting e-prescribing for covered Part D drugs for Part D eligible individuals, and we believe that prescribers should use the same standard for their electronic prescribing of controlled substances.

NCPDP comments: Given that NCPDP created and maintains the NCPDP SCRIPT Standard, NCPDP and its members strongly support the use of the standard for EPCS purposes as proposed by CMS. However, NCPDP is not certain when its affected members and/or their technology end users will be ready to engage in EPCS transactions. Thus, as an organization that strives to support the success of all of its members, NCPDP will not be commenting on the proposal to delay the effective date of the SUPPORT Act EPCS requirement.

NCPDP would like to thank CMS for the opportunity to submit comments on the CMS-1734-P document. NCPDP looks forward to working with CMS to find solutions for the concerns and issues raised in the above comments.

For direct inquiries or questions related to this letter, please contact:

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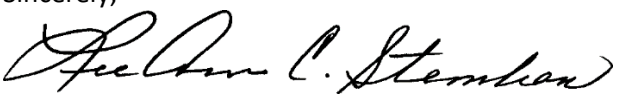
Sincerely,



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cc: NCPDP Board of Trustees