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The Honorable Chiquita Brooks-LaSure, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Baltimore, MD 21244

Re: CMS-1751-P, Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements

Dear Administrator Brooks-LaSure:

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-1751-P:

**CMS: PROPOSED TIMEFRAME FOR EPCS ADOPTION**

**Federal Register page 39329**

*However, we understand that NCPDP is in the process of creating specific guidance for LTC facilities within the SCRIPT 2017071 standard, which would allow willing partners to enable three-way communication between the prescriber, LTC facility and pharmacy to bridge any outstanding gaps that impede adoption of the NCPDP SCRIPT 2017071 standard in the LTC setting. We understand that NCPDP may be able to adopt these changes and integrate them into the LTC workflow by January 1, 2023.*

**NCPDP Comment:** NCPDP is still in the process of creating guidance for LTC facilities specific to enabling the necessary three-way communication within NCPDP SCRIPT Standard Version 2017071.

NCPDP did publish initial guidance in response to a question received from the May 2021 release of NCPDP's *SCRIPT Implementation Recommendations* document regarding the sharing of information with third parties:

**3.6.56 HOW CAN SPECIFIC PATIENT OR MEDICATION INFORMATION BE SHARED WITH A THIRD-PARTY PROVIDER FOR NON-DISPENSING ACTIVITIES?**

Response: Sending or receiving systems may send a copy of a message to a third-party service provider through trading partner agreements when specific conditions are met. Exact conditions are determined by the trading partner agreements. The mode of transmission may be directly between the software vendor and third-party service provider or between an intermediary and third-party service provider. Third party services may include, but are not limited to, reconciliation of patient records, medication updates, medication administration, medication dispensing and packaging and medication monitoring/tracking.

This question was specific to non-dispensing activities, and the response, while allowing the sharing of information with a third-party, indicates this sharing be done using trading partner agreements. A LTC electronic prescribing for controlled substances (EPCS) solution based on the use of trading partner agreements would be very inconsistent with CMS' promotion of a standardized approach to Health Information Technology (HIT) interoperability.

NCPDP does have SCRIPT Standard changes in process to address the ePrescribing three-way communication needs of the LTC community. However, these changes will be included in a future version of the SCRIPT Standard. This change request was approved by NCPDP Work Group 11 (ePrescribing and Related Transaction) during its May 2021 meeting and was included in the August 2021 ballot. Ballot comments will be adjudicated during NCPDP's November 2021 work group meeting. If approved, these changes will be included in and applied to the January 2022 and future versions of the NCPDP SCRIPT Standard. If identified, related concerns will be addressed in future versions of the SCRIPT Standard.

Considering the changes currently being incorporated into the SCRIPT Standard to address the LTC three-way communication needs, we suggest CMS coordinate the timing of its LTC EPCS compliance deadline with the implementation of a newly adopted SCRIPT Standard version in 42 CFR 423.160(b) for industry use.

**CMS: PROPOSED COMPLIANCE THRESHOLD**

**Federal Register page 39330**

*Specifically, we are proposing to revise § 423.160(a)(5) to specify that 70 percent of all prescribing under Part D for Schedule II, III, IV, and V controlled substances be done electronically per calendar year, excluding from that calculation any prescriptions issued while a prescriber falls within an exception or a waiver. We would conduct this calculation by examining PDE data at the end of the calendar year and dividing the number of Part D controlled substances that the prescriber e-prescribed by the total number of Part D controlled substance prescriptions that the prescriber prescribed. We seek comment on this method and the proposal to make 70 percent the compliance threshold for adherence to the EPCS mandate, and what circumstances would make EPCS not feasible.*

**NCPDP Comment:**

NCPDP is supportive of CMS' proposed method of establishing compliance through a threshold to account for the rare situations where transmission is not possible within the standard. While the NCPDP SCRIPT Standard Version 2017071 can successfully transmit the vast majority of prescriptions, there are several situations in which limitations of the standard or communication conditions will result in an inability for the prescription to be transmitted, including:

- Network/internet outages or system downtime
- Patients with names and/or addresses longer than 35 characters
- Patients whose names contain extended ASCII characters (common examples include the 'ñ' and 'é' characters)
- Prescriptions with notes for the pharmacy that exceed 210 characters

In these situations, the NCPDP standard cannot be used by the prescriber to complete the electronic prescribing transaction requiring the practitioner to use an alternative method of prescribing, such as paper. NCPDP is not offering any recommendation on the appropriateness of the 70 percent compliance threshold.

**CMS: PROPOSED CLASSES OF EXCEPTIONS****Federal Register page 39330**

*All August 2020 RFI commenters who commented on this exception supported it, stating that such an exception would promote patient safety, workflow efficiency, and health IT performance. Several commenters noted that requiring EPCS in this circumstance may create an unwarranted artificial workflow structure. We believe that this may be because the EPCS transactions conducted within an organization are commonly handled by a single database that exists within the organization, and should we not grant this exemption, these entities would be required to reconfigure their own processes, rather than leverage their own integrated databases. Were we to implement a requirement to use the NCPDP SCRIPT 2017071 standard within this closed system, this requirement could increase costs and the rate of performance errors, such as data corruption and patient matching errors, which we understand often happens when an entity is forced to split a unified database into a transaction system that relays information to and from the same entity. We seek comment on this assumption.*

**NCPDP Comment:**

NCPDP agrees such an exemption is necessary and appropriate. Without an exemption, health IT teams developing integrated systems for entities functioning 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 both already have access. 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. Such an exemption would align with CMS' existing policy at 42 CFR 423.160(a)(1) of using the NCPDP SCRIPT Standard Version 2017071, because the prescriptions and prescription-related information for covered Medicare Part D drugs for Medicare Part D eligible individuals are not transmitted using electronic media.

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*As stated in our current regulation at § 423.160(a)(3)(iii), we currently allow Part D plans to use either HL7 messages or the NCPDP SCRIPT standard to transmit prescriptions or prescription-related information internally when the sender and the beneficiary are part of the same legal entity. This allowance stands in contrast to our overarching requirement at § 423.160(a)(1) and (3), for prescribers to use the NCPDP SCRIPT standard for most external transactions. We believe that allowing Part D plans to continue to have more discretion over their internal transactions is consistent with our current policy. Therefore, we propose to adopt at § 423.160(a)(5)(i) the EPCS exception listed in section 1860D-4(e)(7)(B)(i) of the Act, for prescriptions issued where the prescriber and dispensing pharmacy are the same entity. We seek comment on this proposal.*

**NCPDP Comment:**

NCPDP agrees such an exemption would give implementers transmitting prescriptions or prescription-related information where the prescriber and dispensing pharmacy are the same legal entity the necessary flexibility to continue using either the HL7® or NCPDP SCRIPT standards at their discretion as allowed at § 423.160(a)(3)(iii).

NCPDP would like to thank CMS for the opportunity to submit comments on the CMS-1751-P document. NCPDP looks forward to working with CMS to increase adoption of EPCS to enhance patient safety, improve efficiencies and reduce abuse.

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

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Respectfully,



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