February 13, 2023

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4201-P
P.O. Box 8013
Baltimore, MD 21244-1850
Submitted via regulations.gov

Re: Proposed Rule CMS-4201-P

To Whom It May Concern:

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 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors 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 business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

NCPDP appreciates this opportunity to provide the following comments to the provisions and references outlined in CMS-4201-P as they relate to standards used to support the Medicare Part D prescription drug program. Our comments focus on *Section S. Standards for Electronic Prescribing* (§ 423.160) and *Section T. Adoption of Health IT Standards* (45 CFR 170.205).

Adoption of NCPDP SCRIPT Standard Version 2022011 and Retirement of NCPDP SCRIPT Standard Version 2017071 (Pgs. 79549 – 51; 79555)

CMS Proposal: "CMS is proposing to require the NCPDP SCRIPT Standard Version 2022011 and retire the current NCPDP SCRIPT Standard Version 2017071 as the e-prescribing standard for transmitting prescriptions and prescription-related information, to include medication history and electronic prior authorization (ePA), after an 18-month transition period beginning July 1, 2023. The agency is specifically soliciting comment on requiring NCPDP SCRIPT version 2022011 and retiring NCPDP SCRIPT standard version 2017071, following a transition period."

NCPDP Response: NCPDP agrees with moving to a new version of the NCPDP SCRIPT Standard and sunsetting the NCPDP SCRIPT Standard Version 2017071. While in the letter to CMS dated January 14, 2022[1], NCPDP requested the naming of Version 2022011, NCPDP requests the version be updated to Version 2023011. The NCPDP SCRIPT Standard Version 2022011 was published in January of 2022. Since that time, there have been new enhancements added to the NCPDP SCRIPT Standard which are needed

[1] National Council for Prescription Drug Programs. Next Version of SCRIPT Standard Recommendations. January 14, 2022. Available at: https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2022/202201NCPDP-SCRIPTNextVersionLetter.pdf.

by the industry resulting in Version 2023011. The new messages and features will improve patient safety and efficiency throughout the health care system.

Enhancements in the NCPDP SCRIPT Standard Version V2023011 include the following:

- A new optional element was added in the header for OtherReferenceNumber to allow any care setting outside of a prescriber or pharmacy, such as a long-term care facility, to submit an additional reference number when the transaction is part of a multi-party communication.
- A response type of Pending was added for use in RxChangeResponse and RxRenewalResponse. This new response type will allow a prescriber to notify a pharmacy when to expect either an approval or denial of the request along with a reason the response is being delayed.
- A new element of RequestExpirationDate was added to the NewRxRequest, RxChangeRequest and RxRenewalRequest to notify the prescriber to not send a response after this date.
- A new element was added to PASelectType for NoneChoiceID. If selected by the provider when the question allows the user to select multiple answers, this new element would cause none of the options to be displayed to the user (i.e., "none of the above") and allows branching to the next question.
- A new element was added for REMSReproductivePotential which replaced the element REMSPatientRiskCategory in the prescribed medication element group in the NewRx and RxChangeRequest message and in the replace medication element group for the RxRenewalResponse.
- A new element group of ReviewingProvider was added to the Resupply and Recertification messages to allow for the reporting of the provider who reviewed the chart and certified continued need of a specific medication.
- Guidance cleanup in the SCRIPT Implementation Guide.

NCPDP requests CMS adopt Version 2023011 now instead of in the future as it will assist in future migrations and will enable participants to immediately use these new enhancements. The NCPDP SCRIPT Standard Version 2023011 is backward compatible with Version 2017071, so either version can be used in a transition period.

Additionally, NCPDP requests CMS include RxHistoryRequest and RxHistoryResponse in its list of transactions codified at § 423.160(b)(2)(v) to clarify which transactions within the NCPDP SCRIPT Standard are appropriate for providing medication history information among Medicare Part D sponsors, prescribers, and dispensers.

CMS Proposal: "CMS also seeks feedback on its proposal requiring compliance with 45 CFR 170.205(b) to align Part D electronic prescribing requirements with standards adopted by ONC."

NCPDP Response: NCPDP supports the alignment of standards to allow for better coordination between all stakeholders in implementing the new standards. Specifically, NCPDP supports CMS's proposal to amend § 423.160(b) by cross referencing 45 CFR 170.205(b) where ONC intends to adopt the new NCPDP SCRIPT Standard instead of independently naming the NCPDP SCRIPT Standard and corresponding implementation guide. Additionally, NCPDP supports the same proposed alignment for prescription transactions, medication history transactions and electronic prior authorization (ePA) transactions.

NCPDP agrees with CMS that this proposed approach would avoid future misalignment between CMS and ONC.

CMS Proposal: "CMS is seeking comment on whether the proposed date of January 1, 2025, to retire NCPDP SCRIPT Standard Version 2017071 provides a sufficient transition period for industry and other interested stakeholders or if delaying this date to January 1, 2026, or later offers advantages or disadvantages."

NCPDP Response: NCPDP recommends at least two years from the effective date of the final rule to complete the transitional period and suggests additional time be incorporated to accommodate time for testing. Therefore, delaying to January 1, 2026, is preferred.

CMS Proposal: *"*CMS is requesting comment on the appropriateness of this proposed expiration date for NCPDP SCRIPT standard version 2017071, and whether they should consider finalizing a transition period of an additional year or a longer period. Additionally, CMS is interested in whether commenters believe an extended transition period, during which use of both standards would be allowed for programs requiring use of a standard in 45 CFR 170.205(b), would be appropriate."

NCPDP Response: NCPDP recommends an implementation timeframe of no less than two years (24 months) following the effective date of the final rule. Many organizations rely upon the publication of the final rule to begin efforts towards compliance, and budgets are generally approved before the fourth quarter of the calendar year. In addition, state level mandates, such as California's first-time requirement for the use of the RxTransfer message, have already placed a burden on developers and implementers of these proposed rules. Further, CMS's proposal to update the SCRIPT Standard and mandate use of the RTPB Standard in this rulemaking as well as the recent proposal under CMS-0056-P[2] which updates the NCPDP Telecommunication Standard and other standards will create a challenge in the industry with coordinating budgets, resources and timing to be simultaneously developed, tested and implemented. NCPDP respectfully ask CMS to take these challenges into consideration as they consider final rule development.

Since a compliance date of January 1 is a requirement, NCPDP reiterates the need for at least two years from the effective date of the final rule to complete the transitional period and suggests additional time be incorporated to accommodate time for testing.

Additional NCPDP Comments on NCPDP SCRIPT Standard

In *Section 3. Adoption of NCPDP SCRIPT Standard Version 2022011 as the Part D Electronic Prescribing Standard, Retirement of NCPDP SCRIPT Standard Version 2017071, and Related Changes in § 423.160*, CMS lists transactions for prescriptions they propose to codify at *§ 423.160(b)(2)(v)(A) – (Y)*.

NCPDP Comment: NCPDP requests under RxTransfer, CMS correct a typographical error by removing the "i" following the "l" within "*REMSIinitiationRequest*" and "*REMSIinitiationResponse*" to "*REMSInitiationRequest*" and "*REMSInitiationResponse" on* pg. 79550. NCPDP requests similar corrections to § 423.160 Standards for electronic prescribing (v) on page 79730 from "(V)*REMSIinitiationRequest*" and "(W)*REMSIinitiationResponse*" to "(V)*REMSInitiationRequest*" and "(W)*REMSInitiationResponse".*

[2] 87 FR 67634

Adoption of the NCPDP Real-Time Prescription Benefit (RTPB) Standard (pgs. 79551-52; 79555)

CMS Proposal: "CMS is proposing to require the NCPDP Real-Time Prescription Benefit (RTPB) Version 12 proposed for adoption at 45 CFR 170.205(c) as the standard for prescriber real-time benefit tools (RTBTs) and to incorporate this standard by reference in 45 CFR 170.299. Part D sponsors' RTBT must comply with 45 CFR 170.205(c) as of January 1, 2025."

NCPDP Response: NCPDP supports CMS's proposal to adopt the NCPDP RTPB Standard Version 12. The NCPDP RTPB Standard was published in October of 2021. Since that time, there have been new enhancements added to the NCPDP RTPB Standard which are needed by the industry resulting in Version 13.

Enhancements to the NCPDP RTPB Standard Version 13 include:

- Added Coverage Status Message to assist in communicating coverage information at a product level which is not codified. By adding this field, the payer will be able to communicate important information regarding coverage and provide clarifying or additional information.
- Added values to the Coverage Restriction Code and data elements to the RTPB Standard to codify information communicated in the Message to reduce the number of free text messages on the response.
- Added next available fill date to communicate when the patient is eligible to receive a prescription refill in a discrete field instead of via a free text message.
- Added fields to communicate formulary status and preference level. This allows for the communication of the formulary status of both submitted product and alternative products to help understand pricing on the response.
- Added data elements to convey the patient's address, state/province, zip/postal code and country on the request transaction to aid in coverage determination.

Adopting Version 13 now, instead of in the future, will help in future migrations and will enable participants to use these new enhancements now.

While NCPDP supports the adoption of the RTPB Standard as proposed in the rule but prefers Version 13, NCPDP strongly recommends a 24 month implementation period following the effective date of the final rule. It is more feasible for the following reasons:

On August 20, 2021, NCPDP submitted comments to CMS[3] requesting the adoption of NCPDP's Real-Time Prescription Benefit Standard Version 12. In the August 2021 communication NCPDP requested an implementation timeframe of two years (or 24 months) following the publication of a final rule. NCPDP continues to assert that a two-year implementation timeframe is still in alignment with industry needs. There are current solutions implemented in the market utilizing proprietary formats and providers and their partners will need 24 months to obtain development funding, complete systems analysis work and develop and test new software solutions to assure scale and compliance.

[3] National Council for Prescription Drug Programs. Adoption of NCPDP Real-Time Prescription Benefit Standard Version 12. August 20, 2021. Available at: https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2021/20210820_To_CMS_RTPBandFandBStandardsAdoptionRequest.pdf

Like previous comments, NCPDP would like to note a compliance date of January 1 is a challenge for many stakeholders and creates issues related to member eligibility as it relates to the RTPB Standard. A significant number of pharmacy benefit plan changes occur on January 1 and these changes frequently lead to coverage eligibility challenges. As such, there may be confusion regarding member eligibility and drug coverage information which can result in delays in access to therapy. To operate properly, the RTPB transaction(s) are dependent on accurate member eligibility. Many organizations enforce a code freeze prior to January 1 to ensure all changes are correctly implemented and tested and cannot be the cause of errors which should be attributed to data changes. This would force an unnecessary rush to complete coding for RTPB in addition to plan year changes which could result in challenges with implementation.

Since a compliance date of January 1 is a requirement, NCPDP reiterates the need for at least two years from the effective date of the final rule to complete the transitional period and suggests additional time be incorporated to accommodate time for testing before the common year-end code freeze referenced above.

NCPDP respectfully ask CMS to take these challenges into consideration as they consider final rule development.

Additional NCPDP Comments on NCPDP RTPB Standard

On page 79551 of its proposal, CMS states, "The NCPDP RTPB Standard Version 12 enables the real-time exchange of information about patient eligibility, patient-specific formulary and benefit information, and preferred pharmacy network participation status. For a submitted drug product, the RTPB Standard will indicate coverage status, coverage restrictions, and patient financial responsibility and the RTPB Standard also supports providing information on alternative pharmacies and products."

NCPDP Comment: NCPDP would like to note "preferred pharmacy network participation status" is not an accurate statement. The NCPDP RTPB Standard enables the communication of the patient's preferred pharmacy on the request transaction, but the response transaction does not identify a pharmacy's preferred network participation status. Additionally, CMS states the NCPDP RTPB Standard, "will indicate…patient financial responsibility." NCPDP would like to clarify the NCPDP RTPB Standard will only provide an *estimate* of the patient financial responsibility, because each RTPB transaction (request and response) reflects a moment in time and is designed to provide an estimate of the patient's out of pocket costs. A patient's actual out of pocket cost may vary depending on the timing between the RTPB request(s) and the corresponding NCPDP claim billing request/response transactions, as well as the order of the claim billing transactions when multiple prescriptions are dispensed.

CMS notes on page 79551 of its proposal, "The NCPDP RTPB Standard Version 12 is designed for prescriber, not beneficiary, RTBT applications. CMS emphasizes they are not proposing the proposed standard be required for beneficiary RTBTs but are also not prohibiting the practice."

NCPDP Comment: NCPDP's RTPB Standard was not designed to support a beneficiary RTBT; however, NCPDP agrees with CMS on not prohibiting the use of the NCPDP RTPB Standard for beneficiary RTBT. NCPDP also agrees with not requiring the proposed standard for beneficiary RTBTs.

Other Sections for NCPDP Comment

Aligned Approach to Standards Adoption (pgs 79553—4)
CMS Proposal: *"*ONC and CMS are seeking to pursue a new approach to alignment of standards in this proposed rule where HHS would adopt the standards specified under the Secretary's authority to adopt health IT standards in the Public Health Service Act (PHSA)."

NCPDP Response: NCPDP supports the new approach to the alignment of standards to allow for better coordination between all stakeholders in implementing the new standards.

Standards and Eligibility Transactions (Pg. 79552)
CMS Proposal: *"*CMS is proposing to streamline the Part D regulation by indicating eligibility transactions must comply with the applicable HIPAA regulations, as opposed to naming standards independently, which would ensure, should the HIPAA standards be updated as a result of HHS rulemaking, the Part D regulation would be synchronized with the required HIPAA standards."

NCPDP Response: NCPDP supports the proposal to comply with 45 CFR §162.1202 regarding eligibility transactions in electronic prescribing.

ONC Health IT Certification Program and Certification Criteria
In its proposal, CMS has been clear that ONC, in future rulemaking, will consider updates to the ONC Health IT Certification Program and certification criteria relative to both the NCPDP SCRIPT and RTPB standards. NCPDP believes the ONC Health IT Certification Program is an important part of the process in advancing the use and adoption of industry technical standards and implementation guides to improve patient access to care and reduce burden and cost.

Standards which have been incorporated into ONC's Health IT Certification Program are eligible for consideration for the ONC established, voluntary Standards Version Advancement Process (SVAP). SVAP enables health IT developers to incorporate newer versions of Secretary-adopted standards and implementation specifications, as part of the "Real World Testing" Condition and Maintenance of Certification requirement (§ 170.405) of the 21st Century Cures Act. Using SVAP, certified health IT developers are permitted to voluntarily use a more advanced version of standard(s) and implementation specification(s) approved by the National Coordinator than is adopted in the ONC 2015 Edition Certification Criteria.

NCPDP encourages ONC to move forward in advancing modified certification criterion for the NCPDP SCRIPT Standard and for adopting certification criterion for the NCPDP RTPB Standard.

NCPDP looks forward to collaboratively working with CMS to improve the quality of care of Medicare patients.

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

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Respectfully,

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