January 5, 2024

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4205-P
P.O. Box 8013
Baltimore, MD 21244
Submitted electronically to www.regulations.gov

Re: CMS-4205-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 previously responded[1] to CMS's proposed rule CMS-4201-P, "*Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications*" where CMS proposed updates to the standards to be used by Medicare Part D prescription drug plans for electronic prescribing (e-prescribing) that have been subsequently withdrawn in CMS-4205-P. NCPDP appreciates CMS's review and consideration of our comments which have been reflected in the new proposal. NCPDP's comments to CMS-4205-P focus on *III. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, Sections III.B.4.* through *III.B.9.*, *III.C.5* and *III.C.8* of the new proposed rule.

III. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs
B. Standards for Electronic Prescribing

Section III.B.4: Requiring NCPDP SCRIPT Standard Version 2023011 as the Part D Electronic Prescribing Standard, Retirement of NCPDP SCRIPT Standard Version 2017071, and Related Conforming Changes in §423.160

[1] National Council for Prescription Drug Programs. Response to CMS-4201-P. Available at: https://www.regulations.gov/comment/CMS-2022-0191-0543.

CMS Proposal (Pg. 78494*):* *In summary, with respect to changes related to adopting, via cross-reference to ONC proposals in section III.C.8.a., NCPDP SCRIPT standard version 2023011 and retiring NCPDP SCRIPT standard version 2017071, we propose a revised paragraph § 423.160(b)(1) to:*

- *Consolidate all transactions for electronic prescribing, ePA, and medication history for which use of the NCPDP SCRIPT standard is mandatory at § 423.160(b)(1)(i)(A) through (Z); and*
- *Indicate that communication of prescriptions and prescription-related transactions listed must comply with a standard in 45 CFR 170.205(b). In conjunction with ONC proposals in section III.C.8.a., this cross-reference would permit a transition period when either NCPDP SCRIPT standard versions 2017071 or 2023011 may be used beginning as of the effective date of a final rule and ending January 1, 2027, because, as ONC has proposed at 45 CFR 170.205(b)(1), the NCPDP SCRIPT standard version 2017071 would expire January 1, 2027, after which only NCPDP SCRIPT standard version 2023011 would be available for HHS use.*

NCPDP Response: NCPDP appreciates CMS listing all transactions associated with the NCPDP SCRIPT standard requirements in one location in the regulation as we had requested in our comments to CMS-4201-P.

Please see NCPDP's response to section III.C.8a below regarding our support of the transition to NCPDP SCRIPT Standard Version 2023011.

CMS Proposal (Pg. 78494*):* *We are not proposing a change in the EPCS compliance date for covered Part D controlled substance prescriptions for Part D beneficiaries in LTC on the basis of the proposed adoption of NCPDP SCRIPT Standard version 2023011; however, we invite comment on the status of EPCS in LTC and the degree to which LTC facilities have been able to implement guidance from NCPDP to meet the EPCS requirement.*

NCPDP Response: NCPDP attempted to create guidance on three-way communication among the prescriber, LTC facility and pharmacy using the NCPDP SCRIPT Standard Version 2017071, but it was not realistic in that version of the standard.

Section III.B.5: Requiring NCPDP Real-Time Prescription Benefit (RTPB) Standard Version 13

CMS Proposal (Pg. 78495): *As discussed in section III.C.8.b. of this proposed rule, ONC proposes to adopt the NCPDP RTPB standard version 13 at 45 CFR 170.205(c)(1). CMS therefore propose at § 423.160(b)(5) to require that beginning January 1, 2027, Part D sponsors' prescriber RTBT must comply with a standard in 45 CFR 170.205(c).*

NCPDP Response: NCPDP agrees with the naming of NCPDP Real-Time Prescription Benefit Standard Version 13 and the proposed implementation date of January 1, 2027, as this date meets the requested minimum two years to implement the standard. NCPDP would anticipate the final rule to be issued by December 31, 2024, to allow for the two-year implementation timeframe with the January 1, 2027, implementation date.

CMS Request (Pg. 78495): *CMS takes interest in how adoption of the proposed NCPDP RTPB standard version 13 could alter functionality of RTBTs already in use. CMS created requirements for RTBTs in the absence of an industry-wide standard because of their potential to increase drug price transparency and*

lower out-of-pocket costs for Medicare Part D enrollees. The impact of RTBTs is contingent on prescribers actually receiving the patient-specific information in the response from the payer. CMS appreciates that this is relatively new technology and that there are multiple factors that contribute to the overall impact of RTBTs in real-world settings. Nevertheless, we seek comment on the issue raised by the commenter. We ask interested parties for their perspective on whether requiring the NCPDP RTPB standard version 13 would limit the ability to send more than one drug or pharmacy per RTBT transaction, and if so, whether the benefit of adopting a standard for prescriber RTBTs in order to enable widespread integration across EHRs and payers outweighs such limitation.

NCPDP Response: NCPDP supports the naming of the NCPDP Real-Time Prescription Benefit (RTPB) Standard Version 13. Some current proprietary implementations of a real-time prescription benefit tool support the submission of up to three additional products (alternative products) in a request and expect the adjudicator/pharmacy benefit manager (PBM) to process all submitted products (up to four products) for a single response. Version 13 of the NCPDP RTPB Standard does not support the submission of up to four products in a request but does support the communication of a coverage status for multiple alternatives to the single submitted product in the response. The NCPDP Real-Time Prescription Benefit Standard Task Group is discussing an enhancement for a future version of the standard enabling the submission of up to four products in a single RTPB request. Until a future version supporting multiple products in a single RTPB request is implemented, industry participants seeking to submit multiple products for a patient will have to submit each in a distinct request, based on the adjudicator/PBM requirements. Since it has been established through industry consensus, the task group believes the current standard will meet the industry's needs.

CMS Proposal (Pg.78495): *The NCPDP RTPB standard version 13 standard is designed for prescriber, not beneficiary (that is, consumer), RTBTs. CMS emphasizes that we are not proposing a required standard for beneficiary RTBTs. Beneficiary RTBTs are made available directly to Part D plan enrollees by the Part D sponsor; therefore, beneficiary RTBT applications do not necessarily interface with an electronic prescribing system or EHR, as prescriber RTBTs must. Consequently, CMS believes that Part D sponsors can retain the flexibility to use beneficiary RTBTs that are based on an available standard or a custom application, as long as the information presented to enrollees meets CMS's requirements codified at § 423.128(d)(4). The requirements for the beneficiary RTBT are discussed in the final rule titled ''Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,'' which appeared in the January 19, 2021 Federal Register (86 FR 5864).We decline to propose a standard for beneficiary RTBTs at this time, however we welcome comments on this topic which may be considered for future rulemaking.*

NCPDP Response: NCPDP's RTPB Standard was not designed to support a beneficiary RTBT; therefore, we agree with not requiring the proposed standard for beneficiary RTBTs.

Section III.B.6: Requiring NCPDP Formulary and Benefit Standard Version 60 and Retirement of NCPDP Formulary and Benefit Standard Version 3.0

CMS Proposal (Pg. 78496): *Following an approach similar to those proposed in sections III.B.4. and III.B.5. of this proposed rule, CMS proposes at § 423.160(b)(3) that transmitting formulary and benefit information between prescribers and Medicare Part D sponsors must either utilize NCPDP F&B standard version 3.0 or comply with a standard in 45 CFR 170.205(u), where ONC proposes to adopt, at 45 CFR 170.205(u)(1), NCPDP F&B standard version 60 as described in section III.C.8.c. of this proposed rule. After January 1, 2027, entities transmitting formulary and benefit information would be required to comply with a standard in 45 CFR 170.205(u) exclusively, if finalized as proposed.*

Since ONC did not previously adopt NCPDP F&B standard version 3.0, we are maintaining the incorporation by reference of that version in the Part D regulation at § 423.160(c)(1)(i) to permit a transition period where either NCPDP F&B standard version 3.0 or NCPDP F&B version 60 could be used until January 1, 2027.

NCPDP Response: NCPDP supports ONC maintaining the incorporation by reference of NCPDP Formulary and Benefit Standard Version 3.0 in the Part D regulation at § 423.160(c)(1)(i) to permit a transition period where either NCPDP Formulary and Benefit Standard Version 3.0 or NCPDP Formulary and Benefit Standard Version 60 could be used until January 1, 2027.

Please see NCPDP's response to Section III.C.8c below for our further comments supporting the actions regarding the NCPDP Formulary and Benefit (F&B) Standard.

Section III.B.7: Date for Required Use of NCPDP SCRIPT Standard Version 2023011, NCPDP RTPB Standard Version 13, and NCPDP F&B Standard Version 60

CMS Proposal (Pg. 78497)*: ONC is proposing January 1, 2027, as the date NCPDP SCRIPT standard version 2023011 would be the required version of this standard, as a product of the proposed expiration for NCPDP SCRIPT standard version 2017071 and CMS's proposed cross-reference, in § 423.160(b)(1), to a standard in 45 CFR 170.205(b). CMS is proposing the required use of NCPDP F&B standard version 60 and NCPDP RTPB standard version 13 by January 1, 2027, in the text of § 423.160(b)(3) and (5), respectively, as previously discussed.*

We are also aware that Part D sponsors and the health IT industry are awaiting HHS' final rule on the proposals to update the NCPDP Telecommunication standard from version D.0 to version F6 (87 FR 67638), update the equivalent NCPDP Batch Standard version 15 (87 FR 67639), and implement the NCPDP Batch Standard Pharmacy Subrogation version 10 (87 FR 67640) proposed in the November 2022 Administrative Simplification proposed rule. Taking all of these proposals into consideration, we ask interested parties to comment on the proposed January 1, 2027, date for the required use of NCPDP SCRIPT standard version 2023011, NCPDP RTPB standard version 13, and NCPDP F&B standard version 60.

NCPDP Response: NCPDP agrees with the proposed timeline of January 1, 2027, for requiring the NCPDP SCRIPT Standard Version 2023011, NCPDP Real-Time Prescription Benefit Standard Version 13 and NCPDP Formulary and Benefit Standard Version 60 assuming the rule is finalized by December 31, 2024. This will give the industry a two-year implementation timeframe from the effective date of the final rule which is necessary for stakeholders to successfully complete the transition by the required date.

As NCPDP previously stated in its response to CMS-4201-P, 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. Developers will need to design, develop, test and deploy changes to their customers' systems. Testing is also done in multiple phases; testing technical conformance to the new standard, workflow testing of the new standard to validate the software can properly utilize the changed and new features of the standard and finally, end-to-end testing to validate usage of the standard with trading partners. Prescribers, pharmacies and health plans will need time to upgrade and modify configuration to their health IT systems, implement changes to their prescribing processes and to train their employees.

Section III.B.8: Standards for Eligibility Transactions

CMS Proposal (Pg. 78497): *We propose to revise the Part D requirements to indicate that eligibility transactions must comply with 45 CFR 162.1202. The requirements for eligibility transactions currently codified at § 423.160(b)(3)(i) and (ii) name the Accredited Standards Committee X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 5010, April 2008, ASC X12N/ 005010x279 and the NCPDP Telecommunication Standard Specification, Version D, Release 0 (Version D.0), August 2007, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 2 (Version 1.2), January 2006 supporting Telecommunications Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007. We adopted these standards to align with those adopted at 45 CFR 162.1202, pursuant to the final rule titled ''Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards,'' which appeared in the January 16, 2009, Federal Register (74 FR 3326).*

The November 2022 Administrative Simplification proposed rule proposes to update the HIPAA standards used for eligibility transactions (87 FR 67638). We therefore propose to update the Part D regulation by proposing, at § 423.160(b)(2), that eligibility inquiries and responses between the Part D sponsor and prescribers and between the Part D sponsor and dispensers must comply with the applicable HIPAA regulation in 45 CFR 162.1202, as opposed to naming standards independently, which would ensure, should the HIPAA standards for eligibility transactions be updated as a result of HHS rulemaking or in the future, that the Part D regulation would be synchronized with the required HIPAA standards. We foresee no immediate impact of this proposed change since the HIPAA regulation at 45 CFR 162.1202 currently identifies the same standards as those named in the Part D regulation at § 423.160(b)(3)(i) and (ii), but we believe establishing a cross-reference would help avoid potential future conflicts and mitigate potential compliance challenges for the healthcare industry and enforcement challenges for HHS. Thus, we propose to delete existing § 423.160(b)(3)(i) and (ii) and modify § 423.160(b)(2) (as renumbered per the technical proposals in section III.B.9. of this proposed rule) to require that eligibility transactions must comply with 45 CFR 162.1202.

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

C. Adoption of Health IT Standards and Incorporation by Reference (45 CFR 170.205 and 170.299)

Section III.C.5 Aligned Approach to Standards Adoption

CMS Proposal (Pg. 78500)*: Historically, the ONC Health IT Certification Program and the Part D Program have maintained complementary policies of aligning health IT certification criteria and associated standards related to electronic prescribing, medication history, and electronic prior authorization for prescriptions. While CMS and ONC have worked closely together to ensure consistent adoption of standards through regulatory actions, we recognize that the practice of different HHS components conducting parallel adoption of the same standards may result in additional regulatory burden and confusion for interested parties. For instance, due to discrepancies between regulatory timelines, adoption of the NCPDP SCRIPT standard version 2017071 in different rules (respectively, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule (85 FR 25642) and 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 which appeared in the April 16, 2018 Federal Register (83 FR 16440)) led to a period where ONC had to exercise special enforcement discretion in the ONC Health IT Certification Program.40 Given these concerns, ONC and CMS proposals in the December 2022 proposed rule (87 FR 79552 through 79557), CMS and ONC proposals reflected a new approach to alignment of standards under which ONC proposed to adopt and incorporate by reference, on behalf of HHS, the NCPDP SCRIPT standard version 2022011 and the NCPDP RTPB standard version 12 in a single Code of Federal Regulations location at 45 CFR 170.205, where CMS proposed to cross-reference these standards for requirements in the Part D program.*

We note that the proposals in this rule continue to reflect an aligned approach with CMS to adoption of health IT standards for eprescribing and related purposes. We believe our proposed adoption of these standards in a single CFR location for HHS use will help to address concerns around alignment across HHS programs.

NCPDP Response: NCPDP agrees with CMS that the proposed adoption of these standards in a single CFR location for HHS use will help address concerns around alignment across HHS programs. NCPDP supports the new proposed approach to standards alignment allowing for better coordination among all stakeholders implementing new standards.

NCPDP applauds CMS and ONC's collaboration in proposing this new, novel approach to standards alignment as it will allow for a coordinated approach to name new NCPDP standards and update current standards (e.g., NCPDP SCRIPT Standard for e-prescribing) instead of independently proposing new and updated standards in Part D regulations. Specifically, NCPDP looks forward to engaging with ONC in their Standards Version Advancement Process (SVAP) and agree that the proposed change allowing for ONC to name a standard, and subsequently allowing for CMS to reference ONC regarding such named standards, ensures consistency and standardization in the process. Additionally, this new process would also allow ONC and NCPDP to collaborate on testing new versions of standards while still complying with regulations.

Section III.C.8a: NCPDP SCRIPT Standard Version 2023011 (45 CFR 170.205(b))

CMS Proposal Pg. 78501): *We propose to adopt NCPDP SCRIPT standard version 2023011 in 45 CFR 170.205(b)(2), replacing NCPDP SCRIPT standard version 10.6 which is currently in 170.205(b)(2). We propose to incorporate NCPDP SCRIPT standard version 2023011 by reference in 45 CFR 170.299. Regarding NCPDP SCRIPT standard version 2017071, CMS proposes to revise the regulatory text in 45 CFR*

170.205(b)(1) to specify that adoption of this standard will expire on January 1, 2027. . If these proposals are finalized, this would mean that both the 2017071 and 2023011 versions of the NCPDP SCRIPT standard would be available for HHS use from the effective date of a final rule until January 1, 2027. On and after January 1, 2027, only the 2023011 version of the NCPDP SCRIPT standard would be available for HHS use, for instance, where use of a standard in 45 CFR 170.205(b) is required. We refer readers to section III.B.4. of this proposed rule, where CMS discusses its proposal at § 423.160(b)(1) to require use of a standard in 45 CFR 170.205(b) for communication of a prescription or prescription-related information to fulfill the requirements for prescriptions, electronic prior authorization, and medication history.

NCPDP Response: NCPDP agrees with moving to NCPDP SCRIPT Standard Version 2023011 and sunsetting the NCPDP SCRIPT Standard Version 2017071. NCPDP SCRIPT Standard Version 2023011 includes several new features that will improve patient safety and efficiency throughout the healthcare system including but not limited to:

- Extensibility
- Redesign of the Product/Drug groupings
    - DrugCoded – Mandatory NDC Number
    - Compound Information – no change to requirements
    - NonDrugCoded – does not require NDC
- Added Observation elements to REMS transactions
- Added ProhibitRenewalRequest to RxChangeResponse and RxRenewalResponse
- Added Push or Unsolicited options to RxTransfer
- Structured and Codified Sig Structure was modified
- Added a Pending response type for use in RxChangeResponse and RxRenewalResponse
- Added a new element group of ReviewingProvider to Resupply and Recertification
- Added support for
    - Dental Procedure Codes
    - RxBarCode
    - PatientConditions
    - SexAssignedAtBirth
    - TherapeuticSubstitutionIndicator
    - Patient Pronouns
    - Multi-party communications and withdrawal/retracting of a previous sent message using the MessageIndicatorFlag

The NCPDP SCRIPT Standard Version 2023011 is backward compatible with version 2017071, so either version can be used in a transition period.

Section III.C.8b: NCPDP Real-Time Prescription Benefit (RTPB) Standard Version 13 (45 CFR 170.205(c))

CMS Proposal (Pg. 78502)*: We are proposing in 45 CFR 170.205(c) to add a new section heading ''Real-Time Prescription Benefit.'' We are also proposing to adopt the NCPDP Real-Time Prescription Benefit standard version 13 45 in 45 CFR 170.205(c)(1) and to incorporate this standard by reference in 45 CFR 170.299. We refer readers to section III.B.5. of this rule, where CMS proposes at § 423.160(b)(5) to require Part D sponsors' RTBTs to comply with a standard in 45 CFR 170.205(c) by January 1, 2027, to fulfill the requirements for real-time benefit tools. As previously noted, ONC will consider proposals to require use of*

this standard to support real-time benefit tool functionality in the ONC Health IT Certification Program, consistent with section 119 of the CAA, in future rulemaking.

NCPDP Response: NCPDP agrees with the naming of NCPDP Real-Time Prescription Benefit Standard Version 13 and the proposed implementation date of January 1, 2027.

Section III.C.8c NCPDP Formulary and Benefit (F&B) Standard Version 60 (45 CFR 170.205(u))

CMS Proposal (Pg. 78502): *We propose to add a new paragraph heading at 45 CFR 170.205(u), ''Formulary and benefit.'' We propose to adopt the NCPDP Formulary and Benefit standard version 60 at 45 CFR 170.205(u)(1) and to incorporate this standard by reference in 45 CFR 170.299.*

NCPDP Response: NCPDP appreciates CMS' continued recognition of the important role the NCPDP Formulary and Benefit Standard serves, both as a foundation for many other electronic prescribing functions (e.g., ePA and real-time benefit check) and as a complimentary standard (e.g., specialty medication eligibility). NCPDP also appreciates CMS' response to NCPDP's April 4, 2023, letter, notably the response to the requests to adopt the NCPDP Formulary and Benefit Standard Version 60 to replace the NCPDP Formulary and Benefit Standard Version 3.0 and provide at least a 24-month implementation period. This is a needed upgrade to a standard last updated over 15 years ago, to support CMS' priorities such as indication-based formularies and pharmacy networks.

NCPDP supports CMS' proposals to adopt the NCPDP Formulary and Benefit Standard Version 60 at 45 CFR 170.205(u)(1) and to incorporate this standard by reference in 45 CFR 170.299. NCPDP also supports CMS' proposed Formulary and Benefit standard transition period and CMS's corresponding proposal to retire the use of the NCPDP Formulary and Benefit Standard Version 3.0 by January 1, 2027.

NCPDP and its members appreciate the opportunity to provide comments to CMS as they relate to NCPDP standards used to support the Medicare Part D prescription drug program. NCPDP thanks CMS for their thoughtful consideration of our comments. NCPDP looks forward to working with CMS to ensure a smooth implementation of this rulemaking as we work collaboratively to improve the quality of care for Medicare patients.

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

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Respectfully,

Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)