



Office of the National Coordinator
for Health Information Technology

HHS Alignment – Pharmacy Standards in Part D NPRM

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Contract Year 2024 Part C/D Policy and Technical Changes Proposed Rule

- On December 14, 2022, CMS released the “Contract Year 2024 Policy and Technical Changes” NPRM including proposals for Medicare Advantage (Part C) and the Medicare Prescription Drug Benefit (Part D).
- The Part C/D Technical Changes rule included a “rider” in which ONC proposes to adopt two pharmacy standards on behalf of HHS under authority in Section 3004 of the Public Health Service Act (87 FR 79552).
- Proposals by CMS and ONC included in the joint rulemaking reflect an aligned approach to adopting and updating certain pharmacy standards which are used to exchange information between prescribers, dispensers, intermediaries and Medicare prescription drug plans (PDPs).
- Comment period closes February 13, 2023.



Collaborative Approach to CMS/ONC Standards Adoption

- 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.
- The current practice of different HHS components conducting parallel adoption of the same standards may result in additional regulatory burden and confusion for stakeholders.
- Previous adoption of the NCPDP SCRIPT standard version 2017071 on separate timelines by each program led to a period where ONC had to exercise special enforcement discretion in the ONC Health IT Certification Program.
- Through the collaborative approach to adoption of standards in this proposed rule, ONC and CMS are seeking to align requirements across HHS programs and mitigate potential compliance challenges for the pharmacy industry.





ONC Standards Adoption Proposals

- Proposes to adopt two standards in 45 CFR 170.205 under authority in the Public Health Service Act.
- Proposes to adopt NCPDP SCRIPT standard version 2022011 on behalf of the Secretary and retire the current NCPDP SCRIPT version 2017071 by January 1, 2025, allowing for a transition period.
- Proposes to adopt the NCPDP Real-Time Prescription Benefit (RTPB) standard version 12.
- Does not propose any updates to the ONC Health IT Certification Program at this time but notes that ONC will seek to align with these standards in any future rulemaking.
 - This will include rulemaking to address the provision in the Consolidated Appropriations Act, 2021 specifying that a “qualified electronic health record” must include or be capable of including a real-time benefit tool.

Part D Program Proposals

- CMS proposals for the Part D program incorporate these standards in Part D program requirements through cross-reference to ONC's standards adoption proposals.
- Through cross-reference, CMS proposals would require use of NCPDP SCRIPT standard version 2022011 and retire the current NCPDP SCRIPT version 2017071 after a transition period as the e-prescribing standard for transmitting prescriptions and prescription-related information for Part D, including medication history and electronic prior authorization (ePA) transactions.
- CMS proposals would also require the use of the NCPDP Real-Time Prescription Benefit (RTPB) standard version 12 for prescriber real-time benefit tools (RTBTs) implemented by Part D plan sponsors, which CMS finalized in the May 2019 part D final rule.





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Questions/Discussion



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