

January 27, 2023

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

Submitted electronically at <http://www.regulations.gov>

In reference to: *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 – File code CMS-4201-P*

Point-of-Care Partners (POCP) appreciates the opportunity to respond to the above referenced Centers for Medicare and Medicaid Services (CMS), Office of the National Coordinator for Health Information Technology (ONC), and Department of Health and Human Services (HHS) proposed rule.

POCP brings a perspective that is unique to those held by providers, payers, and health IT vendors. As healthcare management consultants since 2003, we have led the development of standards and transactions that have evolved since the adoption of the Health Insurance Portability and Accountability Act (HIPAA) and Medicare Part D. We have frequently been called upon by health care regulators and supporting organizations to provide expert testimony at hearings involving health IT standards.

For over two decades, as members of the National Council for Prescription Drug Programs (NCPDP), POCP has helped shape the standards for prescription benefit Claims (Telecommunication), ePrescribing and ePA (SCRIPT), Formulary and Benefit (F&B), and Real-Time Prescription Benefit Standard (RTPB). Our familiarity with the implementation requirements of these standards, and perspective as health IT management consultants, allows us to consider impacts of regulations for diverse stakeholders, including patients, providers, payers, life sciences companies, and health IT vendors.

Point-of-Care Partners commends CMS' effort to revise regulations governing Medicare Advantage (MA or Part C), the Medicare Prescription Drug Benefit (Part D), Medicare cost plans, and Programs of All-Inclusive Care for the Elderly (PACE). We have assessed the parameters set out in this proposed rule and share our observations and recommendations detailed below.

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Adoption of NCPDP SCRIPT Standard Implementation Guide, Version 2022011, January 2022 (Approval Date for ANSI: December 2, 2021)

POCP agrees with moving to a new version of the NCPDP SCRIPT Standard and sunsetting the NCPDP SCRIPT Standard Version 2017071. The NCPDP SCRIPT 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 by the industry resulting in V2023011. The new messages and features will improve patient safety and health care system efficiency.

Enhancements in NCPDP SCRIPT Version V2023011 include the following:

- Added a new optional element in the header for OtherReferenceNumber to allow any care setting outside of a prescribing 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.
- Added a response type of Pending 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.
- Added a new element of RequestExpirationDate to the NewRxRequest, RxChangeRequest and RxRenewalRequest to notify the prescriber to not send a response after this date.
- Added a new element to PAMSelectType for NoneChoiceID. When the question allows the user to select multiple answers, this new element, if selected by the provider, would cause none of the options to be displayed to the user and allowing branching to the next question.
- Added a new element for REMSReproductivePotential which replaced the element REMSPatientRiskCategory in prescribed medication in the NewRx and RxChangeRequest message and in the replace medication for the RxRenewalResponse.
- Added a new element group of ReviewingProvider to the Resupply and Recertification messages allow the reporting of the provider who reviewed the chart and certified the continued need of a specific medication.
- General guidance cleanup in the SCRIPT Implementation Guide.

POCP recommends CMS adopt V2023011 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 Version 2023011 is backward compatible with Version 2017071 so either version can be used in a transition period.

Additionally, to clarify within the regulatory text which transactions within the NCPDP SCRIPT Standard are appropriate for providing medication history information among Medicare Part D sponsors, prescribers, and dispensers, POCP requests CMS include RxHistoryRequest and RxHistoryResponse in its list of transactions to codify at § 423.160(b)(4).

We also concur with the approach of cross-referencing Part D requirements with standards adopted by the Office of the National Coordinator for Health Information Technology (ONC) and the standards adopted for electronic transactions in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations.

Adoption of the NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 12, October 2021 (Approval Date for ANSI: September 27, 2021)

POCP supports CMS's recommendation to adopt and utilize the NCPDP RTPB Standard; however, due to new and relevant transactions found in NCPDP's Real-Time Prescription Benefit Standard, IG, Version 13, October 2022 (Approval Date for ANSI: May 2022), we recommend CMS to adopt Version 13 instead of Version 12.

Enhancements in 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.
- To reduce the number of free text messages on the response, values were added to the Coverage Restriction Code and the addition of data elements to the RTPB Standard to codify information communicated in the Message.
- 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.
- To aid in coverage determination, added data elements to convey the patient's address, state/province, zip/postal code, and country on the request transaction.

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

CMS has not addressed a standard for consumer or beneficiary facing RTPB within this proposed rule. We believe that addressing beneficiary RTPB is also important and therefore recommend that CMS follow NCPDP's lead in supporting the use of the CARIN Alliance consumer facing RTPB Standard. The NCPDP RTPB Standard is provider-facing but does support the use of the HL7 FHIR CARIN Consumer Real Time Pharmacy Benefit Check for consumer-facing RTPB data exchange. NCPDP has created a sub-task group that evaluates, compares, and syncs the NCPDP RTPB standard with the CARIN Alliance efforts to ensure alignment between the two RTPB standards.

SCRIPT and RTPB Standards Certification

In this proposed rulemaking, the agencies have 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. POCP supports this future rulemaking effort. We believe 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 that improve patient access to care and reduce burden and cost.

Standards that 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.

We encourage ONC to move forward in advancing modified certification criterion for the NCPDP SCRIPT Standard v2023011 and for adopting certification criterion for the NCPDP RTPB Standard v13.

Timing of Adoption and Use

We believe many in the industry are ready to move forward with implementing and using the NCPDP SCRIPT Standard Implementation Guide, NCPDP SCRIPT Version V2023011, as well as the NCPDP Real-Time Prescription Benefit Standard, IG, v13; therefore, we support the January 1, 2025, implementation date for both the NCPDP SCRIPT and RTPB Standards, as denoted, for industry adoption and use.

Medication Therapy Management (MTM) Program Eligibility

MTM programs and services help contribute to medication error prevention and optimization of therapeutic outcomes. It is important that as many patients as possible are afforded the opportunity to be a part of a comprehensive medication management program. POCP supports CMS' efforts to reduce eligibility gaps so that more Part D enrollees would be eligible for MTM services.

Provider Directories

POCP concurs that improving the quality and usability of provider directories is a key component of improving interoperability; however, the maintenance and updating of provider directories continues to be a health care challenge and incentives are needed. We do believe that the content should support all patients and their search to locate the most appropriate provider to meet their needs.

We recommend that CMS consider industry solutions in the market as well as the efforts being undertaken by industry innovators within Health Level 7 (HL7) FAST, and the guidance and framework being established by this multi-stakeholder accelerator. HL7 FAST efforts establish exchange standards to support a systemic process for the creation, maintenance, access, and use of a National Provider Directory.

Health Equity

The lingering issue of health inequity and literacy in the US healthcare system continues to limit access to affordable and high-quality care. These systemic issues create financial waste and costs and impact the ability for individuals to achieve optimal health.

POCP supports CMS' efforts to require additional health education opportunities to enrollees and other health equity related policies and other federal initiatives that are working to solve the issue of health inequity in the US.

Close

We commend CMS in its efforts to improve healthcare for individuals who rely on coverage from Medicare Part C, Part D, and PACE, by calling for the adoption of the NCPDP SCRIPT and RTPB Standards. Advancing the use of ePrescribing, prior authorization and data and cost transparency solutions assist in reducing provider and payer burden as well as provide information at the point-of-care to assist physicians and patients make informed decisions about medication options taking into account affordability – a key driver in medication non-adherence. This will also help the entire healthcare ecosystem achieve our shared goal of improving health equity for the most vulnerable segments of our population.

Sincerely,

A handwritten signature in black ink that reads "Anthony J. Schueth". The signature is written in a cursive, flowing style.

Tony Schueth, CEO & Managing Partner
Point-of-Care Partners, LLC