

$$M = \frac{y_i + y_{i+1}}{2}$$

Eq. 1065.602-19

Example:

$$y_2 = 41.780$$

$$y_3 = 41.861$$

$$M = \frac{41.780 + 41.861}{2}$$

$$M = 41.821$$

\* \* \* \* \*

■ 7. On page 29818, starting in the third column, paragraph (e)(4) of § 1065.656 is corrected to read as follows:

**§ 1065.656 [Corrected]**

\* \* \* \* \*

(e) \* \* \*

(4) Table 3 to this paragraph (e)(4) follows:

TABLE 3 TO PARAGRAPH (e)(4) OF § 1065.656—DEFAULT VALUES OF  $\tau, \chi, \phi, \xi,$  AND  $\omega$

Fuel	Atomic carbon, oxygen, and nitrogen-to-hydrogen ratios $C\tau, H\chi, O\phi, S\xi, N\omega$
Hydrogen .....	$C_0H_2O_0S_0N_0$ .
Ammonia .....	$C_0H_3O_0S_0N_1$ .

\* \* \* \* \*

**§ 1065.750 [Corrected]**

■ 8. On page 29823, table 1 to paragraph (a)(1)(ii) of § 1065.750 is corrected by removing the table heading “TABLE 1 TO PARAGRAPH (a)(1)(ii) OF § 1065.750—GENERAL SPECIFICATIONS FOR PURIFIED GASES <sup>A</sup>” and adding in its place “TABLE 1 TO PARAGRAPH (a)(1)(ii) OF § 1065.750—GENERAL SPECIFICATIONS FOR PURIFIED GASES <sup>a</sup>”.

*Alejandra Nunez,*  
Principal Deputy Assistant Administrator,  
Office of Air and Radiation.

[FR Doc. 2024–13196 Filed 6–14–24; 8:45 am]

BILLING CODE 6560–50–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 423**

**Office of the Secretary**

**45 CFR Part 170**

[CMS–4205–F2]

RIN 0938–AV24

**Medicare Program; Medicare Prescription Drug Benefit Program; Health Information Technology Standards and Implementation Specifications**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

**ACTION:** Final rule.

**SUMMARY:** This final rule will revise the Medicare Prescription Drug Benefit (Part D) and ONC regulations to implement changes related to required standards for electronic prescribing and adoption of health information technology (IT) standards for HHS use.

**DATES:** These regulations are effective July 17, 2024. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of July 17, 2024. The incorporation by reference of certain other publications listed in the rule was approved by the Director as of January 1, 2014, June 15, 2018, and June 30, 2020.

**FOR FURTHER INFORMATION CONTACT:**

Maureen Connors, (410) 786–4132—Part D Standards for Electronic Prescribing.

Alexander Baker, (202) 260–2048—Health IT Standards.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In this final rule, CMS and ONC address remaining proposals from the proposed rule titled “Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications” (88 FR 78476), which appeared in the November 15, 2023 *Federal Register* (hereinafter referred to as the “November 2023 proposed rule”) that were not finalized.

We are finalizing changes to Part D requirements for electronic prescribing standards so that the standards required by CMS meet the needs of the health care industry. To promote alignment across HHS, in this final rule, we will require Part D sponsors, prescribers, and dispensers of covered Part D drugs for Part D eligible individuals to comply

with standards CMS has either adopted directly or is requiring by cross-referencing standards ONC adopts for electronically transmitting prescriptions and prescription-related information.

Under current requirements, Part D sponsors, prescribers, and dispensers of covered Part D drugs for Part D eligible individuals are required to comply with the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2017071 for electronically transmitting prescriptions and prescription-related information, medication history information, and electronic prior authorization (ePA); and the NCPDP Formulary and Benefit (F&B) standard version 3.0 for electronically transmitting formulary and benefit information. Part D sponsors also are required to implement one or more electronic real-time benefit tools (RTBTs) capable of integrating with at least one prescriber’s electronic prescribing system or electronic health record (EHR), but CMS does not currently require compliance with a standard for RTBTs.

ONC is adopting NCPDP SCRIPT standard version 2023011, NCPDP F&B standard version 60, and NCPDP Real-Time Prescription Benefit (RTPB) standard version 13 for HHS use. ONC is also revising its regulation so that NCPDP SCRIPT standard version 2017071 will expire for the purposes of HHS use on January 1, 2028.

As finalized, Part D standards for electronic prescribing regulations will indicate that prescriptions, medication history, and ePA must comply with a standard adopted by ONC, which will include the NCPDP SCRIPT standard version 2017071 and NCPDP SCRIPT standard version 2023011 standards. Taken in conjunction with the January 1, 2028 expiration date for NCPDP SCRIPT standard version 2017071 that ONC finalizes in this final rule, entities will be permitted to use either version of the NCPDP SCRIPT standard until

NCPDP SCRIPT standard version 2017071 expires. Therefore, as of January 1, 2028, entities will be required to exclusively use NCPDP SCRIPT standard version 2023011.

With respect to electronic transmission of formulary and benefits information, we are finalizing the requirement that Part D sponsors, prescribers, and dispensers of covered Part D drugs for Part D eligible individuals can use NCPDP F&B standard version 3.0 or comply with a standard adopted by ONC, which finalizes its adoption of NCPDP F&B standard version 60 in this final rule. However, we are finalizing the requirement that, beginning January 1, 2027, these entities must comply with a standard adopted by ONC only. Therefore, as of January 1, 2027, Part D sponsors, prescribers, and dispensers of covered Part D drugs for Part D eligible individuals will be required to exclusively use NCPDP F&B standard version 60 for the electronic transmission of formulary and benefits information.

Additionally, we are finalizing a requirement that by January 1, 2027, Part D sponsor RTBTs must comply with a standard adopted by ONC, which finalizes its adoption of NCPDP RTPB standard version 13 in this final rule.

This final rule also finalizes a provision that, while not changing requirements, will cross-reference Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations in 45 CFR part 162 for eligibility transactions so that Part D requirements will automatically align with any potential future updates to the required standards for eligibility transactions. This final rule also reorganizes requirements and makes technical changes throughout § 423.160.

## II. Enhancements to the Medicare Prescription Drug Benefit Program

### A. Standards for Electronic Prescribing (§ 423.160)

#### 1. Legislative Background

Section 1860D–4(e) of the Social Security Act (the Act) requires the adoption of Part D electronic prescribing (or e-prescribing) standards. Part D sponsors are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. For a further discussion of the statutory requirements at section 1860D–4(e) of the Act, refer to the proposed rule titled “Medicare Program; E-Prescribing and the Prescription Drug Program,” which appeared in the February 4, 2005 **Federal Register** (70

FR 6255). Section 6062 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), hereinafter referred to as the SUPPORT Act, amended section 1860D–4(e)(2) of the Act to require the electronic transmission of ePA requests and responses for the Part D e-prescribing program to ensure secure ePA request and response transactions between prescribers and Part D sponsors for covered Part D drugs prescribed to Part D eligible individuals. Such electronic transmissions must comply with technical standards adopted by the Secretary. Section 119(a) of Subtitle B of Title I, Division CC of the Consolidated Appropriations Act, 2021, (CAA, 2021) added section 1860D–4(o) of the Act to require, after the Secretary has adopted a standard under section 1860D–4(o)(3) of the Act and at a time determined appropriate by the Secretary, Part D sponsors to implement one or more electronic RTBTs meeting the requirements described in section 1860D–4(o)(2) of the Act. There is generally no requirement that Part D prescribers or dispensers implement e-prescribing, with the exception of required electronic prescribing of Schedule II, III, IV, and V controlled substances that are Part D drugs, consistent with section 1860D–4(e)(7) of the Act as added by section 2003 of the SUPPORT Act and as specified at § 423.160(a)(5). However, prescribers and dispensers who electronically transmit and receive prescription and certain other information regarding covered Part D drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect.

#### 2. Regulatory History

As specified at § 423.160(a)(1), Part D sponsors are required to support the Part D e-prescribing program transaction standards as part of their electronic prescription drug programs, as described under § 423.159(c). Likewise, as specified at § 423.160(a)(2), prescribers and dispensers that conduct electronic transactions for covered Part D drugs for Part D eligible individuals for which a program standard has been adopted must do so using the adopted standard. Transaction standards are periodically updated to take new knowledge, technology, and other considerations into account. As CMS adopted specific versions of the standards when it initially adopted the foundation and final e-prescribing standards, there was a need to establish a process by which the standards could

be updated or replaced over time to ensure that the standards did not hold back progress in the health care industry. CMS discussed these processes in the final rule titled “Medicare Program; E-Prescribing and the Prescription Drug Program,” (hereinafter referred to as “the November 2005 final rule”) which appeared in the November 7, 2005 **Federal Register** (70 FR 67579). An account of successive adoption of new and retirement of previous versions of various e-prescribing standards is described in the final rule titled “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014,” which appeared in the December 10, 2013 **Federal Register** (78 FR 74229); the proposed rule titled “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,” which appeared in the November 28, 2017 **Federal Register** (82 FR 56336); and the corresponding final rule (83 FR 16440), which appeared in the April 16, 2018 **Federal Register**. The final rule titled “Medicare Program; Secure Electronic Prior Authorization For Medicare Part D,” which appeared in the December 31, 2020 **Federal Register** (85 FR 86824), codified the requirement that Part D sponsors support the use of NCPDP SCRIPT standard version 2017071 for certain ePA transactions (85 FR 86832).

The final rule titled “Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses,” (herein after referred to as “the May 2019 final rule”) which appeared in the May 23, 2019 **Federal Register** (84 FR 23832), codified at § 423.160(b)(7) the requirement that Part D sponsors adopt an electronic RTBT capable of integrating with at least one prescriber’s electronic prescribing or electronic health record (EHR) system, but did not name a standard since no standard had been identified as the industry standard at the time (84 FR 23851). The electronic standards for eligibility transactions were codified in the final rule titled “Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction,” which appeared in the May 16, 2012 **Federal Register** (77 FR 29001), to align with the applicable HIPAA transaction standards.

The Part D program has historically adopted electronic prescribing

standards independently of other HHS components that may adopt electronic prescribing standards under separate authorities; however, past experience has demonstrated that duplicative adoption of health IT standards by other agencies within HHS under separate authorities can create significant burden on the health care industry as well as HHS when those standards impact the same technology systems. Notably, independent adoption of the NCPDP SCRIPT standard version 2017071 by CMS in various subsections of § 423.160 (83 FR 16638) in 2018, which required use of the standard beginning in 2020, led to a period where ONC had to exercise special enforcement discretion in its Health Information Technology (IT) Certification Program until the same version was incorporated into regulation at 45 CFR 170.205(b)(1) through the final rule titled “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program,” (hereinafter referred to as the “ONC Cures Act final rule”), which appeared in the May 1, 2020 **Federal Register** (85 FR 25679). This resulted in significant impact on both ONC and CMS program resources. Similarly, the final rule titled “Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction,” which appeared in the May 16, 2012 **Federal Register** (77 FR 29002), noted that, in instances in which an e-prescribing standard has also been adopted as a HIPAA transaction standard in 45 CFR part 162, the process for updating the e-prescribing standard will have to be coordinated with the maintenance and modification of the applicable HIPAA transaction standard (77 FR 29018).

### 3. Withdrawal of Previous Proposals and Summary of New Proposals

In the proposed rule titled, “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” (hereinafter referred to as “the December 2022 proposed rule”), which appeared in the **Federal Register** on December 27, 2022 (87 FR 79452), we proposed updates to the electronic prescribing standards to be used by Part D sponsors, prescribers, and dispensers when electronically transmitting

prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals. The proposals in the December 2022 proposed rule included a novel approach to updating electronic prescribing standards by proposing to cross-reference Part D requirements with standards adopted by the Office of the National Coordinator for Health Information Technology (ONC) and the standards adopted by HHS for electronic transactions under HIPAA,<sup>1</sup> rather than the historical approach of adopting electronic prescribing standards in the Part D regulations independently or making conforming amendments to the Part D regulations in response to updated HIPAA standards for eligibility transactions. We proposed this approach in concert with ONC in order to mitigate potential compliance challenges for the health care industry and enforcement challenges for HHS that could result from independent adoption of such standards.<sup>2</sup>

As discussed in the November 2023 proposed rule, we withdrew all proposals contained in section III.S. Standards for Electronic Prescribing (87 FR 79548) of the December 2022 proposed rule (88 FR 78488). This approach allowed us to incorporate the feedback we received on prior proposals, seek comment on concerns raised in response to prior proposals, add new proposals, reorganize and propose technical changes to the electronic prescribing regulations at § 423.160, and allow the public to comment on all Medicare Part D electronic prescribing-related proposals simultaneously.

In sections II.A.4. through II.A.11. of this rule, we discuss the proposals related to standards for electronic prescribing that we put forth in the November 2023 proposed rule, which encompassed all of the following:

- Requiring use of NCPDP SCRIPT standard version 2023011, proposed for adoption for HHS use at 45 CFR 170.205(b)(2), and retiring use of NCPDP SCRIPT standard version 2017071 for communication of a prescription or prescription-related information

<sup>1</sup> HIPAA mandated the adoption of standards for electronically conducting certain health care administrative transactions between certain entities. HIPAA administrative requirements are codified at 45 CFR part 162. See also: <https://www.cms.gov/about-cms/what-we-do/administrative-simplification>.

<sup>2</sup> Due to discrepancies between prior regulatory timelines, adoption of the NCPDP SCRIPT standard version 2017071 in different rules led to a period where ONC had to exercise special enforcement discretion in the ONC Health IT Certification Program. For additional discussion, see section II.B.5. of this final rule.

supported by Part D sponsors beginning January 1, 2027. This proposal included a transition period beginning on the effective date of the final rule during which either version of the NCPDP SCRIPT standard could be used. Under this proposal, the transition period would end on January 1, 2027, which is the date that ONC proposed at 45 CFR 170.205(b)(1) that NCPDP SCRIPT standard version 2017071 would expire for the purposes of HHS use, as described in section II.B.8.a. of this rule.

- Requiring use of NCPDP RTPB standard version 13, proposed for adoption for HHS use at 45 CFR 170.205(c)(1), for prescriber RTBTs implemented by Part D sponsors beginning January 1, 2027.
- Requiring use of NCPDP Formulary and Benefit (F&B) standard version 60, proposed for adoption at 45 CFR 170.205(u)(1), and retiring use of NCPDP F&B standard version 3.0 for transmitting formulary and benefit information between prescribers and Part D sponsors beginning January 1, 2027. This proposal included a transition period beginning on the effective date of the final rule and ending January 1, 2027, during which entities would be permitted to use either NCPDP F&B standard version 3.0 (currently adopted in regulation at § 423.160(b)(5)(iii) and proposed to be moved to § 423.160(b)(3) consistent with the proposed technical changes discussed in section II.A.10 of this rule) or NCPDP F&B standard version 60, proposed for adoption for HHS use at 45 CFR 170.205(u)(1).
- Cross-referencing standards adopted for eligibility transactions in HIPAA regulations at 45 CFR 162.1202 for requirements related to eligibility inquiries.
- Making multiple technical changes to the regulation text throughout § 423.160 by removing requirements and incorporations by reference that are no longer applicable, re-organizing existing requirements, and correcting a technical error.

We proposed a novel approach to updating e-prescribing standards by cross-referencing Part D e-prescribing requirements with standards, including any expiration dates, adopted by ONC, as discussed in section II.B.5. of this rule, and the standards adopted by HHS for electronic transactions under HIPAA. This approach differed from our historical approach of adopting e-prescribing standards in the Part D regulations independently or undertaking rulemaking to make conforming amendments to the Part D regulations in response to updated HIPAA standards for eligibility

transactions.<sup>3</sup> As ONC notes in section II.B.5. of this rule, independent adoption of the NCPDP SCRIPT standard version 2017071 in different rules<sup>4</sup> led to a period where ONC had to exercise special enforcement discretion in the ONC Health IT Certification Program. We believe the proposed approach mitigates potential compliance challenges for the health care industry and enforcement challenges for HHS that could result from independent adoption of such standards or asynchronous rulemaking cycles across programs. CMS invited comment on all aspects of these proposals. We also proposed to cross-reference ONC regulations adopting NCPDP SCRIPT standard version 2023011, NCPDP RTPB standard version 13, and NCPDP F&B standard version 60. We solicited comment on the effect of the proposals that, taken together, would require use of these standards by January 1, 2027 as a result of ONC's proposals to adopt these standards and retire previous versions, as well as our proposal to require use of NCPDP F&B standard version 60 by that date.

The NCPDP SCRIPT standards are used to exchange information among prescribers, dispensers, intermediaries, and Medicare prescription drug plans (PDPs). NCPDP requested that CMS adopt NCPDP SCRIPT standard version 2023011 because this version provides a number of enhancements to support electronic prescribing and transmission of prescription-related information.<sup>5</sup>

<sup>3</sup> HIPAA eligibility transaction standards were updated in 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 3296). Conforming amendments to the Part D regulation were made in the final rule titled "Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction," which appeared in the May 16, 2012 *Federal Register* (77 FR 29002).

<sup>4</sup> *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule*, which appeared in the May 1, 2020 *Federal Register* (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).

<sup>5</sup> National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 2023011. NCPDP SCRIPT standard implementation guides are available to NCPDP members for free and to non-members for a fee at <https://standards.ncdp.org/Access-to-Standards.aspx>. The NCPDP SCRIPT standard version 2023011 implementation guide proposed for incorporation by reference in sections II.A.11 and II.B.10. of this rule can be viewed by interested

Accordingly, we proposed to update § 423.160 to specify where transactions for electronic prescribing, medication history, and ePA are required to utilize the NCPDP SCRIPT standard. As described in section II.A.7. of this final rule, we solicited comment on the date by which use of the updated version of this and other standards in this rule would be required.

The NCPDP RTPB standard enables the real-time exchange of patient-specific eligibility, product coverage (including any restrictions and alternatives), and estimated cost sharing so prescribers have access to this information through a RTBT application at the point-of-prescribing.<sup>6,7</sup> As discussed in section II.A.5. of this rule, as currently codified at § 423.160(b)(7), CMS requires that Part D sponsors implement one or more electronic RTBTs that are capable of integrating with at least one prescriber's electronic prescribing system or electronic health record, as of January 1, 2021; however, at the time CMS established this requirement, no single industry standard for real-time prescription benefit applications was available. NCPDP has since developed the NCPDP RTPB standard. We proposed to require the most current version, NCPDP RTPB standard version 13, as the standard for prescriber RTBTs at § 423.160(b)(5) starting January 1, 2027.

The NCPDP F&B standard is a batch standard that provides formulary and benefit information at the plan level rather than at the patient level. The NCPDP F&B standard complements other standards utilized for electronic prescribing, electronic prior authorization, and real-time prescription benefit applications.<sup>8,9</sup> We

parties for free by following the instructions provided in those sections.

<sup>6</sup> National Council for Prescription Drug Programs (NCPDP) Real-Time Prescription Benefit Standard, Implementation Guide, Version 13. NCPDP RTPB standard implementation guides are available to NCPDP members for free and to non-members for a fee at <https://standards.ncdp.org/Access-to-Standards.aspx>. The NCPDP RTPB standard version 13 implementation guide incorporated by reference in sections II.A.11. and II.B.10. of this rule can be viewed by interested parties for free by following the instructions provided in those sections.

<sup>7</sup> Bhardwaj S, Miller SD, Bertram A, Smith K, Merrey J, Davison A. Implementation and cost validation of a real-time benefit tool. *Am J Manag Care*. 2022 Oct 1;28(10):e363–e369. doi: 10.37765/ajmc.2022.89254.

<sup>8</sup> National Council for Prescription Drug Programs (NCPDP) Formulary and Benefit Standard, Implementation Guide, Version 60. NCPDP F&B standard implementation guides are available to NCPDP members for free and to non-members for a fee at <https://standards.ncdp.org/Access-to-Standards.aspx>. The NCPDP F&B standard version 60 implementation guide incorporated by reference

proposed to require use of NCPDP F&B standard version 60, and retire NCPDP F&B standard version 3.0, beginning January 1, 2027, after a transition period during which either version may be used.

Eligibility inquiries utilize the NCPDP Telecommunication standard or Accredited Standards Committee X12N 270/271 inquiry and response transaction for pharmacy or other health benefits, respectively. The Part D program has adopted standards based on the HIPAA electronic transaction standards, which have not been updated for more than a decade. HHS has proposed updates to the HIPAA electronic transaction standards for retail pharmacies (87 FR 67638) in the proposed rule titled "Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Adoption of Pharmacy Subrogation Standard" (hereinafter referred to as the "November 2022 Administrative Simplification proposed rule"), which appeared in the November 9, 2022 *Federal Register* (87 FR 67634).

In the November 2023 proposed rule, we proposed to update the Part D regulation at § 423.160(b)(3) to require that eligibility transactions utilize the applicable standard named as the HIPAA standard for electronic eligibility transactions at 45 CFR 162.1202. Since 45 CFR 162.1202 currently identifies the same standards that are named at § 423.160(b)(3)(i) and (ii), we anticipated there would be no immediate impact from this proposed change in regulatory language. We proposed this change to ensure that Part D electronic prescribing requirements for eligibility transactions align with the HIPAA standard for electronic eligibility transactions, should a newer version of the NCPDP Telecommunication (or other) standards be adopted as the HIPAA standard for these types of electronic transactions, if HHS' proposals in the November 2022 Administrative Simplification proposed rule are finalized or as a result of any future HHS rules.

in sections II.A.11 and II.B.10. of this rule can be viewed by interested parties for free by following the instructions provided in those sections.

<sup>9</sup> Babbar P, Solomon MR, Stember L, Hill JW, Weiker M. Formulary & Benefit and Real-Time Pharmacy Benefit: Electronic standards delivering value to prescribers and pharmacists. *J Am Pharm Assoc*. 2023 May–June;63(3):725–730. <https://doi.org/10.1016/j.japh.2023.01.016>.

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

The NCPDP SCRIPT standard has been the adopted electronic prescribing standard for transmitting prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals since foundation standards were named in the final rule titled “Medicare Program; E-Prescribing and the Prescription Drug Program,” which appeared in the November 7, 2005 **Federal Register** (70 FR 67568), at the start of the Part D program. The NCPDP SCRIPT standard is used to exchange information among prescribers, dispensers, intermediaries, and Medicare prescription drug plans. In addition to electronic prescribing, the NCPDP SCRIPT standard is used in electronic prior authorization (ePA) and medication history transactions.

Although electronic prescribing is optional for physicians, except as to Schedule II, III, IV, and V controlled substances that are Part D drugs prescribed under Part D, and pharmacies, the Medicare Part D statute and regulations require drug plans participating in the prescription benefit to support electronic prescribing, and physicians and pharmacies who elect to transmit prescriptions and related communications electronically must utilize the adopted standards except in limited circumstances, as codified at § 423.160(a)(3).

NCPDP’s standards development process involves a consensus-based approach to solve emerging needs of the pharmacy industry or to adapt NCPDP standards to changes made by other standards development organizations.<sup>10</sup> Emerging needs of the pharmacy industry may be the result of legislative or regulatory changes, health IT innovations, patient safety issues, claims processing issues, or electronic prescribing-related process automation.<sup>11</sup> Changes to standards are consensus-based and driven by the NCPDP membership, which includes broad representation from pharmacies, insurers, pharmacy benefit managers, Federal and State government agencies,

and vendors serving all the stakeholders.<sup>12 13</sup>

In a letter to CMS dated January 14, 2022, NCPDP requested that CMS adopt NCPDP SCRIPT standard version 2022011, given the number of updates and enhancements that had been added to the standard since NCPDP SCRIPT standard version 2017071 was adopted.<sup>14</sup> NCPDP summarized the major enhancements in NCPDP SCRIPT standard version 2022011 relative to the currently required NCPDP SCRIPT standard version 2017071. Those summarized enhancements include—

- General extensibility;<sup>15</sup>
- Redesign of the Product/Drug groupings requiring National Drug Code (NDC) for DrugCoded element, but not for NonDrugCoded element;
- Addition of Observation elements to Risk Evaluation and Mitigation Strategies (REMS) transactions;
- Addition of ProhibitRenewalRequest to RxChangeResponse and RxRenewalResponse;
- Modification of Structured and Codified Sig Structure format; and
- Additional support related to dental procedure codes, RxBarCode, PatientConditions, patient gender and pronouns, TherapeuticSubstitutionIndicator, multi-party communications, and withdrawal/retracting of a previously sent message using the MessageIndicatorFlag.

Subsequently, in the December 2022 proposed rule, CMS proposed to require NCPDP SCRIPT standard version 2022011 and retire NCPDP SCRIPT standard version 2017071, after a transition period, by cross-referencing the standards as proposed for adoption by ONC. In response to this proposal, NCPDP and many other commenters recommended that CMS instead adopt the more current NCPDP SCRIPT standard version 2023011. NCPDP SCRIPT standard version 2023011, like NCPDP SCRIPT standard version 2022011, includes the functionality that supports a 3-way transaction (for

example, multi-party communication) among prescriber, facility, and pharmacy, which will enable EPCS in the long-term care (LTC) setting.<sup>16</sup> In its comments on the December 2022 proposed rule,<sup>17</sup> NCPDP highlighted specific enhancements within NCPDP SCRIPT standard version 2023011 that are not present in NCPDP SCRIPT standard version 2022011, which include—

- Addition of an optional element in the header for OtherReferenceNumber for multi-party communication transactions, such as those in LTC;
- Addition of a response type of Pending for RxChangeResponse and RxRenewalResponse for communicating when to expect an approval or denial of the request or delays in approval or denial of requests;
- Addition of a new RequestExpirationDate element to NewRxRequest, RxChangeRequest, and RxRenewalRequest to notify the prescriber to not send a response after this date;
- Addition of a new element NoneChoiceID to PAMSelectType so that a “none of the above” answer can be selected by the provider and allow branching to the next question in a series;
- Addition of a new element for REMSReproductivePotential replacing REMSPatientRiskCategory in the prescribed medication element group in the NewRx and RxChangeRequest message and in the replace medication element group for the RxRenewalResponse;
- Addition of a new element group of ReviewingProvider 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; and
- Revised guidance in the SCRIPT Implementation Guide.

NCPDP has also published frequently asked questions<sup>18</sup> related to the use of

<sup>16</sup> National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 2023011. NCPDP SCRIPT standard implementation guides are available to NCPDP members for free and to non-members for a fee at <https://standards.ncdpd.org/Access-to-Standards.aspx>. The NCPDP SCRIPT standard version 2023011 implementation guide incorporated by reference in sections II.A.11 and II.B.10. of this rule can be viewed by interested parties for free by following the instructions provided in those sections.

<sup>17</sup> [https://standards.ncdpd.org/Standards/media/pdf/Correspondence/2023/20230213\\_To\\_CMS\\_CMS\\_4201\\_P\\_NPRM.pdf](https://standards.ncdpd.org/Standards/media/pdf/Correspondence/2023/20230213_To_CMS_CMS_4201_P_NPRM.pdf).

<sup>18</sup> Frequently Asked Questions 5.1.11 and 5.1.12. SCRIPT Implementation Recommendations. March 2024. Available from <https://ncdpd.org/NCPDP/media/pdf/SCRIPT-Implementation-Recommendations.pdf>.

<sup>12</sup> NCPDP University. Voting: The Life Cycle of Standards Approval. Accessed August 15, 2023, from <https://member.ncdpd.org> (member-only content).

<sup>13</sup> <https://www.ncdpd.org/Membership-diversity.aspx>.

<sup>14</sup> <https://standards.ncdpd.org/Standards/media/pdf/Correspondence/2022/202201NCPDP-SCRIPT-NextVersionLetter.pdf>.

<sup>15</sup> Extensibility is a term in software engineering that is defined as the quality of being designed to allow the addition of new capabilities or functionality. See: Ashaolu B. What is Extensibility? Converged. February 17, 2021. Available from: <https://converged.propelsoftware.com/blogs/what-is-extensibility>.

<sup>10</sup> <https://standards.ncdpd.org/Our-Process.aspx>.

<sup>11</sup> NCPDP University. How Industry Needs Drive Changes in Standards. Accessed August 15, 2023, from <https://member.ncdpd.org> (member-only content).

NCPDP SCRIPT standards for electronic transfer of controlled substance prescriptions between pharmacies, as permitted by the Drug Enforcement Administration (DEA) final rule “Transfer of Electronic Prescriptions for Schedules II–V Controlled Substances Between Pharmacies for Initial Filling,” (hereinafter referred to as “the July 2023 DEA final rule”) which appeared in the **Federal Register** on July 27, 2023 (88 FR 48365). The July 2023 DEA final rule permits the transfer of electronic prescriptions for schedule II–V controlled substances between retail pharmacies for initial filling, upon request of the patient, on a one-time basis, in accordance with requirements codified at 21 CFR 1306.08(e) through (i) and subject to State or other applicable law. NCPDP SCRIPT standard version 2017071 does not support the transfer of electronic controlled substance prescriptions; however, NCPDP SCRIPT standard version 2022011 and later, including NCPDP SCRIPT standard version 2023011, allow for the transfer of electronic controlled substance prescriptions since these later versions contain data elements required to document the transfer between pharmacies. NCPDP SCRIPT standard versions 2022011 and later also contain additional RxTransfer transaction features that facilitate the transfer of electronic prescriptions for controlled substances by pharmacies by allowing pharmacies to initiate transfers of prescriptions to other pharmacies (that is, “push” transactions) in addition to the functionality that currently exists in the NCPDP SCRIPT standard version 2017071 that allows pharmacies to request transfers from other pharmacies (that is, “pull” transactions).

NCPDP SCRIPT standard version 2023011 is fully backwards compatible with NCPDP SCRIPT standard version 2017071. This allows for a less burdensome implementation process and flexible adoption timeline for pharmacies, payers, prescribers, health IT vendors, and intermediaries involved in electronic prescribing, since backwards compatibility permits a transition period where both versions of the NCPDP SCRIPT standards may be used simultaneously without the need for entities involved to utilize a translator program.

Even though we withdrew the proposals contained in section III.S. (Standards for Electronic Prescribing) in the December 2022 proposed rule (87

FR 79548), we considered comments we received on the December 2022 proposed rule when crafting the proposals discussed in this rule. For instance, several commenters requested that CMS clearly indicate that the proposed version of the NCPDP SCRIPT standard would apply to medication history functions. Several commenters noted that the regulation text at § 423.160(b)(4)(ii) does not list the NCPDP SCRIPT standard-specific medication history transactions. Commenters requested that CMS list the corresponding medication history transactions (RxHistoryRequest and RxHistoryResponse) in the regulation text in order to minimize ambiguity. After considering these comments, in the November 2023 proposed rule, we proposed to list the RxHistoryRequest and RxHistoryResponse transactions at § 423.160(b)(1)(i)(U) subsequent to our technical reorganization of the section discussed in section II.A.10. of this rule, rather than list the transactions under § 423.160(b)(4).

With respect to ePA transactions in the NCPDP SCRIPT standard currently listed at § 423.160(b)(8)(i)(A) through (D) (PAInitiationRequest, PAINitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, PACancelResponse) and a new ePA transaction (PANotification) available in NCPDP SCRIPT standard version 2023011, we proposed to list all transactions at § 423.160(b)(1)(i)(V)–(Z). We proposed new language at § 423.160(b)(1) to indicate that the transactions listed must comply with a standard in proposed 45 CFR 170.205(b) “as applicable to the version of the standard in use,” since an older version of a standard may not support the same transactions as the newer version of the standard. For example, during the proposed transition period where either NCPDP SCRIPT standard version 2017071 or NCPDP SCRIPT standard version 2023011 may be used, entities that are still using NCPDP SCRIPT standard version 2017071 would not be expected to use the PANotification transaction because the PANotification transaction is only supported in the NCPDP SCRIPT standard version 2023011.

Since the NCPDP SCRIPT standard version 2023011 is fully backwards compatible with NCPDP SCRIPT standard version 2017071, the pharmacies, payers, prescribers, health IT vendors, and intermediaries involved

in electronic prescribing can accommodate a transition period when either version may be used. That is, during a transition period, transactions taking place between entities using different versions of the same standard maintain interoperability without the need for entities to utilize (that is, purchase) a translator software program. The cross-reference to proposed 45 CFR 170.205(b) permits a transition period starting as of the effective date of a final rule during which either NCPDP SCRIPT standard version 2017071 or NCPDP SCRIPT standard version 2023011 may be used.

Instead of proposing to independently adopt NCPDP SCRIPT standard version 2023011, we proposed at § 423.160(b)(1) to cross-reference a standard in 45 CFR 170.205(b). ONC proposed to adopt NCPDP SCRIPT standard version 2023011 in 45 CFR 170.205(b)(2) as described in section III.C.8.a. of the November 2023 proposed rule. This approach enables CMS and ONC to avoid misalignment from independent adoption of NCPDP SCRIPT standard version 2023011 for their respective programs. Updates to the standard would impact requirements for both programs at the same time, ensure consistency, and promote alignment for providers, payers, and health IT developers participating in and supporting the same prescription transactions. See section II.B.5. of this rule for additional discussion of this coordination effort.

In its letter to CMS requesting CMS adopt NCPDP SCRIPT standard version 2022011, NCPDP requested that CMS identify certain transactions for prescriptions for which use of the standard is mandatory.<sup>19</sup> As previously mentioned in this preamble, in response to the December 2022 proposed rule, NCPDP and other commenters requested additional transactions be named in regulation. As part of our proposed reorganization of § 423.160, we proposed to list all transactions associated with the NCPDP SCRIPT standard requirements in one place in the regulation. We proposed the transactions for prescriptions, ePA, and medication history for which use of the standard is mandatory at § 423.160(b)(1)(i)(A) through (Z), as described in Table 1.

<sup>19</sup> <https://standards.ncdp.org/Standards/media/pdf/Correspondence/2022/202201NCPDP-SCRIPT-NextVersionLetter.pdf>.

TABLE 1—PROPOSED TRANSACTIONS FOR COMMUNICATION OF PRESCRIPTION AND PRESCRIPTION RELATED INFORMATION USING THE NCPDP SCRIPT STANDARD

Transaction	Function supported by transaction <sup>20</sup>
GetMessage .....	Requests from a mailbox, a renewal prescription request, prescription change request, new prescription request, prescription fill status notification, verification, transfer request, transfer response, transfer confirmation or an error or other transactions that have been sent by a pharmacy or prescriber system.
Status .....	Relays acceptance of a transaction back to the sender.
Error .....	Indicates an error has occurred indicating the request was terminated.
RxChangeRequest and RxChangeResponse .....	Request from a pharmacy to a prescriber asking for a change in a new or “fillable” prescription; additional usage includes verification of prescriber credentials and request on a prior authorization from the payer. Response is sent from a prescriber to the requesting pharmacy to either approve, approve with change, validate, or deny the request.
RxRenewalRequest and RxRenewalResponse .....	Request from the pharmacy to the prescriber requesting additional refills. Response is sent from the prescriber to the requesting pharmacy to allow pharmacist to provide a patient with additional refills, a new prescription, or decline to do either.
Resupply .....	Request from a Long Term or Post-Acute Care (LTPAC) organization to a pharmacy to send an additional supply of medication for an existing order.
Verify .....	Response to a pharmacy or prescriber indicating that a transaction requesting a return receipt has been received.
CancelRx and CancelRxResponse .....	Request from the prescriber to the pharmacy to inactivate a previously sent prescription. Response is sent from the pharmacy to the prescriber to acknowledge a cancel request.
RxFill .....	Indicates the dispensing or activity status. It is the notification from one entity to another conveying the status of dispensing activities or other clinical activities.
DrugAdministration .....	Communicates drug administration events from a prescriber/care facility to the pharmacy or other entity. It is a notification from a prescriber/care facility to a pharmacy or other entity that a drug administration event has occurred.
NewRxRequest .....	Request from a pharmacy to a prescriber for a new prescription for a patient. If approved, a NewRx transaction will be sent.
NewRx .....	New prescription is sent from the prescriber to the pharmacy electronically so it can be dispensed to a patient.
NewRxResponseDenied .....	Denied response to a previously sent NewRxRequest.
RxTransferInitiationRequest (previously named RxTransferRequest in NCPDP SCRIPT standard version 2017071).	Used when the destination pharmacy is asking for a transfer of one or more prescriptions for a specific patient from the source pharmacy.
RxTransfer (previously named RxTransferResponse NCPDP SCRIPT standard version 2017071).	In the solicited model, it is the response to the RxTransferInitiationRequest which includes the prescription(s) being transferred from the source pharmacy to the destination pharmacy or a rejection of the transfer request. In the unsolicited model, it is a push of the prescription(s) being transferred from the source pharmacy to the destination pharmacy.
RxTransferConfirm .....	Used by the destination pharmacy to confirm the transfer prescription has been received and the transfer is complete.
RxFillIndicatorChange .....	Sent to the receiver to indicate the sender is changing the types of RxFill responses that were previously requested. The sender may modify the fill status notification of transactions previously selected or cancel future RxFill transactions.
Recertification .....	Notification on behalf of a reviewing provider to a pharmacy recertifying the continued administration of a medication order. Used in LTPAC only.
REMSInitiationRequest and REMSInitiationResponse .....	Request to the REMS Administrator for the information required to submit a REMS request (REMSRequest) for a specified patient and drug. Response is from the REMS Administrator with the information required to submit a REMS request (REMSRequest) for a specified patient and drug.
REMSRequest and REMSResponse .....	Request to the REMS Administrator with information (answers to question set; clinical documents) to make a REMS determination (approved, denied, pended, etc.). Response is the determination from the REMS administrator whether dispensing authorization can be granted.
RxHistoryRequest and RxHistoryResponse .....	Request from one entity to another for a list of medications that have been prescribed, dispensed, claimed or indicated by the patient. Response includes the medications that were dispensed or obtained within a certain timeframe, optionally including the prescriber that prescribed them.



TABLE 1—PROPOSED TRANSACTIONS FOR COMMUNICATION OF PRESCRIPTION AND PRESCRIPTION RELATED INFORMATION USING THE NCPDP SCRIPT STANDARD—Continued

Transaction	Function supported by transaction <sup>20</sup>
PAInitiationRequest and PAINitiationResponse .....	Request from the submitter to a payer for the information required to submit a prior authorization request (PARequest) for a specified patient and product. Response is from a payer to the submitter with the information required to submit a prior authorization request (PARequest) for a specified patient and product.
PARequest and PAResponse .....	Request from the submitter to the payer with information (answers to question set; clinical documents) for the payer to make a PA determination (approved, denied, pending, etc.). Response from the payer to the submitter indicates the status of a PARequest. Response could be a PA determination, notice that the request is in process, or specify that more information is required.
PAAppealRequest and PAAppealResponse .....	Request from the submitter to the payer to appeal a PA determination. Response from the payer to the submitter indicates what information is needed for an appeal or the status or outcome of a PAAppealRequest.
PACancelRequest and PACancelResponse .....	Request from the submitter to the payer to notify the payer that the PA request is no longer needed. Response from the payer to the submitter indicates if the PA request was cancelled or not.
PANotification .....	Alerts the pharmacist or prescriber when a PA has been requested, or when a PA determination has been received.

The transactions specific to electronic prescribing remain the same as those required for NCPDP SCRIPT standard version 2017071 (currently codified at § 423.160(b)(2)(iv)(A) through (Z)), except where renamed as noted in Table 1. The transactions specific to ePA are also the same as those required with NCPDP SCRIPT standard version 2017071 (with one additional transaction—PA Notification), which was incorporated into the standard after NCPDP SCRIPT standard version 2017071. As discussed in section II.B.8.a. of this rule, NCPDP SCRIPT standard version 2023011 was proposed for adoption at 45 CFR 170.205(b)(2), and NCPDP SCRIPT standard version 2017071 was proposed to expire January 1, 2027 at 45 CFR 170.205(b)(1).

As stated previously, in response to the December 2022 proposed rule, several commenters pointed out that if mandatory use of an updated version of the NCPDP SCRIPT standard is delayed, then the EPCS requirement in LTC facilities should also be delayed accordingly, since NCPDP SCRIPT standard version 2017071 lacks appropriate guidance for LTC facilities. CMS was aware of this limitation in the

NCPDP SCRIPT standard version 2017071, and acknowledged the challenges to EPCS faced by LTC facilities in the proposed rule “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” (hereinafter referred to as “the July 2022 proposed rule”), which appeared in the **Federal Register** on July 23, 2021 (86 FR 39104). However, in the July 2022 proposed rule, CMS also stated that we understood that NCPDP was in the process of creating specific guidance for LTC facilities within the NCPDP SCRIPT standard version 2017071, which would allow willing partners to enable 3-way communication between the prescriber, LTC facility, and pharmacy to bridge any outstanding gaps that impede adoption of the NCPDP SCRIPT standard version 2017071 in the LTC setting (86 FR 39329).

Similarly, in the “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; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements” final rule (hereinafter referred to as “the November 2021 final rule”), which appeared in the **Federal Register** on November 19, 2021 (86 FR 64996), CMS

acknowledged that although 3-way communication is not as seamless in NCPDP SCRIPT standard version 2017071 as it was expected to be in later versions, EPCS was still possible with some modifications (86 FR 65364). CMS delayed EPCS compliance for prescribers’ prescriptions written for beneficiaries in a LTC facility from January 1, 2022 to no earlier than January 1, 2025, in order to give prescribers additional time to make the necessary changes to conduct electronic prescribing of covered Part D controlled substance prescriptions for Part D beneficiaries in LTC facilities using NCPDP SCRIPT standard version 2017071 (86 FR 65365). We did not propose 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 invited 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.

As proposed, § 423.160(b)(1) would require use of a version of the NCPDP SCRIPT standard adopted in 45 CFR 170.205(b) to carry out the transactions listed in § 423.160(b)(1)(i)(A) through (Z). However, it would not require that all transactions be utilized if they are not needed or are not relevant to the entity. We refer readers to ONC’s Interoperability Standards Advisory (ISA) website for descriptions and adoption level of transactions in the

<sup>20</sup> Section 4. Business Functions, and Section 5. Transactions. National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 2023011. NCPDP SCRIPT standard implementation guides are available to NCPDP members for free and to non-members for a fee at <https://standards.ncdp.org/Access-to-Standards.aspx>. The NCPDP SCRIPT standard version 2023011 implementation guide incorporated by reference in sections II.A.11 and II.B.10. of this rule can be viewed by interested parties for free by following the instructions provided in those sections.



NCPDP SCRIPT standard.<sup>21</sup> For example, we have been informed that the “GetMessage” transaction described in Table 1 is not widely used among prescribers. For this reason, we are reiterating guidance<sup>22</sup> that the NCPDP SCRIPT standard transactions named are not themselves mandatory, but rather they are to be used as applicable to the entities specified at §§ 423.160(a)(1) and (2) when they are completing or supporting the transmission of information related to electronic prescriptions, electronic prior authorization, or medication history. We believe the pharmacies, payers, prescribers, health IT vendors, and intermediaries involved in electronic prescribing have been utilizing the standards in this manner, based on discussions with NCPDP. We would also like to use this opportunity to note that where entities are permitted to use more than one version of the NCPDP SCRIPT standard because more than one version of the NCPDP SCRIPT standard is adopted in 45 CFR 170.205(b), to the extent practicable, entities can utilize transactions available in different versions of the standard simultaneously. For example, as of the effective date of this final rule, entities would be permitted to use the NCPDP SCRIPT standard version 2023011 for RxTransferInitiationRequest, RxTransfer, and RxTransferConfirm transactions, but could continue to use NCPDP SCRIPT standard version 2017071 for other transactions until NCPDP SCRIPT standard version 2017071 expires for HHS use on January 1, 2028. This would enable entities to expedite implementing the functionality necessary for the transfer of electronic controlled substance prescriptions consistent with DEA requirements, as previously described, while implementing other updates associated with NCPDP SCRIPT standard version 2023011 at a later time.

In summary, with respect to changes related to requiring, via cross-reference to ONC regulations (as discussed in section II.B.8.a. of this final rule), NCPDP SCRIPT standard version 2023011 and retiring NCPDP SCRIPT standard version 2017071, we proposed a revised paragraph § 423.160(b)(1) that would—

- 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)–(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 (discussed in section II.B.8.a. of this rule), 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 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.

We solicited comment on these proposals. A discussion of the comments received, along with our responses, follows.

*Comment:* All commenters supported the proposal to update NCPDP SCRIPT standard version 2017071 to NCPDP SCRIPT standard version 202311 for the electronic transmission of prescriptions and prescription-related information, including medication history and ePA.

*Response:* We thank commenters for their support.

*Comment:* Several commenters expressed concern over the proposed date of January 1, 2027 when use of NCPDP SCRIPT standard version 2023011 would be required.

*Response:* See section II.A.7. of this rule for discussion of this concern.

*Comment:* One commenter requested that the exemption from the use of the NCPDP SCRIPT standard (and when use of HL7 messages are permitted) for the transmission of prescriptions and prescription-related information internally when the sender and recipient are part of the same legal entity be extended to the prescription transfer transactions when the sender and the recipient are not part of the same legal entity. For example, transferring a prescription between a pharmacy that is part of a health maintenance organization (HMO) and pharmacy that is not part of the HMO could be done using HL7 messaging rather than the NCPDP SCRIPT standard version 2023011

RxTransferInitiationRequest, RxTransfer, and RxTransferConfirm transactions (or NCPDP SCRIPT standard version 2017071 RxTransferRequest, RxTransferResponse, and RxTransferConfirm transactions).

*Response:* The commenter did not provide an explanation for why the commenter requested that we create an

exemption from use of the NCPDP SCRIPT standard for prescription transfer transactions between pharmacies, so CMS attempted to investigate the issue raised by the commenter. We found evidence that prescription transfer transactions are at a low level of adoption<sup>23</sup> for NCPDP SCRIPT standard version 2017071 despite the fact that CMS has required the use of NCPDP SCRIPT standard transactions for the transfer of prescriptions for Part D drugs for Part D eligible individuals between pharmacies since January 1, 2020, when NCPDP SCRIPT standard version 2017071 was adopted (83 FR 16635–16638). We did not receive any comments identifying issues with prescription transfer transactions when we proposed the update to NCPDP SCRIPT standard version 2022011 in the December 2022 proposed rule. NCPDP SCRIPT standard version 2022011 contained enhancements to prescription transfer transactions that were not available in NCPDP SCRIPT standard version 2017071,<sup>24</sup> and these enhancements are maintained in NCPDP SCRIPT standard version 2023011. Since we are unable to determine an underlying reason for the low adoption rate of NCPDP SCRIPT standard version 2017071 transactions for prescription transfers between pharmacies, and since we only received one comment requesting an exemption from use of the NCPDP SCRIPT standard version 2023011 for prescription transfers between pharmacies, we decline to create a new exemption and will finalize as proposed the requirement to use RxTransferInitiationRequest (previously named RxTransferRequest), RxTransfer (previously named RxTransferResponse), and RxTransferConfirm transactions for prescription transfers between pharmacies, when such transactions take place electronically.

*Comment:* We received many comments on EPCS in LTC. Many commenters requested that CMS move the EPCS compliance date for LTC to January 1, 2027 to align with the proposed date by which NCPDP SCRIPT standard version 2023011 would be required. Some commenters stated that NCPDP was unable to create guidance to implement EPCS in LTC using the NCPDP SCRIPT standard version 2017071 because the coding infrastructure did not exist to support

<sup>21</sup> <https://www.healthit.gov/isa/section/pharmacy interoperability>.

<sup>22</sup> Supporting Electronic Prescribing Under Medicare Part D. September 19, 2008. <https://www.hhs.gov/guidance/document/supporting-electronic-prescribing-under-medicare-part-d>.

<sup>23</sup> <https://www.healthit.gov/isa/allows-a-pharmacy-request-respond-or-confirm-a-prescription-transfer>.

<sup>24</sup> <https://standards.ncdp.org/Standards/media/pdf/Correspondence/2022/202201NCPDP-SCRIPT NextVersionLetter.pdf>.

the necessary three-way communication between the prescriber, LTC facility, and pharmacy. A commenter indicated that they had successfully implemented EPCS in LTC using NCPDP SCRIPT standard version 2017071 but acknowledged that the enhancements in NCPDP SCRIPT standard version 2023011 would improve the experience for LTC providers.

*Response:* We thank commenters for their feedback. As we stated in the November 2023 proposed rule, we did not propose a change to the EPCS compliance date for LTC and therefore cannot finalize a change in this final rule. Changes to the CMS EPCS program requirements have been taking place through the annual Medicare Physician Fee Schedule rulemaking process,<sup>25</sup> therefore CMS will consider making any changes through that process. In light of the fact that we are further delaying the required use of NCPDP SCRIPT standard version 2023011 to January 1, 2028, as discussed in section II.A.7. of this final rule, we will consider the feedback received for future rulemaking.

*Comment:* A commenter suggested embedding the ePA process within the electronic medical record (EMR).

*Response:* We thank the commenter for being eager to integrate ePA into their practice; however, how the NCPDP SCRIPT and other standards are incorporated into EMR/electronic health record (EHR) design and workflow is outside the scope of this proposal. We refer the commenter to a Request for Information titled “Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria” (87 FR 3475), which appeared in the **Federal Register** on January 24, 2022, and which describes ONC’s approach to considering updates to the ONC Health IT Certification Program that could support the availability of ePA in certified health IT for use by health care providers.

After consideration of the public comments we received, we are finalizing our proposal to require, at § 423.160(b)(1), that communication of a prescription and prescription-related information must comply with a standard in 45 CFR 170.205(b) for the transactions listed at § 423.160(b)(1)(i)(A) through (Z), as applicable to the version of the standard in use. We are also finalizing our proposals to consolidate required transactions for prescriptions (§ 423.160(b)(1)(i)(A) through (T)), medication history

(§ 423.160(b)(1)(i)(U), and electronic prior authorization (§ 423.160(b)(1)(i)(V) through (Z)) together since all transactions are specific to the NCPDP SCRIPT standard versions ONC has previously adopted or is adopting at 45 CFR 170.205(b) as described in section II.B.8.a. of this final rule.

Taken in conjunction with the standards and expiration date adopted by ONC, as described in section II.B.8.a. of this final rule, § 423.160(b)(1) will require use of NCPDP SCRIPT standard version 2023011, which ONC is adopting at 45 CFR 170.205(b)(2), beginning January 1, 2028, and retire use of NCPDP SCRIPT standard version 2017071, which ONC previously adopted at 45 CFR 170.205(b)(1) and to which it is applying an expiration date of January 1, 2028. As both NCPDP SCRIPT standard version 2017071 and NCPDP SCRIPT standard version 2023011 will be adopted at 45 CFR 170.205(b) and unexpired as of the effective date of this final rule, entities subject to the requirement at § 423.160(b)(1) may use either version of the NCPDP SCRIPT standard during the transition period beginning the effective date of this final rule, and ending December 31, 2027, which is the last day before NCPDP SCRIPT standard version 2017071 will expire for the purposes of HHS use.

#### 5. Requiring NCPDP Real-Time Prescription Benefit (RTPB) Standard Version 13

In the May 2019 final rule, which implemented the statutory provision at section 1860D–4(e)(2)(D) of the Act, CMS required at § 423.160(b)(7) that Part D plan sponsors implement, by January 1, 2021, one or more electronic RTBT capable of integrating with at least one prescriber’s e-prescribing system or EHR to provide prescribers with complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit information. CMS indicated that the formulary and benefit information provided by the tool should include cost, clinically appropriate formulary alternatives, and utilization management requirements because, at that time, an industry standard for RTBTs had not been identified (84 FR 23833). NCPDP has since developed and tested the NCPDP RTPB standard for use with RTBT applications. The NCPDP RTPB standard enables the real-time exchange of information about patient eligibility and patient-specific formulary and benefit information. For a submitted drug product, the NCPDP RTPB standard will indicate coverage status, coverage restrictions, and estimated patient financial responsibility.

“Estimated” financial responsibility accounts for the fact that the RTPB transaction transmits the patient’s cost sharing at that particular moment in time, which could later change if the claim is processed at a later date or in a different sequence relative to other claims (for example, an RTPB transaction could show a cost sharing that reflects a deductible or particular stage in the Part D benefit which could be different from when the prescription claim is actually processed by the pharmacy if other claims were processed in the interim). The NCPDP RTPB standard also supports providing information on alternative pharmacies and products. In an August 20, 2021 letter to CMS, NCPDP described these features and recommended adoption of NCPDP RTPB standard version 12.<sup>26</sup> Subsequently, in the December 2022 proposed rule, CMS proposed that Part D sponsors’ RTBTs comply with NCPDP RTPB standard version 12. In response to that proposal, NCPDP and many other interested parties provided comments to CMS recommending that CMS instead require NCPDP RTPB standard version 13. In their comments on the December 2022 proposed rule,<sup>27</sup> NCPDP listed enhancements in NCPDP RTPB standard version 13 that improve the information communicated between the payer and the prescriber. These enhancements include—

- Addition of a Coverage Status Message to enable the payer to communicate at the product level coverage information that is not codified (that is, values that are not discrete data elements or specific code values);
- Addition of values to the Coverage Restriction Code and data elements to codify information communicated and reduce the number of free text messages on the response;
- Addition of a 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;
- Addition of fields to communicate formulary status and preference level of both submitted and alternative products in order to clarify pricing; and
- Addition of data elements on the request transaction to convey the patient’s address, state/province, zip/postal code and country to aid in coverage determinations.

Though we withdrew the proposals contained in section III.S. Standards for

<sup>26</sup> [https://standards.ncdp.org/Standards/media/pdf/Correspondence/2021/20210820\\_To\\_CMS\\_RTPBAndFandBStandardsAdoptionRequest.pdf](https://standards.ncdp.org/Standards/media/pdf/Correspondence/2021/20210820_To_CMS_RTPBAndFandBStandardsAdoptionRequest.pdf).

<sup>27</sup> [https://standards.ncdp.org/Standards/media/pdf/Correspondence/2023/20230213\\_To\\_CMS\\_CMS\\_4201\\_P\\_NPRM.pdf](https://standards.ncdp.org/Standards/media/pdf/Correspondence/2023/20230213_To_CMS_CMS_4201_P_NPRM.pdf).

<sup>25</sup> See 85 FR 84472, 86 FR 64996, 87 FR 69404, 88 FR 78818.

Electronic Prescribing in the December 2022 proposed rule (87 FR 79548), we considered comments we received on the December 2022 proposed rule when crafting the proposals related to RTBTs discussed in this final rule. A commenter on the December 2022 proposed rule requested that CMS specify that adoption of the NCPDP RTPB standard should not impede what the commenter refers to as the industry standard of sending 4 drugs or 4 pharmacies for pricing in a single transaction. We understand that each transaction between a prescriber EHR and the payer or processor is associated with a degree of latency (that is, the amount of time it takes for the RTBT request to travel from the electronic prescribing system to the payer or processor and return a response with the patient's cost sharing and formulary status information for the submitted drug). In order to populate information on alternative formulary drugs or alternative pharmacies, if one alternative is submitted per transaction, then the latency associated with each transaction becomes additive. If the total latency is too long, then either the RTBT request may "time out" and a response may never be presented to the prescriber, or the prescriber may simply not wait long enough for the RTBT response before moving on through the electronic prescribing process. To illustrate the concept at the center of this issue, if each RTBT transaction is associated with 1 second of latency, then 1 transaction containing the submitted drug, plus 3 alternatives should return the patient-specific cost and formulary status information for all 4 drugs within 1 second. However, if the submitted drug and each alternative are sent as separate transactions, then the total time to return the RTBT response becomes 4 seconds (1 second  $\times$  4 transactions). This longer response time increases the likelihood that the prescriber will not wait for the information to populate or that the EHR system will cause the transaction to time out, meaning the patient-specific cost and formulary status information are not presented to the prescriber. 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.<sup>28 29 30</sup> Nevertheless, we sought comment in the November 2023 proposed rule on the issue raised by the commenter in the December 2022 proposed rule.

We solicited 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.

The NCPDP RTPB standard version 13 standard is designed for prescriber, not beneficiary (that is, consumer), RTBTs. CMS emphasizes that we did not propose 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 declined to propose a standard for beneficiary RTBTs, however we welcomed comments on this topic to consider for future rulemaking.

<sup>28</sup> Everson J, Dusetzina SB. Real-time Prescription Benefit Tools—The Promise and Peril. *JAMA Intern Med.* 2022;182(11):1137–1138. doi:10.1001/jamainternmed.2022.3962.

<sup>29</sup> Real-Time Benefit Check: Key Insights and Challenges. May 2021. Accessed January 1, 2023. Available at: <https://www.hmpgloballearningnetwork.com/site/frmc/cover-story/real-time-benefit-check-key-insights-and-challenges>.

<sup>30</sup> American Medical Association. Council on Medical Service. Access to Health Plan Information regarding Lower-Cost Prescription Options (Resolution 213–NOV–20). Available from [https://councilreports.ama-assn.org/councilreports/downloadreport?uri=/councilreports/n21\\_cms\\_report\\_2.pdf](https://councilreports.ama-assn.org/councilreports/downloadreport?uri=/councilreports/n21_cms_report_2.pdf).

As discussed in section II.B.8.b. of this rule, ONC proposed to adopt the NCPDP RTPB standard version 13 at 45 CFR 170.205(c)(1). We therefore proposed 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).

We solicited comment on these proposals and the related issues raised. A discussion of the comments received, along with our responses, follows.

*Comment:* All commenters supported the proposal to require NCPDP RTPB standard version 13 for prescriber RTBTs implemented by Part D sponsors. Several commenters shared their support for CMS's efforts to require a standard to improve transparency and efficiency in the electronic prescribing process for both prescribers and patients. Many commenters expressed support for the standard as a means to move away from limited proprietary RTBTs and move towards widespread access to accurate, detailed, patient-specific cost and coverage information for prescribers at the point of prescribing.

*Response:* We thank commenters for their support and for their enthusiasm towards utilizing RTBTs generally.

*Comment:* Several commenters expressed concern over the proposed date of January 1, 2027 when use of NCPDP RTPB standard version 13 would be required.

*Response:* See section II.A.7. of this rule for discussion of this concern.

*Comment:* Several commenters shared their thoughts regarding the issue of whether the number of medications that can be sent in a single request transaction in NCPDP RTPB standard version 13 would present a barrier to existing RTBT functionality. One commenter did not believe the standard would pose a barrier and that implementers could still send more than one transaction simultaneously. Another commenter confirmed that there are occasionally latency issues, but that overall enhancements offered by NCPDP RTPB standard version 13 would outweigh any potential latency issues. Commenters noted that even though the initial request only supports 1 drug per transaction, the response provides multiple alternatives, which meets the health care industry's needs.

*Response:* We thank commenters for their feedback on this topic. We are reassured that requiring NCPDP RTPB standard version 13 for prescriber RTBTs implemented by Part D sponsors will meet the health care industry's needs and will enhance rather than impede existing RTBT functionality.

*Comment:* Several commenters opined on the specific information communicated in the RTBT response. A commenter requested that CMS address the number and order of pharmacy results based on patient preferences and the frequency and timeliness of Part D plan and RTBT vendor updates to pharmacy network files. The commenter indicated that pharmacies need a dispute process when RTBT responses provide inaccurate pharmacy network status.

Other commenters raised the topic of negotiated prices being displayed in RTBT results, as required for qualifying RTBTs as described in section 119(a) of Subtitle B of Title I of Division CC of the CAA, 2021.<sup>31</sup> One commenter supported the use of RTBTs to display a full negotiated price to improve drug cost transparency. Another commenter expressed concern about disclosing negotiated prices, stating that disclosure of such information would have anticompetitive effects and unless CMS and ONC implemented protections to ensure this data is used only to support patient and consumer decision making, there is potential risk of disclosure of negotiated prices to third parties through abuse of RTBT transactions.

*Response:* With respect to the number and ordering of pharmacy results in a transaction response, the request to address pharmacy ordering in the NCPDP RTPB standard version 13 response transaction results is outside the scope of our proposal. The issue of pharmacy network status not being updated in a timely manner is also outside the scope of the current proposal since it relates to Part D plans' and their vendors' internal operations. The value of the RTBT is to provide patient-specific drug coverage information that accurately reflects what an enrollee would pay if presenting to a particular pharmacy at that moment in time; therefore, an RTBT response that does not return accurate information undermines the utility of and confidence in these tools. Part D sponsors should be ensuring that pharmacy network files are updated in a timely manner so that when an enrollee indicates their preferred pharmacy to their prescriber, the RTBT can return accurate coverage information. Pharmacies can also submit complaints to Medicare for review by CMS if they believe that their network participation status is not being

accurately reflected by a Part D sponsor.<sup>32</sup>

With respect to display of negotiated prices in the RTBT, the NCPDP RTPB standard version 13 does not include fields to support the exchange of negotiated prices. We refer commenters and interested parties to discussion in the May 2019 final rule, in which we addressed comments received in response to encouraging Part D sponsors to include negotiated prices in RTBT (84 FR 23850). When we finalized the requirement at § 423.160(b)(7) in the May 2019 final rule (which we are renumbering to § 423.160(b)(5) in this final rule) for Part D sponsors to implement, no later than January 1, 2021, one or more RTBTs capable of integrating with at least one prescriber's e-prescribing system or electronic health record, we encouraged, but did not require, Part D sponsors' RTBTs to include negotiated prices.

CAA, 2021 was then enacted after the May 2019 final rule appeared in the **Federal Register**. Section 119(a) of Subtitle B of Title I of Division CC of the CAA, 2021 added section 1860D–4(o) of the Act to require Part D sponsors to implement one or more RTBTs that meet specified requirements after the Secretary has adopted a standard for RTBTs and at a time determined appropriate by the Secretary. The law specified that RTBTs must be capable of, with respect to a covered Part D drug for a specific Part D enrollee, transmitting cost sharing information and the negotiated price of a drug and its formulary alternatives, among other requirements. Similarly, section 119(b) of Subtitle B of Title I of Division CC of the CAA, 2021 amended the definition of a “qualified electronic health record” in section 3000(13) of the Public Health Service Act to require that a qualified electronic health record include an RTBT capable of transmitting cost sharing information and the negotiated price of a drug and its formulary alternatives, among other requirements.

In a proposed rule titled “Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing” (88 FR 23746), which appeared in the April 18, 2023 **Federal Register**, ONC discussed limitations of NCPDP RTPB standard version 12, specifically that it does not include fields that support the exchange of negotiated prices. Furthermore, ONC requested comment on pharmacy interoperability functionality within the ONC Health IT Certification Program,

including real-time prescription benefit capabilities, in which ONC noted that these fields were not included in the NCPDP RTPB standard due to concerns regarding confidentiality and challenges in determining a negotiated price in real time (88 FR 23850). Section 119 of Subtitle B of Title I of Division CC of the CAA, 2021 grants the Secretary of Health and Human Services the authority to determine the appropriate time, after adopting a standard, to require Part D sponsors to implement and qualified electronic health records to include, respectively, RTBTs meeting the statutory requirements. CMS and ONC will continue to work with other interested parties to determine how and at what time negotiated price information may be made available in RTBTs. At this time, NCPDP RTPB standard version 13 also lacks fields that support the exchange of negotiated prices, but it is the best available standard and otherwise meets the statutory requirements for RTBTs.

*Comment:* Several commenters provided feedback about beneficiary RTBTs. A commenter recommended that CMS should adopt the same standard for beneficiary RTBTs that is used for prescriber RTBTs since the NCPDP RTPB standard, for example, could be adapted to a consumer-friendly user interface and information that would not be relevant in a beneficiary-facing context could be suppressed. Other commenters noted that the NCPDP RTPB standard was not designed to support a beneficiary RTBT and therefore would not be an appropriate standard for that purpose. A commenter agreed that there is no immediate need to require a standard for beneficiary RTBTs. A commenter emphasized that it is essential for pricing and coverage information displayed in beneficiary RTBTs to match the information provided in prescriber RTBTs, therefore any required standard for beneficiary RTBTs must guarantee that information shared is consistent.

*Response:* We thank commenters for their input and may consider it to inform future rulemaking.

*Comment:* A commenter suggested that RTBTs should be embedded within the EMR/EHR workflow.

*Response:* We thank the commenter for being eager to integrate RTBTs into their practice; however, the manner in which the NCPDP RTPB standard and other standards are incorporated into EMR/EHR design and workflow is outside the scope of this proposal. We refer the commenter to section III.G.2. of the final rule titled “Health Data, Technology, and Interoperability:

<sup>31</sup> Public Law 116–260 (December 27, 2020). <https://www.congress.gov/bill/116th-congress/house-bill/133>.

<sup>32</sup> <https://www.medicare.gov/my/medicare-complaint/>.

Certification Program Updates, Algorithm Transparency, and Information Sharing” (89 FR 1192), which appeared in the January 9, 2024 **Federal Register**, and which describes ONC’s approach to considering updates to the ONC Health IT Certification Program that could support the availability of RTBTs in certified health IT for use by health care providers.

*Comment:* CMS received several comments regarding use of RTBTs. A commenter requested that pharmacists have access to RTBTs. Another commenter requested an exception to the use of RTBTs in LTC or institutional levels of care. A commenter encouraged CMS and ONC to monitor physician utilization of RTBTs to consider the impact in Part D and address barriers to access in future regulation.

*Response:* With respect to pharmacists accessing RTBTs, nothing in § 423.160, standards for electronic prescribing, limits RTBT access to particular health care providers where consistent with applicable law. Our understanding is that a decision to expand access to RTBTs to non-prescribing providers, such as pharmacists or other members of a clinical care team, would be made by each health system.

With respect to the request for an exemption from the use of RTBTs in LTC or institutional levels of care, we point out that Part D regulations have never imposed a requirement with respect to the utilization of RTBTs by prescribers. Since January 1, 2021, CMS has required that Part D sponsors implement at least one RTBT capable of integrating with at least one prescriber’s e-prescribing system or EHR. Our proposal to require that by January 1, 2027, the Part D sponsor RTBT must comply with NCPDP RTPB standard version 13, which ONC is adopting at 45 CFR 170.205(c)(1), does not impose any new requirement on prescribers to integrate RTBTs into their e-prescribing systems or EHRs or to utilize RTBTs.

With respect to monitoring real-world use of RTBTs, we intend to monitor the published literature and will explore other vehicles for monitoring progress in this area as resources permit.

After consideration of the public comments we received, we are finalizing the requirement as proposed at § 423.160(b)(5) that beginning January 1, 2027, Part D sponsors’ prescriber RTBT must comply with a standard in 45 CFR 170.205(c), where ONC is adopting the NCPDP RTPB standard version 13 at 45 CFR 170.205(c)(1) as described in section II.B.8.b. of this rule.

6. Requiring NCPDP Formulary and Benefit Standard Version 60 and Retirement of NCPDP Formulary and Benefit Standard Version 3.0

The NCPDP Formulary and Benefit (F&B) standard provides a uniform means for prescription drug plan sponsors to communicate plan-level formulary and benefit information to prescribers through electronic prescribing/EHR systems. The NCPDP F&B standard transmits, on a batch basis, data on the formulary status of drugs, preferred alternatives, coverage restrictions (that is, utilization management requirements), and cost sharing consistent with the benefit design (for example, cost sharing for drugs on a particular tier). The NCPDP F&B standard serves as a foundation for other electronic prescribing functions including ePA, real-time benefit check, and specialty medication eligibility when used in conjunction with other standards.<sup>33</sup> NCPDP F&B standard version 3.0 is required for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors, consistent with the text of §§ 423.160(b)(1)(v) and 423.160(b)(5)(iii). In an April 4, 2023 letter to CMS, NCPDP requested that CMS adopt NCPDP F&B standard version 60 to replace NCPDP F&B standard version 3.0.<sup>34</sup> A detailed change log was attached to the letter and is available at the link in the footnote. As described in the letter, compared with NCPDP F&B standard version 3.0, NCPDP F&B standard version 60 includes all of the following major enhancements:

- Normalization of all files (lists), which allows for smaller files and reusability.
- All files have expiration dates.
- Redesigned alternative and step medication files to reduce file sizes and to include support for reason for use (that is, diagnosis).
- Step medication files support a more complex step medication program.
- Updated coverage files to include support for electronic prior authorization and specialty drugs.
- Updated copay files to allow a minimum and maximum copay range without a percent copay and to support deductibles and pharmacy networks.

<sup>33</sup> Babbrah P, Solomon MR, Stember LA, Hill JW, Weiker M. Formulary & benefit and real-time pharmacy Benefit: Electronic standards delivering value to prescribers and pharmacists. *J Am Pharm Assoc* (2003). 2023 May–Jun;63(3):725–730. doi: 10.1016/j.japh.2023.01.016.

<sup>34</sup> <https://standards.ncdpd.org/Standards/media/pdf/Correspondence/2023/20230404-to-CMS-Formulary-and-Benefit-V60-Request.pdf>.

In its letter to CMS, NCPDP requested mandatory use of NCPDP F&B version 60 24 months after the effective date of a final rule adopting the standard. NCPDP F&B standard version 60 is backwards compatible with NCPDP F&B standard version 3.0, permitting a transition period where both versions of the NCPDP F&B standard may be used simultaneously without the need for entities involved to utilize a translator program.

Following an approach similar to those discussed in sections II.A.4. and II.A.5. of this rule, CMS proposed at § 423.160(b)(3) that electronic transmission of 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 proposed to adopt, at 45 CFR 170.205(u)(1), NCPDP F&B standard version 60 as described in section II.B.8.c. of this rule. CMS proposed that beginning January 1, 2027, entities transmitting formulary and benefit information would be required to comply with a standard in 45 CFR 170.205(u) exclusively. As a result of these proposals, there would be a transition period where either NCPDP F&B standard version 3.0 or NCPDP F&B standard version 60 could be used until January 1, 2027. Since ONC did not previously adopt NCPDP F&B standard version 3.0, we would be maintaining adoption of the standard at § 423.160(b)(3) (previously adopted at § 423.160(b)(5)(iii)) and the incorporation by reference of that version in the Part D regulation at § 423.160(c)(1).

We solicited comment on these proposals. A discussion of the comments received, along with our responses, follows.

*Comment:* All commenters supported the proposal to update NCPDP F&B standard version 3.0 to NCPDP F&B standard version 60. Several commenters acknowledged the complementary role of the NCPDP F&B standard with NCPDP SCRIPT and NCPDP RTPB standards.

*Response:* We thank commenters for their support.

*Comment:* Several commenters expressed concern over the proposed date of January 1, 2027 when use of the NCPDP F&B standard version 60 would be required.

*Response:* For a discussion of the responses to these comments, see section II.A.7. of this rule.

After consideration of the public comments received, we are finalizing the requirement, beginning January 1, 2027 and as proposed at § 423.160(b)(3),

for transmission of formulary and benefit information between Medicare Part D sponsors and prescribers to comply with a standard in 45 CFR 170.205(u), where ONC is adopting NCPDP F&B standard version 60. We are finalizing our proposal to retire use of NCPDP F&B standard version 3.0 for transmitting formulary and benefit information between prescribers and Part D sponsors effective January 1, 2027. A transition period where entities will be permitted to use either NCPDP F&B standard version 3.0 (named at § 423.160(b)(3) consistent with the technical changes in this rule) will begin on the effective date of the final rule and continue through December 31, 2026. Beginning January 1, 2027, only a version of the standard adopted for HHS use at 45 CFR 170.205(u) will be permitted for use, which will be NCPDP F&B standard version 60 as described in section II.B.8.c. of this rule.

#### 7. Date for Required Use of NCPDP SCRIPT Standard Version 2023011, NCPDP RTPB Standard Version 13, and NCPDP F&B Standard Version 60 and Transition Period for NCPDP SCRIPT and F&B Standards

As discussed in the November 2023 proposed rule, we have received feedback on a number of practical considerations for determining a realistic timeframe to implement new or update existing electronic prescribing standards. We have been informed that organizations generally do not budget for new requirements until a final rule has been published establishing a particular new requirement and, therefore, the timing of when a final rule is finalized relative to budget approval cycles can determine if a requirement can be accounted for in the organization's next annual budget. The health IT industry has indicated to CMS that it requires at least 2 years to design, develop, test, and certify software with trading partners; perform DEA audits for EPCS compliance; and roll out updated software to provider organizations and partners who then must train end users before a transition to a new or updated version of a standard is complete. This account is consistent with NCPDP's requests for up to 24-month implementation timeframes for new standards.<sup>35</sup> <sup>36</sup> A commenter on the December 2022 proposed rule requested that CMS either permit 3 years from a final rule before requiring use of a new

or updated version of a standard, or use enforcement discretion if requiring use of a new or updated version of a standard less than 3 years from a final rule. CMS will generally aim to provide entities with at least 2 years from when a final rule is finalized. However, we qualify that in some cases less time may be provided if determined to be necessary.

We routinely receive feedback requesting that we do not require the use of new or updated electronic prescribing standards starting on January 1 due to end-of-year "code freezes," which prohibit updates to internal systems and plan enrollment changes that contribute to a general high workload at the start of a new plan year. We remind entities impacted by the proposed regulatory changes that, consistent with § 423.516, we are prohibited from imposing new, significant regulatory requirements on Part D sponsors midyear. Consistent with the approach discussed in this rule to align CMS' requirements for certain Part D electronic prescribing standards by cross-referencing standards adopted in ONC regulations, CMS and ONC will coordinate to establish appropriate timeframes for updating adopted standards and expiration dates for prior versions of adopted standards. CMS, working with ONC, will consider transition periods longer than 24 months following publication of a final rule to permit a sufficient transition period prior to January 1. Since a new, significant requirement must be effective January 1, a new or updated version of a standard could be required January 1 of the year following 24 months after a final rule is effective. Part D sponsors would need to plan accordingly to completely transition to the updated version of the standard ahead of the January 1 date to meet their internal production calendars.

ONC proposed 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 our proposed cross-reference in § 423.160(b)(1) to a standard in 45 CFR 170.205(b). We proposed 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) via cross-reference to a standard in 45 CFR 170.205(u) and 170.205(c), respectively. As discussed in sections II.A.4 and II.A.6 of this rule, since NCPDP SCRIPT standard version 2023011 and NCPDP F&B standard version 60 are backwards compatible with NCPDP SCRIPT

standard version 2017071 and NCPDP F&B standard version 3.0, respectively, we proposed to permit a transition period when either version could be used. The transition period would begin upon the effective date of the final rule and end on January 1, 2027, which is the expiration date for NCPDP SCRIPT standard version 2017071 proposed by ONC and the date after which CMS proposed to no longer permit use of NCPDP F&B standard version 3.0.

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 asked 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. We noted that the compliance date for the proposals in HHS' November 2022 Administrative Simplification proposed rule was expressly outside the scope of our proposals, and we did not seek comment on it; however, we solicited comments on the feasibility of updating multiple standards simultaneously. A discussion of the comments received, along with our responses, follows.

*Comment:* Most commenters supported January 1, 2027 as the date for required use of NCPDP SCRIPT standard version 2023011, NCPDP RTPB standard version 13, and NCPDP F&B standard version 60.

*Response:* We thank commenters for their support.

*Comment:* Several commenters requested that the date for required use of NCPDP SCRIPT standard version 2023011, NCPDP RTPB standard version 13, and NCPDP F&B standard version 60 be delayed to January 1, 2028. Commenters expressed concern with implementing multiple standards simultaneously at a time when Part D plan and pharmacy benefit manager resources are also focused on system changes related to sections of the Inflation Reduction Act of 2022<sup>37</sup> that

<sup>35</sup> [https://standards.ncdp.org/Standards/media/pdf/Correspondence/2021/20210820\\_To\\_CMS\\_RTPBAndFandBStandardsAdoptionRequest.pdf](https://standards.ncdp.org/Standards/media/pdf/Correspondence/2021/20210820_To_CMS_RTPBAndFandBStandardsAdoptionRequest.pdf).

<sup>36</sup> <https://standards.ncdp.org/Standards/media/pdf/Correspondence/2022/202201NCPDP-SCRIPTNextVersionLetter.pdf>.

<sup>37</sup> Public Law 117–169. <https://www.congress.gov/bills/117/congress/house-bill/5376/text>.

impact Part D sponsors and take effect in 2025 and 2026. A commenter indicated that updating standards in the LTC setting are uniquely challenging such that necessary changes could not be implemented before June 30, 2027.

*Response:* We acknowledge these concerns and seek to strike a balance between advancing standards and providing a reasonable timeline for the health care industry to implement standards successfully. When considering this request, we considered when each standard was last updated and competing needs of the health care industry that each standard addresses. For example, the last time we adopted a newer version of the NCPDP F&B standard was in 2015 (78 FR 74789), whereas we adopted a newer version of the NCPDP SCRIPT standard in 2020 (83 FR 16637). As discussed in section II.A.5. of this rule, we have not previously required a standard for prescriber RTBTs implemented by Part D sponsors, and many commenters supported adoption of a standard in order to enable widespread prescriber access to real-time pharmacy benefit information for their patients at the time of prescribing.

We are concerned that delaying the full and required implementation of all standards until January 1, 2028 would create a scenario where, by the time impacted parties have implemented NCPDP SCRIPT standard version 2023011, NCPDP RTPB standard version 13, and NCPDP F&B standard version 60, NCPDP will have already created newer versions that merit adoption. We are aware of the challenges that are created when cycles of updating standards and adoption in regulation do not occur in tandem. CMS and ONC are open to working with standards development organizations and health care industry representatives to improve the process through which updated standards are incorporated into regulation in the future such that updates can be made in a timely manner.

CMS and ONC have taken the aforementioned factors and comments received into account and are delaying the required use of NCPDP SCRIPT standard version 2023011 to January 1, 2028. We are finalizing this change by finalizing the proposed § 423.160(b)(1), which requires compliance with a standard in 45 CFR 170.205(b), in conjunction with ONC finalizing January 1, 2028 as the expiration date for NCPDP SCRIPT standard version 2017071 in 45 CFR 170.205(b)(1) (as discussed in section II.B.8.a. of this final rule). We are finalizing without modification the requirement to use

NCPDP F&B standard version 60 by January 1, 2027 by requiring at § 423.160(b)(3), beginning January 1, 2027, compliance with a standard in 45 CFR 170.205(u), where ONC is adopting NCPDP F&B standard version 60 (as discussed in section II.B.8.c. of this final rule). We are finalizing the requirement to use NCPDP RTPB standard version 13 by January 1, 2027 by requiring at § 423.160(b)(5), beginning January 1, 2027, compliance with a standard in 45 CFR 170.205(c), where ONC is adopting NCPDP RTPB standard version 13 (as discussed in section II.B.8.b. of this final rule). The NCPDP F&B standard has not been updated as recently as the NCPDP SCRIPT standard has been updated from the perspective of Part D requirements. Further, we believe that maintaining the proposed timeline to require use of NCPDP RTPB standard version 13 and exclusive use of NCPDP F&B standard version 60 by January 1, 2027 is warranted in order to support prescribers' access to accurate cost and coverage information at the point of prescribing through use of these complimentary standards.

*Comment:* A few commenters provided feedback on the transition periods permitted by CMS' proposals. A commenter offered general support for permitting transition periods when backwards compatible versions of standards are available since such periods offer flexibility to the health IT industry and all entities subject to Part D electronic prescribing requirements. Another commenter indicated that if CMS is not specifying the exact dates of transition periods in regulation, there may be confusion among health IT vendors with respect to when system updates can begin. The commenter requested that CMS provide additional communication to the health IT vendor community.

*Response:* As discussed in section II.A.8. of this rule, we believe, and most commenters agree, that the aligned approach between CMS and ONC will help alleviate compliance challenges for the health IT vendor community, but we acknowledge that our proposed approach to cross-reference ONC regulations in Part D regulations in § 423.160 is a significant change from the previous approach of naming standards and specific transition periods in the Part D regulations. Part D sponsors will need to engage with their health IT vendors following the effective date of this, and future, final rules to plan for the transition to new required standards. We do not generally intend to specify dates for transition periods in regulation in the future, but we will consider additional means of

communicating the updated requirements to Part D sponsors, including specifying the dates of transition periods, to minimize any confusion.

After consideration of the public comments received, we are finalizing the requirement for exclusive use of NCPDP SCRIPT standard version 2023011 by January 1, 2028 as a result of ONC modifying the proposed expiration date for NCPDP SCRIPT standard version 2017071 at 45 CFR 170.205(b)(1) as discussed in section II.B.8.a. of this rule. The transition period during which either NCPDP SCRIPT standard version 2017071 or NCPDP SCRIPT standard version 2023011 may be used will begin on July 7, 2024, the effective date of this final rule, and end on December 31, 2027. We are finalizing the requirement for exclusive use of NCPDP F&B standard version 60 by January 1, 2027 as proposed by requiring at § 423.160(b)(3), beginning January 1, 2027, compliance with a standard in 45 CFR 170.205(u), where ONC is adopting NCPDP F&B standard version 60 (as discussed in section II.B.8.c. of this final rule). The transition period during which either NCPDP F&B standard version 3.0 or NCPDP F&B standard version 60 can be used, will begin on July 7, 2024, the effective date of this final rule, and end on December 31, 2026. We are finalizing the required use of NCPDP RTPB standard version 13 for prescriber RTBTs supported by Part D sponsors by January 1, 2027 as proposed by requiring at § 423.160(b)(5), beginning January 1, 2027, compliance with a standard in 45 CFR 170.205(c), where ONC is adopting NCPDP RTPB standard version 13 (as discussed in section II.B.8.b. of this final rule).

#### 8. CMS–ONC Aligned Approach To Adoption of Electronic Prescribing Standards

We proposed a novel approach to updating e-prescribing standards by cross-referencing Part D e-prescribing requirements with standards, including any expiration dates, adopted by ONC, as discussed in section II.B.5. of this rule. The proposed approach would enable CMS and ONC to avoid misalignment from independent adoption of standards for their respective programs. Updates to the adopted standards would impact requirements for both programs at the same time, ensure consistency, and promote alignment for providers, payers, and health IT developers participating in and supporting the same prescription transactions. A discussion of the comments received on



our proposal, along with our responses, follows.

*Comment:* The majority of commenters supported the proposed aligned approach and agreed that it would alleviate compliance challenges for developers and generally help promote consistency and coordination among all parties implementing new standards.

*Response:* We thank commenters for their support.

*Comment:* A few commenters did not support or expressed concerns about the aligned approach. A commenter raised the point that Part D sponsors are not required to use certified health IT; therefore, the approach to cross-reference standards adopted by ONC in Part D regulation could create confusion about the scope of ONC requirements. A few commenters emphasized that CMS and ONC need to assure process alignment across agencies when ONC adopts new standards so that CMS representatives continue to be involved in determining the new requirements and timing. A commenter noted that there should be a notification process, such as a **Federal Register** announcement or Health Plan Management System (HPMS) memorandum to inform Part D sponsors if ONC plans to update the adopted standards in the future.

*Response:* We thank commenters for sharing their concerns and recommendations. We agree that the success of the proposed aligned approach with cross-references is contingent on collaboration and communication among CMS, ONC, and the entities that are subject to CMS and ONC requirements. CMS and ONC will continue to work together on future rulemaking to ensure that future standards that are adopted meet the needs of the respective programs. We will consider the means to ensure that the relevant entities are notified of proposed rules as they are published in the **Federal Register** for public comment and are notified of final rules that finalize relevant proposals. As described in section II.A.11. of this rule, in order for CMS to require use of standards in § 423.160 by cross citation to 45 CFR 170.205(b), (c), and (u), those standards must be published in full in the **Federal Register** or CFR. Therefore, CMS will be required to incorporate by reference in § 423.160 the standards that ONC updates at 45 CFR 170.205(b), (c), and (u). We believe the incorporation by reference in § 423.160 will help to mitigate confusion regarding the standards that are applicable to Part D requirements. We acknowledge that since the expiration dates of standards

will be located in ONC regulations, CMS will consider a targeted announcement to Part D sponsors via HPMS memorandum or email. CMS will continue to participate in NCPDP task groups to ensure that Part D sponsors, pharmacies, and prescribers can continue to coordinate with CMS on issues and challenges related to electronic prescribing standards in Part D. In turn, CMS will work closely with ONC to ensure that any concerns related to electronic prescribing standards in Part D are considered in future rulemaking.

*Comment:* A commenter recommended that CMS should maintain its own standards version advancement process (SVAP) that is focused on the needs of health plans, since the ONC Health IT Certification Program is focused on providers and health IT vendors.

*Response:* We thank the commenter for their recommendation. ONC's SVAP permits health IT developers to voluntarily update health IT products certified under the ONC Health IT Certification Program (Certification Program) to newer versions of adopted standards as part of the "Real World Testing" Condition and Maintenance of Certification requirement at 45 CFR 170.405.<sup>38</sup> Although the ONC SVAP permits the use of newer versions of adopted standards in its ONC Health IT Certification Program, this flexibility does not extend to the Part D program requirements for electronic prescribing. Entities to which the requirements at § 423.160 apply must only use the standard version or versions specified in regulation. We did not propose an equivalent process to ONC's SVAP process for Part D sponsors' electronic prescription drug programs but will take the idea into consideration for future rulemaking.

*Comment:* A commenter recommended that CMS and ONC consider aligning federal requirements for electronic prescribing standards with state requirements or to encourage states to follow standards and timelines adopted at the federal level.

*Response:* The recommendation is outside the scope of our proposals. State regulators may refer to federal regulations to inform requirements related to electronic prescribing standards at the state level.

After consideration of the public comments we received, we are finalizing our proposals to update e-prescribing standards by cross-referencing Part D e-prescribing

requirements with standards, including any expiration dates, adopted by ONC, as discussed in section II.B.5. of this rule.

#### 9. Standards for Eligibility Transactions

We proposed 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 67634). We therefore proposed 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 would have to 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 health care industry and enforcement challenges for HHS.

Thus, we proposed to delete existing paragraphs §§ 423.160(b)(3)(i) and (ii)

<sup>38</sup> <https://www.healthit.gov/topic/standards-version-advancement-process-svap>.

and modify paragraph § 423.160(b)(2) (as renumbered per the technical revisions discussed in section II.A.10. of this rule) to require that eligibility transactions must comply with 45 CFR 162.1202.

We solicited comment on these proposals. A discussion of the comments received, along with our responses, follows.

*Comment:* All comments received on this proposal were supportive. Several commenters agreed that the cross-reference to HIPAA regulation will alleviate compliance challenges for those required to comply with Part D and HIPAA regulations.

*Response:* We thank commenters for their support.

*Comment:* A commenter requested that CMS institute a notification process to ensure that entities subject to Part D requirements are made aware of updates when HHS updates the required standards for eligibility transactions.

*Response:* Consistent with 45 CFR 162.100, the regulations at 45 CFR 162.1202 apply to covered entities as defined at 45 CFR 160.103. Entities subject to Part D regulations are among those covered entities.<sup>39</sup> We believe that HHS has the means to reach covered entities when it undertakes rulemaking and when new requirements are finalized. Therefore, we do not believe CMS would need to issue separate notice.

After consideration of the public comments we received, we are finalizing, in § 423.160(b)(2), the cross-reference to 45 CFR 162.1202 for eligibility transactions as proposed.

#### 10. Technical Changes Throughout § 423.160

In the spirit of alignment with ONC's approach to adopting standards, we reviewed § 423.160 in its entirety and identified areas where we could reorganize text throughout this section. We do not believe we should continue to list historical requirements that are no longer relevant and have resulted in repetitive content being added to the regulations. We proposed removing reference to old effective dates (for example, "After January 1, 2009 . . ." at § 423.160(a)(3)(ii)). Additionally, certain exemptions have long since expired. For example, at § 423.160(a)(3)(iv), entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing

facility) that in turn forwards the prescription to a dispenser have not been exempt from using the SCRIPT standard since November 1, 2014.

We proposed a correction at § 423.160(a)(3)(iii), where regulation text refers to prescriptions and prescription-related information transmitted "internally when the sender and the beneficiary are part of the same legal entity." The exemption currently at § 423.160(a)(3)(iii) was previously codified at § 423.160(a)(3)(ii) as "Entities may use either HL7 messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity . . ." as finalized in the November 2005 final rule, which codified the foundation standards for Medicare Part D electronic prescription drug programs (70 FR 67594). Paragraph § 423.160(a)(ii) was redesignated as paragraph § 423.160(a)(iii) subsequent to changes made in the final rule titled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions," (hereinafter referred to as "the November 2007 final rule") which appeared in the November 27, 2007 **Federal Register** (72 FR 66222). There is no indication of intent in the November 2007 final rule to change the wording in § 423.160(a)(iii) when it was redesignated, nor can we find evidence of when this paragraph may have been altered in subsequent rules. Therefore, we believe the word "recipient" was inadvertently changed to "beneficiary" in the distant past, and we proposed to change this back to "recipient."

Paragraphs § 423.160(a)(1)–(2) already indicate that the entities listed must comply with the applicable standards in § 423.160(b); therefore, the language currently at § 423.160(b)(1), "Entities described in paragraph (a) of this section must comply with the following adopted standards for transactions under this section," is redundant. We proposed to remove it from the text of § 423.160(b)(1). Moreover, §§ 423.160(b)(1)(i) through (iv) and 423.160(b)(2)(i) through (iii) contain long-outdated requirements going back to the start of the electronic prescribing program in Medicare Part D. We proposed to delete references to outdated requirements so that the regulation text would include only

relevant and applicable requirements. Transition periods would no longer be specifically spelled out as starting at a particular date (historically, 6 months after the effective date of a final rule). Rather, the transition period would begin as of the effective date of a final rule effectuating a change from one version of a standard to a new version and would last until the prior version of the standard is expired, as proposed to be codified in ONC regulation, or until the date specified in Part D regulation. For versions of standards adopted by ONC, CMS will consider the necessary transition period when working with ONC to establish the appropriate expiration date for prior versions of standards in rulemaking. This would align the Part D approach with the approach that ONC has used in its own regulations.

As currently organized, separate sections for "Prescription" at § 423.160(b)(2), "Medication History" at § 423.160(b)(4), and "Electronic Prior Authorization" at § 423.160(b)(8) have resulted in multiple versions of the NCPDP SCRIPT standard, and relevant transactions, being repeated in these sections. Because §§ 423.160(a)(1) and (2) state that the entities listed must comply "with the applicable standards in paragraph (b)," we believe that we could group the functions in paragraph (b) according to the standard used for those functions to avoid repetition. Therefore, we proposed to combine "Prescriptions, electronic prior authorization, and medication history" at § 423.160(b)(1), which would require the use of the NCPDP SCRIPT standard version or versions as proposed via cross-reference to ONC regulations. We proposed to delete §§ 423.160(b)(4) and (8). We proposed to relocate the ePA transactions previously listed at § 423.160(b)(8)(i)(A) through (D) to § 423.160(b)(1)(i)(V) through (Y). We proposed to delete reference to versions of the NCPDP F&B standard, currently codified at §§ 423.160(b)(5), 423.160(b)(5)(i), and 423.160(b)(5)(ii), that are no longer applicable. The remaining paragraphs in § 423.160(b) would be renumbered such that § 423.160(b)(2) would refer to eligibility, § 423.160(b)(3) would refer to formulary and benefits, § 423.160(b)(4) would refer to provider identifier, and § 423.160(b)(5) would refer to real-time benefit tools.

We proposed to delete standards incorporated by reference at § 423.160(c) that are: no longer applicable (that is, are associated with outdated requirements that we proposed to delete); or are already incorporated by reference by HHS at 45 CFR 162.920.

<sup>39</sup> <https://www.cms.gov/priorities/key-initiatives/burden-reduction/administrative-simplification/hipaa-covered-entities>.

The standards incorporated by reference at §§ 423.160(c)(1)(i), (ii), (iv), and (v) would no longer be applicable, and we proposed to delete them. The standards for eligibility transactions currently incorporated by reference at §§ 423.160(c)(1)(iii) and 423.160(c)(2) have already been incorporated by reference by HHS at 45 CFR 162.920. We proposed to delete these incorporations by reference in light of our proposal in section II.A.9. of this rule to indicate that entities would be required to comply with 45 CFR 162.1202. That citation indicates where the applicable standards have been incorporated by reference in HHS regulations.

We believe these changes would improve the overall readability of the section. With the exception of changes described in sections II.A.4., II.A.5., II.A.6., and II.A.9., we do not intend for technical changes to alter current requirements.

We solicited comment on these proposals. We received no comments on our proposed technical changes and the correction and therefore are finalizing them as proposed.

#### 11. Incorporation by Reference and Availability of Incorporation by Reference Materials

The Office of the Federal Register (OFR) has regulations concerning incorporation by reference (IBR) at 1 CFR part 51. If the regulations reference a standard, either in general or by name, in another section, IBR approval is required. In order for CMS to require use of standards in § 423.160 by cross citation to 45 CFR 170.205(b), (c), and (u), those standards must be published in full in the **Federal Register** or CFR. Therefore, CMS must incorporate by reference the materials referenced in the proposals in sections II.A.4., II.A.5., and II.A.6. of this rule which cross cite standards in ONC regulations.

For a final rule, agencies must discuss in the preamble to the final rule ways that the materials the agency proposes to incorporate by reference are reasonably available to interested parties or how the agency worked to make the materials reasonably available. Additionally, the preamble to the final rule must summarize the materials. See section II.B.10. of this final rule for summaries of the standards CMS and ONC are incorporating by reference.

Consistent with those requirements, CMS has established procedures to ensure that interested parties can review and inspect relevant materials. The proposals related to the Part D electronic prescribing standards have relied on the following materials, which

we proposed to incorporate by reference where specified—

- NCPDP SCRIPT Standard, Implementation Guide Version 2017071, (Approval Date for American National Standards Institute [ANSI]: July 28, 2017), which is currently incorporated by reference at § 423.160(c)(1)(vii). We proposed to renumber this incorporation by reference as § 423.160(c)(2);

- NCPDP SCRIPT Standard, Implementation Guide Version 2023011, (Approval Date for ANSI: January 17, 2023). We proposed to incorporate by reference at § 423.160(c)(3);

- NCPDP Real-Time Prescription Benefit Standard, Implementation Guide Version 13, (Approval Date for ANSI: May 19, 2022). We proposed to incorporate by reference at § 423.160(c)(4);

- NCPDP Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), (Approval Date for ANSI: January 28, 2011), which is currently incorporated by reference at § 423.160(c)(1)(vi). We proposed to renumber this incorporation by reference as § 423.160(c)(1); and

- NCPDP Formulary and Benefit Standard, Implementation Guide Version 60, (Approval Date for ANSI: April 12, 2023). We proposed to incorporate by reference at § 423.160(c)(5).

NCPDP members may access these materials through the member portal at <https://standards.ncdpd.org/Access-to-Standards.aspx>. Non-NCPDP members may obtain these materials for information purposes by contacting CMS at 7500 Security Boulevard, Baltimore, Maryland 21244; by calling (410) 786-4132 or (877) 267-2323 (toll free); or emailing [PartDPolicy@cms.hhs.gov](mailto:PartDPolicy@cms.hhs.gov).

We received no comments on these proposals and therefore are finalizing the incorporation by reference provisions with typographical and technical changes to § 423.160(c).

The following standards are already approved for the sections in which they appear in the amendatory text of this rule: NCPDP SCRIPT Standard, Implementation Guide Version 2017071 and NCPDP Formulary and Benefit Standard, Implementation Guide, Version 3, Release 0 (Version 3.0).

#### 12. Summary of Standards for Electronic Prescribing Proposals

We received a few general comments that were not specific to any of the particular proposals. A discussion of the comments received, along with our responses, follows.

*Comment:* A few commenters suggested that HHS should require payers outside Part D to use the same standards required in Part D.

*Response:* We thank commenters for their suggestions acknowledging the role of CMS in advancing the adoption of updated standards through our requirements for Part D. We appreciate the fact that commenters believe that the standards required for electronic prescribing in Part D would provide value to electronic prescribing processes in other areas.

*Comment:* A commenter indicated that CMS should monitor the implementation progress of the required standards to assure there are no disruptions in care during the transition to, or as a result of, the implementation of the new versions of the standards.

*Response:* CMS monitors complaints received and will investigate complaints that suggest that required standards are not implemented appropriately.

In consideration of the public comments received and the discussion in sections II.A.4. through II.A.11. of this rule, we are finalizing all of the following:

- Requiring in § 423.160(b)(1) that Part D sponsors, prescribers, and dispensers of Part D drugs for Part D eligible individuals comply with a standard in 45 CFR 170.205(b) for communication of a prescription or prescription-related information. Under paragraph 45 CFR 170.205(b), ONC is adopting NCPDP SCRIPT standard version 2023011 in 45 CFR 170.205(b)(2) and finalizing an expiration date of January 1, 2028 for NCPDP SCRIPT standard version 2017071 in 45 CFR 170.205(b)(1). A transition period will begin on the effective date of the final rule, when either version of the NCPDP SCRIPT standard may be used. The transition period will end on December 31, 2027 because as of January 1, 2028, NCPDP SCRIPT standard version 2017071 will expire for the purposes of HHS use, as described in section II.B.8.a. of this rule. Starting January 1, 2028, NCPDP SCRIPT standard version 2023011 will be the only version of the NCPDP SCRIPT standard available for HHS use and for purposes of the Medicare Part D electronic prescribing program.

- Requiring in § 423.160(b)(5), beginning January 1, 2027, prescriber RTBTs implemented by Part D sponsors to comply with a standard in 45 CFR 170.205(c), where ONC is adopting NCPDP RTPB standard version 13, as described in section II.B.8.b. of this rule.

- Requiring in § 423.160(b)(3), beginning January 1, 2027, transmission of formulary and benefit information

between prescribers and Medicare Part D sponsors to comply with a standard in 45 CFR 170.205(u), where ONC is adopting NCPDP F&B standard version 60, and retiring use of NCPDP F&B standard version 3.0 for transmitting formulary and benefit information between prescribers and Part D sponsors. This requirement includes a transition period beginning on the effective date of the final rule, and ending December 31, 2026, where entities will be permitted to use either NCPDP F&B standard version 3.0 (named at § 423.160(b)(3) consistent with the technical changes in this rule) or NCPDP F&B standard version 60, adopted at 45 CFR 170.205(u). Starting January 1, 2027, only a version of the NCPDP F&B standard adopted for HHS use at 45 CFR 170.205(u) will be permitted for use in Part D electronic prescription drug program, which will be NCPDP F&B standard version 60 as discussed in section II.B.8.c. of this rule.

- Cross-referencing in § 423.160(b)(2) standards adopted for eligibility transactions in HIPAA regulations at 45 CFR 162.1202 for requirements related to eligibility inquiries and responses.

- Making multiple technical changes to the regulation text throughout § 423.160 for clarity by removing requirements and incorporations by reference that are no longer applicable or redundant, reorganizing existing requirements, and correcting a technical error.

- Incorporating by reference NCPDP SCRIPT Standard, Implementation Guide Version 2023011 at § 423.160(c)(3); NCPDP Real-Time Prescription Benefit Standard, Implementation Guide Version 13 at § 423.160(c)(4); and NCPDP Formulary and Benefit Standard, Implementation Guide Version 60, at § 423.160(c)(5).

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

#### 1. Overview

In this section, ONC proposed to adopt standards for electronic prescribing and related activities on behalf of HHS under the authority in section 3004 of the Public Health Service Act (42 U.S.C. 300jj-14). ONC proposed these standards for adoption by HHS as part of a nationwide health information technology infrastructure that supports reducing burden and health care costs and improving patient care. ONC proposed to adopt these standards on behalf of HHS in one location within the Code of Federal Regulations for HHS use, including by the Part D Program as proposed in

section II.A. of this final rule. These proposals reflected a unified approach across the Department to adopt standards for electronic prescribing (e-prescribing) activities that have previously been adopted separately by CMS and ONC under independent authorities. This approach is intended to increase alignment across HHS and reduce regulatory burden for interested parties subject to program requirements that incorporate these standards.

In the 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” (hereinafter referred to as the “December 2022 proposed rule”), which appeared in the **Federal Register** on December 27, 2022 (87 FR 79552 through 79557), we proposed to adopt NCPDP SCRIPT standard version 2022011 and NCPDP Real-Time Prescription Benefit (RTPB) standard version 12, as well as related proposals. As discussed in the November 2023 proposed rule, we withdrew the proposals in sections III.T. and III.U. of the December 2022 proposed rule (87 FR 79552 through 79557). We issued a series of new proposals in the November 2023 proposed rule that took into consideration the feedback we received from commenters on the December 2022 proposed rule and further built on these proposals (88 FR 78499 through 78503). Additionally, summaries of the standards we proposed to adopt and subsequently incorporate by reference in the Code of Federal Regulations can be found below in section II.B.10. of this rule.

#### 2. Statutory Authority

The Health Information Technology for Economic and Clinical Health Act (HITECH Act), Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created “Title XXX—Health Information Technology and Quality” (Title XXX) to improve health care quality, safety, and efficiency through the promotion of health IT and exchange of electronic health information (EHI). Subsequently, Title IV of the 21st Century Cures Act (Pub. L. 114–255) (hereinafter referred to as the “Cures Act”) amended portions of

the HITECH Act by modifying or adding certain provisions to the PHSA relating to health IT.

#### 3. Adoption of Standards and Implementation Specifications

Section 3001 of the PHSA directs the National Coordinator for Health Information Technology (National Coordinator) to perform duties in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information. Section 3001(b) of the PHSA establishes a series of core goals for development of a nationwide health information technology infrastructure that—

- Ensures that each patient’s health information is secure and protected, in accordance with applicable law;
- Improves health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient-centered medical care;
- Reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;
- Provides appropriate information to help guide medical decisions at the time and place of care;
- Ensures the inclusion of meaningful public input in such development of such infrastructure;
- Improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;
- Improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;
- Facilitates health and clinical research and health care quality;
- Promotes early detection, prevention, and management of chronic diseases;
- Promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services; and
- Improves efforts to reduce health disparities.

Section 3004 of the PHSA identifies a process for the adoption of health IT standards, implementation specifications, and certification criteria, and authorizes the Secretary to adopt such standards, implementation specifications, and certification criteria. As specified in section 3004(a)(1) of the

PHSA, the Secretary is required, in consultation with representatives of other relevant Federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator under section 3001(c) of the PHSA and subsequently determine whether to propose the adoption of any grouping of such standards, implementation specifications, or certification criteria. The Secretary is required to publish all determinations in the **Federal Register**.

Section 3004(b)(3) of the PHSA, which is titled “Subsequent Standards Activity,” provides that the Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published by the Health IT Advisory Committee (hereinafter referred to as the “HITAC”). As noted in the final rule, “2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications,” which appeared in the October 16, 2015 **Federal Register**, we consider this provision in the broader context of the HITECH Act and the Cures Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HITAC and endorsed by the National Coordinator, as well as other appropriate and necessary health IT standards, implementation specifications, and certification criteria (80 FR 62606).

Under the authority outlined in section 3004(b)(3) of the PHSA, the Secretary may adopt standards, implementation specifications, and certification criteria as necessary even if those standards have not been recommended and endorsed through the process established for the HITAC under section 3002(b)(2) and (3) of the PHSA. Moreover, while HHS has traditionally adopted standards and implementation specifications at the same time as adopting certification criteria that reference those standards, the Secretary’s authority under section 3004(b)(3) of the PHSA is not limited to adopting standards or implementation specifications at the same time certification criteria are adopted.

Finally, the Cures Act amended the PHSA by adding section 3004(c), which specifies that in adopting and implementing standards under section 3004, the Secretary shall give deference to standards published by standards development organizations and

voluntary consensus-based standards bodies.

#### 4. Alignment With Federal Advisory Committee Activities

The HITECH Act established two Federal advisory committees, the HIT Policy Committee (hereinafter referred to as the “HITPC”) and the HIT Standards Committee (hereinafter referred to as the “HITSC”). Each was responsible for advising the National Coordinator on different aspects of health IT policy, standards, implementation specifications, and certification criteria.

Section 4003(e) of the Cures Act amended section 3002 of the PHSA and replaced the HITPC and HITSC with one committee, the HITAC. After that change, section 3002(a) of the PHSA establishes that the HITAC advises and recommends to the National Coordinator standards, implementation specifications, and certification criteria relating to the implementation of a health IT infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information. The Cures Act specifically directed the HITAC to advise on two areas: (1) a policy framework to advance an interoperable health information technology infrastructure (section 3002(b)(1) of the PHSA); and (2) priority target areas for standards, implementation specifications, and certification criteria (section 3002(b)(2) of the PHSA).

For the policy framework, as described in section 3002(b)(1)(A) of the PHSA, the Cures Act tasked the HITAC with providing recommendations to the National Coordinator on a policy framework for adoption by the Secretary consistent with the Federal Health IT Strategic Plan under section 3001(c)(3) of the PHSA. In February of 2018, the HITAC made recommendations to the National Coordinator for the initial policy framework<sup>40</sup> and subsequently published a schedule in the **Federal Register** and an annual report on the work of the HITAC and ONC to implement and evolve that framework.<sup>41</sup> For the priority target areas for standards, implementation specifications, and certification criteria, section 3002(b)(2)(A) of the PHSA identified that in general, the HITAC

<sup>40</sup> HITAC Policy Framework Recommendations, February 21, 2018: [https://www.healthit.gov/sites/default/files/page/2019-07/2018-02-21\\_HITAC\\_Policy-Framework\\_FINAL\\_508-signed.pdf](https://www.healthit.gov/sites/default/files/page/2019-07/2018-02-21_HITAC_Policy-Framework_FINAL_508-signed.pdf).

<sup>41</sup> Health Information Technology Advisory Committee (HITAC) Annual Report for Fiscal Year 2019 published March 2, 2020: [https://www.healthit.gov/sites/default/files/page/2020-03/HITAC%20Annual%20Report%20for%20FY19\\_508.pdf](https://www.healthit.gov/sites/default/files/page/2020-03/HITAC%20Annual%20Report%20for%20FY19_508.pdf).

would recommend to the National Coordinator, for purposes of adoption under section 3004 of the PHSA, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. In October of 2019, the HITAC finalized recommendations on priority target areas for standards, implementation specifications, and certification criteria.<sup>42</sup>

#### 5. Aligned Approach to 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. 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, the ONC Cures Act 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.<sup>43</sup> Given these concerns, ONC and CMS proposals in the December 2022 proposed rule (87 FR 79552 through 79557) reflected a new approach to alignment of standards under which ONC proposed to adopt, on behalf of HHS, the NCPDP SCRIPT standard version 2022011 and the NCPDP RTPB standard version 12 in a

<sup>42</sup> HITAC recommendations on priority target areas, October 16, 2019: [https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16\\_ISP\\_TF\\_Final\\_Report\\_signed\\_508.pdf](https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf).

<sup>43</sup> See the archived version of the Certification Companion Guide for the “electronic prescribing” certification criterion in 45 CFR 170.315(b)(3): [https://www.healthit.gov/sites/default/files/page/2020-12/b3\\_ccg.pdf](https://www.healthit.gov/sites/default/files/page/2020-12/b3_ccg.pdf).

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.

Additional discussion of this approach can be found in the December 2022 proposed rule (87 FR 79552 through 79557) and CMS's discussion in sections II.A.3. through II.A.7. of this final rule. We note that this rule also reflects an aligned approach with CMS to adoption of health IT standards for e-prescribing and related purposes. We believe our adoption of these standards in a single CFR location for HHS use will help to address concerns around alignment across HHS programs.

*Comment:* Commenters supported the approach reflected in our proposed adoption of standards and alignment within a single CFR location, which they stated would reduce burden and cost, improve care, and improve coordination.

*Response:* We thank commenters for their support.

## 6. Regulatory History

For a summary of past standards adoption activities under section 3004 of the PHSA intended to ensure alignment for electronic prescribing and related activities across the ONC Health IT Certification Program and the Part D Program, we refer readers to the December 2022 proposed rule (87 FR 79553). For a summary of previous notice-and-comment rulemaking related to formulary and benefit management capabilities in the ONC Health IT Certification Program, we refer readers to the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" proposed rule (hereinafter referred to as the "HTI-1 Proposed Rule") (88 FR 23853 through 23854).

## 7. Interoperability Standards Advisory

ONC's Interoperability Standards Advisory (ISA) supports the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the health care industry to address specific interoperability needs.<sup>44</sup> The ISA is updated on an annual basis based on recommendations received from public comments and subject matter expert feedback. This public comment process reflects ongoing dialogue, debate, and consensus among industry interested parties when more than one standard or implementation specification could be

used to address a specific interoperability need.

ONC currently identifies the standards adopted in this section within the ISA as available standards for a variety of potential use cases. The NCPDP SCRIPT standard version 2023011, the NCPDP RTPB standard version 13, and the NCPDP Formulary and Benefit (F&B) standard version 60 are currently identified in sections of the ISA including the "Pharmacy Interoperability"<sup>45</sup> and "Administrative Transactions—Non-Claims."<sup>46</sup> We encourage interested parties to review the ISA to better understand key applications for the implementation specifications proposed for adoption in this rule.

## 8. Proposal To Adopt Standards for Use by HHS

Consistent with section 3004(b)(3) of the PHSA and the efforts, as previously described, to evaluate and identify standards for adoption, we proposed to adopt the following standards in 45 CFR 170.205(b)(2), (c)(1), and (u)(1), on behalf of the Secretary, to support the continued development of a nationwide health information technology infrastructure as described under section 3001(b) of the PHSA, and to support Federal alignment of standards for interoperability and health information exchange. Specifically, we proposed to adopt the following standards:

- NCPDP SCRIPT Standard, Implementation Guide, Version 2023011.
- NCPDP Real-Time Prescription Benefit (RTPB) Standard, Implementation Guide, Version 13.
- NCPDP Formulary and Benefit (F&B) Standard, Implementation Guide, Version 60.

In addition to comments on the individual proposals below, we also invited comments on whether there are alternative versions, including any newer versions, of these or other standards that we should consider for adoption for HHS use. In particular, we stated we were interested in, and would consider for adoption in a final rule, any newer version of the proposed standard(s) that may correct any unidentified errors or clarify ambiguities that would support successful implementation of the standard(s) and the interoperability of health IT.

<sup>45</sup> See <https://www.healthit.gov/isa/section/pharmacyinteroperability>.

<sup>46</sup> See <https://www.healthit.gov/isa/section/administrative-transactions-non-claims>.

a. NCPDP SCRIPT Standard Version 2023011 (45 CFR 170.205(b)(2))

ONC has previously adopted three versions of the NCPDP SCRIPT standard in 45 CFR 170.205. Most recently, we adopted NCPDP SCRIPT standard version 2017071 in the ONC Cures Act final rule to facilitate the transfer of prescription data among pharmacies, prescribers, and payers (85 FR 25678).

The updated NCPDP SCRIPT standard version 2023011 includes important enhancements relative to NCPDP SCRIPT standard version 2017071. Enhancements have been added to support electronic prior authorization functions as well as electronic transfer of prescriptions between pharmacies. NCPDP SCRIPT standard version 2023011 also includes functionality that supports a 3-way transaction among prescriber, facility, and pharmacy, which will enable electronic prescribing of controlled substances in the long-term care (LTC) setting.<sup>47</sup>

We proposed 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 proposed to incorporate NCPDP SCRIPT standard version 2023011 by reference in 45 CFR 170.299. Regarding NCPDP SCRIPT standard version 2017071, we proposed 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. We stated that if these proposals were 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, we stated that 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 II.A.4. of this final 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 requirements for prescriptions, electronic prior authorization, and medication history.

We requested comment on these proposals and received several comments. A discussion of these comments, along with our responses follows.

*Comment:* Commenters supported the proposed adoption of the NCPDP

<sup>47</sup> See [https://standards.ncdpd.org/Standards/media/pdf/Correspondence/2023/20230213\\_To\\_CMS\\_CMS\\_4201\\_P\\_NPRM.pdf](https://standards.ncdpd.org/Standards/media/pdf/Correspondence/2023/20230213_To_CMS_CMS_4201_P_NPRM.pdf).

<sup>44</sup> See <https://www.healthit.gov/isa>.

SCRIPT standard version 2023011, stating that it would improve patient safety, avoid mistakes and errors, and improve information-sharing. Commenters noted that the NCPDP SCRIPT standard version 2023011 includes important enhancements to support the electronic transfer of prescriptions between pharmacies.

*Response:* We thank commenters for their support.

*Comment:* Some commenters agreed with January 1, 2027 as the proposed date by which NCPDP SCRIPT standard version 2023011 would be the only available version of the NCPDP SCRIPT standard for use, due to the proposed expiration of NCPDP SCRIPT standard version 2017071 on that date, while other commenters suggested that we delay the date to January 1, 2028. A few commenters noted that January 1 (the start of the year) can also be difficult with end of year work and suggested a middle of the year date instead.

*Response:* We recognize that, as a result of CMS finalizing their proposals in section II.A.4. of this final rule, which cross-reference our standards adoption proposals in this section, Part D sponsors will need to make a series of changes to different systems in order to ensure compliance with the required standards. Taking into consideration comments on Part D requirements related to the other standards we have proposed for adoption, we agree with CMS that a staggered approach to these updates will allow Part D sponsors to ensure successful adoption and implementation.

Thus, we are modifying our proposal in 45 CFR 170.205(b)(1) for the expiration of NCPDP SCRIPT standard version 2017071 from January 1, 2027, to instead be January 1, 2028. As a result of this modified final policy, the requirements for Part D sponsors finalized in section II.A.4. of this final rule, which cross-reference the standards in 45 CFR 170.205(b), will allow for an additional transitional year before Part D sponsors must only use NCPDP SCRIPT standard version 2023011.

We disagree with commenters that a middle of the year date should be used as a compliance date, as January 1 follows many other CMS and ONC program compliance dates, and we believe it is important to maintain consistency in our alignment with these programs. As discussed in the November 2023 proposed rule (88 FR 78498), our proposed expiration date for the NCPDP SCRIPT standard version 2017071 would allow for a period when a requirement to use a standard in 45 CFR 170.205(b) would allow for the use

of either version of the NCPDP SCRIPT standard adopted at that location. Thus, implementers including Part D sponsors that must use a standard in 45 CFR 170.205(b) have flexibility to determine the most appropriate time to update their systems, until January 1, 2028.

After consideration of the public comments we received, we are finalizing our proposal to adopt NCPDP SCRIPT standard version 2023011 in 45 CFR 170.205(b)(2) and incorporate it by reference in 45 CFR 170.299. We are modifying our proposal to revise the regulatory text in 45 CFR 170.205(b)(1) with respect to the proposed expiration date for NCPDP SCRIPT standard version 2017071 and finalizing that this standard will expire on January 1, 2028. After this date, only NCPDP SCRIPT standard version 2023011 will be available for HHS use. We refer readers to section II.A. of this final rule for additional information where CMS discusses its final policies 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.

#### b. NCPDP Real-Time Prescription Benefit (RTPB) Standard Version 13 (45 CFR 170.205(c)(1))

The NCPDP RTPB standard version 13 enables the exchange of coverage status and estimated patient financial responsibility for a submitted product and pharmacy and identifies coverage restrictions and alternatives when they exist. See section II.A.5. of this final rule for a description of NCPDP RTPB standard functionality and enhancements of NCPDP RTPB standard version 13 relative to NCPDP RTPB standard version 12.

In the November 2023 proposed rule, we noted that our proposal to adopt this standard supports the requirements of Division CC, Title I, Subtitle B, section 119 of the Consolidated Appropriations Act, 2021 (CAA), Public Law 116–260, which required sponsors of Medicare prescription drug plans to implement a real-time benefit tool (RTBT) that meets technical standards named by the Secretary, in consultation with ONC. In addition, section 119(b) of the CAA amended the definition of a “qualified electronic health record” in section 3000(13) of the PHSA to specify that a “qualified electronic health record” must include or be capable of including a RTBT. We stated that ONC intends to address this provision in future rulemaking for the ONC Health IT Certification Program and would ensure

alignment with the proposed NCPDP RTPB standard version 13, if finalized, and related proposals in the Part D program where appropriate.

We also noted that the HITAC had previously addressed real-time prescription benefit standards, consistent with its statutory role to recommend standards. In 2019, the HITAC accepted the recommendations included in the 2018 report of the Interoperability Priorities Task Force, including recommendations to continue to monitor standards then being developed for real-time prescription benefit transactions, and, when the standards are sufficiently validated, to require EHR vendors to provide functionality that integrates real time patient-specific prescription benefit checking into the prescribing workflow.<sup>48</sup> In early 2020, the National Committee on Vital and Health Statistics (NCVHS) and HITAC convened another task force, the Intersection of Clinical and Administrative Data (ICAD) Task Force, which was charged with convening industry experts and producing recommendations related to electronic prior authorizations. The task force report was presented to HITAC in November 2020<sup>49</sup> and discussed the NCPDP RTPB standard as an important tool for addressing administrative transactions around prescribing.

We proposed in 45 CFR 170.205(c) to add a new section heading for “Real-time prescription benefit.” We also proposed to adopt the NCPDP RTPB standard version 13<sup>50</sup> in 45 CFR 170.205(c)(1) and to incorporate this standard by reference in 45 CFR 170.299. We referred readers to section III.B.5. of the November 2023 proposed rule, where CMS proposed at 42 CFR 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, we stated that ONC would consider proposals to require use of this standard to support RTBT functionality in the ONC Health IT Certification Program, consistent with section 119 of the CAA, in future rulemaking.

We requested comment on these proposals and received several comments. A discussion of these

<sup>48</sup> See [https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16\\_ISP\\_TF\\_Final\\_Report\\_signed\\_508.pdf](https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf).

<sup>49</sup> See [https://www.healthit.gov/sites/default/files/page/2020-11/2020-11-17\\_ICAD\\_TF\\_FINAL\\_Report\\_HITAC.pdf](https://www.healthit.gov/sites/default/files/page/2020-11/2020-11-17_ICAD_TF_FINAL_Report_HITAC.pdf).

<sup>50</sup> See <https://standards.ncdpd.org/Access-to-Standards.aspx>.



comments, along with our responses follows.

*Comment:* Commenters supported our proposal to adopt the NCPDP RTPB standard version 13, noting that use of this standard is necessary to provide clinicians and patients with transparency about coverage requirements and cost information for informed decision making.

*Response:* We thank commenters for their support.

After consideration of the public comments received, we are finalizing our proposal to add a new section heading at 45 CFR 170.205(c), “Real-time prescription benefit.” We are also finalizing our proposal to adopt the NCPDP RTPB standard version 13<sup>51</sup> in 45 CFR 170.205(c)(1) and incorporate it by reference in 45 CFR 170.299. We refer readers to section II.A. of this rule for additional information on CMS’s finalized policy 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.

#### c. NCPDP Formulary and Benefit (F&B) Standard Version 60 (45 CFR 170.205(u))

The NCPDP F&B standard version 60<sup>52</sup> provides a uniform means for prescription drug plan sponsors to communicate plan-level formulary and benefit information to prescribers through electronic prescribing/EHR systems. The NCPDP F&B standard transmits, on a batch basis, data on the formulary status of drugs, preferred alternatives, coverage restrictions (that is, utilization management requirements), and cost sharing consistent with the benefit design (for example, cost sharing for drugs on a particular tier). The NCPDP F&B standard serves as a foundation for other electronic prescribing transactions including ePA, real-time benefit check, and specialty medication eligibility when used in conjunction with other standards.

We proposed to add a new paragraph heading at 45 CFR 170.205(u), “Formulary and benefit.” We proposed to adopt the NCPDP F&B standard version 60 at 45 CFR 170.205(u)(1) and to incorporate this standard by reference in 45 CFR 170.299. We referred readers to section III.B.6. of the November 2023 proposed rule, where CMS proposed at § 423.160(b)(3) to require, by January 1,

2027, use of a standard in 45 CFR 170.205(u) by Part D sponsors to fulfill the requirements for exchange of formulary and benefit information with prescribers.

We requested comment on these proposals and received several comments. A discussion of these comments, along with our responses, follows.

*Comment:* Commenters supported the adoption of the NCPDP F&B standard version 60, noting that this standard provides numerous enhancements and a uniformed means for prescription drug plan sponsors to communicate plan-level formulary and benefit information to prescribers through prescribing/EHR systems on a batch basis.

*Response:* We thank commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to add a new paragraph heading at 45 CFR 170.205(u), “Formulary and benefit.” We are also finalizing our proposal to adopt the NCPDP F&B standard version 60 at 45 CFR 170.205(u)(1) and to incorporate this standard by reference in 45 CFR 170.299. We refer readers to section II.A. of this rule for additional information on policies CMS is finalizing at 42 CFR 423.160(b)(3) to require, by January 1, 2027, use of a standard in 45 CFR 170.205(u) for transmitting formulary and benefit information between prescribers and Medicare Part D sponsors.

#### 9. ONC Health IT Certification Program

In the November 2023 proposed rule, we did not propose new or revised certification criteria based on the proposed adoption of standards in the proposed rule. We noted that section 119 of the CAA does not require ONC to adopt certification criteria for real-time prescription benefit capabilities at the same time as a standard is adopted by HHS. We therefore proposed to adopt the NCPDP Real-Time Prescription Benefit standard for HHS use and as previously discussed, stated that ONC would address new or revised certification criteria referencing the standard, if finalized, in separate rulemaking. We noted that ONC published a Request for Information in the HTI–1 Proposed Rule seeking information related to potential establishment of a “real-time prescription benefit” criterion (88 FR 23853 through 23854). We also noted that ONC would continue to collaborate with CMS to ensure that any future proposals in the ONC Health IT Certification Program continue to

advance alignment with program requirements under the Part D Program.

We believe the approach reflected in the standards we have adopted in this final rule will support Federal alignment and coordination of Federal activities with adopted standards and implementation specifications for a wide range of systems, use cases, and data types within the broad scope of health information exchange. Historically, State, Federal, and local partners have leveraged the standards adopted by ONC on behalf of HHS to inform program requirements, technical requirements for grants and funding opportunities, and systems implementation for health information exchange. We believe the adoption of these standards will support HHS partners in setting technical requirements and advancing the use of innovative health IT solutions for electronic prescribing and related activities.

#### 10. Incorporation by Reference (45 CFR 170.299)

The Office of the Federal Register has established requirements for materials (for example, standards and implementation specifications) that agencies incorporate by reference in the Code of Federal Regulations (79 FR 66267; 1 CFR 51.5(a)). Specifically, 1 CFR 51.5(a) requires agencies to discuss, in the preamble of a final rule, the ways that the materials they incorporate by reference are reasonably available to interested parties or how they worked to make those materials reasonably available to interested parties; and summarize, in the preamble of the final rule, the material they incorporate by reference.

To make the materials reasonably available, we provide a uniform resource locator (URL) for the standards and implementation specifications. In many cases, these standards and implementation specifications are directly accessible through the URLs provided. In instances where they are not directly available, we note the steps and requirements necessary to gain access to the standard or implementation specification. In most of these instances, access to the standard or implementation specification can be gained through no-cost (monetary) participation, subscription, or membership with the applicable standards developing organization (SDO) or custodial organization. In certain instances, where noted, access requires a fee or paid membership. As an alternative, a copy of the standards may be viewed for free at the U.S. Department of Health and Human

<sup>51</sup> See <https://standards.ncdpd.org/Access-to-Standards.aspx>.

<sup>52</sup> See <https://standards.ncdpd.org/Access-to-Standards.aspx>.

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The National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 3701 *et seq.*) and the Office of Management and Budget (OMB) Circular A-119 require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA and OMB Circular A-119 provide exceptions to selecting only standards developed or adopted by voluntary consensus standards bodies, namely when doing so would be inconsistent with applicable law or otherwise impractical. We have followed the NTTAA and OMB Circular A-119 in adopting standards and implementation specifications and note that the technical standards adopted in 45 CFR 170.205 in this final rule were developed by NCPDP, which is an ANSI-accredited, not-for-profit membership organization using a consensus-based process for standards development.

As required by 1 CFR 51.5(a), we provide summaries of the standards we have adopted and incorporate by reference in the Code of Federal Regulations. We also provide relevant information about these standards and implementation specifications in the preamble where these standards are adopted. We are finalizing revisions to § 170.299(k) with the following standards as well as typographical and technical revisions:

- NCPDP SCRIPT Standard, Implementation Guide, Version 2023011, (Approval Date for ANSI: January 17, 2023) URL: <https://standards.ncdpd.org/Access-to-Standards.aspx>.

Access requires registration, a membership fee, a user account, and a license agreement to obtain a copy of the standard.

*Summary:* SCRIPT is a standard created to facilitate the transfer of prescription data between pharmacies, prescribers, and payers. The current standard supports transactions regarding new prescriptions, prescription changes, renewal requests, prescription fill status notification, and prescription cancellation. Enhancements have been added for drug utilization review/use (DUR/DUE) alerts and formulary information as well as transactions to relay medication history and for a facility to notify a pharmacy

of resident information. Enhancements have been added to support electronic prior authorization functions as well as electronic transfer of prescriptions between pharmacies.

- NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 13, (Approval Date for ANSI: May 19, 2022) URL: <https://standards.ncdpd.org/Access-to-Standards.aspx>.

Access requires registration, a membership fee, a user account, and a license agreement to obtain a copy of the standard.

*Summary:* The NCPDP Real-Time Prescription Benefit Standard Implementation Guide is intended to meet the industry need within the pharmacy services sector to facilitate the ability for pharmacy benefit payers/processors to communicate to providers and to ensure a consistent implementation of the standard throughout the industry. The NCPDP Real-Time Prescription Benefit standard enables the exchange of patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and identifies coverage restrictions, and alternatives when they exist.

- NCPDP Formulary and Benefit Standard, Implementation Guide, Version 60, (Approval Date for ANSI: April 12, 2023) URL: <https://standards.ncdpd.org/Access-to-Standards.aspx>.

Access requires registration, a membership fee, a user account, and a license agreement to obtain a copy of the standard.

*Summary:* This NCPDP Formulary and Benefit Standard Implementation Guide is intended to provide a standard means for pharmacy benefit payers (including health plans and pharmacy benefit managers) to communicate formulary and benefit information to prescribers via technology vendor systems.

The following standard is already approved for the section in which it appears in the amendatory text of this rule: NCPDP SCRIPT Standard, Implementation Guide Version 2017071.

### III. Collection of Information Requirements

#### A. Background

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a “collection of information,” as defined under 5 CFR 1320.3(c) of the PRA’s implementing regulations, is submitted to the Office of Management and Budget (OMB) for

review and approval. To fairly evaluate whether an information collection requirement (ICR) should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In our December 2022 (CMS-4201-P; RIN 0938-AU96; 87 FR 79452) and November 2023 (CMS-4205-P; RIN 0938-AV24; 88 FR 78476) proposed rules, we solicited public comment on each of the aforementioned issues for the following information collection requirements.

#### B. ICRs Regarding Standards for Electronic Prescribing (42 CFR 423.160 and 45 CFR 170.205 and 170.299)

In sections II.A. and II.B. of this final rule, we discuss proposals, which we are finalizing in this rule, to update the standards to be used for electronic transmission of prescriptions and prescription-related information for Part D covered drugs for Part D eligible individuals. This includes: (1) adopting the National Council for Prescription Drug Plans (NCPDP) SCRIPT standard version 2023011 at 45 CFR 170.205(b)(2), and, after a transition period, retiring use of NCPDP SCRIPT standard version 2017071 for communication of a prescription or prescription-related information supported by Part D sponsors; (2) requiring use of NCPDP RTPB standard version 13 for prescriber RTBTs implemented by Part D sponsors; and (3) requiring use of NCPDP Formulary and Benefit (F&B) standard version 60, at 45 CFR 170.205(u), and retiring use of NCPDP F&B standard version 3.0 for transmitting formulary and benefit information between prescribers and Part D sponsors. These proposals update existing standards that are exempt from the PRA, as explained in this section.

The initial electronic prescribing standards for the Medicare Part D program were adopted in the final rule “Medicare Program; Standards for E-Prescribing Under Medicare Part D and Identification of Backward Compatible Version of Adopted Standard for E-Prescribing and the Medicare Prescription Drug Program (Version 8.1)” (hereinafter referred to as the “Initial Standards final rule”),

which appeared in the April 4, 2008 **Federal Register** (73 FR 18918). The Initial Standards final rule implemented the first update to the electronic prescribing foundation standards in the Part D program that had been adopted in the final rule “Medicare Program; E-Prescribing and the Prescription Drug Program” (hereinafter referred to as the “Foundation Standards final rule”), which appeared in the November 7, 2005 **Federal Register** (70 FR 67568). The Initial Standards final rule adopted the updated the NCPDP SCRIPT standard version 8.1 and retired the previous NCPDP SCRIPT standard version 5.0. With respect to ICRs in the Initial Standards final rule, CMS explained that the burden associated with the requirement that Part D sponsors must support and comply with the adopted electronic prescribing standards when prescriptions and prescription-related information is transmitted electronically for covered Part D drugs, prescribed for Part D eligible individuals is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) because use of standards for electronic prescribing constitutes a usual and customary business practice (73 FR 18931).

Subsequent rules that have updated electronic prescribing standards in the Medicare Part D program also considered such practice as exempt from the PRA. Specifically—

- The “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013” final rule, which appeared in the November 16, 2012, **Federal Register** (77 FR 68892). This final rule updated the electronic prescribing standards in Medicare Part D from NCPDP SCRIPT standard version 8.1 to version 10.6;

- The “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014” final rule, which appeared in the **Federal Register** on December 10, 2013 (78 FR 74230). This final rule updated the electronic prescribing standards in Medicare Part D from NCPDP F&B standard version 1.0 to version 3.0; 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 **Federal Register** on April 16, 2018 (83 FR 16640). This final rule updated the electronic prescribing standards in Medicare Part D from NCPDP SCRIPT standard version 10.6 to version 2017071.

Once electronic prescribing has been enabled through electronic prescribing systems or EHRs it is a usual and customary business practice that health IT and EHR vendors will update the systems regularly in order to meet the business needs of their customers utilizing electronic prescribing. Updating systems with new versions of electronic prescribing standards is one such update, and NCPDP SCRIPT is the industry standard for electronic prescribing of drugs covered under a pharmacy benefit. CMS does not require that pharmacies accept electronic prescriptions, but pharmacies that do would likewise have their systems updated by their health IT software providers as a usual and customary business practice to meet their business needs. We believe the burden associated with using the NCPDP SCRIPT standard version 2023011 will be the same as using NCPDP SCRIPT standard version 2017071 for transmission of prescription and prescription-related information. We do not anticipate that updating NCPDP SCRIPT standard version 2017071 to NCPDP SCRIPT standard version 2023011 will result in costs that are beyond those associated with usual and customary business practices. CMS does not require prescribers to utilize formulary and benefit information in the process of electronic prescribing, but for prescribers who do, we believe the burden associated with using NCPDP F&B standard version 60 will be the same as using NCPDP F&B standard version 3.0. We do not anticipate that updating NCPDP F&B standard version 3.0 to NCPDP F&B standard version 60 will result in costs that are beyond those that are usual and customary business practices. We believe this to be true for health IT and EHR vendors serving the business needs of their customers and Part D sponsors who likewise have a business interest in facilitating prescribers’ ability to select preferred formulary products at the time of prescribing.

Part D sponsors have been required to support RTBTs since January 1, 2021, as finalized in the “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses” final rule, which appeared in the **Federal Register** on May 23, 2019 (84 FR 23832). Because Part D sponsors have invested in the hardware, software, and connectivity necessary to utilize RTBTs, we believe that adopting the

NCPDP RTPB standard version 13 will impose de minimis cost on the industry and that costs will be largely offset by the advantages and efficiencies associated with interoperability that a standard brings. CMS does not require prescribers to utilize RTBTs, but for prescribers who do utilize RTBTs, we believe that the burden associated with using an RTBT that does not use a standard will be the same as using an RTBT that uses NCPDP RTPB standard version 13.

The operations associated with updates to standards finalized in this rule are analogous to the operations associated with updates to standards in the prior rules described. Therefore, the provisions in sections II.A. and II.B. of this rule are exempt from the requirements of the PRA.

We received no comments on the proposed ICR narrative in the December 2022 or November 2023 proposed rules. Therefore, we are finalizing the ICR narrative as is.

#### IV. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled “Modernizing Regulatory Review” (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 entitled “Modernizing Regulatory Review” (hereinafter, the Modernizing E.O.) amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$200 million or more in any 1 year, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or

safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive Order.

A Regulatory Impact Analysis (RIA) must be prepared for regulatory actions that are significant under section 3(f)(1). Based on our estimates, OMB's Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is not significant per section 3(f)(1) as measured by the \$200 million or more in any one year threshold, since we calculated no burden associated with the provisions in this rule. Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has also determined that this rule does not meet the criteria set forth in 5 U.S.C. 804(2).

The RFA requires agencies to consider the effect of any provision on small entities and present alternatives, if necessary, for regulatory relief to those small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The entities affected by this final rule include Part D sponsors, prescribers, and dispensers (that is, pharmacies) that electronically transmit prescriptions or prescription-related information for Part D drugs for Part D-eligible individuals, directly or through an intermediary. As indicated in section III.B. of this rule, the information collection requirements for the provisions in this rule are exempt from the PRA because the requirement to utilize a standard for electronic prescribing is classified as a usual and customary business practice. Consequently, we have not calculated burden estimates for entities affected by this final rule, regardless of size. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section

1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately \$183 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on May 6, 2024.

### List of Subjects

#### 42 CFR Part 423

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Incorporation by reference, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

#### 45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Healthcare, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and record keeping requirements, Public health, Security.

For the reasons set forth in the preamble, the Centers for Medicare &

Medicaid Services amends 42 CFR part 423 and the Department of Health and Human Services amends 45 CFR part 170 as set forth below:

### PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 1. The authority citation for part 423 continues to read as follows:

**Authority:** 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 2. Section 423.160 is revised to read as follows:

#### § 423.160 Standards for electronic prescribing.

(a) *General rules.* (1) Part D sponsors must establish and maintain an electronic prescription drug program that complies with the applicable standards in paragraph (b) of this section when transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals.

(2) Except as provided in paragraph (a)(3) of this section, prescribers and dispensers that transmit, directly or through an intermediary, prescriptions and prescription-related information using electronic media (including entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider, such as a nursing facility, that in turn forwards the prescription to a dispenser), must comply with the applicable standards in paragraph (b) of this section when e-prescribing for covered Part D drugs for Part D eligible individuals.

(3)(i) Entities transmitting prescriptions or prescription-related information must utilize the NCPDP SCRIPT standard, consistent with paragraph (b)(1) of this section, in all instances other than temporary/transient network transmission failures.

(ii) Electronic transmission of prescriptions or prescription-related information by means of computer-generated facsimile is only permitted in instances of temporary/transient transmission failure and communication problems that would preclude the use of the NCPDP SCRIPT standard adopted by this section.

(iii) Entities may use either HL7 messages or the NCPDP SCRIPT standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity. If an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy), it must

use the adopted NCPDP SCRIPT standard or other applicable adopted standards. Any pharmacy within an entity must be able to receive electronic prescription transmittals for Medicare beneficiaries from outside the entity using the adopted NCPDP SCRIPT standard. This exemption does not supersede any HIPAA requirement that may require the use of a HIPAA transaction standard within an organization.

(4) In accordance with section 1860D-4(e)(5) of the Act, the standards under this paragraph (b) of this section supersede any State law or regulation that—

(i) Is contrary to the standards or restricts the ability to carry out Part D of Title XVIII of the Act; and

(ii) Pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under Part D of Title XVIII of the Act.

(5) Beginning on January 1, 2021, prescribers must, except in the circumstances described in paragraphs (a)(5)(i) through (iii) of this section, conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically using the applicable standards in paragraph (b) of this section, subject to the exemption in paragraph (a)(3)(iii) of this section. Prescriptions written for a beneficiary in a long-term care facility will not be included in determining compliance until January 1, 2025. Compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a long-term care facility will commence on or after January 1, 2025. Compliance actions against prescribers who do not meet the compliance threshold based on other prescriptions will commence on or after January 1, 2023. Prescribers will be exempt from this requirement in the following situations:

(i) Prescriber issues 100 or fewer controlled substance prescriptions for Part D drugs per calendar year as determined using CMS claims data with dates of service as of December 31st of the current year.

(ii) Prescriber has an address in PECOS in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. If a prescriber does not have an address in PECOS, prescriber has an address in NPES in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity. Starting in the 2024 measurement year, CMS will identify

which emergencies or disasters qualify for this exception.

(iii) Prescriber has received a CMS-approved waiver because the prescriber is unable to conduct electronic prescribing of controlled substances (EPCS) due to circumstances beyond the prescriber's control.

(b) *Standards*—(1) *Prescriptions, electronic prior authorization, and medication history.* The communication of a prescription or prescription-related information must comply with a standard in 45 CFR 170.205(b) (incorporated by reference, *see* paragraph (c) of this section) for the following transactions, as applicable to the version of the standard in use:

- (i)(A) GetMessage.
- (B) Status.
- (C) Error.
- (D) RxChangeRequest and RxChangeResponse.
- (E) RxRenewalRequest and RxRenewalResponse.
- (F) Resupply.
- (G) Verify.
- (H) CancelRx and CancelRxResponse.
- (I) RxFill.
- (J) DrugAdministration.
- (K) NewRxRequest.
- (L) NewRx.
- (M) NewRxResponseDenied.
- (N) RxTransferInitiationRequest.
- (O) RxTransfer.
- (P) RxTransferConfirm.
- (Q) RxFillIndicatorChange.
- (R) Recertification.
- (S) REMSInitiationRequest and REMSInitiationResponse.
- (T) REMSRequest and REMSResponse.
- (U) RxHistoryRequest and RxHistoryResponse.
- (V) PAInitiationRequest and PAInitiationResponse.
- (W) PARRequest and PARResponse.
- (X) PAAppealRequest and PAAppealResponse.
- (Y) PACancelRequest and PACancelResponse.
- (Z) PANotification.
- (ii) [Reserved]

(2) *Eligibility.* Eligibility inquiries and responses between the Part D sponsor and prescribers and between the Part D sponsor and dispensers must comply with 45 CFR 162.1202.

(3) *Formulary and benefits.* The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), (incorporated by reference, *see* paragraph (c) of this section) or comply with a standard in 45 CFR 170.205(u) (incorporated by reference, *see* paragraph (c) of this section) for transmitting formulary and benefits

information between prescribers and Part D sponsors. Beginning January 1, 2027, transmission of formulary and benefit information between prescribers and Part D sponsors must comply with a standard in 45 CFR 170.205(u) (incorporated by reference, *see* paragraph (c) of this section).

(4) *Provider identifier.* The National Provider Identifier (NPI), as defined at 45 CFR 162.406, to identify an individual health care provider to Medicare Part D sponsors, prescribers and dispensers, in electronically transmitted prescriptions or prescription-related materials for Medicare Part D covered drugs for Medicare Part D eligible individuals.

(5) *Real-time benefit tools.* Part D sponsors must implement one or more electronic real-time benefit tools (RTBT) that are capable of integrating with at least one prescriber's e-Prescribing (eRx) system or electronic health record (EHR) to provide complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit information to the prescriber in real time for assessing coverage under the Part D plan. Such information must include enrollee cost-sharing information, clinically appropriate formulary alternatives, when available, and the formulary status of each drug presented including any utilization management requirements applicable to each alternative drug. Beginning January 1, 2027, Part D sponsors' RTBT must comply with a standard in 45 CFR 170.205(c) (incorporated by reference, *see* paragraph (c) of this section).

(c) *Incorporation by reference.* The material listed in this paragraph (c) is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Centers for Medicare & Medicaid Services (CMS) and at the National Archives and Records Administration (NARA). Contact CMS at: CMS 7500 Security Boulevard, Baltimore, Maryland 21244; phone: (410) 786-4132 or (877) 267-2323; email: [PartDPolicy@cms.hhs.gov](mailto:PartDPolicy@cms.hhs.gov). For information on the availability of this material at NARA, visit [www.archives.gov/federal-register/cfr/ibr-locations](http://www.archives.gov/federal-register/cfr/ibr-locations) or email [fr.inspection@nara.gov](mailto:fr.inspection@nara.gov). The material may be obtained from National Council for Prescription Drug Programs (NCPDP), Incorporated, 9240 E Raintree Drive, Scottsdale, AZ 85260-7518; phone: (480) 477-1000; email: [info@ncdpd.org](mailto:info@ncdpd.org); website: [www.ncdpd.org](http://www.ncdpd.org).

(1) NCPDP Formulary and Benefit Standard, Implementation Guide,

Version 3, Release 0 (Version 3.0), ANSI-approved January 28, 2011.

(2) NCPDP SCRIPT Standard, Implementation Guide Version 2017071, ANSI-approved July 28, 2017.

(3) NCPDP SCRIPT Standard, Implementation Guide Version 2023011, ANSI-approved January 17, 2023.

(4) NCPDP Real-Time Prescription Benefit Standard, Implementation Guide Version 13, ANSI-approved May 19, 2022.

(5) NCPDP Formulary and Benefit Standard, Implementation Guide Version 60, ANSI-approved April 12, 2023.

#### Title 45—Public Welfare

### PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 3. The authority citation for part 170 continues to read as follows:

**Authority:** 42 U.S.C. 300jj–11; 42 U.S.C. 300jj–14; 5 U.S.C. 552.

■ 4. Section 170.205 is amended by—

■ a. Revising paragraphs (b)(1) and (2).

■ b. Adding paragraph (c); and

■ c. Adding paragraph (u).

The revision and additions read as follows:

#### § 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

\* \* \* \* \*

(b) \* \* \*

(1) *Standard.* National Council for Prescription Drug Programs (NCPDP): SCRIPT Standard Implementation Guide; Version 2017071 (incorporated by reference in § 170.299). The Secretary's adoption of this standard expires on January 1, 2028.

(2) *Standard.* NCPDP SCRIPT Standard, Implementation Guide, Version 2023011 (incorporated by reference in § 170.299).

(c) *Real-time prescription benefit*—(1) *Standard.* NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 13 (incorporated by reference in § 170.299).

(2) [Reserved]

\* \* \* \* \*

(u) *Formulary and benefit*—(1) *Standard.* NCPDP Formulary and Benefit Standard Version 60 (incorporated by reference in § 170.299).

(2) [Reserved]

\* \* \* \* \*

■ 4. Section 170.299 is amended by revising paragraph (k) to read as follows:

#### § 170.299 Incorporation by reference.

\* \* \* \* \*

(k) National Council for Prescription Drug Programs (NCPDP), Incorporated, 9240 E Raintree Drive, Scottsdale, AZ 85260–7518; phone (480) 477–1000; fax: (480) 767–1042; website: [www.ncdp.org](http://www.ncdp.org).

(1) NCPDP SCRIPT Standard, Implementation Guide, Version 2017071, ANSI-approved July 28, 2017; IBR approved for § 170.205(b).

(2) NCPDP SCRIPT Standard, Implementation Guide, Version 2023011, ANSI-approved January 17, 2023; IBR approved for § 170.205(b).

(3) NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 13, ANSI-approved May 19, 2022; IBR approved for § 170.205(c).

(4) NCPDP Formulary and Benefit Standard, Implementation Guide, Version 60, ANSI-approved April 12, 2023; IBR approved for § 170.205(u).

\* \* \* \* \*

#### Xavier Becerra,

*Secretary, Department of Health and Human Services.*

[FR Doc. 2024–12842 Filed 6–13–24; 4:15 pm]

#### BILLING CODE P

### FEDERAL COMMUNICATIONS COMMISSION

#### 47 CFR Part 10

[PS Docket Nos. 15–94 and 15–91; FCC 23–88; FR ID 225472]

#### Emergency Alert System; Wireless Emergency Alerts

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule; announcement of effective date.

**SUMMARY:** In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved until May 31, 2027, an information collection associated with the Commission's *Third Report and Order*, FCC 23–88 (Order), in which the Commission, among other things, adopted a new rule that provided Participating Commercial Mobile Service (CMS) Providers may support up to two Wireless Emergency Alert (WEA) tests that the public receives by default per county or county equivalent per calendar year. This document is consistent with the Order, which stated the Commission would publish a document in the **Federal Register** announcing the effective date of the new rules.

**DATES:** The amendment of 47 CFR 10.350(d) published at 88 FR 86824 on December 15, 2023, is effective on July 17, 2024.

#### FOR FURTHER INFORMATION CONTACT:

David Kirschner, Attorney-Advisor, Public Safety and Homeland Security Bureau, Cybersecurity and Communications Reliability Division at (202) 418–0695 or via email: [David.Kirschner@fcc.gov](mailto:David.Kirschner@fcc.gov) or Nicole Ongele at (202) 418–2991 or via email: [Nicole.Ongele@fcc.gov](mailto:Nicole.Ongele@fcc.gov).

**SUPPLEMENTARY INFORMATION:** This document announces that, on May 29, 2024, OMB approved the information collection requirements relating to § 10.350(d) contained in the Commission's Order FCC 23–88, published at 88 FR 86824, December 15, 2023. The OMB Control Number is 3060–1126. The Commission publishes this document as an effective date of the rule. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Nicole Ongele, Federal Communications Commission, 45 L Street NE, Washington, DC 20554. Please include OMB Control Number 3060–1126, in your correspondence. The Commission will also accept your comments via email at [PRA@fcc.gov](mailto:PRA@fcc.gov).

#### Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C.3507), the FCC is notifying the public that it received OMB approval on May 29, 2024, for the information collection requirements contained in 47 CFR 10.350(d) of the Commission's rules.

Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–1126.

The foregoing notification is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

*OMB Control Number:* 3060–1126.

*OMB Approval Date:* May 29, 2024.

*OMB Expiration Date:* May 31, 2027.

*Title:* Testing and Logging Requirements for Wireless Emergency Alerts.