January 23, 2019

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4180–P
P.O. Box 8013
Baltimore, MD 21244–8013
Submitted electronically at http://www.regulations.gov/

Re: 42 CFR Parts 422 and 423 Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

Dear Sir or Madam,

NCPDP appreciates the efforts of the Centers for Medicare & Medicaid Services (CMS) to move the industry towards more transparency around a patient's anticipated medication costs and the need for a standard mechanism to support the exchange of this data among industry stakeholders.

NCPDP is a not-for-profit ANSI-accredited Standards Development Organization (SDO) consisting of more than 1,500 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

To avoid the burden for Electronic Health Record (EHR) vendors and Part D payers of integrating with multiple real-time benefit tool (RTBT) transaction formats utilizing varying data content, one standard should be recognized. Establishing one standard leverages workflow and the success of other standards named in HIPAA (NCPDP Telecommunication) and MMA (NCPDP SCRIPT and NCPDP Formulary and Benefit) regulations.

As CMS has recognized, without a standard, the burden on the EHR vendors is significant, especially for smaller vendors who often support smaller practices and/or specialty practices. EHR vendors may not be positioned or may find it difficult to support multiple RTBTs, so the benefits anticipated from an RTBT implementation may not occur. A payer may support one RTBT while the requesting provider supports another, leading to disconnects in the exchange of information. Allowing multiple RTBTs without a standard will not achieve the goal of presenting real-time pharmacy benefit information to all providers for all patients. EHR vendors will require software upgrades to enable an integrated RTBT and practices

and vendors need time to implement these upgrades. Following one standard rather than a multitude of proprietary solutions will assist in EHR adoption.

NCPDP encourages CMS to work with NCPDP to develop the RTBT standard. NCPDP is developing a real-time prescription benefit (RTPB) standard in conjunction with experts across the pharmacy industry to convey real-time pricing and formulary information to providers, to provide complete, accurate, timely and clinically appropriate patient-specific pharmacy benefit information capable of integrating with prescribers' ePrescribing (eRx) and EHR systems, and to improve the quality and access to care for the patient.

It is noted that the proposed rule encourages payers to return the drug's negotiated price, in addition to the patient's costs. The NCPDP draft RTPB standard, as it currently exists, does not include fields to support the exchange of "each drug's negotiated price". This information was not included because of the inherent challenges in determining the negotiated price in real time (e.g., rebates calculated later, the definition of "negotiated price" being revised, and exclusion of Usual and Customary price information) and concerns regarding the confidentiality of drug pricing agreements.

NCPDP requests CMS please confirm the elements listed in the Notice of Proposed Rule Making (NPRM) ("patient's cost-sharing information, additional formulary alternatives, formulary status of clinically appropriate formulary alternatives, including any utilization management requirements, such as step therapy, quantity limits and prior authorization, and indications-based restrictions, for each specific alternative presented") constitutes "complete, accurate, timely, clinically appropriate and patient-specific real-time formulary and benefit information".

NCPDP requests CMS postpone the mandated January 1, 2020 deadline for implementation of an electronic RTBT. Successful integration of a RTBT standard should consider time required for other industry mandates such as the implementation of the NCPDP SCRIPT Standard v2017071 which is required for January 1, 2020. NCPDP recommends the following timeline:

- NCPDP RTPB Standard anticipated to be published January 2020
- Development, testing and validation of the standard April-October 2020
- Corrections to the standard May-November 2020
- New version of the standard published January 2021 and named in regulation with compliance required no later than January 1, 2022.

This timeline accounts for trading partner testing and likely corrections to the standard that will be identified through trading partner testing. It also accounts for the planning required, as well as the development efforts, to successfully implement a new standard transaction between trading partners. EHR vendors will be focused throughout 2019 on the implementation of the new SCRIPT Standard. Without EHR participation, a RTBT is meaningless as providers will not have access to the RTBT functionality.

NCPDP also requests CMS investigate the possibility of not publishing a date of the standard when naming a standard. Today, standards are adopted using the following method: Name of SDO, Name of Standard, Version/Release, Date. For example, the National Council for Prescription Drug Programs Telecommunication Standard, Version D.0, August 2010. Eliminating the August 2010 in the example provides the SDO and the industry with a mechanism to make maintenance modifications to a named standard and version without the burden of rulemaking.

In addition, please note this NPRM incorrectly references Formulary and Benefit Standard v1.0; this is not the version currently named in regulation. References to the Formulary and Benefit Standard should only name Version 3.0. Refer to § 423.160 Standards for electronic prescribing, (b),(5),(iii):

> Formulary and benefits. The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), April 2012 (incorporation by reference in paragraph (c)(1)(vi) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

Thank you for the opportunity to comment on 42 CFR Parts 422 and 423. NCPDP looks forward to working with CMS to facilitate adoption of a RTBT standard by all stakeholders.

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

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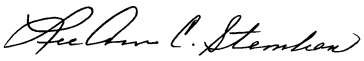
Sincerely,



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cc: Standardization Committee