



Draft Regulation for the Implementation of a New York State-Wide Real-Time Prescription Benefit Standard

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Summary

The following Sample Language and Summary of the Regulatory Impact Statement have been written to enable New York Department of Health regulators to improve real-time benefit tools (RTBTs). Specifically, the regulation establishes the National Council for Prescription Drug Programs Real-Time Prescription Benefit (NCPDP RTPB) Standard as the statewide real-time prescription benefit (RTPB) standard.

The language and context included below follow examples in New York State Department of Health's current [proposed rulemaking records](#). For language that was derived from existing laws or regulation in the Sample Language section, the footnotes cite the original source. These footnotes are included for the reader's benefit, but are not meant to be included in the final regulation.

The proposed regulation can be organized into three groups of changes:

1. **98-1.2.** In this section, new definitions relevant to RTBTs are added.
2. **98-1.23, paragraphs (a)-(d).** In this section, the new paragraphs define RTBT requirements for insurers.
3. **98-1.23, paragraphs (e)-(g).** In this section, the new paragraphs define the Department of Health's means of governance. Specifically, (e) enables the Department to audit insurers, (f) enables the Department to grant extensions, variance and waivers to insurers, and (g) enables the Department to penalize insurers who do not comply and who were not granted accommodations according to (f).

Sample Language

Pursuant to the authority vested in the Commissioner of Health by section 4403 of the Public Health Law, Part 98 Section 1.23 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is added, and Part 98 [Section 1.2](#) is amended, to be effective upon publication of a Notice of Adoption in the New York State Register.¹

Part 98 Section 1.2 is appended with:

(qq) "Pharmacy benefit manager" (PBMs) means an entity that contracts with pharmacies or pharmacy contracting agents on behalf of a health plan, state agency, insurer, managed care organization, or other third party payor to provide pharmacy health benefit services or administration.²

(rr) "Electronic health record" means a digital version of a patient's paper chart and medical history that makes information available instantly and securely to authorized users.³

(ss) "Electronic prescribing system" means a system that enables prescribers to enter prescription information into a computer prescription device and securely transmit the prescription to pharmacies using a special software program and connectivity to a transmission network.⁴

(tt) "NCPDP" means the National Council for Prescription Drug Programs.

(uu) "Prescriber" means a health care provider licensed to prescribe medication or medical devices in the state.⁵

(vv) "Real-time benefit tool" or "RTBT" means an electronic prescription decision support tool

that is capable of integrating with prescribers' electronic prescribing and electronic health record systems. A new Part 98 Section 1.23 is added to read as follows:⁶

A new Part 98 Section 1.23 is added to read as follows:

98-1.23 Standards for Real-Time Benefit Tools

- a. Plans implementing RTBTs are required to use an NCPDP Real-Time Pharmacy Benefit (RTPB) Standard in their implementation.
- b. Plans must communicate drug cost, benefit and coverage data according to an NCPDP RTPB Standard to PBMs or other entities implementing RTBTs on their behalf.
- c. Plans subject to (a) of this Part shall determine the applicable NCPDP RTPB Standard by using:
 - i. the most recent version of the NCPDP RTPB Standard, or
 - ii. the most recent version of the NCPDP RTPB Standard adopted by a relevant federal or state governing body, including the Center for Medicare & Medicaid Services (CMS) or the Office of the National Coordinator for Health Information Technology (ONC).⁷
- d. If the version corresponding to (c)(i) or (c)(ii) changes, the Department of Health may set a compliance date of at least one year and no more than two years from the date that existing RTBTs must be compliant with the new version.
- e. The Department of Health may audit any plans to whom this Part is applicable at any time.
- f. Plans may submit a written request to the Department for an extension, variance, or waiver of completing implementations using the RTPB Standard. The written request shall include: the specific requirement to be extended, varied, or waived; an explanation of the reason or cause; the methodology proposed to eliminate the need for future extension, variance, or waiver; and the time frame required to come into compliance. Plans are permitted to submit one request per compliance deadline, or per granted extension, variance or waiver. The Department can choose to grant extensions, variance and waivers at its discretion. If a request is pending with the Department, plans are not granted any intermediate extensions, variance or waivers, and will be held to the most recent compliance requirements.
- g. Any plan that violates this section shall be liable pursuant to the provisions of the Public Health

Law, including, but not limited to, sections 12 of the Public Health Law, and applicable sections of New York State Insurance Law and regulations.⁸

Summary of the Regulatory Impact Statement

STATUTORY AUTHORITY

Public Health Law (PHL) § 4403 enables the Commissioner to adopt and amend rules and regulations in service of Article 44. This includes rules and regulations to ensure health maintenance organizations meet the following criteria listed in PHL § 4403:

“(b) it has the capability of organizing, marketing, managing, promoting and operating a comprehensive health services plan;

(c) it is financially responsible and may be expected to meet its obligations to its enrolled members.”⁹

It is not new for the Department of Health to name a standard in regulation. The Department of Health has previously been directed to regulate healthcare information technology standards in PHL § 4903. For example, in PHL § 4903, the Commissioner of Health and the Superintendent of Financial Services are directed to establish an electronic prior authorization standard.¹⁰

PURPOSE OF REGULATION

Prior authorization—the process of getting a health insurer’s approval before a physician provides a treatment¹¹—has been shown to harm patients’ access to treatments by delaying timely healthcare.¹² RTBTs are a software product that can decrease how PAs harm patients by giving physicians real-time access to PA information and by helping physicians avoid PAs altogether.¹³ However, because RTBTs today vary in the RTPB standards they follow, RTBTs have not yet realized their potential in addressing the harms of PA.

BENEFITS OF REGULATION

Establishing a single RTPB standard would define one set of technical specifications that insurers must meet when implementing RTBTs. Because RTBTs today vary in the RTPB standards they follow, RTBTs are inconsistent in their usability and reliability.

Requiring all New York insurers to meet the NCPDP RTPB standard when implementing RTBTs will

make RTBTs more usable and more reliable. They will be more usable because the heterogeneous RTBT landscape—which physicians laboriously navigate—will be transformed to a unified experience. And they will be more reliable because the NCPDP RTPB standard requires insurers to provide cost and coverage information important to patient care, which is omitted by other alternative standards. As a result, physicians will be more able to use RTBTs to prevent care delays and denials due to PA.

STATE AND LOCAL COST

There are minimal expected state and local costs for this rule.

COSTS TO REGULATED ENTITIES

[CMS-4180-F](#) requires Part D plan sponsors to implement RTBTs that integrate with at least one electronic prescribing system or electronic health record. In that rule, they determined that the implementation provided “qualitative savings.” Because of the complicated nature of calculating drug cost savings associated with an RTBT, they provided qualitative evidence that the implementation of RTBTs should not be a meaningful cost to plans.¹⁴ This should be agnostic of the standard that’s used, inclusive of the NCPDP RTPB Standard.

DUPLICATION

This regulation does not conflict with any state or federal rules.

Federal

The final rule [CMS-4180-F](#) requires Part D plan sponsors to implement RTBTs. However, it does not name a standard for the RTBTs.¹⁵ [HR133](#) asks the Department of Health and Human Services to establish a standard.¹⁶ HHS has not yet established a standard. The expected action from HHS will be for CMS to set the NCPDP RTPB standard for Medicare and Medicaid plans.

State

In New York State, [Senate Bill 4620A](#) asks state plans to implement RTBTs by July 1, 2023, but also does not name a specific standard.¹⁷

ALTERNATIVES

Other standards that are in use for pharmacy benefit information are:

- NCPDP SCRIPT Standard
- NCPDP Telecommunications Standard
- HL7 Consumer Real-time Pharmacy Benefit Check Standard

It is determined that compared to these three alternative standards, the NCPDP RTPB Standard is the best standard for insurers to use in their RTBT implementations. This was determined by assessing if the technical transactions defined in each standard meet a list of RTBT requirements. The list of RTBT requirements we used in this assessment is taken from Senate Bill 4620A,¹⁸ an RTBT bill in New York State. More information about a comparison of the different standards can be found [here](#).

COMPLIANCE SCHEDULE

There are no compliance schedules required for this rule.

Endnotes

- 1 This header was derived from text in existing proposed regulation. Source: “All Payer Database,” Proposed Regulations, New York State Department of Health, last modified August 31, 2016, <https://regs.health.ny.gov/sites/default/files/proposed-regulations/All%20Payer%20Database.pdf>.
- 2 This definition was derived from existing law. Source: Public Health Law, Consolidated Laws of New York (2021), § 280-a.
- 3 This definition was derived from an existing bill. Source: New York State Legislature, Senate, Enacts the “Patient Rx Information and Choice Expansion Act,” SB 4620A, 2021-2022 Legislative Session, 2nd sess., introduced in Senate February 8, 2021, <https://www.nysenate.gov/legislation/bills/2021/s4620>.
- 4 This definition was derived from an existing bill, as cited in footnote 3.
- 5 This definition was derived from an existing bill, as cited in footnote 3.
- 6 This definition was derived from an existing bill, as cited in footnote 3.
- 7 CMS and ONC are named as relevant governing bodies as they were the agencies named in an existing bill, as cited in footnote 3.
- 8 The language for (e), (f) and (g) defining the Department’s means of governance are derived from existing DOH regulation. Source: “APD Data Submission,” New York Codes, Rules and Regulations, Title 10 (2021): Section 350.2, <https://regs.health.ny.gov/volume-c-title-10/373299820/section-3502-apd-data-submission>.
- 9 Public Health Law, Consolidated Laws of New York (2021), § 4403.
- 10 Public Health Law, Consolidated Laws of New York (2021), § 4903.
- 11 Lee Ann Stember, “The Practice Manager’s Impetus for a Real-Time Prescription Benefit Standard,” Medical Group Management Association, August 14, 2019, <https://www.mgma.com/resources/health-information-technology/the-practice-manager%E2%80%99s-impetus-for-a-real-time-pre>.
- 12 “2020 AMA Prior Authorization (PA) Physician Survey,” American Medical Association, last modified April 2020, <https://www.ama-assn.org/system/files/2021-04/prior-authorization-survey.pdf>.
- 13 “NCPDP Foundation RTPB Grant: Final Report,” Johns Hopkins Medicine, accessed October 15, 2021, http://ncdpfoundation.org/pdf/NCPDPFoundationRTPBGrant_FinalReport.pdf.
- 14 “Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses,” Code of Federal Regulations, title 42 (2019), <https://www.federalregister.gov/documents/2019/05/23/2019-10521/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses>.
- 15 *Id.*
- 16 U.S. Congress, House, Consolidated Appropriations Act, 2021, HR 133, 116th Cong., 1st sess., introduced in House January 3, 2019, <https://www.congress.gov/bill/116th-congress/house-bill/133>.

17 New York State Legislature, Senate, Enacts the “Patient Rx Information and Choice Expansion Act,” SB 4620A, 2021-2022 Legislative Session, 2nd sess., introduced in Senate February 8, 2021, <https://www.nysenate.gov/legislation/bills/2021/s4620>.

18 *Id.*