



June 27, 2023

Michelle Baass
Director
California State Department of Health Services
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

The Honorable Ricardo Lara
Insurance Commissioner
California Department of Insurance
300 Capitol Mall, 17th Floor
Sacramento, CA 95814

Sent via electronic mail

Dear Ms. Baass and Commissioner Lara:

Re: Section 1367.207 of the Health and Safety Code and Section 10123.204 of the Insurance Code added by Assembly Bill 2352 Prescription drug coverage

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) Accredited Standards Developer (ASD) consisting of more than 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors 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 business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system. For over 40 years, NCPDP has been committed to furthering the electronic exchange of information between healthcare stakeholders.

NCPDP is writing to provide information to you about its Real-Time Prescription Benefit (RTPB) Standard and how it relates to the intent of the above referenced sections and a conflict with the definition of standard Application Programming Interface (API) in the sections. While the NCPDP RTPB Standard provides the transparency the sections are seeking, the API definition referenced is not in alignment with the NCPDP RTPB Standard which supports providing patient out-of-pocket costs and other information the statute is requiring at the point of prescribing.

NCPDP RTPB Standard

NCPDP developed the RTPB Standard to enable the real-time exchange of patient-specific formulary and benefit information between providers/prescribers and pharmacy benefit managers (PBMs)/processors. The RTPB standard contains two different syntaxes, Extensible Markup Language (XML) and Electronic Data Interchange (EDI). NCPDP's Member Source™ API solutions can be implemented to comply with NCPDP's operating rules to support the XML format of RTPB with REST and SOAP protocols.

NCPDP's RTPB Standard and Member Source™ API solutions support the requirements in the recent additions to the Section 1367.207 of the Health and Safety Code and Section 10123.204 of the Insurance Code:

Upon request of an enrollee or an enrollee's prescribing provider, furnish all of the following information regarding a prescription drug to the enrollee or the enrollee's prescribing health care provider:

(A) The enrollee's eligibility for the prescription drug.

(B) The most current formulary or formularies.

(C) Cost-sharing information for the prescription drug and other formulary alternatives, consistent with cost-sharing requirements as set forth in the contract and accurate at the time it is provided, including any variance in cost sharing based on the patient's preferred dispensing pharmacy, whether retail or mail order, or the health care provider.

(D) Applicable utilization management requirements for the prescription drug and other formulary alternatives.

(2) Respond in real time to a request made pursuant to paragraph (1) through a standard API.

The RTPB Standard request transaction may be submitted to any processor with an Issuer Identification Number (IIN) and allows for the transmission of information about the patient, their insurance identifiers, a product, the prescriber, the patient's preferred pharmacy and any diagnosis code.

The response transaction has been designed to provide information about the patient's eligibility and the preferred pharmacy's network participation status. For the submitted product, information is provided regarding its coverage status, any coverage restrictions, and estimated patient financial responsibility amount for the pharmacy on the request as well as up five alternative pharmacies. The response also supports information about up to ten alternative products. In addition, to the estimated financial responsibility, the estimated plan cost or estimated combined plan and patient savings may also be communicated when allowed by the plan.

On December 14, 2022, the Centers for Medicare & Medicaid Services released a Notice of Proposed Rulemaking (NPRM) CMS-4201-P that put forth a proposal to adopt Version 12 of the NCPDP RTPB Standard as the standard for prescriber real-time benefit tools. Additionally, the Office of the National Coordinator for Health Information Technology has expressed their intention to consider the adoption of and reference to the NCPDP RTPB Standard as part of a potential establishment of a real-time prescription benefit health IT certification criterion in their Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing NPRM.

However, in Section 1367.207 of the Health and Safety Code and Section 10123.204 of the Insurance Code, the definition for standard API "means an application interface that is standardized for vendors to conform to in order to access the information pursuant to Section 170.215 of Title 45 of the Code of Federal Regulations" and the Federal Code only references HL7® FHIR® solutions. The implementation guides and resources of HL7® FHIR® mentioned in the Federal Code do not meet all the requirements outlined in the newly added Section 1367.207 of the Health and Safety Code and Section 10123.204 of the Insurance Code. Consequently, implementers will need to use extensions and improvised solutions to meet the requirements.

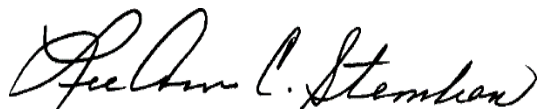
As you implement and enforce Section 1367.207 of the Health and Safety Code and Section 10123.204 of the Insurance Code, NCPDP appreciates your consideration of the information we have provided about the use and utility of the RTPB Standard in the pharmacy industry today and the conflict highlighted

between RTPB and the FHIR® resources incorporated by reference in the legislation. NCPDP welcomes the opportunity to serve as subject matter experts on the RTPB Standard and to work with the California State Department of Health Services and the California Department of Insurance if further education or clarification is needed.

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

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Respectfully,



Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)

cc:

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