June 20, 2023

Office of the National Coordinator for Health IT
Department of Health and Human Services
Attention: HTI-1 Proposed Rule
Mary E. Switzer Building
Mail Stop: 7033A
330 C St. SW, Washington D.C. 20201
Submitted to regulations.gov

Re: HTI-1 Proposed Rule

To Whom It May Concern:

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.

NCPDP appreciates the opportunity to review and submit comments to the Office of the National Coordinator for Health Information Technology (ONC) on its Proposed Rule: *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1).* NCPDP's comments focus on *Section G, 2. Request for Information; Request for Information on Pharmacy Interoperability Functionality Within the ONC Health IT Certification Program Including Real-Time Prescription Benefit Capabilities,* on pgs. 23848 - 23855.

a. Background

ONC requests comment from the public about specific issues related to establishing a certification criterion utilizing NCPDP RTPB standard version 12, as well as other potential actions in the Program that could support complementary and interoperable workflows.

NCPDP Response: If ONC were to establish a certification criterion, NCPDP supports utilizing the NCPDP Real-Time Prescription Benefit (RTPB) Standard. The NCPDP RTPB Standard Version 12 (Version 12) was published in October 2021. Since that time, enhancements have been made to the RTPB Standard which are needed by the industry, resulting in NCPDP RTPB Standard Version 13 (Version 13). Enhancements to Version 13 include:

- Added Coverage Status Message to assist in communicating coverage information at a product level which is not codified. By adding this field, the payer will be able to communicate important information regarding coverage and provide clarifying or additional information.

- Added values to the Coverage Restriction Code and data elements to the RTPB Standard to codify information communicated in the Message to reduce the number of free text messages on the response.
- Added next available fill date to communicate when the patient is eligible to receive a prescription refill in a discrete field instead of via a free text message.
- Added fields to communicate formulary status and preference level. This allows for the communication of the formulary status of both submitted product and alternative products to help understand pricing on the response.
- Added data elements to convey the patient's address, state/province, zip/postal code and country on the request transaction to aid in coverage determination.

NCPDP recently submitted comments[1] to CMS-4201-P in response to CMS's proposal for the adoption of Version 12. In its comments, NCPDP supported the adoption of the RTPB Standard as proposed but prefer CMS name Version 13 to benefit from the enhancements outlined above. Similarly, should ONC propose to establish criterion utilizing the RTPB Standard, NCPDP suggests utilizing Version 13 now, instead of in the future, as it will help in future migrations and enables immediate use of the new enhancements. If ONC were to adopt certification criterion for a real-time benefit tool, they should align with CMS Part D rulemaking to ensure both regulatory bodies are using the same version of the standard.

On page 23849 of the Proposed Rule, ONC states that with the initiation and use of the RTPB Standard, "when the patient arrives at the pharmacy, the medication could be filled and dispensed immediately, and the patient would already be aware of price and copay responsibility information. This scenario is only one of many possibilities." NCPDP would like to clarify the RTPB Standard will only provide an *estimate* of the patient financial responsibility, because each RTPB transaction (request and response) reflects a moment in time and is designed to provide an estimate of the patient's out of pocket costs. A patient's actual out of pocket cost may vary depending on the timing between the RTPB request(s) and the corresponding NCPDP claim billing request/response transactions, as well as the order of the claim billing transactions when multiple prescriptions are dispensed and pharmacy submitted data that impacts pricing.

c. Real-Time Prescription Benefit Certification Criterion

i. Potential Transactions and Capabilities to Test

ONC seeks comment on whether inclusion of the proposed testing scenarios under a real-time prescription benefit certification criterion would effectively test a certified Health IT Module's capacity to successfully send and receive RTPB transactions in accordance with the NCPDP RTPB standard version 12.

NCPDP Response: The RTPB 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, facilitating the ability for pharmacy benefit payers/processors to communicate to providers.

[1] National Council for Prescription Drug Programs. Proposed Rule CMS-4201-P. February 13, 2023. Available at: https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2023/20230213_To_CMS_CMS_4201_P_NPRM.pdf.

ONC Question:

i. Is the set of testing scenarios described above appropriate for a real-time prescription benefit certification criterion?

ONC Proposed Testing Scenario

- *"To receive a response correctly displaying Out-of-Network provider;"*

  NCPDP Response: The RTPB Standard does not support a response that indicates if a provider (prescriber) is out of network. NCPDP requests the testing scenario of "To receive a response correctly displaying Out-of-Network provider" be removed. The standard does support communication of a provider's status if the patient is restricted to who may prescribe the requested medication for them. NCPDP recommends replacing the testing scenario of "to receive a response correctly displaying the submitted provider is not an allowed provider" with a testing scenario of "To receive a response correctly displaying the restriction of a patient to a specific prescriber."

ONC Proposed Testing Scenario

- *"To receive status and error messages such as "Transmission accepted and transaction processed," "Transmission accepted and transaction not processed," and "Transmission rejected, and transaction not processed" for different scenarios."*

  NCPDP Response: The terms "status and error messages" may cause some confusion for those seeking certification. In the RTPB Standard, to effectively communicate transmission and transaction statuses, the Header Response Status (501-F1) and the Transaction Response Status (112-AN) are used in the EDI format and the RTPBResponse/Response based message is used in the XML format. Both formats support messaging identifying if a transmission is accepted/not accepted or a transaction is processed/not processed.

ONC Proposed Testing Scenario

- *"Transmission accepted and transaction processed," "Transmission accepted and transaction not processed,"*

  NCPDP Response: NCPDP recommends the removal of "Transmission accepted and transaction processed" and "Transmission accepted and transaction not processed" because they are inherently included in the other test scenarios already identified. Scenarios appropriate for "Transmission rejected, and transaction not processed" would be:
  - To receive a response correctly displaying there is missing or invalid information.
  - To receive a response indicating various other errors such as "Transaction not processed", or "Time Out".

ONC Question:

ii. Should ONC consider other testing scenarios as part of a real-time prescription benefit certification criterion?

NCPDP Response: NCPDP recommends additional testing scenarios related to the functionality supported by the enhancements to the NCPDP RTPB Standard Version 13 if Version 13 is adopted.

- To receive a response correctly displaying Coverage Status Message when applicable.

- To receive a response correctly displaying the next available fill date when prescription is not eligible for dispensing until a specified date.
- To receive a response correctly displaying formulary status and preference level, when applicable.

ONC Question:

iii. Are there other testing considerations ONC should take into account in structuring a real-time prescription benefit certification criterion?

NCPDP Response: NCPDP also recommends ONC organize the test scenarios based on coverage restriction codes and reject codes as follows (NCPDP Proposed Scenarios in **Bold**):

Specifically, ONC is considering a set of scenarios in which the Health IT Module under test would need to demonstrate capacity:

- To allow end users to choose a specific patient, product, and pharmacy, then successfully transmit a request for patient and product specific benefit information directly to a Pharmacy Benefit Manager (PBM), or optionally to a PBM through an intermediary;
- To receive a response correctly displaying price and coverage details of the submitted and covered products, including alternative pharmacies or medications;
- To receive a response correctly displaying a Drug Utilization Evaluation (DUE) Alert;
- To receive a response correctly displaying Prior Authorization is required;
- To receive a response correctly displaying other restrictions to a patient's coverage including;
    - To receive a response correctly displaying a component of the request (e.g., quantity) is not covered;
    - To receive a response correctly displaying the identified product is considered a benefit exclusion;
    - **To receive a response correctly displaying the restriction of a patient to a specific prescriber.**
    - **To receive a response correctly displaying Coverage Status Message when applicable.**
    - **To receive a response correctly displaying the next available fill date when prescription is not eligible for dispensing until a specified date.**
    - **To receive a response correctly displaying formulary status and preference level, when applicable.**
- To receive a response indicating the transaction was rejected due to an error including;
    - To receive a response correctly displaying a message indicating "Patient not found" or "Patient not eligible;"
    - To receive a response correctly displaying the restriction of a patient to a specific prescriber.
    - **To receive a response correctly displaying there is missing or invalid information.**
    - **To receive a response indicating various other errors such as "Transaction not processed", or "Time Out".**

ONC Question: *ONC seeks comment on the value of negotiated price to patients and prescribers to aid in their discussions and decision-making during prescribing.*

NCPDP Response: NCPDP does not support inclusion of negotiated price in the RTPB transaction. First and foremost, prescribers should consider the financial impact to the patient, and any financial consideration that may impact their bottom line should be secondary when selecting a product to prescribe. While some prescribers may also be dispensers, the RTPB transaction should not be used to communicate a plan paid amount since it is included in a pharmacy claim transaction. The RTPB standard supports the inclusion of estimated patient financial responsibility, including deductible and copay amounts. NCPDP would consider a request to add, to a future version, an indicator to inform the prescriber the requested medication may put the member into a different benefit tier or they may reach their maximum annual benefit.

The negotiated price is just that, an amount negotiated between two parties (pharmacy and payer), often covered by contractual terms that preclude sharing the information with other parties. If payers believe it is important to communicate payer/pharmacy negotiated price to prescribers and doing so will benefit members and "prescribers to aid in their discussions and decision-making during prescribing", the use case can be brought forth to NCPDP and addressed for consideration in a future version of the RTPB Standard. NCPDP would explore alternative methods of providing relative payer cost of alternative medications without degrading payer system processing times or revealing proprietary contract information.

ii. Requirements for Use of XML or EDI Format

ONC is seeking comment on whether the real-time prescription benefit certification criterion under consideration should only require and test XML format or both XML and EDI formats.

NCPDP Response: The RTPB standard contains two different syntaxes for the exchange of real-time prescription benefit information (XML and EDI). ONC should provide test tools allowing systems to certify using the format(s) they have chosen to implement. The RTPB standard does not require implementers support both syntaxes and allows for implementers to use intermediaries to facilitate the translation between the two syntaxes, so the certification criterion should only require testing against one format. The industry has shown this approach works. As ONC notes, when the NCPDP SCRIPT Standard Version 10.6 supported both EDI and XML and was required by ONC for certification and by CMS for Part D prescriptions, translation could occur and did not pose barriers to interoperability when transmitting prescriptions between prescribers and pharmacies.

iii. Requirements for Use of NDC or RxNorm Codes

ONC requests comment on whether a potential real-time prescription benefit certification criterion should require demonstration of compliance with both NDC and RxNorm.

ONC Question: *Would requiring demonstration of compliance with both NDC and RxNorm in a real-time prescription benefit criterion support improved adoption, maintenance, and harmonization between code sets?*

NCPDP Response: No. Pharmacy claims using the NCPDP Telecommunication Standard use the code sets defined by the NCPDP Product Identifier Standard which includes National Drug Code (NDC), Universal Product Code (UPC), National Health Related Item Code (NHRIC), and Unique Device Identifier (UDI), but does not include RxNorm. Real Time Prescription Benefit integration closely mimics the pharmacy claims submission process, so if pharmacy benefit managers do not process claims using RxNorm codes it is unclear if there is any benefit to EHRs supporting RxNorm if a pharmacy benefit manager will not use the data.

ONC Question: *Would either NDC or RxNorm alone provide sufficient information for applications to provide reliable, accurate clinical decision support, such as dosing guidance, drug drug interaction or drug allergy checks?*

NCPDP Response: USCDI V3 Allergies and Intolerances class Substance (Drug Class) element uses the SNOMED CT code system. Thus, regardless of whether the real-time prescription benefit feature used NDC or RxNorm it would also need the ability to check using SNOMED CT. This means a mapping between code systems as well as ontology. Today, dosing guidance, drug-drug interactions and other checks (drug utilization review/evaluation) are performed using the NDC.

ONC Question: *What would be the consequences (positive or negative, intended or unintended) of establishing "RxNorm as the single source of clinical data for clinical care, research and administrative workflows, replacing NDC for such purposes," as recommended by the HITAC?*

NCPDP Response: In 2021, NCPDP submitted comments to ONC via the Health Information Technology Advisory Committee (HITAC) on its recommendation to treat RxNorm as the source terminology set for electronic prescribing standards and to use RxNorm as the single source of clinical data for clinical care, research, and administrative workflows, replacing NDC for such purposes.[2] In its letter, NCPDP strongly opposed replacing the use of the National Drug Code (NDC) with RxNorm values due to patient safety concerns and the disruptive impact such a change would have on the pharmacy industry.

NCPDP remains concerned with utilizing RxNorm as the single source of clinical data for clinical care, research, and administrative workflows. While RxNorm is useful for communication of clinical data for clinical care, the NDC is critical for specific product identification in research, dispensing and administrative workflows. The NDC is the key, unique, product identifier and is the standard of practice used throughout the pharmacy industry to identify the specific product. The industry heavily relies on the NDC in all aspects of its business, including, but not limited to, drug ordering, medication dispensing, reporting, billing and patient safety. RxNorm lacks the specificity required to uniquely identify a product and utilizing it as the single source terminology set would compromise patient safety and unnecessarily increase healthcare administrative burden and cost.

ONC should also consider NDC is named in HIPAA and utilized by multiple governmental agencies, including but not limited to:

[2] National Council for Prescription Drug Program. Health Information Technology Advisory Committee (HITAC); ISP-TF-2021_Recommentation 03 – Foundational Standards – Terminology. 2021. Available at https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2021/NCPDPLettertoONConRxNorm.pdf.

- the FDA, to report adverse events,
- the DEA, to report products excepted from their otherwise assigned schedule, and
- CMS, for rebates and drug formularies.

These agencies could not migrate from NDC to RxNorm as the key product identifier since the required specificity is lacking for multisource drugs in RxNorm.

Additionally, formulary management, prescription claim billing/product dispensing, prior authorization, real time prescription drug benefit, drug rebates, etc. would be impacted since these processes require precise and specific product information, including package size and manufacturer, which can only be provided via NDC. Payers and manufacturers rely on the use of the NDC in pharmacy transactions.

Given the concerns outlined above and in NCPDP's 2021 letter to ONC, NCPDP continues to support the use of both RxNorm and NDC without replacing NDC for RxNorm as the single source of clinical data for clinical care, research and administrative workflows.

iv. ICD-10-CM and SNOMED-CT in the Clinical Segment

ONC seeks comments that may help inform their consideration on whether to require the Clinical Segment in the NCPDP RTPB standard version 12 as part of any future real-time prescription benefit certification criterion, and whether to require that Health IT modules under pre-certification testing, real world testing after certification, and (as applicable) ONC-ACB's in the field surveillance for such criterion demonstrate use of both ICD-10-CM and SNOMED CT within the clinical segment.

NCPDP Response:

The RTPB standard supports sending a primary and secondary diagnosis where one code/qualifier can be sent for each diagnosis depending on what the receiver requires. Given this structure, both ICD-10 and SNOMED cannot be sent for a single diagnosis. Currently, ICD-10 is the preferred code set used by pharmacies and pharmacy benefit managers and has been mandated for use by HIPAA. Therefore, requiring EHRs to send SNOMED codes may create an interoperability challenge if the receiving entity does not support that code set. The use of mapping could help to ensure the interoperable exchange of information.

v. Patient Specific Benefit Information

ONC is requesting comment on whether a real-time prescription benefit certification criterion should require conformance to the Patient Segment specified in NCPDP SCRIPT standard version 2022011 (replacing the NCPDP RTPB standard version 12 Patient (Demographic) Segment) to support the identification and linkage of records needed to support the successful exchange of patient-specific benefit information, specifically:

***ONC Question:** Would requiring the Patient Segment identified in NCPDP SCRIPT standard version 2022011 as part of a real-time prescription benefit certification criterion support improved patient matching?*

NCPDP Response: NCPDP is not aware of patient matching issues with the RTPB Standard and would like ONC to clarify what patient matching issues with RTPB they are seeking to resolve. The matching process with RTPB is the same method that is used in the claims adjudication process to validate a patient which has been successful for decades. Any patient matching issues with RTPB are more likely to evolve from inaccuracies in patient information at the point of data input. Requiring additional information, such as the Patient Segment, would not resolve manual data input inaccuracies which is the main issue leading to system mismatches.

ONC Question: *What additional burden would requiring the Patient Segment identified in NCPDP SCRIPT standard version 2022011 as part of a real-time prescription benefit certification criterion impose on health IT developers seeking to certify Health IT Modules to this criterion?*

NCPDP Response: The NCPDP Formulary and Benefit Standard does not include a patient segment. Furthermore, the patient segment in the NCPDP SCRIPT Standard cannot be interchanged into the RTPB Standard nor the F & B Standard. These are each unique standards with individual schema that cannot be intermingled and would therefore not be feasible.

ONC Question: *Should ONC consider requiring alternative or additional demographic data elements or sets of demographic data elements as part of a real-time prescription benefit certification criterion to further improve patient matching? For instance, should ONC consider requiring the Patient Demographics/Information data class identified in USCDI Version 3? What additional benefit would this offer to health IT developers, health care providers, patients, and the healthcare industry in general? What additional burden would these or other alternatives impose on health IT developers?*

NCPDP Response: It is not reasonable to require the full USCDI V3 Patient Demographics/Information data class for this purpose because some data elements such as "Related Person's Name" and "Occupation" are irrelevant to this use case.

vi. System and Workflow Integration

ONC is seeking comment on how to address the statutory requirements and policy goals for the criterion with respect to workflow and data integration.

NCPDP Response: While NCPDP does not manage workflow and data integration, NCPDP standards are built by a diverse group of industry stakeholders who keep system workflow and integration top of mind throughout the entire standards development process from concept development to new standards and updates to existing standards.

vii. Real Time Prescription Benefit Certification Scope

ONC Notes, "*the NCPDP RTPB standard version 12 will continue to mature and evolve over time in response to new or unidentified challenges and as needs emerge."*

NCPDP Response: NCPDP continuously updates, enhances, or creates new standards based on needs that are identified by its membership. For example, enhancements were made to the RTPB Standard to address industry needs which resulted in NCPDP RTPB Standard Version 13 as noted in a previously answered question above. Therefore, if ONC were to establish a certification criterion for RTPB, NCPDP supports utilizing Version 13. Enhancements to Version 13 are also

outlined in NCPDP's recently submitted comments[3] to CMS-4201-P in response to CMS's proposal for the adoption of Version 12.

ONC is requesting comments on whether a real-time prescription benefit criterion should also require demonstration of support for products that are not defined as medications but may also be included in a RTPB transaction, namely vaccines and medical devices or supplies.

***ONC Question**: Specifically, what challenges would be involved in supporting the exchange of prescription benefit information for vaccines, medical devices, or supplies? What additional burden would exchange of information on vaccines, medical devices, or supplies as part of a certification criterion impose on health IT developers?*

NCPDP Response: NCPDP standards support the identification of products and services via multiple product/service identifier code sets. The RTPB Standard supports these code sets. However, today's industry only supports code sets used in the pharmacy benefit including identification of products such as drugs, vaccines, or devices. Because the industry does not currently support all code sets supported by the standard, two conditions currently must be met to use the RTPB Standard for vaccines and devices: (i.) A vaccine must have an assigned NDC or a device must have a UPC that is reformatted to comply with the NCPDP Product Identifier Standard. This is managed by the drug compendia. Additionally, the vaccine or device must be covered under the pharmacy benefit. For vaccines, there is limited submission of RTPB transactions because they are frequently billed under the patient's medical benefit. For devices, there is limited submission of RTPB transactions because, so few are covered under the pharmacy benefit. Regarding certification criterion challenges, NCPDP recommends ONC limit vaccine and device certification criteria to products assigned an NDC, or UPC reformatted according to the NCPDP Product Identifier Standard and covered under the pharmacy benefit (e.g., blood glucose monitoring devices). ONC should be mindful of current rulemaking in progress by the FDA to revise the NDC format and drug product barcode label requirements that could affect current identifiers for medications and drug products. In addition, the industry has not migrated to support the UDI.

***ONC Question:** Alternatively, should ONC require conformance to the NCPDP Formulary and Benefit Standard for devices? The NCPDP Formulary and Benefit Standard supports the exchange of UDIs for devices, and adoption of this standard may support other critical RTPB processes. What are effective ways to support accurate device identification within and beyond the real-time prescription benefit workflow, while aligning with FDA regulations and related requirements? What additional opportunities might arise from requiring conformance to the NCPDP Formulary and Benefit Standard?*

NCPDP Response: The Formulary & Benefit (F&B) and RTPB standards are complementary. With minimal data entry by the prescriber, F&B provides group-level coverage information that helps guide the prescriber to the optimal prescription. RTPB provides member-specific drug pricing

[3] National Council for Prescription Drug Programs. Proposed Rule CMS-4201-P. February 13, 2023. Available at: https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2023/20230213_To_CMS_CMS_4201_P_NPRM.pdf.

based on the prescription details. When prescribing, the first drug benefit information displayed is F&B. It can appear early in the workflow in locations such as the physician favorites, the renewals queue and the drug search. F&B can provide group/plan level formulary status, copay, PAs and other coverage restrictions. When the drug is selected in F&B, drug alternatives may appear depending on its formulary status. After the drug has been confirmed in F&B, the prescriber continues writing the prescription including entering pharmacy, quantity and days supply in order to run an RTPB transaction. The provider can confirm coverage and see the price of the requested drug as well as additional alternatives in RTPB. After confirming benefit information via both F&B and RTPB, the prescriber sends the prescription to the pharmacy.

d. Health IT Ecosystem for Pharmacy Interoperability

i. Formulary and Benefit Management

ONC seeks information on formulary and benefit management and electronic prior authorization capabilities that work in tandem with real-time prescription benefit functionality in the context of electronic prescribing workflows.

NCPDP Response: Today, the prior authorization (PA) process involves prescribers, payers, pharmacists and patients in a cumbersome flow of information which may result in delays in treatment and dissatisfaction for all. Prescribers are often not aware that a prior authorization review is needed until the prescription claim is rejected at the pharmacy. Widespread industry implementation of ePA in the beginning of the provider workflow through the use of the F & B Standard to indicate that a prior authorization may be necessary and RTPB which will confirm the PA requirement expedites patient access to their needed medications. As a result, it helps reduce the administrative burden for providers, pharmacists and health plans, and support enhanced delivery and experience of care which is a core pillar of the 2020 - 2025 Federal Health It Strategic Plan. For example, research from an NCPDP foundation funded grant supported the use of both the NCPDP F&B and RTPB standards. The research confirmed when the F&B Standard is used in conjunction with the RTPB Standard, prescribers have a complete view of patient-specific medication options and costs to select the most clinically appropriate medication at the point of care[4].

ONC Question: *Should ONC propose a new certification criterion that would enable a user to use a Health IT Module to obtain formulary and benefits information using a more recent NCPDP Formulary and Benefit standard?*

NCPDP Response: On November 6, 2020, NCPDP sent a letter[5] to CMS recommending adoption of the NCPDP Formulary and Benefit Standard Version 53 for Part D recipients. On May 10, 2022,

[4] Formulary & benefit and real-time pharmacy Benefit: Electronic standards delivering value to prescribers and pharmacists. Available at: https://www.japha.org/article/S1544-3191(23)00016-X/fulltext

[5] National Council for Prescription Drug Programs. November 6, 2020. Available at: https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2020/20201106_to_CMS__FormularyAndBenefitNextVersionRequest.pdf

NCPDP rescinded this request[6] due to concerns around backward compatibility, and as such ONC should not use Version 53 if they were to adopt a certification criterion for Formulary and Benefit. On April 4, 2023, NCPDP sent a letter[7] to CMS recommending the adoption of the NCPDP Formulary and Benefit Standard Version 60 (Version 60). If ONC were to adopt certification criterion it should align with the version named by CMS.

The Formulary and Benefit Standard has been updated to Version 60 to meet industry needs and current usage. Updates include the following: All files (lists) have been normalized, which allows for smaller files and reusability, and have expiration dates. The alternative and step medication files have been redesigned to reduce file sizes and to include support for reason for use (diagnosis). The step medication files now support a more complex step medication program. Coverage files have been updated to include support for electronic prior authorization and specialty drugs. The copay files have been updated to allow a minimum and maximum copay range without a percentage copay.

NCPDP does not recommend new certification criterion that would enable a user to use a Health IT Module to obtain formulary and benefits information. Our understanding is ONC certification requirements would only certify the transaction itself and would remove the ability to utilize translations and other approved methodologies of providing Version 60 data.

ONC Question: *What are the key benefits health care providers would likely experience from availability of functionality within certified health IT utilizing the most recent NCPDP Formulary and Benefit standard? If formulary check capabilities have already been widely adopted, how would certification of these capabilities benefit providers?*

NCPDP Response: As recognized earlier, the F&B standard provides significant value to prescribers based on its maturity as a standard and ubiquity in EHRs as part of embedded provider workflow. F&B was created to help providers understand their patient's drug benefit information at a glance early in the prescribing process. This helps lower costs for patients, reduces delays in treatment, and makes prescribing more efficient by reducing call backs and prescription rewriting. F&B answers questions like: Is the drug covered? Does the drug have a prior authorization? What are the more benefit preferred options? Are there any quantity limits? There are numerous studies that demonstrate F&B's value to providers and care delivery in general by reducing drug costs and improving adherence, and F&B should continue to play a role in the prescribing process and complement the RTPB Standard.

Regarding the question: "...how would certification of these capabilities benefit providers?", NCPDP is not aware of how an ONC certification would further improve the prescriber experience.

ii. Electronic Prior Authorization

[6] National Council for Prescription Drug Programs. May 10, 2022. Available at: https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2022/Rescind-Formulary-and-Benefit-Request.pdf).

[7] National Council for Prescription Drug Programs. April 4, 2023. Available at: https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2023/20230404-to-CMS-Formulary-and-Benefit-V60-Request.pdf

ONC invites comments on the potential incorporation of these transactions into the "Electronic prescribing" certification criterion and whether we should consider requiring certification to these transactions in a future rulemaking.

NCPDP Response: The integration of RTPB and electronic prior authorization (ePA) can assist in alleviating medication access issues by initiating the ePA process in the point of care workflow while the prescriber enters a new prescription. This should be a consideration of ONC when deciding on requiring certification to these transactions in future rulemaking.

NCPDP and its members appreciate the opportunity to provide comments to ONC as they relate to the NCPDP Real-Time Prescription Benefit Standard capabilities and pharmacy interoperability within the ONC Health IT Certification Program. NCPDP looks forward to serving as a trusted partner and resource should ONC consider developing future rulemaking.

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)