SUBMITTED VIA ELECTRONIC MAIL

Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
Attention: Health Information Technology Advisory Committee (HITAC)
Michael Berry – HITAC Staff
David McCallie – ISPTF Co-Chair
Arien Malec – ISPTF Co-Chair
Aaron Miri – HITAC Co-Chair
Denise Webb – HITAC Co-Chair

RE: Health Information Technology Advisory Committee (HITAC); ISP-TF-2021_Recommendation 03 - Foundational Standards – Terminology

Health Information Technology Advisory Committee (HITAC):

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 1,700 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.

For over 40 years NCPDP has been committed to furthering the interoperable, electronic exchange of information between healthcare stakeholders. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting and other functions in the pharmacy industry as named in the Health Insurance Portability and Accountability Act (HIPAA). The NCPDP SCRIPT Standard, Telecommunication Standard and the Formulary and Benefit Standard are the standards in use in electronic prescribing as named in the Medicare Modernization Act (MMA) of 2003.

NCPDP strongly opposes replacing the use of National Drug Code (NDC) with RxNorm values due to the disruptive impact such a change would have on the pharmacy industry. 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. As the Standards Development Organization for the pharmacy industry, NCPDP is very concerned with the impact the replacement of the NDC with RxNorm as the single source terminology set to harmonize administrative and electronic prescribing standards would have on the entire healthcare industry. 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.

NCPDP submits the below comments to ONC regarding HITAC's recommendation (f):

> **"*ONC work with FDA and CMS to continue to harmonize NDC to RxNorm, treating RxNorm as the source terminology set, and to harmonize administrative and electronic prescribing standards to use RxNorm as the single source of clinical data for clinical care, research, and administrative workflows, replacing NDC for such purposes*."**

Background

NDC Codes

NCPDP members represent all types of prescription drug participants in the healthcare industry. Members use the NDC as the unique drug product identifier in the health information technology systems and databases that support their businesses and clinical practices. The NDC is a unique, three-segment number required by the FDA and provided by drug establishments to identify all drugs manufactured, prepared, propagated, compounded or processed for sale in the U.S. at their facilities.[1] The NDC is a "smart" identifier in that the three segments comprising the NDC number identify the labeler, product and trade package size, respectively[2]. The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures (including re-packers or re-labelers) or distributes (under its own name) the drug[2]. The second segment, the product code, identifies a specific drug, strength, dosage form and formulation of the drug for a particular firm[2]. The third segment, the package code, identifies package sizes and types[2]. The manufacturer/producer assigns the product and package codes[2]. The NDC will be in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1[2]. The FDA publishes the NDC numbers as provided by drug establishments in the NDC Directory daily. The NDC Directory contains information on active and certified finished and unfinished drugs submitted to FDA in structured product labeling (SPL) electronic listing files by labelers and is freely available.[3]

The healthcare industry has taken advantage of the NDC configuration, and significant business system logic has been built around each of the labeler, product and package size segments of the NDC. The NDC distinctly identifies the product and is used throughout the pharmacy industry to accurately communicate the specific product for functions such as recalls, safety checks, ordering, dispensing, billing, drug rebates

[1] https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory

[2] See Section 2. NDC, of the National Drug Code Database Background Information from the FDA at https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information (accessed 6/23/2021)

[3] NDCs are freely available from:
FDA National Drug Code Directory at: https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm
FDA via the NDC Application Programming Interface (API) at: https://open.fda.gov/apis/drug/ndc/
NLM's DailyMed Structured Product Labeling (SPL) Resources webpage at: https://dailymed.nlm.nih.gov/dailymed/spl-resources-all-drug-labels.cfm

and reporting. Table 1 in the Appendix provides additional details regarding the numerous systems and processes where the NDC is used within the healthcare industry.

Because of the pervasiveness of the NDC, the majority of NCPDP standards include the NDC as the primary drug identifier. The NCPDP Telecommunication Standard is used to process 4 billion[4] claims transactions per year, the vast majority of which include the NDC of the dispensed prescription. Another 1.9 billion[5] prescriptions are sent electronically from prescribers to pharmacies using the NCPDP SCRIPT Standard, where NDCs are almost exclusively used to represent the drug prescribed. Additionally, pharmacies use the NDC in electronic prescribing transactions to accurately report the specific product dispensed in patient medication history to prescribers and other entities as well as to request prescription renewals, prescription transfers and medication changes. RxNorm does not identify the specific packaged product dispensed and would not be as useful in such transactions. Table 2 in the Appendix lists all NCPDP standards used today between various healthcare industry participants that include the NDC to identify products. This list provides a comprehensive view of how the NDC is utilized in the healthcare industry.

Pharmacy automation (e.g., automated dispensing devices, central fill processing, etc.), workflow and processing systems are designed to base product selection on the NDC, all of which is derived from the NDC transmitted to the pharmacy on an electronic prescription using the NCPDP SCRIPT Standard. The NDC is used as a unique identifier for final safety checks to ensure the correct medication is dispensed at the point of care. This verification can be manual or electronic. In fact, it is so critical as a safety check that the FDA requires the NDC be included as a data element in the Human Readable Product Identifier on a product label.[6]

Additionally, the NDC is named in HIPAA and utilized by multiple governmental agencies, including but not limited to:

- 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. Modifications to NCPDP standards regarding the NDC would be subject to our ANSI-accredited processes, MMA and HIPAA. Timelines would need to be coordinated with the naming of the appropriate version of the standard. NCPDP has requested a new version of the Telecommunication Standard be named for use under HIPAA, and the pharmacy industry recently moved to a newer version of the SCRIPT Standard. Any changes in the mandatory drug identifiers would likely require more than a decade for implementation.

RxNorm

[4] 2017 data based on the IQVIA National Prescription Audit (NPA™) database
[5] Per the Surescripts, LLC 2017 National Progress Report
[6] https://www.fda.gov/media/116304/download (See section IX Questions and Answers - #4)

RxNorm is a normalized naming system for generic and branded drugs, which is used as a tool for supporting semantic interoperation between drug terminologies and pharmacy knowledge base systems[7]. RxNorm is produced monthly by the NLM with incremental files provided on a weekly basis. With this existing schedule, a drug could be approved on a Monday and would not be added to the RxNorm incremental (weekly) file until the following Wednesday, more than 10 days after the drug approval. At that point, the drug information must be disseminated from compendial sources to the user audience, requiring several additional days of unavailability.

For comparison, NDC numbers are available prior to the drug's FDA approval so sufficient information is available for products upon approval to support most industry uses and particularly, claims billing that enables dispensing.

At the most granular level of RxNorm, the drug nomenclature aggregates one or more NDCs at a higher, less specific level called the semantic clinical drug (SCD) level. RxNorm aggregates different generic manufacturers/labelers with the same route, strength and dosage form under the same RxNorm concept unique identifier (RxCUI) in a one RxCUI to many NDCs relationship.

The goal of RxNorm is to allow computer systems to communicate drug-related information efficiently and unambiguously. While RxNorm contains the names of prescription and many over-the-counter drugs available in the United States, it does not contain the name of all products dispensed by pharmacies nor the manufacturer/labeler details. According to the RxNorm documentation, the following products are currently considered out of scope for RxNorm:

- Most Diagnostic products
- Medical devices
- Medical foods
- Compounded drugs
- Homeopathic products
- Radiopharmaceuticals

Concerns

NCPDP has numerous concerns with the recommendation to treat RxNorm as the single source terminology set:

1. Patient Safety Concerns

Reliance on RxNorm as the single source terminology set would eliminate the ability to properly incorporate product recalls and drug discontinuations into EHR and pharmacy systems, as well as report adverse events to the FDA. Patient care would be at risk by losing the specificity of the manufacturer/labeler and package size provided by the NDC. It would not be possible for EHR and pharmacy systems, reverse distributors, distributors, manufacturers and regulatory agencies to identify the individual product.

2. Risk of Medication Errors

[7] See "What is RxNorm?" from the RxNorm Overview at https://www.nlm.nih.gov/research/umls/rxnorm/overview.html

RxNorm lacks specificity and rarely maps to an NDC in a one-to-one relationship. Adoption of RxNorm until a complete, accurate crosswalk can be developed and implemented, would increase the risk of medication errors on electronic prescriptions since pharmacies may not be able to correctly identify the specific product at time of dispensing or accurately track and monitor what products were dispensed to patients. All pharmacies rely on the NDC as the unique product identifier. There have been numerous reports of errors when RxNorm is incorrectly mapped, including, but not limited to:

a. TEPMETKO is supplied both as a box of 60 tablets or a box of 30 tablets. Each box has a different NDC. RxNorm has only created one code for this branded drug and both NDCs are mapped to this product. RxNorm aggregated 2 NDCs that are different products in the pharmacy. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=80a0f1b9-071a-47f5-9e67-32d638a669dc

b. Dulcolax (bisacodyl) 5mg DR tab RxCUI = 209613 was incorrectly mapped to KAOPECTATE bismuth subsalicylate)262 MG/15 ML SUSP 41167040002, which is a completely different drug.

c. Products with the same drug but distinct delivery characteristics not considered to be equivalent by the FDA have been assigned the same RxCUI. One such example was Potassium CL 10mEq vs KLor-Con 10mEq.

3. *Increasing Administrative Burden*

Prescribers send many prescriptions to pharmacies electronically for products that are not represented by RxNorm, including, but not limited to, diabetic testing supplies, devices and OTC products. These products are identified today by specific product identifiers in an NDC-format, allowing them to be sent electronically. Additionally, RxNorm information about new products introduced to the market may not be available for several weeks due to the lag in publishing of RxNorm files.

Replacement of the NDC with RxNorm would require products not available on RxNorm to be transmitted orally, by fax or via a paper prescription to a pharmacy, which would place additional administrative burden on providers, increase the risk of transcription errors as well as decrease patient adherence[8]. These issues would need to be rectified before RxNorm could be named the single source terminology set.

4. Additional Areas of Impact

Reliance on RxNorm as the single source technology would have a direct impact to the entire healthcare industry, including payers, manufacturers, adherence companies, regulatory data repositories (such as REMS, PDMPs and HIEs), distributors and providers. 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. Payers and manufacturers rely on the use of the NDC in pharmacy transactions. NDC numbers have been widely used as a product identifier for over 40 years in the

[8] https://surescripts.com/news-center/press-releases/detail/212_eprescribing

healthcare industry and have been the primary identifier in ePrescriptions for over a decade. Systems and databases are specifically coded to utilize these identifiers and reliance on RxNorm as the single source terminology would cause severe administrative and technology disruption to the industry without clear benefit.

5. Previously Declined by CMS for Administrative Purposes

In one of the *Transparency In Coverage Final Rule* responses CMS provided a comment suggesting the use of the RxCUI[9]:

> The NDC, in contrast, is a unique 10-digit or 11-digit 3-segment number, which provides a universal product identifier for drugs in the United States. The three segments of the NDC identify: the labeler (any firm that manufactures the drug); the product (specific strength, dosage form, and formulation of a drug); and the commercial package size and types. As noted above, multiple NDCs can be encompassed by one RxCUI, which is why there are many fewer RxCUI codes than NDCs. **However, the accuracy of pricing information requires precise and specific product information, including package size and manufacturer. The Departments are concerned that permitting drug pricing information disclosures to be made through RxCUIs would potentially lead to inaccurate or misleading information being provided to the consumer.** If drug pricing information is provided in the machine-readable files in the form of RxCUIs, then plans and issuers may not be able to provide the manufacturer negotiated rate, especially for those RxCUIs that include NDCs from several manufacturers.

CMS is already aware that RxNorm is not intended to be applicable to the purpose of being a universal product identifier for drugs in the United States. RxNorm may be a clinically appropriate identifier, but it is not and should not become one that is administratively appropriate. Making it so is likely to compromise the value of the identifier for clinical uses. These are necessarily dissimilar and relatively opposed use cases.

Conclusion

NCPDP's primary concern is patient safety. Adoption of RxNorm as the single source for product identification would be extremely disruptive to the pharmacy industry. While treating RxNorm as the single source terminology set could improve communication of clinical data for clinical care, it would definitely compromise patient safety when dispensing the medication as well as increase administrative burden on all stakeholders. The pharmacy industry relies on the NDC in all aspects of its business, including, but not limited to, dispensing, reporting, billing and patient safety processes. The NDC is the key, unique, product identifier which is the standard of practice for the pharmacy industry to properly identify the specific product ensuring patient safety. RxNorm lacks the specificity required to identify all products routinely and uniquely. A more comprehensive solution must be developed that addresses all stakeholders impacted before RxNorm can be considered to replace some aspects of describing prescription drugs.

[9] (See page 240 of https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/CMS-Transparency-in-Coverage-9915F.pdf

NCPDP asks HITAC to reconsider its recommendation to utilize RxNorm as the single source terminology set for electronic prescribing standards until a complete, reliable, open-source mapping between NDC and RxNorm or other solution can be developed.

Thank you for your consideration of our input. NCPDP welcomes the opportunity to work with ONC, FDA and CMS to develop a viable solution and appropriate timeline.

Respectfully,

Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260
(480) 477-1000 x 108

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

Margaret Weiker
Vice President, Standards Development
NCPDP
standards@ncpdp.org

cc:
Steve Posnack, ONC Deputy National Coordinator for HIT

Appendix

Table 1 Healthcare Industry Use of NDC[10]

Industry Segment	Industry Participant	Industry Uses/Systems
Drug Supply Chain	Drug Companies	Product Recalls
		REMS Programs
		Product Order Fulfillment
		Rebates
	Drug Wholesalers	Product Ordering and Fulfillment
		Product Recalls
		Inventory Management
	Drug Depots/Warehouses	Product Ordering and Fulfillment
		Product Recalls
		Inventory Management
Drug Data Compendia		Drug Information and Pricing Files
		RxNorm Data Reconciliation
		Product Billing Unit Reconciliation
		Patient Clinical Screening Modules
Healthcare Providers	Prescribers	Electronic Prescribing
		Drug Benefit Formulary Look-up: Real Time Prescription Benefit Check
		REMS Programs
		Product Ordering
		Prior Authorization

[10] This table is provided for illustrative purposes and is not intended to be comprehensive.

Industry Segment	Industry Participant	Industry Uses/Systems
		Drug-Drug, Drug-Allergy Interaction and Clinical Decision Support
		Adverse Event Reporting
		Product Recalls
		Patient Medical Records
		Medication History
	Inpatient & Long-Term Care Facilities	Patient Medication Administration Record
		Product Ordering
		Drug Clinical Protocols
	Dispensers/Pharmacies	Prescription Dispensing
		Prior Authorization
		Product Ordering/Recalls/Returns
		Claims Billing
		Inventory Management
		REMS Programs
		Prospective Drug Utilization Review
		Pharmacy Quality Reporting
		Drug-Drug, Drug-Allergy Interaction and Clinical Decision Support
		Patient Medication History Records
		Medication Therapy Management
		Prescription Audit and Quality Management
		Bar Code Scanning

Industry Segment	Industry Participant	Industry Uses/Systems
Clearinghouses/Intermediaries/ Switches		Data Validation
		REMS Programs
Payers/PBMs/Claim Processors		Claims Adjudication
		Claims Payment
		Pharmacy and Claims Auditing
		Patient Medication Reviews; Medical Management
		Clinical Decision Support
		Drug Benefit Formularies
		Prior Authorization
		Manufacturer Rebates
Federal Government Agencies	CMS Medicare Part D	Drug Benefit Design
		Drug Formularies
		PDE Analysis
		Star Ratings
		Program Integrity
	CMS Medicare Part B	Formularies
		Benefit Design
		Program Integrity
	CMS Medicaid	NADAC and FUL Drug Pricing Files
	CMS CCIIO	Transparency in Coverage Pharmacy Pricing File (CMS-9915-F)
	HRSA	340B Program
	CDC	Strategic National Stockpile
		Immunization Registry
	DEA	Product Exemption Reporting
	FDA	REMS Programs

Industry Segment	Industry Participant	Industry Uses/Systems
		Adverse Event Reporting
		Track and Trace
	Department of Defense	See above uses by other agencies
	Veterans Affairs	See above uses by other agencies
	Indian Health Services	See above uses by other agencies
	Other regulatory agencies	See above uses by other agencies
State Government	State Medicaid Agencies	Manufacturer Rebates
		Drug Formularies
		Claims Adjudication
		Prior Authorization
	Prescription Drug Monitoring Programs (State and Local)	Pharmacy Reporting Databases
		Patient Controlled Substance Prescription Reporting
	Public Health Agencies	Immunization Registry

Table 2 NCPDP Standards Which Include NDC

Standard Name	Standard Description
Audit	Defines the record layout for batch audit transactions between Auditors and Providers to support electronic audit transactions that facilitate requests, responses, and final outcomes transmissions for both “Desk Top” claim audits and for in-store audit notices. This standard addresses the types of communication between Auditors and Providers and allows communication to occur in an electronic environment rather than paper-based.
Batch Transaction	Uses the functionality, syntax, formatting, data set, and rules of the Telecommunication Standard to "wrap" in a detail record for an implementer to "code once". A batch header and trailer are included to support a batch method of delivery.

Standard Name	Standard Description
Batch Standard Subrogation	Provides a uniform approach to efficiently process post-payment subrogation claims and eliminate the numerous custom formats used in the industry today.
Benefit Integration	Is intended to meet an industry need to facilitate the integration and exchange of accumulators between Benefit Partners to administer integrated benefits. It supports the communication of accumulator data in a standard format via transactions used to facilitate the delivery and receipt of this information. These transactions provide administrative efficiencies and allow for an industry standard to be used to share accumulator data (such as deductible and out of pocket) between Benefit Partners to administer integrated benefits for a member.
Billing Unit	Provides a consistent and well-defined billing unit for use in pharmacy transactions. This results in time savings and accuracy in billing and reimbursement.
Formulary and Benefit *	Provides 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.
Manufacturer Rebate, Utilization, Plan, Formulary, Market Basket and Reconciliation Flat File	Supports the electronic submission of rebate information from Pharmacy Management Organizations (PMOs) to Pharmaceutical Industry Contracting Organizations (PICOs).
Medical Rebates Data Submission	Provides a standardized format for health plans' rebate submissions to multiple manufacturers throughout the industry.
Post Adjudication	Supplies detailed drug or utilization claim information after the claim has been adjudicated.
Prescription Drug Monitoring Programs (PDMP) Reporting	Provides guidelines for implementing the Prescription Drug Monitoring Programs (PDMP) Reporting Standard format to ensure a consistent implementation of the standard.
Prescription File Transfer	To electronically transfer prescription files between pharmacies.
Prior Authorization Transfer	Transferring existing prior authorization data between payer/processors when transitioning clients, performing system database or platform changes.
Product Identifier	Provides education and general guidance for consistent formatting and utilization of product identifiers used within the NCPDP standards.

Standard Name	Standard Description
Real Time Prescription Benefit	Provides real-time pricing and formulary information to providers within workflow
SCRIPT *	Developed for transmitting prescription information electronically between prescribers, pharmacies, payers, and other entities for new prescriptions, changes of prescriptions, prescription refill requests, prescription fill status notifications, cancellation notifications, relaying of medication history, transactions for long-term care, electronic prior authorization and other transactions.
Specialized	Developed for transmitting information electronically between prescribers, providers, payers, pharmacies and other entities for medication therapy management, census events, central fill functions and other transactions.
Specialty Pharmacy Data Reporting	Provides a standardized format for the data submitted by specialty pharmacy to drug manufacturers/others to support programs and agreements between the parties.
Telecommunication Standard: *Claim Billing, Reversal, Rebill; Predetermination of Benefits; Prior Authorization; Information Reporting* *	Developed to provide a standard format for the electronic submission of third-party drug claims and other transactions between pharmacy providers, insurance carriers, third-party administrators, and other responsible parties. The Telecommunication Standard includes transactions for eligibility verification, claim and service billing, predetermination of benefits, prior authorization, and information reporting.
Uniform Healthcare Payer Data	Used by Client Groups, Pharmacy Benefit Managers (PBMs), Fiscal Agents, Vendors, and Administrative Oversight Organizations and state entities to share pharmacy claim data used to support statistical reporting, evaluation of healthcare, and state or regional reporting requirements. This standard should only be used for data submission to a state agency or to a state-sponsored healthcare payer data collection initiative.
Universal Claim Forms (*Universal and Worker's Compensation*)	For Telecommunication 5.1, D.0, and Workers' Compensation/Property and Casualty manual claims processing.

* Indicates that these Standards are named in Regulation (e.g., MMA or HIPAA)