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July 9, 2021

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, Michael.Berry@hhs.gov – HITAC Staff
David McCallie, dmccallie@gmail.com - ISPTF Co-Chair
Arien Malec, arien.malec@changehealthcare.com - ISPTF Co-Chair
Aaron Miri, aaron.miri@austin.utexas.edu – HITAC Co-Chair
Denise Webb, HITAC Co-Chair

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

Mr. Malec and Mr. McCallie:

Thank you for the opportunity to submit comments to the Interoperability Standards Priority 2021 Task Force (ISPTF) regarding its proposed recommendation to the ONC HITAC that ONC work with the U.S. Food and Drug Administration (FDA) and The Centers for Medicare and Medicaid Services (CMS) to continue to harmonize the National Drug Code (NDC) to RxNorm. The ISPTF in its proposal is further recommending the treatment of 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.

As a part of McKesson Healthcare Technology Solutions, CoverMyMeds is a leading medication access company, helping people get the medicine they need to live healthy lives. We help patients navigate medication access throughout their wellness journey through a comprehensive set of benefit and access support solutions such as electronic prior authorization (ePA), Specialty (AMP) and Consumer-Facing Price Transparency.

Since 2008, CoverMyMeds has seamlessly connected the health care network to help reduce prescription abandonment and increase speed to therapy for all patients. CoverMyMeds' network includes more than 75% of all electronic health record systems (EHRs), 50,000+ pharmacies, 750,000 providers and most health plans and PBMs. By facilitating appropriate access to medications, we help customers avoid billions of dollars each year in administrative waste and avoidable medical spending caused by prescription abandonment.

General Comments

CoverMyMeds is committed to advocating for interoperable, electronic exchange of information between healthcare stakeholders. We respect and appreciate the efforts of the ONC, and specifically the HITAC relative to endeavoring to improve interoperability and the exchange of clinical and administrative data. However, CoverMyMeds does not support replacing the use of

the National Drug Code (NDC) with RxNorm values and is concerned with the vast impact the replacement of the NDC with RxNorm as the source terminology set to harmonize administrative and electronic prescribing standards would have on the entire healthcare industry.

The prescription services industry, inclusive of EHRs, providers, pharmacies, pharmacy benefit management companies, health plans and patients extensively utilize the NDC in all aspects of business operations, including, but not limited to, dispensing, reporting, billing, quality and patient safety reporting and auditing. The NDC is the key, unique, product identifier used to identify the specific product being prescribed, dispensed, and ensuring patient safety.

NDC

Three segments that make up the NDC identifies the labeler, product, and trade package size, respectively.

- The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufacturers (including re-packers or re-labelers) or distributes (under its own name) the drug.
- The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular firm.
- The third segment, the package code, identifies package size and types. Both the product and package codes are assigned by the firm.
- The NDC will be in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1.
- The FDA publishes the NDC numbers in the NDC Directory daily.
    - The NDC Directory contains information on active and certified finished and unfinished drugs submitted to the FDA in structured product labeling (SPL) electronic listing files by labelers.

The National Council for Prescription Drug Programs (NCPDP) an American National Standards Institute (ANSI) Standards Development Organization (SDO) is the industry recognized SDO for the pharmacy services industry. The NCPDP has been developing standards for interoperable data exchange for over forty years. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting, and other functions in the pharmacy services industry and 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). The NDC is the prime data element and indicator found in these NCPDP Standards and named in the federal regulations.

RxNorm

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. RxNorm, produced by the National Library of Medicine (NLM), is updated on a weekly basis, and published weekly as incremental update release files; also, monthly as the fully complete RxNorm release files.

- For example, a drug could be approved on Monday and would not get added to the RxNorm weekly incremental release files until the following Wednesday, over 10 days after the drug is approved.
    - 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 U.S., it does not contain the name of all products dispensed by pharmacies.

RxNorm may potentially be used by EHR systems to map from the NDC dispensed by the pharmacy for clinical care as well as administrative processes within a single EHR system. However, RxNorm should not be utilized as the single source technology set in any electronic prescribing standards since these transactions are used to communicate outside the EHR system. Pharmacies must be able to properly identify the product to be dispensed. RxNorm does not provide such assurances.

RxNorm lacks the specificity required to uniquely identify a product and utilizing it as the source terminology set would compromise patient safety and introduce unnecessary burden throughout the industry.

Specific Concerns

- Impact to the Prescription Services Industry

  As mentioned above, the healthcare industry has taken advantage of the NDC configuration, product and system implementations. Business logic has been built around each of the labeler, product, and package size segments of the NDC. Pharmacy automation, workflow and processing systems are designed to base product selection on the NDC, all of which is communicated to the pharmacy on an electronic prescription using the NCPDP SCRIPT Standard.
    - The NDC distinctly identifies the product and is used throughout the pharmacy industry to accurately communicate the specific product for function such as recalls, safety checks, ordering, dispensing, billing, drug rebates, and reporting.
    - The majority of NCPDP standards include the NDC as the primary drug identifier. The NCPDP Telecommunication Standard is used to process 4 billion claim transactions per year, each of which includes the NDC of the dispensed prescription. Prescriptions are sent electronically from prescribers to pharmacies using the NCPDP SCRIPT standard, where NDCs are used to represent the drug prescribed.
    - Pharmacies use the NDC in electronic prescribing transactions to accurately report the specific product dispensed to prescribers and other entities and request prescription renewals.

  By losing the specificity of the manufacturer/labeler and package size provided by the NDC, it would not be possible to track drug safety recalls and drug shortages for a specific drug product.

- RxNorm does not identify the specific packaged product dispensed and would not be useful in such transactions. 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 does (SCD) and/or semantic branded dose (SBD) level.
- RxNorm aggregates different generic manufacturers/labelers with the same route, strength, and dosage form under the same RXCUI in a one RXCUI to many NDCs relationship.

RxNorm's lack of specificity would also be a major issue for electronic health records (EHRs) and clinical information systems. Elimination of the NDC on electronic prescriptions will result in multiple patient safety issues. There have been numerous reports of errors when RxNorm is incorrectly mapped to an obsolete NDC.

- The NDC is used as a final safety check in dispensing, as a unique identifier, 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.

Replacement of the NDC with RxNorm on electronic prescriptions will not harmonize the industry nor reduce burden for the prescriber nor the pharmacy since RxNorm does not enable pharmacies to uniquely identify the specific packaged product prescribed and dispensed.

- RxNorm is not specific enough for sole usage in the pharmacy industry since it does not always map directly as a one-to-one relationship to an individual NDC for a packaged generic or branded product.
- Additionally, reliance on RxNorm as the single source terminology set will eliminate the ability to properly incorporate product recalls into EHR and pharmacy systems since products recalls are initiated by manufacturers at the NDC and Lot level.
- Use of RxNorm would result in confusion and administrative burden to all healthcare providers, including prescribers, when recalls are issued.

- Market Destabilization and Consolidation

  Given the points listed above, an overhaul of this nature to pharmacy service industry processes and systems would have large scale impact on many entities. Considering the potential cost associated with a change like this, there is potential to have significant disruption to stakeholders operating within the space. The effects could cause smaller organizations that lack the necessary resources at their disposal to implement these changes to close their business and stop operations. This would result in market destabilization, consolidation, and negatively impact the ongoing and industry-wide efforts to reduce healthcare cost and burden; further impacting patients, who will inevitably have the burden of cost passed onto them as consumers.

- Most Recent Federal Regulation Reference

Within the CMS final rule titled, "*Transparency in Coverage*" (CMS-9915-F), CMS references commenters recommendation within this final rule that a more useful unit for reporting for drugs would be the RxNorm concept unique identifier (RxCUI). In this instance, the commenters suggested the use of the RxCUIs, further suggesting that it would minimize burden by reducing the list of entries, highlighting the lesser amount of active RxCUIs versus NDCs, and because existing prescription drug machine-readable file requirement for Medicare Part D and QHPs use RxCUIs.

CMS responds to the commenter suggestions with the following points:

- Multiple NDCs can be encompassed by one RxCUI; however, the accuracy of pricing information requires precise and specific product information, including package size and manufacturer.
- Replacement of NDCs by RxCUIs would lead to inaccurate or misleading information being provided to the consumer; further explaining that if RxCUI is used, in this instance, within the machine-readable files, then plans and issuers may not be able to provide the manufacturer negotiated rate, especially for those RxCUIs that include NDCs from several manufacturers.
- NDCs are more generally used by the Part D and QHP programs when information is required to be submitted to CMS for payment programs, not RxCUIs.
- The NDC is a standard billing code required for prescription drug transactions and should remain.

Conclusion

CoverMyMeds continues to support improvements to and technological advances within the prior authorization process that serve to benefit patient access to the medications prescribed, while reducing barriers related to prior authorization for providers and patient care teams. Adoption of RxNorm as the single source for product identification would be very disruptive to the pharmacy services industry. Treating RxNorm as the single source terminology set does not provide the granular detail needed for these systems to function accurately and would compromise patient safety as well as increase administrative burden on all downstream providers.

If you have questions, please contact Kim Diehl-Boyd, Vice President, Industry Relations and Government Affairs, at kdiehlboyd@covermymeds.com or 615-663-5579.

Thank you,

Kim Boyd

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