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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2008-N-0120, Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the Food and Drug Administration's (FDA) request for comments relating to standards for standardized numerical identifier, validation, track and trace, and authentication for prescription drugs. The Society's more than 30,000 members include pharmacists and pharmacy technicians who practice in a variety of health-system settings, including inpatient, outpatient, home care, and long-term-care settings.

ASHP is concerned about the current lack of interoperability of all data that identifies drug products. Radio-frequency identification (RFID) and bar-code technologies in the e-pedigree process should be usable within the systems to which they belong. Barcode point-of-care systems, pharmacy robotics, pharmacy packagers, re-packagers, and other automated compounding devices must be able to utilize the identifiers determined for e-pedigree. This usability will allow for enhanced patient safety since there will be one universal identifier agreed upon by all involved in the medication use process.

Currently, ASHP members are struggling with inconsistencies relating to the National Drug Code (NDC) and its application to barcode point-of-care, clinical information systems, and hospital financial systems. ASHP would like to discuss opportunities for collaboration with the FDA regarding the standardization and usability of the NDC and/or other alternative drug identification systems.

ASHP appreciates the agency's willingness to solicit information from various stakeholders concerning the standards FDA is developing under section 505d(b) of the Food and Drug Administration Amendments Act of 2007. The following comments address the questions listed under Section A, Standard Numerical Identifier, and are annotated and organized to identify the specific questions to which they refer. The ASHP Section of Pharmacy Informatics and Technology provided significant input into this response.

A. Standard Numerical Identifier

1. Characteristics

a. Should the standardized numerical identifier contain recognizable characteristics (e.g., National Drug Code number) or be random codes?

A standardized numerical identifier should contain encoded elements that permit the various users of that code to locate the information they need. The significant failures of the NDC code in clinical usage relate to the failure of NDC administration to ensure that the NDC numbers are sufficiently descriptive. While assignment of a "non-intelligent" number is easier to administer, it requires a significant public infrastructure to enable reasonable use for clinical and research purposes.

b. Should there be a common header for item/product segregation based on product type: biologic, solid oral dosage form, etc.? If so, please elaborate.

A standardized identifier should have multiple layers of abstraction, either directly in its structure or through participation in a larger code set. These layers of abstraction must meet following the needs of various stakeholders:

- A unique identifier of the clinical drug in use is essential, including a unique identifier for the drug (or combination of drugs), strength, route and form.
- The Centers for Medicare and Medicaid Services (CMS) and other payors should know which drug vendors are utilized.
- CMS and other payors should know which drugs are being used
- FDA should have a clear identifier for every licensed drug, reflecting drug, amount and form.
- The pharmaceutical manufacturing community and the supply chain community should be able to easily track containers of specific drugs across the supply chain.
- The retail pharmacy community should be able to communicate reliably with e-prescribing systems regarding selected and used medications.
- Electronic Medical Records (EMR) and Regional Health Information Organizations (RHIO) should be able to communicate effectively across systems regarding medication use.
- Bar Code Point-of-Care (BPOC) and other medication safety initiatives should be able to reliably identify medications and validate their appropriateness prior to use

- Researchers should be able to search patient care databases, and other databases, to reliably identify forms and doses of the drugs.

An encoding structure referencing a larger encoding scheme, such as RxNorm, embedded within the current NDC structure, would provide an encoding scheme that would be reliably unique, easily clinically parsed, and easily managed at multiple layers of abstraction.

c. How can parties in the supply chain ensure that the numbers are unique and are not duplicated?

A standardized identifier must be reliably unique. In order for a number to be reliably unique, its components must be administered by a central authority, however all components need not be administered by the same authority.

For example, if the NDC number were to be modified so that its components included the RxNorm CUI as the drug/form/dose component of the code, the FDA could continue to be the authority for the labeler code, the National Library of Medicine could become the central authority for the drug/form/dose component, and the vendor could remain the authority for the package encoding. Uniqueness involves more than careful assignment of values. It also involves a consistent format (as opposed to the current permitted 3 variants of the NDC code) that is always represented in both human-readable and machine-readable formats. Uniqueness also involves permanence. The code must not only be currently unique but, for clinical and research purposes, must always refer to the same entity, even if that entity no longer exists.

d. How much value would there be in having the numerical identifier in more than one place for the product (e.g., package and pallet level)?

The supply chain benefits from being able to read an identifier and know that it represents a specific amount of a specific drug item (as opposed to reading a code that always describes one dose and having to read something else to know we are looking at a pallet of 10,000).

e. Should the numerical identifier be machine readable, human readable, or both?

The numerical identifier should be machine readable and human readable. Not all venues support machine-readable coding, however, particularly in acute care settings, there is growing use of machine-readable encoding to ensure medications administered to patients are appropriate when dispensed from the pharmacy and during administration to the patient.

f. Should the numerical identifier include the lot number and/or batch number?

When an identifier is represented in human-readable form on the label of a drug package, inclusion of the batch and expiration information is not necessary because that information is already represented elsewhere on the label in human-readable form. Additionally, it is questionable whether inclusion of that information in the identifier itself would be readily identifiable and readable to all stakeholders

However, a variety of clinical applications lose some of their potential value because the machine-readable form of the identifier does not include this information. Machine-readable encodings of the NDC code (or other identifier) should also contain lot/batch and expiration information so that information can be included in clinical records without engendering unmanageable administrative costs.

2. Standards

a. Do standards currently exist for a standardized numerical identifier of prescription drugs?

1) If so, please describe and comment on their application and use.

The NDC code is the current standard, although it has a number of deficiencies, particularly relating to clinical use and interoperability. The National Library of Medicine administers RxNorm, a multi-level taxonomy for drug nomenclature updated every time the FDA approves a new drug entity.

Various proprietary numerical identifiers exist from companies such as FirstDataBank, MediSpan, MicroMedex and others. However, they constitute an additional expenditure and foster an environment where sharing of information on a patient's drug therapy in a codified (and therefore understandable) manner is not possible due to the incompatibility of these code sets.

2) To what extent do these standards reflect stakeholder consensus?

The NDC code reflects no stakeholder consensus, although FDA, CMS, and the pharmaceutical manufacturing community may have the opportunity to provide input. Development consideration has not included the needs of the healthcare community at large, including caregivers and researchers. RxNorm reflects a consensus standard.

The proprietary code sets have been imbedded in pharmacy and medical information systems and may satisfy the consensus of that information system. However sharing the information is problematic.

3) Comment on whether any of these standards should be the standard adopted by FDA.

The adoption of RxNorm by FDA as the official arbiter of the second portion of the NDC code would be clinically useful.

4) If yes, why? Compare this standard with other standards that exist.

The only other standard is the NDC code itself which has significant shortcomings for this purpose across the continuum of use.

5) If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

N/A

6) Has this standard been adopted by other countries?

This question does not fall within ASHP's area of expertise.

b. Are standards in development or planned for standardized numerical identifiers of prescription drugs in the supply chain? If so, who is developing these standards and what is the timeline for completion?

This question does not fall within ASHP's area of expertise.

c. What are the elements, provisions, and particular considerations that should be included in a standardized numerical identifier of prescription drugs? Please be specific in your response and include examples, where possible.

Current U.S. experience indicates that there is value in having a standardized identification number (SIN) and that elements of the current NDC code support most supply-chain activities. However, the NDC code does not support clinical use, research, and interoperability of systems.

The following is a list of nine features that should be included in a standardized numerical identifier of prescription drugs:¹

- 1) The standardized numerical identifier should be permanent. Reuse should never be permitted.
- 2) It should be available for use at little or no cost. Availability would encourage usage.
- 3) The standardized numerical identifier should be maintained by a primary code-assigning authority. Portions of the current NDC code could be maintained by different authorities (see answer to (A)(1)(c), above).

¹ The aspects of a standardized code set and the following list of nine features were outlined in: Desiderata for Controlled Medical Vocabularies in the Twenty-First Century, Cimino JJ, Methods Inf. Med. 1998 Nov;37(4-5):394-403.

- 4) The content must be updated and made available as soon as drugs enter the market, as is already the case with RxNorm.
- 5) It should be "backwards compatible" with the NDC system, to allow for a smooth transition.
- 6) The standardized numerical identifier should be designed for compatibility with evolving international standards and should adhere to an accepted, common information model.
- 7) Concepts and relationships should be organized in formal classes for query and presentation and must support abstraction at multiple levels of detail (i.e. granularity).
- 8) The standardized numerical identifier should have multiple user views and settings which will define how statements are composed and recorded.
- 9) It should build from "atomic" concepts and should support synonyms and lexical variants.

The identifier must be unique, permanent, reliably updated, readable, and point to a larger encoding structure that can be used to facilitate multiple layers of inquiry.

The identifier should also be used universally by all third party payors including CMS. It should contain a universally accepted unit of measure and quantity at the lowest billable unit. Billing codes for medications should be universal and HCPCS codes should be eliminated when billing medications.

d. Please comment on implementation of standardized numerical identifiers of prescription drugs in the U.S. supply chain.

Current implementation of the NDC code is aimed primarily at simplifying supply chain management but not at maintaining adequate security and reliability, particularly in computer-based implementations.

- The NDC code as it exists today is maintained in several different and competing lists (where, in some cases, the same code represents different drugs)
- Reuse is currently permitted, meaning that the same NDC code can represent multiple drugs in a patient's longitudinal medical record
- Manufacturers assign all but the labeler code of the NDC, meaning that there is no consistency in the way other portions of the identifier are assigned. In a view of the FDA web site for a Cefazolin 1 gram vial, there are many drug/form/strength codes for a Cefazolin 1 gram vial. In one case, the same manufacturer uses two different codes for a Cefazolin 1 gram vial, and in another, the same code is used by 1 manufacturer for a 1 gram vial and by another manufacturer for a 10 gram vial. This means that it is not possible algorithmically to look at an NDC code and determine which drug/strength/form it represents without referencing the vendor's catalog

- The publicly available FDA list of NDC codes is not updated on a timely basis
- The NDC code for a specific drug by a specific vendor changes for reasons that do not affect clinical use, but confound use of the NDC code for clinical or research purposes. It is possible that, because of the time it takes changes to proceed through the supply chain, the same organization can have the same product from the same vendor on its shelves with two or more different NDC codes.

e. Please comment on any technical or information technology concerns related to a standardized numerical identifier.

Machine-readable implementations vary significantly in quality. Experience in health-system pharmacies across the country indicates that the presence of the identifier on a package does not guarantee that it can be read because: (1) the selected symbology requires technology that is not universally available; (2) the placement of the code vis-a-vis the shape and size of the container renders it unable to be scanned; and/or (3) the quality of the printing is sufficiently poor that it cannot be scanned.

Health systems that implement BPOC indicate that they are required to "pre-scan" every incoming dose upon receipt to determine whether it can be correctly identified when it reaches the floor. This requirement creates a significant administrative burden on the pharmacy.

f. Comment on any "lessons learned" from foreign experience with standardized numerical identifiers.

This question does not fall within ASHP's area of expertise.

3. Economic Impact

a. What are the usual practices and associated costs that now exist for applying bar codes and other technologies for standardized numerical identifiers on packages and pallets?

Due to the lack of a standardized identifier, many hospitals repackage and/or relabel products prior to distribution throughout the facility. This additional step not only creates another opportunity for medication errors (if a product is relabeled incorrectly it is difficult for any technology to intercept it before it is administered), but it is also a significant administrative burden to the hospital.

b. What are the associated costs for the application, use, and maintenance of standardized numerical identifiers?

Conversion to the use of a new NDC format is associated with marginal cost in terms of code administration, since the technology and programs for generating the code already exist. Additional costs would accrue from:

- 1) Ensuring publication of timely (and preferably free) database of number assignments.
- 2) Conversion of labeling for currently available commercial products.
- 3) Extension of encoding to samples and non-prescription drugs.
- 4) Replacement of bar code symbologies where those currently used are limited to the encoding of 10 characters.
- 5) Replacement of formulary lists for CMS and private payors with the newly generated codes.

c. What are the associated costs or processes for updating the standards as needed?

Changing the format of standardized numerical identifiers will affect the entire supply chain, and precipitate the following costs: (1) costs for approval of modified coding (costs to the pharmaceutical industry, FDA); (2) costs for moving modified labeling into the supply chain (costs to the pharmaceutical industry); (3) costs for modifying software to use the new coding (costs to the pharmaceutical industry, health information technology (HIT) vendors, healthcare systems, payors).

d. What are the benefits of using standardized numerical identifiers?

A standardized numerical identifier offers the following benefits:

- Automated tracking through the supply chain
- Automated clinical safety verification
- Reliable information tracking in the longitudinal patient record for clinical and research purposes
- Reliable interoperability between computer systems of suppliers, providers, and payors.

CMS, State Medicaid, and private insurers should use a universal numerical identifier. With the current requirement for NDC codes for all outpatient Medicaid claims², the universal numerical identifier should also contain the unit of measure and the quantity per NDC as required by third party insurers.

² 42 C.F.R. 447.520, implementing Section 6002 of the Deficit Reduction Act of 2005.

4. Harmonization With Other Countries

a. What standards or unique identification systems do other countries have in place, currently under development, or planned for the future? If they are under development, please include a timeline for completion.

Conversion to a coding structure that employs a recognized standard should contribute to the harmonization effort.

b. Comment on any “lessons learned” from foreign experience with standardized numerical identifiers.

This question does not fall within ASHP’s area of expertise.

ASHP appreciates this opportunity to present its written comments on FDA’s request for comments. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,



Justine Coffey, JD, LLM
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