American Health Packaging®
An AmerisourceBergen Company

Avoiding incorrect reads when scanning

A guide for barcoded unit dose products

Patient safety is the top priority for health systems. As a result, Bar Code Medication Administration (BCMA) initiatives continue to grow as do the accompanying unit dose products utilized to scan at the patient bedside. With the growth of barcoded products, scanning errors can occasionally result. This paper summarizes the reason for many of the errors and recommended actions to remedy the situation.

Current FDA regulations require, "...a bar code that contains at a minimum, the appropriate National Drug Code (NDC) number in a linear bar code that meets European Article Number/Uniform Code Council (EAN.UCC) (now known as "The GS1") or Health Industry Business Communications Council (HIBCC) standards." (21CFR 201.25).

The NDC is a unique, three-segmented number which is a universal product identifier for human drugs. Combined, both the NDC and barcode requirements are intended to help reduce the number of medication errors that occur in hospitals and other health care settings (69FR911). A unique NDC is to be assigned to a specific packaging level and is not to be applied to more than one packaging level, i.e., blister level, carton/"set of blisters" level, and case level. Because of this, manufacturers assign a different configuration code (the last two digits of the NDC) for a blister card and for a carton. The packaging code is defined differently by different labelers. An example would be a packaging code of "01" for 10 blister cards of 10 tablets/capsules each (10 x 10) and a code of "11" for a single blister card of 10 tablets/capsules.

Background

The NDC code started as a 9-digit code in 1969, and quickly expanded to a 10-digit code with a live-digit labeler code. To maintain compatibility with older assigned four-digit labeler codes already in use, the FDA defined three acceptable formats for the

three-segment NDC number as 4-4-2, 5-3-2, and 5-4-1. This can create a problem for drug databases in the healthcare industry because now there are three fields that have two possible numeric lengths.

To make things even more complicated, the United States Department of Health and Human Services (HHS) requirements for calculating and reporting average manufacturer's price, determining Federal Financial Participation (FFP), providing outpatient drug coverage for State medical plans, and other Medicaid payments for drugs (42CFR 447.500) to use an 11-digit NDC using only a three segment 5-4-2 format (42CFR 447.502). To meet the HHS requirement, the FDA required 10-digit NDC must be converted to an HHS 11-digit NDC by inserting a zero at one of three possible locations. Most software automatically performs this conversion after a barcode scan following established rules based on the format of the 10-digit NDC. For instance, when a hospital scans a Hospital Unit Dose (HUD) carton for a drug product such as "Alprazolam Tablets, USP 0.25 mg 10x10 (C-IV)," the bar code provides the 10-digit 1111101801 (NDC 11111-018-01). The hospital's database software then converts the 10-digit NDC into an 11-digit NDC following the 5-3-2 to 5-4-2 rule and inserts a zero after the fifth digit, 11111001801 (NDC11 11111-0018-01). This identifies the correct drug product for FFP, Medicaid, and other reporting and transactional purposes.

A Common Cause of Errors

An increasing number of hospitals are adopting the BCMA initiative to document electronically the administration of medications at the bedside or other point of care. Because of this, there is more attention on scanning the blister barcode as well as the carton barcode.

The barcode for a single unit does blister from a card of 10 blisters containing a tablet of "Alprazolam 0.25 mg (C-IV)" could be 1111101811 (NDC 11111-018-11). This number is registered with the FDA, but many healthcare data providers do not include the unit blister NDC in their data distribution as they are only concerned with the saleable drug product's Stock-keeping Unit (SKU). The blister card is not sold individually.

This means a hospital that subscribes to a data service may not have the blister level barcode numbers, just the carton level barcode numbers. When the database software gets the scanned data, it will try to match the blister NDC to a known carton NDC in its database to determine a match. If the database is only using 11 digit transactional NDCs for reference, the software will insert a zero into a "best guess" location to create a matching 11-digit NDC.

Therefore, a blister barcode scan of a drug product such as "Alprazolam Tablet, USP 0.25 mg (C-IV)" would try to turn the read code 1111101811 (NDC 11111-018-11) by assuming the format is 5-4-1 and insert a zero into the third segment of the NDC. This would make the 11 digit NDC 11111018101 (NDC11

11111-0181-01). This then becomes an error. The drug product identified after the database conversion would now be a different drug product such as "Sertraline Tablets, USP 50 mg 10x10" rather than the actual "Alprazolam Tablets, USP 0.25 mg 10x10 (C-IV)."

Solution

There are two approaches to help solve the NDC11 conversion issue:

1. The first approach is to work with a pharmacy or hospital organization's associated information management department or contracted data supplier to determine how best to include the blister level barcode numbers in the hospital data feeds. Some suppliers may supply a map of carton to blister barcode numbers with a list of applicable drug products and their associated barcode symbols that may be scanned to input into or "teach" a drug product database the blister level barcodes. For database administrators who have the ability to import data from external sources, a supplier may provide CSV text file.

2. The second approach is the adoption and phased roll out of the GS1 standard for item identification known as the Global Trade Item Number (GTIN). The adoption of the 14-digit GTIN: avoids the confusion surrounding the back-and-forth conversion between NDC10 and NDC11 formats in databases; solves the problem that the use of the NDC alone as barcode data does not provide the unique product identification desired by the FDA, adds error checking to ensure accurate barcode reads, provides a systemic hierarchy of identification at all levels of packaging for accurate sharing of information between supply chain partners and end consumers, and positions the product to be globally accepted. Any attempt to change a read barcode number increases the chance for medication errors. GS1 specifications state "The GTIN-14 must be processed in its entirety and not broken down into its constituent elements." As with the first approach, leading suppliers are working with healthcare data companies to develop a process to provide the GTIN data in subsequent data streams. In addition, several have made available "Unit Dose GTIN Bar Code Conversion" documents which provide a map between NDC and GTIN numbers with a list of applicable drug products and their associated barcode symbols that may be scanned to "teach" a drug product database the blister level barcodes. A CSV data file can assist database administrators who have the ability to import data from external sources.

Conclusion

To avoid scanning errors, it is recommended to resist the reliance of software to convert NDC data into NDC11 data. The one method of choice would be to map the full 10-digit NDC to the associated full 11-digit NDC in the drug product database for a reliable two-way conversion to the item identification required for an end reporting process. In addition, make sure both blister and carton-level NDCs are stored in the database.

This will avoid introducing errors by incorrectly converting the blister-level NDC to a carton-level NDC. Be sure to add a 14-digit GTIN column to drug product databases to map it to both 10-digit and 11-digit NDCs.

Because the 14-digit GTIN contains the 10-digit NDC, avoid the temptation to truncate the scanned GTIN code down to the 10-digit NDC. Any manipulation of the scanned data prior to database action could introduce an identification error.

This document was originally published by American Health Packaging, October, 2013, updated October, 2022.


American
Health
Packaging®
An AmerisourceBergen Company