From: Michael E. Coughlin, President and CEO, ScriptPro

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Re: Food and Drug Administration (FDA), HHS, Public Meeting
Bar Code Label Requirements for Human Drug Products
July 26, 2002, from 9 a.m. to 5 p.m.
Natcher Auditorium, Building 45
National Institutes of Health, Bethesda, MD

RECOMMENDATIONS FOR THE DEVELOPMENT OF A REGULATION ON BAR CODE LABELING FOR HUMAN DRUG PRODUCTS, INCLUDING BIOLOGIC PRODUCTS

I. Background

ScriptPro develops and provides dispensing automation and robotics for pharmacies. We are dedicated to helping pharmacies lower operating costs, reduce dispensing errors and increase customer service.

We have focused on those pharmacy dispensing settings where the largest number of prescriptions are filled: community and ambulatory pharmacies. These settings involve people working to execute health-critical tasks accurately, at a fast pace and typically in small spaces close in proximity to the general public.

Our systems are operated to a large extent by bar code scanning. Bar code scanning provides a level of efficiency, accuracy and speed that would otherwise not be possible. These systems are user-tested and being used by thousands of pharmacists and pharmacy technicians every day in every type of community and ambulatory pharmacy setting.

In maintaining the databases for our systems, we work extensively with drug products and their bar codes. ScriptPro's research laboratory has samples of most of the drugs and related medical supplies that are dispensed in community and ambulatory pharmacies across the United States.

Bar code labels for drug products are required for efficient and accurate pharmacy dispensing systems. We certainly support initiatives that will provide more and better bar code information for drugs. However, there are serious shortcomings and errors inherent in the drug product bar codes that we have on drug products today. We should develop and execute a plan for fixing these problems in conjunction with expansion of the use of bar codes. If we do not, we will create an even bigger problem for someone else to solve later.

I will explain this in more detail below, and I will develop a short list of recommendations that will be summarized at the end.

II. Dispensing Errors - Cause and Prevention

We have analyzed dispensing errors in community and ambulatory pharmacies to determine how systems can be applied to prevent them. We have been engaged for some time in funding independent research to find out how to absolutely minimize dispensing errors. Some of these studies are soon to be published.

The most basic dispensing errors are:

- Prescription filled with wrong drug.
- Prescription filled with wrong strength.
- Wrong prescription label or auxiliary labels omitted.

An insurance company has reported that more than 80% of claims against pharmacists in the community and ambulatory practice settings arise from these basic mistakes. (Source: Baker, Kenneth R., Pharmacists Mutual Claims Study 1989-1997, Speech, National Association of Chain Drug Stores.)

Automated dispensing systems depend on drug product bar codes to prevent errors in both robotic and manual prescription dispensing processes. I will describe these processes below in some detail. Appendix A depicts these processes in actual operation.

1. Most prescriptions are filled using countable tablets and capsules. In robotic dispensing of countable tablets and capsules, they are poured into the robot's dispensing cell and then automatically counted out into prescription vials by the robot as needed.

    a. When refilling the dispensing cell, the bar code on the drug product (stock bottle) is scanned and matched to the bar code on the cell. A picture of the tablet or capsule is displayed for further verification.

    b. Prescriptions are then transmitted to the robot and queued for dispensing.

    c. The robot verifies the bar code on the dispensing cell before it counts out the drug.

    d. Then the robot counts the tablets or capsules into the vial.

    e. Next the robot prints and applies the prescription label. The label contains a bar code, a picture of the drug, descriptive information regarding the drug and auxiliary labels.

    f. The operator scans the label bar code and the system displays an image of the drug for final verification by a pharmacist.

    There are more than 2,000 systems of this type in use today. Pharmacists using these systems have claimed that it is almost impossible to dispense the wrong drug or strength, or attach the wrong label.

"I could tell immediately that with the bar code technology, the SP 200 would improve our error rate. The time-saving features of the ScriptPro system are evident as well."
--Danny Cottrel
President, Brewton Medical Center Pharmacy, Brewton, AL

With bar code scanning, the SP 200 is virtually foolproof. It is extremely accurate on making sure the patient gets the right drug."
--Dan Brown
Director of Pharmacy, San Joaquin General Hospital, French Camp, CA

2. Prescriptions that are not filled using countable tablets and capsules are typically filled using prepackaged items such as inhalers, birth control packs, etc. These are often called "unit-of-use medications" or "patient packs." In robotic dispensing of patient packs, they are presented to the robot and automatically stored. They are then picked by the robot for dispensing as needed.

a. When presenting a patient pack to the robot for storage, the bar code on the drug product (patient pack) is scanned. This identifies the drug to the robot so that it can be stored and tracked automatically.

b. Prescriptions are then transmitted to the robot and queued for dispensing.

c. The robot then picks the patient pack for dispensing.

d. The operator then scans the bar code on the patient pack, again verifying its identification.

e. Next the robot prints the prescription label and presents it to the operator for application to the patient pack. The label contains a bar code identifying the drug, a picture of the drug, descriptive information regarding the drug and auxiliary labels.

f. The operator scans the label bar code and the system displays an image of the drug for final verification by a pharmacist.

The robotic systems described above support efficient and accurate dispensing of most prescription drugs. There are also systems that support the manual dispensing of prescriptions. These systems use the bar code labels on drug products as well to prevent basic dispensing errors.

3. For manual dispensing, the prescriptions are queued on the screen at a prescription filling station. The operator uses the station to manually fill and label the prescriptions.

a. The screen display shows the operator which prescriptions are to be filled.

b. The operator fills a prescription by picking the required drug product and scanning its bar code at the station. The filling is aborted unless the bar code scan confirms that the correct drug product has been selected.

c. The station then prints the prescription label and presents it to the operator for application to the drug product. The label contains a bar code, a picture of the drug, descriptive information regarding the drug and auxiliary labels.

d. The operator scans the label bar code and the system displays an image of the drug for final verification by a pharmacist.

There are other dispensing errors that can occur:

- Wrong prescription in bag provided to patient.
- Wrong bag provided to patient.
- Failure to provide all prescriptions.
- Failure to provide counseling to patient.

Again, bar codes are used to prevent errors:

1. When filling the bag.

   a. The station prints a bar code label for the bag that is to be given to the patient. This bar code is unique and associates all prescriptions for the patient with the bag.

   b. Bar codes on prescription labels are then matched to the bar code on the bag. The bag is not considered complete until all prescriptions for the patient have been scanned and matched.

2. When providing the bag to the patient.

   a. Patient presents card (or other document) with identifying bar code.

   b. Scan of patient card prompts display of bag(s) to be provided.

   c. Bag labels are scanned for match to patient.

   d. Patient is prompted to obtain counseling and sign for receipt of prescription via electronic signature device.

These systems prevent errors by controlling and tracking every step in the dispensing process. They record every action, every drug product and every person involved. Bar codes form the electronic chain that holds the system together. The electronic chain runs:

- from the drug product bar code
- to the prescription label bar code

- to the prescription bag bar code
- to the patient bar code
- to the electronic signature of the patient that confirms receipt of the prescription and counseling

Attached to every link in the chain is the bar code of the person responsible for that step. The final link is the patient's own signature. Reports and inquiries are available to track the entire dispensing process.

The first link in the chain is the drug product bar code. Without that link, there can be no complete chain.

III. Bar Code Driven Systems

The systems described above are literally driven by bar codes on drug products. In other words, the routine actions of the personnel and equipment are to a large extent determined by what the bar code scanners read. This design makes the systems easy to use, efficient and foolproof. It also frees up the people involved so they can focus on the critically important, non-routine items like patient care, counseling and medical analysis.

The good news is that some of the most serious problems facing community and ambulatory pharmacies can be addressed simultaneously using the efficiency and accuracy of bar code driven systems:

- There is a critical shortage of pharmacists.
- Dispensing errors occur too often.
- Patient wait time is a source of dissatisfaction.
- Pharmacies often fail to provide adequate patient counseling.

In other words, by improving the use of bar codes on drug products, we can make a significant contribution toward solving a number of serious problems facing our healthcare systems. Virtually everyone involved will benefit.

IV. Bar Codes on Drug Products - Shortcomings

There are shortcomings in the bar codes on drug products and related medical supplies that are prescribed along with them. These shortcomings undermine the efficiency of pharmacy dispensing and present opportunities for errors to occur.

- Some drug products do not have any identifying bar code.
- Lot number and expiration date information is not in bar code format.
- Bar codes in use do not always allow positive identification of drug products.
- There are fundamental flaws in the systems that assign identifying numbers and bar codes to drug products. This results in multiple drug products having the same bar codes and other problems.

1. No identifying bar codes on some drug products.

   a. A drug product is identified by its National Drug Code (NDC number), which is assigned pursuant to a plan administered by the FDA.

   b. Most drug stock bottles and packages display the NDC in character form, and also as both character and graphic elements of the Uniform Product Code (UPC number and bar code). The UPC is an industry assigned number used primarily for stockkeeping purposes.

   c. However, some drugs (and prescribed medical supplies) do not have UPC bar codes on them. These drugs normally display the NDC, which is used to identify and verify the drug manually during the dispensing process. Also, some drugs do not display the NDC at all, and display only the UPC.

   d. The NDC number is normally the middle part of the UPC number, but there is no industry standard (or consistent practice) that assures that the NDC can be determined from the UPC. Sometimes the NDC and UPC are completely different numbers.

   e. This means that guesswork is sometimes required to identify a dispensed drug product. This not only wastes time, but it also opens the door for errors.

   f. We recommend that the NDC be displayed clearly on all pharmaceutical products and prescribed medical supplies, and that the NDC also be included and displayed on these products in bar code form in a standard way (such as in a standard position within the UPC). This will allow all drug stock bottles and packages to be positively identified via their UPC bar code.

2. No lot number and expiration date bar codes on drug products.

   a. Drug stock bottles and packages typically display a lot number and expiration date, but not in bar code form. Those that do, typically display this information in a separate bar code. Dispensing pharmacies must track lot numbers and expiration dates to ensure that drugs are not used beyond expiration dates, deal with recalls, etc.

This information is typically entered manually, and sometimes omitted or entered incorrectly.

b. A simple calculation shows that pharmacists and technicians can waste tremendous amounts of time manually entering and tracking lot numbers and expiration dates. There are approximately three billion prescriptions filled annually in community and ambulatory pharmacies. Assuming a conservative time figure of 15 seconds to enter lot number and expiration date information for each prescription, 12.5 million hours per year are spent on this task alone. This accounts for more than 6,000 Full-Time Employees (FTEs).

c. Prescription volumes are expected to increase by 40% over the next 3-5 years. In other words, in addition to an estimated 6,000 FTE's currently spent on this task, approximately 2,400 additional FTE's will be wasted over the next 3-5 years simply entering lot numbers and expiration dates while dispensing drugs.

d. The shortage of pharmacists has reached a critical level and all projections show that the crisis is in a very early stage with no relief in sight. We are now hearing reports of pharmacy technician shortages.

e. A comparison with pharmacy school projections shows that continued manual entry of lot numbers and expiration dates has the potential to waste 25% or more of the supply of new pharmacists graduating each year.

f. We recommend that all drug products and prescribed medical supplies include, within the identifying bar code (such as within the UPC), the lot number and expiration date so that a single scan of the product can obtain the identity of the product, its lot number and its expiration date. This will allow pharmacy dispensing systems to automatically obtain and utilize lot number and expiration date information without manual entry.

3. Bar codes in use do not allow positive identification of drug products.

a. Manufacturers sometimes make changes in the manufacturing process that modify the physical appearance of a drug without changing it from a therapeutic standpoint. This is sometimes done without assigning a different NDC. For example, the drug might have initially been green. One day the drug is changed to white. However, the manufacturer does not change the NDC since it is considered to be "the same drug." We call this the "multi-version drug" problem. See Appendix B for examples of the multi-version drug problem. Appendix B shows one case where a manufacturer has produced four versions of the drug, all labeled with the same NDC number.

b. Distributors often obtain drugs from manufacturers and repackage or relabel them to sell under their own name. Sometimes these packages are assigned a new NDC and sometimes they are not. Sometimes the packages display two NDC numbers, the

original number from the manufacturer and a new number assigned by the distributor. (See Appendix C for example.)

c. Many drugs come in an outer package (such as a box) with multiple interior packages. The outer package can be dispensed, or it can be opened and the interior packages dispensed separately. Sometimes there is no NDC on the outer package. Sometimes there is no NDC on the interior packages. Sometimes the same NDC is shown on both the outer and interior packages. (See Appendix D for example.)

d. The above situations greatly complicate the dispensing process. They also undermine the ability of dispensing personnel and patients to use visual inspection aids to verify dispensing accuracy.

e. We recommend that a separate NDC (and a separate, single identifying bar code) be used when the appearance of the drug or drug package changes, and that each package that can be dispensed be assigned a unique NDC.

f. Positive identification is important not only for pharmacists, but also for patients. The state of Oregon has implemented regulations requiring prescription labels to display descriptive information to allow patients to positively identify the drugs they are taking. In order to do this, computer systems must be able to determine from the NDC of the drug being dispensed which picture and descriptive information to print on the label. Given the present state of affairs, there are cases where neither the dispensing pharmacist nor the patient can be sure what the drug will look like until the package is actually opened.

4. There is confusion, duplication and errors in the NDC identification numbers and UPC bar codes displayed on drug products.

a. "Labelers" of drug products (i.e. manufacturers and those that repackage or relabel products) typically display both the NDC and the UPC on their product labels.

b. The UPC is displayed in bar code format with the actual number printed below.

c. For drug products, the middle 10 digits of the UPC is typically identical to the NDC, with the first digit of the 12-digit UPC set to "3" and the last digit set as a check digit. However, this is not always the case. Sometimes there is no numerical resemblance between these numbers. (See Appendix E for example.)

d. We recommend that the identifying bar code contain the NDC number in a standard position so that the drug NDC can be positively and directly identified via bar code scan.

5. The NDC numbering system is itself flawed, misused and confusing.

a. The NDC numbering system is based on three separate numbers: Labeler Code, Product ID and Pack Size. However, there is not a coordinated plan as to the exact number of digits in those three numbers.

b. As it has turned out, the Labeler Code can be either four or five digits; the Product ID can be either three or four digits; and the Pack Size can be either one or two digits.

c. However, drug manufacturers, repackagers and labelers, for stockkeeping purposes, need a single number—not three—to identify their drugs. Also, they need the number to be 10 digits so that it fits within the 12-digit UPC number scheme (allowing for a standard leading digit and a trailing check digit). Thus, on drug stock bottles and packages one typically finds the "NDC Number" as a 10-digit concatenation of the three numbers established as the NDC. Sometimes dashes are entered separating these numbers, sometimes not.

d. In other words, the NDC Number is:

The FDA assigned Labeler Code, which may be either four or five digits.

+

The Manufacturer (or Labeler) assigned Product ID, which may be either three or four digits.

+

The Manufacturer (or Labeler) assigned Pack Size (package identifier), which may be either one or two digits.

e. In order for the manufacturers to keep the NDC number to 10 digits, they require that one of the three component numbers be of the "small" size while the other two must be of the "large" size.

f. This plan produced NDC numbers that did not duplicate for a given manufacturer, repackager or relabeler, since the first of the three numbers was assigned uniquely to each of them. However, it did not produce NDC numbers that were unique across the industry as a whole. For example, the concatenation of 0001+1000+01 yields the 10-digit number 0001100001. Likewise, the concatenation of 00011+000+01 yields the same 10-digit number.

g. Pharmacy database providers could not work directly with this numbering system. They could not tolerate duplicate NDC numbers in their databases. Their solution was to convert the 10-digit NDC numbers to 11 digit numbers by adding a zero in front of whichever of the three fields came in the "small" size. Thus, the "NDC" numbers found in most drug databases and displayed on the computer screens and prescription labels used by pharmacists every day are 11 digits. These numbers are derived from the NDC numbers used by the manufacturers by adding a zero either at the front, in the middle, or near the end.

Unfortunately, duplications sometimes occur when converting 11-digit NDC numbers back to 10-digit NDC numbers. This allows drug products to mis-identified. (See Appendix F.)

h. Given this situation of padding the NDC with a zero (somewhere), it is not trivial to determine from a drug database NDC what the manufacturer NDC is. The procedure is as follows:

i. First, determine who the Labeler is and look up the Labeler code. This will be either four or five digits.

ii. If the labeler code is four digits, remove the leading zero from the "NDC" number in the database and you have the manufacturer NDC number.

iii. If the labeler code is five digits, check other reference materials to determine whether the Product ID or the Pack Size has been specified in the "small" size to determine where to add the leading zero.

Appendix G shows examples of the difficulties of translating UPC bar codes to NDC numbers.

i. Some manufacturers have used the “Pack Size” field (i.e. the third element of the NDC) to indicate a property of the product rather than the packaging quantity of the product. Normally, Pack Size is used to distinguish the various package sizes that are available. However, as shown in Appendix H, this field has also been used to designate the length of the needles for various syringes.

j. Sometimes the same bar code references multiple drug products. (See Appendix I for example.)

k. Various types of bar codes are found on drug products and related medical supplies. (See Appendix J for examples.)

l. Appendix K shows an example where three entries in the National Drug Data File (NDDF, supplied by FirstDataBank, Inc.) appear, from their NDC numbers, to be three different package sizes for the same drug. However, the third entry is actually a completely different drug. The source of this misleading data is apparently an error in the expansion of a 10-digit NDC to an 11-digit NDC (described above). Most pharmacy computer applications use the NDDF to perform Drug Utilization Reviews and adjudicate prescription claims. The NDDF is also used by payors to pay prescription claims.

m. Problems such as these are encountered the very first hour of the very first day on the job by anyone who works in a pharmacy. Unfortunately, encountering the problems does not mean that they are understood or solved. As can be seen from the

above, translating from database NDC numbers to manufacturer NDC numbers and interpreting the NDC numbers is cumbersome. It wastes time and confuses people.

These problems cause stress and errors. They are classic "Murphy's Law" examples of how lack of coordination and clarity in establishing standards can produce an incredible, large scale mess. We should clean up this mess before multiplying it by bringing in an even wider range of products. How can we expect those who work in pharmacies to keep up with staggering workloads and avoid dispensing the wrong drugs when they need a road map to identify the very products that the industry provides for them to dispense?

V. Far Reaching Problems

We can testify that the problems described above are far reaching.

1. We develop and maintain systems used in pharmacy dispensing, and we do everything possible to make these systems function efficiently and error-free. This is a very challenging task, given the range of problems and exceptions described above.

2. We develop and maintain drug databases used by these systems. The databases must cope with whatever drug products the pharmaceutical industry turns out and then make sense of how they are labeled. For example, much time is spent dealing with the ongoing problem of multi-version drugs, where drugs change in appearance without new NDC numbers assigned. Also, numerous cross-reference tables must be maintained in order to deal with all of the identification numbers and bar codes found on drug products.

3. We train pharmacists and pharmacy technicians to use these systems. We see the frustration and confusion that these problems cause. Often, the best we can do for the people on the front line is to interrupt robotic processing and let them know that there is an exception that they need to resolve manually.

4. We provide continuous help desk and on-site support and training for the users of these systems. We know firsthand that errors do occur because of these problems.

We believe that the most important steps government can take to help the pharmacy industry cope with the burgeoning workload and avoid dispensing errors is to clean up the identification system for drug products and implement bar code standards.

VI. Recommendations

A. The system for numbering drug products should be fixed, so that the FDA, manufacturers, repackagers, database developers, pharmacists, patients and other interested parties can all reference a drug using the same NDC number in a standard format.

B. The NDC number should be displayed in a standard format on stock bottles and packages for all dispensed drug products and prescribed medical supplies. It should also be displayed

on these products in bar code form in a standard format, possibly within an enhanced UPC bar code.

C. The lot number and expiration date should be displayed on stock bottles and packages for all dispensed drug products and prescribed medical supplies. This information should also be included in bar code form, within the bar code containing the NDC number, in a standard format, possibly within an enhanced UPC bar code.

D. A new NDC (and bar code) should be assigned when the physical appearance of the drug or its package changes.

E. A separate NDC number (and bar code) should be assigned to each drug package that can be dispensed.

F. There should be only one bar code on a drug product or prescribed medical supply item. If the existing UPC bar code cannot be adapted to meet the needs of these products, a single unifying bar code standard should be adopted.