

ScriptPro®

Pharmacy Automation

FAX

DATE: July 12, 2002

TO: Mary C. Gross, Office of Drug Safety
Center for Drug Evaluation and Research
Food and Drug Administration
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FROM: Michael E. Coughlin, President and CEO (913.403.5223)

No. Pages including this cover: 7

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Re: Food and Drug Administration, HHS, Notice of 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.

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Dear Ms. Gross:

Attached please find a summary of the presentation I would like to make at the above meeting. I have also forwarded this to you by email.

Please advise if you need anything else. You can reach me at 913.403.5223 (Direct), 913.208.8561 (Mobile) or mike@scriptpro.com.

Very truly yours,
SCRIPTPRO

Michael E. Coughlin
President and CEO

Enclosure

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APÉ 170

From: Michael E. Coughlin, President and CEO, ScriptPro
 Date: July 12, 2002
 Re: Food and Drug Administration, 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 majority 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. This 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.

Bar code labels for drug products are critical to pharmacy dispensing systems. I will develop here a short list of recommendations which 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.)

Our systems use bar codes to prevent the basic dispensing errors in both robotic and manual prescription dispensing processes.

1. Robotic dispensing.
 - a. Drug products are loaded into a robot. Bar codes on the products are scanned so that the robot can positively identify each product in order to handle it accurately.
 - b. Prescriptions are transmitted to the robot for filling.
 - c. Robot picks the correct product. Bar codes are again verified by robot during picking.
 - d. Robot prints and applies correct prescription label (with bar code).
 - e. Final verification by operator using visual aids (person checks robot by comparing product picked with prescription order and on-screen picture of drug).
2. Manual dispensing.
 - a. Prescriptions are queued up on screen at prescription filling station.
 - b. Person picks drug product and scans bar code at station.
 - c. Station matches product to prescription.
 - d. Station prints prescription label (with bar code) and presents it to person for labeling of product.
 - e. Final verification by operator using visual aids (person checks station by comparing product picked with prescription order and on-screen picture of drug).

There are other errors that can occur:

- Wrong prescription in bag provided to patient.
- Prescription omitted from bag.
- 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. Filling bag.
 - a. Station prints bar code label for bag.
 - b. Bar codes on prescription labels are matched to bag label when filling bag.

2. Providing bag to patient.
 - a. Patient presents card (or other documents) with identifying bar code.
 - b. Scan of patient card prompts display of bag(s) to be provided.
 - c. Bag bar codes are scanned for match to patient.
 - d. Patient prompted to obtain counseling and sign for receipt of prescription via electronic signature device.

These systems track every step in the dispensing process, recording every action, drug product and person involved. Bar codes form the electronic chain that holds the system together. The chain runs from the electronic signature, to the patient bar code, to the bag bar code, to the prescription label bar code, to the drug product bar code. Attached to every link in the chain is the bar code of the person responsible for that step.

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

III. Bar Code Driven Systems

The systems described above are driven by the bar codes. 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:

- Personnel shortages, especially shortage of pharmacists.
- Dispensing errors.
- Patient wait time.
- Failure to provide adequate patient counseling.

IV. Bar Codes on Drug Products - Shortcomings

Unfortunately, there are shortcomings in the bar codes on drug products and related medical supplies that are prescribed along with them. These shortcomings undermine pharmacy dispensing and open up opportunities for errors to occur.

- Some drug products do not have identifying bar codes.
- Lot number and expiration date information is not available in bar code format.
- Bar codes in use do not always allow positive identification of drug products.
- There are 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.

1. No identifying bar codes.
 - a. Some drug products (and prescribed medical supplies) do not have identifying bar codes on them. These products must be identified and verified manually during the dispensing process.
 - b. We recommend that all pharmaceutical products and prescribed medical supplies have identifying bar codes.

2. No lot number and expiration date bar code.
 - a. Drug products typically do not have bar codes indicating lot number and expiration date. This data is critical to insure that drugs are not used beyond their date limits and also in dealing with recalls and other problems. Lot number and expiration date information must be entered manually. This is time consuming and subject to omission and human error.
 - b. A simple calculation shows that the time wasted by pharmacists and technicians manually entering and tracking lot numbers and expiration dates can be staggering. There are approximately 3 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, 12,500,000 hours per year are spent on this task alone. This accounts for over 6,000 FTE's (full time employees).
 - c. These number are expected to increase by 40% over the next 3-5 years. In other words, approximately 2,400 additional FTE's will be wasted over the next 3-5 years entering lot numbers and expiration dates.
 - 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 being turned out each year.
 - f. We recommend that all drug products and prescribed medical supplies include, within the identifying bar code, 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.

3. Bar codes in use do not allow positive identification.
 - a. Manufacturers sometimes make changes in their manufacturing processes that modify the physical appearance of a drug. This is sometimes done without assigning a different identifying number. For example, in the initial release the drug might have been green. One day the drug is changed to red. However, the manufacturer does not change the NDC (National Drug Code) number since it is considered to be "the same drug."
 - b. Drugs are sometimes repackaged without assigning a new identifying number.
 - c. Some drugs come in an outer package with multiple interior packages. The outer package can be opened and the interior packages dispensed separately.

Sometimes the same identifying number is shown on both outer and interior packages.

d. These problems undermine the ability of pharmacy systems to provide visual inspection aids to support dispensing accuracy.

e. We recommend that a new product identifying number (and new bar code) be assigned when the appearance of the drug or drug package changes and that all packages that can be dispensed contain unique identifying numbers.

4. There is confusion, duplication and errors in the identification numbers and 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 number (i.e. the National Drug Code, a 10-digit number administered by the FDA) and the UPC number (i.e. the Uniform Product Code, a 12-digit number administered by the Uniform Code Council) on their product labels.

b. The UPC is typically displayed in bar code format as well. The bar code is typically displayed just above the UPC.

c. The middle ten digits of the UPC number is typically identical to the NDC number, with the first digit 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.

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

5. There are duplicate NDC numbers.

a. The NDC number is designed to be a concatenation of three numbers into a single 10-digit number:

The FDA assigned Labeler Code, which may be either 4 or 5 digits.

+

The Manufacturer (or Labeler) assigned Product ID, which may be either 3 or 4 digits.

+

The Labeler assigned Pack Size (package identifier), which may be either 1 or 2 digits.

b. In other words, the NDC number is a concatenation of three numbers, each of which can come in either a "large" or "small" size. The source of this "large/small" confusion was apparently lack of coordination when the NDC numbering system was established many years ago.

c. In order for the concatenated number to add up to 10 digits, one of the component numbers is of the "small" size and the other two are of the "large" size.



Memo

Re: Consultants Needed Immediately – Income Range \$300,000 to \$750,000 First Year

Who We're Looking For:

Experienced business professionals are immediately needed to satisfy the demand for marketing consulting services:

- > 8 to 10 years (minimum) business experience required
- > Sales experience helpful
- > Public speaking experience helpful
- > Writing skills helpful
- > Marketing and/or advertising experience NOT required

Earn A Top 1% Income By Making Businesses More Money:

We are marketing consultants. We show companies how to get more results—or in other words, how to make more MONEY—from all of their marketing and advertising dollars they spend.

Example: A moving company spends \$3,000 a month in the Yellow Pages for a full-page ad, and that ad generates an average of 70 calls per month. What if you could take that same full page ad that costs \$3,000 a month, and by just changing what it says, and how it says it—now, instead of getting 70 calls a month, the ad generated an average of 955 calls a month? This is getting more results—making more money—with no more money spent. Think about it, if you could get those kinds of results for a company, *do you think you'd be well compensated?*

That's what we do as marketing consultants. We use a proprietary system to get those kinds of results which changes the way companies do their marketing and advertising. Not radical changes that are "creative" or strange or weird. Our process is very systematic, and it works for any kind of company in any industry. Anyone with a strong business background can implement this system.

Our Competitors Hate Our Guts – Care To Join Us?

We compete head to head with large traditional advertising agencies who take money from their clients with no accountability for results. They hate our guts because we expose our results-getting processes to our clients so they can evaluate for themselves and show them step-by-step how to make more money every time they run an ad, produce a brochure, or send a sales person out in the field. The ad agencies hate us so bad because we threaten their very existence; they even call us the "anti-agency."

We are in the middle phases of building a ONE BILLION dollar company that will lead and dominate the entire marketing and advertising industry. We work through highly-trained, highly experienced independent consultants who are trained on our systems and implement them for companies all over the country. This is not a job offering. This notice is for individuals who want to leverage their skills and start their own business.

What You Need To Do Next:

We will be holding a free orientation seminar in your area in about 4 weeks. If you think you might be qualified, and if you're interested—or even if you're just curious... call us and ask for a FREE Seminar Preview Package. It contains a CD Program that gives a complete overview of the business to help you decide whether or not to attend the seminar.

To have the FREE Seminar Preview Package rushed to you, please call (800) 560-6426.

IF YOU RECEIVED THIS FAX IN ERROR AND WOULD LIKE TO HAVE YOUR NUMBER REMOVED FROM OUR DATABASE, CALL TOLL-FREE AT **800-822-9033**.