



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

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Statement on

**BAR CODE LABEL REQUIREMENTS
FOR HUMAN DRUG AND BIOLOGIC PRODUCTS**

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Mr. Chairman and members of the Committee, my name is Edith Rosato, and I am the Vice President of Pharmacy Affairs at the National Association of Chain Drug Stores (NACDS). NACDS is pleased to provide comments on the development of a regulation on bar code labeling for human drug products. NACDS supports the use of bar coding for all prescription products, vaccines and over-the-counter medicines to help improve the quality of pharmacy care provided to patients, as well as create efficiencies in the provision of prescription services.

NACDS membership includes more than 200 chain companies that operate 33,000 community retail pharmacies. Chain pharmacy is the single largest segment of pharmacy practice employing approximately 100,000 pharmacists. Chain community pharmacy fills about 70 percent of the 3 billion prescriptions provided to patients each year.

It is predicted that community pharmacy will fill roughly 4 billion prescriptions by the year 2004. Seventy percent of these prescriptions will be filled by chain pharmacy. This fact, coupled with a continuing shortage of pharmacists—including 6,500 vacancies alone in chain community pharmacy—will require that community pharmacy seek technological solutions to keep up with the increasing demand of prescriptions in an efficient and safe manner.

NACDS supports the use of bar code technology that includes not only the National Drug Code (NDC) but includes the lot number and expiration date of the product down to the unit of dispensing package. With all three pieces of information present, the product can be tracked throughout the supply chain system from point of distribution from the manufacturer to the end-user patient. From a patient safety perspective this is important information to have during a drug recall. Additionally, having this information as part of the bar code makes tracking of inventory much easier. This becomes a useful tool when dealing with returned goods and inventory management.

Patient Quality Features

NACDS supports the use of bar codes as a way to complement the various programs that community pharmacies already have in place to enhance patient quality. Many automated dispensing systems that are in use today in community pharmacy accomplish this goal. A recent chain market survey shows that 45% of the chains surveyed (30% of all stores) use bar code scanning for data entry and prescription verification. One, in particular, allows the pharmacist to scan the bar code on the label of the completed prescription. This allows viewing of an image of the correct product. The pharmacist can compare and double check the image against what is in the pharmacy container before it is ultimately dispensed to the patient.

Pilot tests are also being conducted to investigate the use of bar coding for proper drug selection. The bar code is scanned at the point of data entry, so that the NDC, drug name and strength automatically populates the necessary fields on the computer screen. This eliminates the need to choose one drug from an entire alphabetical list. When all fields are populated, other dispensing functions such as utilization review and billing may also be conducted, since many of these functions depend on the NDC number and specific product information.

Enhancing bar coding would substantially improve the current FDA recall system. In recall or product withdrawal situations, all affected product must be identified and removed from the marketplace. During Class I recalls in particular, the pharmacist must contact every person who has received the drug to warn them of possible adverse reactions as well as to communicate the need for a product withdrawal. If lot numbers were utilized as part of the bar code and recorded as part of the patient's prescription record, identification of the affected patient population becomes an easy task. The pharmacist only needs to contact those patients that have actually received the affected product, eliminating unnecessary alarm that would occur by having to contact all patients that received the drug product. Additionally, the pharmacist would be able to pull this unwanted stock expeditiously from their pharmacy shelves, warehouse or distribution center.

Using bar codes could also facilitate other patient quality initiatives. New technologies exist that allow the physician to send the prescription electronically to the pharmacy provider of the patient's choice. Electronic prescribing helps to eliminate ambiguous abbreviations and specifies all elements needed for a complete order – drug name, dosage, directions and route of administration – reducing the chance for medication-related errors.

Bar Coding Improves Efficiency

Bar code technology also increases efficiency. In fact, bar code technology could be considered as an alternative to keyboard data entry. Bar code scanners are faster than the human eye and much more accurate. Tests have shown that bar coded information has an accuracy rate of 1 error in 10 million characters vs. keyboard data entry error of one in one hundred.¹

Efficiencies and technology in community retail pharmacy have allowed the pharmacist to spend less time on the administrative tasks of filling the prescription, and more time interacting and counseling the patient about the prescription.

A recent study conducted by Arthur Andersen² found that pharmacists still perform many tasks in filling the prescription that do not need to be performed by pharmacists. That is, pharmacists are spending over 2/3 of their time on such tasks as computer data entry; counting and packaging medications; resolving prescription insurance program disputes; and other clerical activities. These non-clinical tasks consume pharmacists' valuable time that could be better devoted to patient care activities. With the number of prescriptions expected to increase, the need for efficiencies in delivering pharmacy services only increases. New technologies, such as automated dispensing systems, allow the pharmacist to become more efficient in preparing the prescription.

¹ SNX: The Bar Code Mechanics (www.snx.com)

² "Pharmacy Activity Cost and Productivity Study" Arthur Andersen, November 1999.

Bar coding Improves Inventory Management

Incorporating bar codes that include NDC, expiration date and lot number could also have a positive effect from a fiscal perspective. These enhancements would have a significant positive impact on inventory management. Today, the pharmacist might use bar code technology on a non-prescription item to check a price, or to determine if there is more stock in a storage room. With the lot and expiration date incorporated into bar coded technology, the pharmacist could purchase product more efficiently. These enhancements could alleviate the reverse distribution system (also known as the returns process) and the associated fiscal burdens. Moreover, the pharmacist could improve the fiscal situation of the pharmacy and distribution center levels by insuring the proper rotation of the product and increasing the inventory turns.

In addition, enhanced bar coding can assist the distribution system of product from a bioterrorism preparedness perspective. The questions of who has product and how it can be moved from place to place could be asked and answered more efficiently with this information.

Conclusion

Community retail pharmacy continues to do its part to help ensure that prescription medications are used correctly. There are other steps that policymakers can take to further improve the use of medications in both the inpatient and outpatient setting. Errors are more effectively eliminated while the medication is in the healthcare professional's control before the prescription is dispensed. Bar coding provides a useful mechanism to improve quality, and as a way to improve many of the fiscal and economic aspects involved with dispensing prescriptions.

And, lastly, it seems feasible to 'phase in' this type of regulation, from a technology aspect. Community pharmacies are at different levels of technology capability. However, knowing when bar coding enhancements (NDC, expiration date, and lot number) will be required will enable us to build this into future technology plans.