

July 12, 2002

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

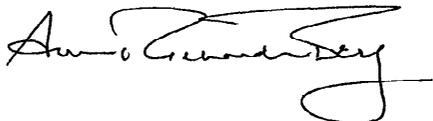
RE: Docket No. 02N-0204

Dear Gentlemen:

I am pleased to submit the enclosed comments on behalf of McKesson Corporation for consideration at the July 26, 2002, public meeting to discuss the development and implementation of possible regulations on bar code labeling for human drug products.

If you have any questions regarding the enclosed statement, please do not hesitate to contact me at (415) 983-8494.

Sincerely,



Ann Richardson Berkey

02N-0204

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McKesson Corporation
Comments Regarding the Development of a Regulation on
Bar Code Labeling for Human Drug Products

Food and Drug Administration
Public Meeting – July 26, 2002

McKesson Corporation is pleased to provide the following comments for consideration at the Food and Drug Administration's July 26, 2002 public meeting on the development of a regulation on bar code labeling for human drug products. We thank the FDA for the opportunity to provide comments on bar coding, and commend the agency for seeking industry input in the development process.

McKesson Corporation is the world's largest pharmaceutical supply management and healthcare information technology company. As the nation's largest healthcare services corporation, we do business with over 5,000 hospitals, 35,000 physician practices, 10,000 extended care facilities, 700 home care agencies, 25,000 retail pharmacies, 600 payors, 450 pharmaceutical manufacturers and 2,000 medical-surgical manufacturers.

We are also the industry leader and only single-source provider of drug distribution, automation, scanning and information technologies to help healthcare organizations reduce medication errors throughout the continuum of care. Over 10,000 hospitals, outpatient, and retail pharmacies are utilizing our bar code-based automation for pharmaceutical products. As such, we are uniquely positioned to provide the FDA with information relative to our experience with pharmaceutical bar coding and currently available technology and automation solutions, and to provide recommendations that will increase patient safety and promote positive health care outcomes.

McKesson supports bar coding of pharmaceutical products to help reduce medication errors and improve efficiencies in the supply chain. For years, McKesson has been developing bar coding technologies that help caregivers prevent medication errors and reduce their associated costs. We pioneered retail pharmacy automation with the Baker Cell pill counting technology with products in over 10,000 retail and outpatient pharmacies world-wide. We invented the first robotic dispensing system, which automates the dispensing of unit-dose bar coded medications, and introduced the product to the hospital market in 1992. We also manufacture medication dispensing cabinets for nursing units that support bar code scanning for accurate drug restocking, and we have incorporated bar code scanning utilizing a hand-held wireless scanner at the point of medication administration at the patient's bedside. McKesson was also the first drug distributor to fully automate our distribution process by implementing radio frequency and scanning technology throughout our entire warehouse and distribution network.

Based on many years of experience in automation technology and information systems, our comments can provide insight into the potential impact that certain requirements would have on hospitals with bar code systems currently in place, and on the technical,

implementation and workflow issues that should be seriously considered before a final rule is proposed.

General Recommendations:

In order to reduce medication errors, bar codes must be available *and* technology must be in place to scan bar codes, while facilitating clinical process and workflow. Our analysis at customer sites indicates that approximately 20-35% of the unit-dose medications currently contain a machine-readable bar code that could be effectively utilized by existing technologies. Increasing the availability of bar codes and implementing technology to leverage them will decrease the number of medication errors.

In general, we believe that proposed requirements should address desired outcomes and not necessarily dictate a specific process for attaining that outcome. The eventual objective is to enhance patient safety and eliminate errors throughout the medication use process. Specific outcomes could include the ability to identify/verify drugs at the bedside or any other point of care, as well as the ability to address a patient's five rights: right drug, right dose, right time, right patient, right route.

Proposed requirements should take into consideration the considerable investments that many hospitals have made to date in bar coding technology and give them the flexibility to support and build upon these investments. For example, hospitals that have invested in scanning and automated dispensing solutions should not have to revamp their infrastructure completely. Early adopters should not be disadvantaged.

We also believe that proposed requirements should not be technology specific. Proposed requirements should be broad enough to maximize the use of current technology, without inhibiting innovation.

Specific Recommendations

Drugs and Biologicals

McKesson supports the requirement for bar coding for all commercially available prescription and non-prescription medications. Bar codes should be available at all levels of packaging, on shipping cases, SKUs, and at the unit-dose level. This requirement should apply not only to unit-dose oral medications, but should also include all unit-dose medications, in all forms, including vials, oral liquids and intravenous medications provided in vials or in IV bags. Vaccines and blood products should also be bar-coded.

Medical Devices

With its commitment to patient safety, McKesson supports the eventual inclusion of certain medical devices in a bar code labeling recommendation. However, because of the complexity of this issue and the need to select the devices to be covered, we recommend that the FDA complete its proposed rule on human drug products and biologics and then explore the feasibility of creating a bar code rule for selected medical devices.

Bar Code Data

The minimum amount of data in a bar code on a unit-dose medication that will prevent medication errors is the National Drug Code (NDC), as issued by the FDA, and the expiration date. Used alone, bar codes will not prevent medication errors; technology and decision support systems must be in place to ensure that patient safety benefits are derived from the use of bar coding. Scanning drug and dose information, such as NDC, and comparing it to the patient profile will ensure accurate dispensing and administration of the medication.

Although the inclusion of lot numbers in bar codes would provide additional tracking capability, they would also add complexity to the workflow and increase costs.

- Increasing the amount of data in the bar code may require that a different bar code type (such as RSS or 2-D) be utilized. This would impact all existing scanning technology currently utilized in hospitals and require upgrades to scanners capable of reading the newer symbology.
- Tracking additional data, particularly lot numbers, would also impact workflow. The pharmacy and nursing staff would have the additional steps of ensuring that the lot number is entered into the formulary each time a new lot is received, and then tracking the dispensing of medication lot numbers at the nursing unit level. This process would be simplified if point of care bar code scanning is in place, and more labor intensive if it is not.
- There is no national standard for lot number formatting; currently the data included, the format and the length of manufacturers' lot numbers vary significantly.
- Most systems currently utilized in hospitals today do not track lot numbers; therefore, a requirement to track lot numbers would also necessitate changes to existing systems or the design of new systems. The cost/benefit of these changes should be considered.

Bar Code Format/Location

Once the information contained in the bar code is determined, uniform standards should be adopted for bar codes; i.e., order of data, format of NDC (10 vs. 11 digit), and format of lot number and expiration date, if required. Currently there is wide variation, even among pharmaceutical companies. A minimum quality standard must also be implemented. We recommend the ANSI bar code print quality grade B, in order to assure that the bar codes are in fact machine-readable.

It also would be beneficial to establish uniform standards for the location and position of the bar code on the immediate product labels, the intermediate container or carton, and

SKU. We recommend that the location and position of the bar code be such that it is possible for a handheld bar code scanner to easily and reliably scan the bar code.

As we noted, McKesson has hundreds of customers in the inpatient hospital setting that currently utilize bar code technology for dispensing and administering medications. A linear bar code containing the 10 digit NDC and 4 digit expiration date is currently used. Attached, as Appendix A, is an example of McKesson's unit-dose bar code specification. These hospitals have various options for obtaining the bar codes in this format on unit dose medications. All the drug wholesalers currently provide them; some manufacturers provide them (i.e. UDL); and the hospitals also have the ability to generate the bar code label in the pharmacy, utilizing commercially available bar code labeling technology. We have worked with most major information system vendors to ensure that this bar code format may be utilized with their systems as well. Results that were achieved from a current customer who used this bar code format are included at the end of this document.

Symbology

We recommend that linear bar codes be used as the initial requirement for bar code symbology. This will allow hospitals that currently use automation to continue to use their existing technology, while capitalizing on the increased number of bar coded products available. Careful consideration should be given to the impact of requiring a newer generation bar code, as these bar codes and scanners have not yet been widely deployed in healthcare. The impact on personnel and workflow requirements may be significant; i.e., the distance allowed between the scanner and the bar code is greatly reduced with the scanning technology required to scan RSS or 2-D bar codes. Implementation of this newer technology would also require that all scanning technology in hospitals today be replaced or upgraded. Thousands of hospitals currently utilize unit-dose packaging technology which is only capable of printing single dimensional barcodes.

Implementation

Ideally, the bar code labeling should occur as early in the supply chain as possible. This may be at the time of manufacturing or re-packaging of unit-dose medications. However, McKesson recommends that proposed requirements allow flexibility in determining the most appropriate point in the process for this labeling. Stakeholder roles should be based on core competencies and supply chain efficiencies. For example, a manufacturer that does not have the resources to invest in state-of-the-art packaging infrastructure should have the option to outsource the packaging.

Bar coding may also be required in the hospital pharmacy for patient specific doses or unit dose medications that are supplied in bulk containers. This labeling is essential if bar code scanning for medication administration is to be accomplished. Standards for the data in these bar codes should also be considered in order to facilitate point of care bar code scanning of these medications.

We believe that implementation requires significant lead-time for development. Stakeholders will need lead-time to develop or modify their existing infrastructure in order to comply with the new requirements. For example, hospitals may need to install

scanners, distributors will need to adjust their inventory management model for an increased number of SKUs, and manufacturers will need to acquire new packaging infrastructure. However, after an adequate lead-time, we recommend rapid execution to minimize the cost associated with managing dual systems and inventory management issues related to SKU proliferation.

Supporting Data

In addition to medication error reduction at the dispensing and administration phases, bar code technology has many additional benefits. The use of bar codes in combination with automated dispensing technology and robotics can free pharmacists from dispensing tasks to perform clinical duties. With the pharmacy work force shortage, automation will become critical to ensuring pharmacy services in some hospitals. Bar codes also provide a means for inventory management and tracking as well as for automating patient billing. Point of care bar code scanning allows for critical checking of the “5 Rights” of medication administration, preventing errors before they occur. It also allows for real-time documentation of medication administration, providing immediate on-line data for clinical care, and accomplishes accurate billing based on what was administered to the patient.

The University of Wisconsin

As early as 1993, the University of Wisconsin Hospitals and Clinics embraced McKesson’s bar code and automation solutions for pharmaceutical distribution through our robotic system (ROBOT-Rx) and our unit based cabinet (AcuDose-Rx). They are currently implementing point-of-care bar code scanning at the bedside (Admin-Rx). The bar code format that the University of Wisconsin is currently utilizing on unit-dose medications is a linear bar code that includes NDC and expiration date. Working with McKesson on clinical programs and ADE tracking, they have demonstrated a significant reduction in medication errors, enhanced efficiency, increased clinician satisfaction, and improved medication documentation. They are currently using bar-code technology and robotics in their outpatient pharmacy as well. They have performed a pre- and post-automation study, using the naïve observer technique, to assess the error reduction associated with their technology implementation.

Results from the University of Wisconsin include:

- Reduction in dispensing errors from 1.43 percent to 0.13 percent, utilizing the ROBOT-Rx and bar-coded medication dispensing
- Return on investment realized in 2 years
- Increase from 89 percent to 95 percent in nursing satisfaction with switch from manual drug dispensing systems to our robotic and cabinet drug dispensing systems
- 79 percent reduction in narcotic discrepancies utilizing the AcuDose-Rx dispensing system

- 85 percent improvement in documentation accuracy in the emergency room and 71 percent reduction in overall discrepancies utilizing the AcuDose-Rx dispensing system
- 89 percent reduction in medication administration errors due to point of care bar code scanning at administration, utilizing the Admin-Rx medication administration system

Eastern Idaho Regional Medical Center

At a Senate Aging Committee hearing in May 2001, Mr. Neil Reed, director of pharmacy at the Eastern Idaho Regional Medical Center, testified on the real, measurable and significant benefits associated with the use of automated technology in the medication delivery process. In his statement, Mr. Reed emphasized the major benefits that have been achieved since his hospital began to use the robotic dispensing technology manufactured and distributed by McKesson. These benefits include improved accuracy in dispensing medications, enhanced patient safety, improved efficiency and deployment of pharmacists and hospital staff, and, ultimately, cost savings for the hospital.

Conclusions

We believe that bar coding of pharmaceutical products and the use of technology to leverage the benefits of bar coding are essential to patient safety. We commend FDA for its willingness to collaborate with industry and health care providers to accomplish this critical goal of reducing medication errors and improving patient safety. In addition to the requirement for industry cooperation in developing standards to support this goal, it is important that hospitals have the funding necessary to implement the technology to support the outcomes that will be required. To that end, McKesson has endorsed the Medication Errors Reduction Act of 2001, legislation that would provide grants to hospitals to purchase or upgrade technology proven to reduce medication errors.

Appendix A

Current Format for Unit-Dose Medications Utilized by McKesson Automation Systems

NDC (National Drug Code) Format

- 1) NDC number consists of 10 digits in a 4-4-2, 5-3-2, or 5-4-1 format.
- 2) The format defines the manufacturer code, product code, and the package code. Multiple NDCs can be mapped to each configured Generic Name, concentration (if applicable), drug form, drug dosage, and drug dosage units in the Connect-Rx database.
- 3) This bar code format contains numbering identifier, NDC number, format indicator, and expiration date.

The bar code is 16 digits in length, all numeric, and encoded in Code 128 symbology. The format is follows:

nNNNNNNNNNNFMMYY

Legend

n: numbering system identifier. This is a UCC standard prefix used to identify the type of code that follows it. The industry standard value to identify an NDC is 3.

NNNNNNNNNN: 10 digit NDC drug identifier

F: Format indicator. This indicates the correct placement of the eleventh digit (padded zero) and or dashes. This is important for interoperability with systems that store NDC information in those formats. Valid values are 1, 2, 3 and are interpreted as follows:

F=1	4-4-2	04-4-2
F=2	5-3-2	5-03-2
F=3	5-4-1	5-4-01

390
1000

FedEx USA Airbill
Express

FedEx
Tracking
Number

8313 0327 5322

Form
ID No.

0215

Recipient's Copy

RECIPIENT: PEEL HERE

1 From This portion can be removed for Recipient's records

Date 7/1/02
FedEx Tracking Number 831303275322

Sender's Name Bill Wilkin
Phone 415 983-8696

Company MCKESSON CORPORATION

Address 1 POST ST STE 375

City SAN FRANCISCO

State CA ZIP 94104-3207

2 Your Internal Billing Reference 75704725

3 To Recipient's Name FOOD INGREDIENTS ADMINISTRATION
Company LOCKETS ADMINISTRATION
Address 5630 FISHERS LANE
23222 1061
City ROCKVILLE

To "HOLD" at FedEx location, print FedEx address

We cannot deliver to P.O. boxes or P.O. ZIP codes.

Dept./Floor/Suite/Room

State MD ZIP 20852



4a Express Package Service

FedEx Priority Overnight Next business morning
 FedEx Standard Overnight Next business afternoon
 FedEx 2Day Second business day
 FedEx Express Saver Third business day
 NEW FedEx Extra Hours Later drop-off with next business afternoon delivery for select locations

4b Express Freight Service

FedEx 1Day Freight* Next business day
 FedEx 2Day Freight Second business day
 FedEx 3Day Freight Third business day

5 Packaging

FedEx Envelope
 FedEx Pak* Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak
 Other Pkg. Includes FedEx Box, FedEx Tube, and customer pkg

6 Special Handling

SATURDAY Delivery Available only for FedEx Priority Overnight and FedEx 2Day to select ZIP codes
 HOLD Weekday at FedEx Location Not available for FedEx First Overnight
 HOLD Saturday at FedEx Location Available only for FedEx Priority Overnight and FedEx 2Day to select locations
Does this shipment contain dangerous goods?
 No Yes As per attached Shipper's Declaration
 Yes Shipper's Declaration not required
Dangerous Goods (incl. Dry Ice) cannot be shipped in FedEx packaging or with FedEx Extra Hours service.
 Dry Ice Dry Ice, 9, UN 1845 x _____ kg
 Cargo Aircraft Only

7 Payment Bill to:

Sender Acct No. in Section 1 will be billed
 Recipient Enter FedEx Acct. No. or Credit Card No. below
 Third Party
 Credit Card
 Obtain Recip. Acct. No.
 Cash/Check

Total Packages _____ Total Weight _____ Total Charges _____

8 Release Signature Sign to authorize delivery without obtaining signature

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims
Questions? Visit our Web site at fedex.com
or call 1.800.Go.FedEx® 800.463.3339
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