



January 9, 2012

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane,
Room 1061
Rockville, MD 20852

**Re: FDA-2011-N-0719; Bar Code Technologies for Drugs and Biological Products;
Retrospective Review under Executive Order 13563; Request for Comments**

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit comments pertaining to the Food and Drug Administration's (FDA's) request for information regarding the 2004 rule that requires certain drug and biological products to have a bar code.¹ Our comments primarily address the thirteen questions the Agency published in the Federal Register on October 26, 2011.² For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams. They work with physicians, nurses, and other health-care professionals to ensure that medicines are used safely and effectively.

ASHP policy encourages health systems to adopt bar-code-enabled medication administration (BCMA) technology to improve patient safety and the accuracy of medication administration and documentation.^{3,4} To support the goal of having all medications electronically verified before they are administered; BCMA systems should be used in all areas of health-systems in which medications are used. The Society urges the Food and Drug Administration (FDA) and other regulatory agencies, standard-setting bodies, contracting entities, health systems, and others to mandate that pharmaceutical manufacturers use symbologies that are readily deciphered by commonly used scanning equipment to code for the National Drug Code (NDC), lot number, and expiration date on all unit dose, unit-of-use, and injectable drug packaging. FDA, pharmaceutical manufacturers and packagers, and the manufacturers of BCMA systems should collaborate to minimize or eliminate the causes of false rejection of valid medication

doses. Although bar-coding systems are currently a widely used point-of-care technology, ASHP recognizes that other types of machine-readable coding (e.g., radio-frequency identification [RFID]) may evolve. ASHP supports the use of new technologies that are as effective as or improve upon existing systems. The Society is pleased that the FDA is conducting further research on such systems and encourage the Agency to continue to study measures that will determine the extent to which BCMA systems reduce preventable medication errors and encourage efficient drug administration.

Further, review of this Final Rule has implications for compliance with State law. For instance, California has enacted an e-pedigree law for "dangerous drugs." In order for California hospitals and health systems to comply with the e-pedigree law, they will need a database that is able to track information that will mitigate and prevent counterfeiting. Linear bar codes are not capable of containing all of the information that is needed to be in compliance with State law (e.g., manufacturer, lot number, date of manufacture, expiration date and the unit size). ASHP recommends that all changes to the Bar Code Final Rule should be consistent with the FDA's March 2010 Final Guidance for Industry: *Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages*⁵ ("SNI Guidance"). A review of the FDA's Guidance on the National Drug Code should be considered with the review of the Bar Code Final Rule.

In the Federal Register notice referenced above, the FDA solicited responses to the following questions about the costs and benefits of any alternative to the linear bar code and our comments, which are based on our members' current practice experience, follow each question below. As the responses are based on the experiences of members who have adopted the use of bar codes in the hospital pharmacy, we address all questions with the exception of Question 9.

1. Is there a need for alternative technologies to the linear bar code? Does the current linear bar code requirement meet the current needs of the health care industry and health care providers?

While the development of the linear bar code was an important first step in implementing important safety systems, further improvements require a bar code that contains more data than a linear format can practically provide. The current linear bar code has the following shortcomings:

- The bar code size limits its application to extremely small packages;
- The inherent linearity of the bar code makes effective scanning impractical on containers with curved or irregular surfaces;

- The size of the bar code prevents inclusion of lot number, expiration date and serialization information that is useful for management of drug recalls and tracking involvement in patient incidents. This requires that such information, where it is provided in encoded form at all, to be printed in a secondary bar code that causes confusion and inhibits patient safety during bar code medication administration (BCMA). Indeed, it was recently documented that Baxter Incorporated removed secondary bar codes from their infusion containers because of staff confusion using BCMA.⁶

In general, a number of challenges facing the users of bar code technology could be addressed with a timely and authoritative reference that permits users to properly decode the contents of a bar code. The current challenges facing healthcare professionals are:

- The bar code encoding includes, but is not limited to, the National Drug Code (NDC) which is a multiple-part “smart” number. That number consists of three parts, only one of which (the identity of the manufacturer or “labeler”) is controlled by the FDA. NDC’s can be, and are, developed and revised by manufacturers on a weekly basis, but are not approved or reported as frequently, nor is there a clearinghouse for what an NDC represents. NDC is *only* a 10-digit number – there are 11-digit representations, but they are generally unofficial – and the bar-code encoded representations are unformatted. Since multiple formats are permitted within those 10 digits, they are nearly impossible to parse or decipher.
- The bar code encoding has no standards that are enforced. The only requirement is that the barcode *contain* the NDC. The result is that the manufacturers are permitted to encode any data they choose in the bar code in any form *as long as the NDC is somewhere in that encoding*. Further, since there is no standardization regarding how the drug code and package code portions of the NDC are assigned, these elements may be difficult to extract from current bar codes by some software.

For example, a large number of bar codes fall into one of the following formats:

- *3nnnnnnnnnnC* – a UPC12 encoding in which 3 indicates that this is a drug, *nnnnnnnnnn* is the 10-digit unformatted NDC, and *C* is a check digit,
- *01103nnnnnnnnnnC* – a variant of GS1 encoding containing the NDC as *nnnnnnnnnn*,

- 01003nnnnnnnnnnC – a variant of GS1 encoding containing the NDC as nnnnnnnnnn,
- nnnnnnnnnn – a bar code containing only the 10-digit NDC, and
- NDC: nnnnnnnnnn – The literal text “NDC:” followed by the 10-digit NDC.

Adoption of the RxNorm Concept Unique Identifiers (CUI) as the drug portion of the NDC would potentially solve this problem and would create a universal standard that would easily identify a specific drug regardless of manufacturer in the case of multi-source drugs.

Further, should the FDA adopt one or more standard encoding structures (such as GS1 and/or the Health Industry Business Communications Council [HIBCC]), software could be developed to parse out the contents of a bar code and recognize independent components such as NDC, lot number, Standardized Numerical Identification (SNI), and expiration date instead of treating bar codes as a single glyph which means that, until BCMA software can be trained to parse the contents of a bar code it will tend to see each new lot of a product as unique and different.

2. How has product coding technology changed since FDA issued the Bar Code Final Rule on February 26, 2004? Please provide information about the maturity, degree of adoption, cost, and ease of use of coding technologies that may be considered as alternatives or in addition to the linear bar code.

Generally, there is widespread use of bar code scanner hardware that supports scanning of a linear bar code in hospitals and health-systems. As Meaningful Use Criteria evolve, bar code scanning in hospitals is becoming the norm. According to data from the *ASHP National Survey of Pharmacy Practice in Hospital Pharmacy Practice – 2011*, 50% of hospitals have implemented bar code medication administration systems, 43% of hospitals utilize machine readable code for restocking automated dispensing cabinets, and 12% of hospitals utilize bar code verification for preparing intravenous medications.

Pharmaceutical manufacturers, in general, have settled on one of two, two-dimensional bar code types: Aztec or Data Matrix. Both symbologies are very informationally dense, and can represent NDC, lot number and expiration date in less physical space than required for the NDC alone in a linear bar code. Two-dimensional bar codes can be applied to and read from curved and irregular surfaces much more effectively than linear codes. Two-dimensional bar codes are now the

symbologies of choice for IV work flow software applications that manage the compounding of IV doses. Scanners for reading these codes are imagers (essentially digital cameras); the cost differential between scanners for linear bar codes and imagers that read both linear and two-dimensional bar codes has dropped dramatically and these technologies are functionally the same. Two-Dimensional Scanners are a benefit for hospitals newly adopting BCMA and pharmacy work flow systems, but it could be a large expense for hospitals that have implemented linear bar code systems to replace all their scanners.

Scanners and imagers both now occur on the market that can *autodiscriminate* encoding symbologies, making standardization on a single symbology relatively useless. The technology has continued to evolve rapidly and is considered reliable as long as the printing of the bar codes themselves is of sufficient quality. Two-dimensional bar codes are without question superior to linear bar codes as they contain much more information in a more compact code than do linear bar codes.

3. What factors other than those listed in question 2 should FDA take into account in considering technologies alternative to or in addition to the linear bar code?

USP Chapter <797> addresses tracking of manufacturer and lot of ingredients used to prepare compounded doses, as do several state pharmacy practice acts; however, the use of linear bar codes requires that to be a manual process, which may result in poor compliance and even poorer data quality. The adoption of the use of two-dimensional bar codes would permit the capture of this information to be done electronically with a simple scan producing much higher compliance and much better data quality. This is a prerequisite to creating a functional drug recall management program.

When RFID and similar alternate ID technologies are discussed, the cost of these chips vs. the virtually free two-dimensional bar code should be considered. RFID may have a place in tracking bulk shipping quantities of items like cases or pallets, but at the unit of use level – the opposite end of the packaging spectrum – they would add cost and complexity to medication scanning for the “5-Rights” (e.g. right patient, right medication, right dose, right route, and right time).

Standardization of formats need to be examined so that bar codes are universally read across all brands of scanner and recognized by various software.

4. What technologies or coding systems warrant FDA's consideration as alternatives to the linear bar code? In your response, the Agency particularly invites comments on the following issues for each technology identified:

A. What is the current state of development and availability of the alternative technology?

The two-dimensional bar code symbology is mature and in full commercial use in North America and other places in the world. Two-dimensional bar codes are readily available, subject to appropriate standardization, and have the capacity for high-reliability encoding (which linear bar codes do not). The HIBCC has a standard set for use of two-dimensional bar code symbology in healthcare. This was first developed at Brigham and Women's Hospital and Partners Healthcare in Boston MA.

Two-dimensional matrix bar codes such as Aztec and Data Matrix bar codes would greatly increase overall success, for the reasons listed below:

- They are designed to capture large amounts of data in a compact space;
- They are not as susceptible to printing defects as are linear bar codes;
- The coding scheme has a high level of redundancy with the data "scattered" throughout the symbol;
- They have a better first read rate on curved surfaces compared to linear;
- If damage to the bar code occurs they have a better chance of having a successful read than do linear bar codes;
- Their smaller size allows them to fit more efficiently on smaller medication packages;
- More software companies are providing the ability to generate, utilize, and maintain two-dimensional bar codes in their systems; and
- More medication manufacturers are converting to the use of two-dimensional bar code technology.

B. Would adoption of this technology as an alternative to the linear bar code further reduce medication errors in hospitals and health care settings? Please provide supporting data, if available.

Adoption of alternative technology to the linear bar code would create numerous opportunities to reduce medication errors in hospitals and health-systems. One obvious area of improvement would be inclusion of simple parameters that are already contained on a medication label, but at present must be read and interpreted by humans, which introduces opportunity for error. If expiration date and/or beyond use date were contained in a bar code

format, those checks can be done automatically within the software they are operating on, closing the loop on the appropriateness of administration for that order. It would also eliminate manual documentation of things like lot number, already a cumbersome requirement for many items like vaccines.

Additionally, capture of lot number and expiration date would allow scanners in pharmacy departments and at the point of care to check for recalled lots at the time of administration – potentially protecting the patient from receiving recalled products that could be harmful if administered.

As previously described, the adoption of two-dimensional encoding would improve the readability of commercial bar codes in the healthcare setting as well as improve the capture of information required by organizations such as CMS and USP.

C. Would adoption of this alternative technology advance public health protections? If so, how? If supporting data exist, please provide this information.

The ability to capture lot number and expiration date information as part of a normal scan would permit the now-difficult and time consuming task of knowing which recalled lots of drugs may have been administered to which patients. It will also facilitate location of expired medications in automated dispensing cabinets, and likely reduce the incidence of expired medications. It will also make it easier to implement electronic IV compounding record keeping by routinely scanning and recording the lot and expiration dates as well as the product, diluents, and IV bag names sizes and concentrations in one bar code scan.

Beyond the issue of identifying recalls, the trending data and utilization information that could be gleaned from a standardized data set of scans, combined with the high degree of accuracy that they provide, will generate meaningful data without adding additional steps to the healthcare delivery process.

In recent years, counterfeit medications have become an increasing problem in the healthcare system. With the increased use of bar codes, and more sophisticated information contained in each code, systems could be configured to reject products that contain a lot number that has been programmed as recalled or flagged as counterfeit, adulterated, or misbranded.

5. Does the adoption of this alternative technology have implications for other FDA or Department of Health and Human Services initiatives (e.g., SNI)?

Adoption of alternative technology will require development of standardized fonts, well developed databases at the Federal level to avoid any duplications, and inspection to prevent attempts to use such bar codes for fraud/counterfeiting purposes. One further area which will require intra-agency coordination (Centers for Disease Control) will be tracking of vaccines. As Meaningful Use Stage 2/3 criteria are developed, additional coordination will need to occur with the Office of the National Coordinator if electronic verification systems are incorporated into the medication management systems and electronic health records.

6. Have you used the linear bar code for authentication or tracking and tracing of prescription drugs?

A. If so, how?

Our members have reported the following uses of the linear bar code for authentications or tracking and tracing of prescription medications:

- Bar code medication administration (BCMA) to verify correct medication, correct patient, correct route of administration, and correct timing of administration;
- Use of bar codes at the NDC level (non-preparation specific);
- Use of the current linear symbology bar codes on pharmaceutical products in an IV Compounding Workflow Management System and within IV Robotic devices;
- Use of specific two-dimensional bar code to track preps to minimize the confusion between linear and two-dimensional bar codes;
- Validation of current drug load into automated medication dispensing machines.

B. Please describe any successes or challenges that you have encountered in adopting linear bar code technology for this purpose.

ASHP members have reported the following successes or challenges encountered in adopting linear bar code technology:

- The scanning process has been successful in preventing numerous medication errors in dose compounding by capturing and preventing the use of inappropriate drug products.
- The primary challenge with bar codes is the freedom with which manufacturers can change the data contained within the bar code.

- Additionally, the extraneous information contained within a linear bar code – data other than the NDC – is continually subject to change. Vendor software does not always recognize and/or interpret these changes, which can result in manual addition/update process that is often unanticipated. Manufacturers do not provide notification when a linear bar code is updated and it is only when the medication arrives on site, often not until the nursing administration step, when a new bar code is identified. However, prospectively reviewing every bar coded medication that arrives, including upon arrival of each and every shipment, is impossible to achieve.
- Any revisions to the Final Rule should include a requirement that manufacturers publish and inform prescribers and pharmacists when any changes are made to the bar code.
- Addition challenges arise from the poor quality of encoding on pharmaceutical containers using the linear symbologies, the lack of an authoritative and reliable list of NDC's, and the current requirement for manual capture of lot and expiration, which has both compliance and data quality issues. Adoption of a two-dimensional symbology with lot and expiration would solve all but the generally poor quality of data of NDC's, which we urge the FDA to address.

C. If not, which if any alternative technologies could reduce medication errors while also serving other functions?

There are likely other less widespread technologies, such as RFID, that may provide similar benefits to those of bar codes. However, these technologies may not be cost-effective at this time, and would require an entirely separate infrastructure to accommodate.

Furthermore, organizations have invested significant resources to purchase, build and maintain bar code recognition software. Switching from bar codes to any other technology, at this point in time, is neither practical nor appropriate. Allowing manufacturers an alternative to bar codes, or trying to support multiple technologies, will likely introduce opportunity for error.

Incorporating more information into the bar code in “stacked” bar codes (e.g., GS1 Composite) would be a logical next step with the ultimate goal of a movement to adoption of two-dimensional bar codes. Not all bar code recognition technology will read two-dimensional bar codes, and to move immediately from linear to two-dimensional bar codes could be a step backward for hospitals with BCMA systems that are unable to read the two-dimensional

format. The interim use of the GS1 Composite bar codes would provide an “upgrade path” without an interruption in patient safety.

7. For hospitals and other health-care facilities that have adopted bar code technologies using linear bar codes:

A. What difficulties did you encounter in adopting the technology?

There are a number of difficulties reported by our members in initially adopting bar coding technologies. They include:

- Hardware issues (initial scanners were originally designed for scanning from a flat surface – not an object);
- User training;
- Difficulties relate to poor quality encoding on pharmaceutical packages;
- Absence of control or adequate reporting of new NDC’s that arrive on the market (and the subsequent excessive work to update databases that support bar code scanning);
- Lack of standardization of the encoded data structure within the bar codes (some use check digits, some are more than 11 digits others are UPC bar codes);
- Lack of ability to capture lot and expiration while scanning products;
- Other difficulties such as ensuring that all bar codes are contained within the bar code tablet for that product; and
- Bar codes that change over time from the same manufacturer.

B. How have productivity and operating costs changed?

As with the adoption of any new technology, there are initial start-up costs to the use of bar codes in the hospital or health-system setting (cost of the scanners, cost of the e-MAR and scanning software, and training), but now that the technology has been in place for a number of years, operating costs generally remain unchanged. For those newly adopting bar coding as a means to manage the hospital or health-system pharmacy, the cost of hardware related to scanning, both linear and two-dimensional, have dropped dramatically (from thousands to hundreds of dollars) and there is more software available to perform scanning.

C. What differences have you seen in medical outcomes?

There has been a decrease in the administration of incorrect medications or wrong patients. No reports of medical outcome changes have been reported by ASHP members. A study by Poon et al (Partners Healthcare) examined 115,164

and 253,984 dispensed medication doses in the pre – and post – bar code implementation periods, respectively. Overall, the rates of target potential adverse drug events (ADEs) and all potential ADEs decreased by 74% and 63%, respectively. Of the three configurations of bar code technology studied, the two configurations that required staff to scan all doses had a 93% to 96% relative reduction in the incidence of target dispensing errors ($P < 0.001$) and 86% to 97% relative reduction in the incidence of potential ADEs ($P < 0.001$). However, the configuration that did not require scanning of every dose had only a 60% relative reduction in the incidence of target dispensing errors ($P < 0.001$) and an increased (by 2.4-fold) incidence of target potential ADEs ($P = 0.014$). There were several potentially life-threatening ADEs involving intravenous dopamine and intravenous heparin in that configuration.⁷

D. What problems have you experienced with the technology?

Those cost and productivity gains has been offset in some cases by the exceptionally poor quality of data related to the actual NDC's and therefore bar codes actually in the supply chain, as well as the poor quality of the encoding that often requires that pharmacists repackage or re-label the pharmaceutical packages with bar codes that actually scan.

8. For hospitals and other health-care facilities that have adopted alternative technologies or non-linear coding:

A. What difficulties did you encounter in adopting the technology?

ASHP members who responded to our inquiry did not report significant difficulty in using two-dimensional bar code scanning.

B. How have productivity and operating costs changed?

Capital expenditures may be slightly higher initially, but the benefits of adopting non-linear coding technologies have outweighed the monetary investment. No appreciable impact is expected on labor expense, and the imagers are reportedly very reliable in field use. A number of our members who provided input to ASHP as we prepared this response have reported using two-dimensional imagers since 2008.

C. What differences have you seen in medical outcomes?

The ability to capture multiple data items with a single scan has improved compliance with, and quality of, data capture.

D. What problems have you experienced with the technology?

Among ASHP members responding to our request, there have been no significant problems reported with using two-dimensional technology. The two-dimensional bar codes read as quickly, if not more quickly, than scans of linear codes and because of its more compact size, adapts more favorably to pharmaceutical containers than does a linear code.

10. How would technology adoption have proceeded since 2004 had the Bar Code Final Rule not gone into effect?

It appears that in the United States, the FDA rule had significant stimulatory effect on the adoption of bar coding for drug identification during the rendering of patient care. It is unlikely that the growth of this industry would have achieved its current penetration without the FDA mandate. The regulation was a springboard for widespread adoption of bar code technology for patient safety in hospitals. Although in theory pharmacists could have applied bar codes manually, the additional high labor costs and patient safety risks associated with this practice would have made adoption slow.

11. What are hospitals' and other health-care facilities' forecasts for technology adoption once incentives in the Economic Stimulus Act of 2008 (Pub. L. 110–185) are no longer in effect?

The pace of adoption of bar code technologies and systems in hospitals does not seem to be affected by the Economic Stimulus Act, which seems to be more aimed at the adoption of electronic medical records than on the adoption of patient-safety technology. In some states like Massachusetts, insurers have included the implementation of BCMA systems in Pay for Performance contracts with hospitals. We would expect this to continue.

12. Would there be an economic impact on those parties who may not be subject to the bar code requirement but who nonetheless may use or adopt or have adopted bar code technology (e.g., hospitals, clinics, public health agencies, and health care providers)?

Please use the following questions to guide your responses.

A. *Current practices.* Describe your current practice(s) at your institution with respect to those products that are required to be labeled with a bar code under

§§ 201.25 and 610.67. Have you encountered any barriers to your ability to use technology at your institution?

As previously stated, there are two primary barriers:

1. A lack of consistency in the formatting of data within the bar code, making it difficult, if not impossible, to extract data from the bar code
2. The lack of consistency in how drugs are identified within the NDC itself, both in terms of undocumented changes in encoding and in terms of inconsistent use of the drug code from manufacturer to manufacturer. If the drug code within the NDC for a specific drug was always the same regardless of manufacturer and located in the same position within the NDC it could be easily extracted for use.

B. *Using an alternative to the linear bar code.* If an alternative to the linear bar code could be placed on the label of at least some of your products, what impact, if any, would that have on your current practice(s)? How would you change your practices, if at all?

It is likely that changes to both hardware and software would need to occur to be able to scan a two-dimensional bar code. However, this technology has many benefits that exceed the costs associated with this change. In using two-dimensional bar codes, hospitals would be better able to manage expired medications in advance, thus likely decreasing drug waste and providing a positive return on investment for the additional expense incurred to get better scanners. Further, it is likely that most hospitals would view two-dimensional scanners as the logical replacement technology at this point, similar to how smart infusion pumps have become the standard replacement technology.

As previously stated, the use of GS1 Composite bar codes can serve as a useful link between the current linear bar code technology and the adoption of two-dimensional bar codes by manufacturers. In other words, if due to label space, manufacturers stop applying a linear bar code on their products and replace them with a two-dimensional bar code only, hospital and health system BCMA systems may be unable to read the two-dimensional format. This would potentially threaten patient safety until an institution's systems could be upgraded. Using GS1 Composite bar codes in the interim could avoid this issue.

C. *Expenses.* What unplanned expenses, if any, would you incur, if an alternative to the linear bar code could be placed on the label of at least some of your

products? If you could foresee using an alternative to the linear bar code, would you modify operations in your facility, and if so, how?

In many cases (i.e., if scanners were recently purchased), current workflow systems are capable of capturing information from a two-dimensional bar. Changes and/or upgrades to vendor software may be necessary to capture and store the additional information, if any, in the bar code. Hospital software and automation vendors may need to upgrade software systems to account for the additional data available and make accommodations to store and use this data throughout the medication use process.

D. *Adverse event reporting and recalls.* Have you encountered challenges/successes in drug identification or reporting with respect to products that contain a bar code on their labels? If so, please describe them. Would an alternative to the linear bar code have an impact on your recall management or adverse event reporting, and if so, how?

As previously discussed, the lack of usable and reliable encoding of lot number and expiration date information on pharmaceutical containers makes the current linear bar code an ineffective tool in the management of event reporting and/or recall management.

If the lot number was part of the bar code and when the bar code was scanned it was recorded in the patient's medical record, then one could identify recalled items which had actually been administered to patients and notify the patients if necessary. This may require additional efforts on the part of hospital software vendors to ensure that this function is included in their software.

13. Are there other parties whose economic interests we should consider?

The following parties should be engaged with as the FDA makes any revisions to the Final Rule:

- Directors of Pharmacy for Hospitals and Health-Systems,
- Pharmaceutical manufacturers,
- eMAR and EHR vendors,
- Pharmacy Information System vendors,
- Pharmacy Automation Vendors (cabinets, carousels, packaging/labeling equipment, etc...),
- Medication safety system vendors (BCMA), and
- Manufacturers of scanners.

ASHP believes that use of bar-code scanning in medication administration, inventory management, dose preparation and packaging, and dispensing of medications can enhance patient safety and the quality of care. Such scanning also provides the opportunity to accumulate and use statistics on the pharmacy distributive operation that can direct more appropriate staffing, identify sources of routine error, and generally permit better management of the drug distribution process. The Society urges the FDA to require that pharmaceutical manufacturers be required to place machine-readable coding that includes the NDC, lot number, and expiration date on all unit dose, unit-of-use, and injectable drug packaging, using symbologies that are readily deciphered by commonly used scanning equipment.

The Society appreciates the opportunity to comment on the FDA's request for comments on Bar Code Technologies for Drugs and Biological Products. Please contact me if you have any questions or wish to discuss our comments further. I can be reached by telephone at 301-664-8806, or by e-mail at ctopoleski@ashp.org.

Sincerely,



Christopher J. Topoleski
Director, Federal Regulatory Affairs

¹ Federal Register, Volume 69, No. 38. Pages 9120 – 9171.

² Federal Register, Volume 76, No. 207. Pages 66235 - 66238.

³ ASHP Statement on Bar-Code-Enabled Medication Administration Technology:
<http://www.ashp.org/DocLibrary/BestPractices/AutoITStBCMA.aspx>

⁴ ASHP Statement on Bar-Code Verification During Inventory, Preparation, and Dispensing of Medications: <http://www.ashp.org/DocLibrary/BestPractices/AutoITStBCVerif.aspx>.

⁵ Federal Register, Volume 75, No. 59. Pages 15440 – 15441.

⁶ Tribble, DA **A step forward in bar coding?** *Am J Health-Sys Pharm* August 1, 2011 68:1406

⁷ <http://www.annals.org/content/145/6/426.abstract>