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June 11, 2003

Dr. Mark McClellan  
Commissioner  
United States Food and Drug Administration  
c/o Dockets Management Branch (HFA-305)  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

**Re: Bar Code Label Requirement for Human Drug Products and Blood, Docket No. 02N-0204, RIN 0910-AC26**

Dear Commissioner McClellan:

Premier, Inc., a strategic alliance of more than 1,500 not-for-profit hospitals and health systems across the U.S., appreciates the opportunity to comment on the FDA's March 14, 2003 proposed rule to require the bar code labeling of hospital-administered human drug and biological products. We believe that the proposed rule, in its intent and ultimate implementation, represents a critical advance in the health industry's efforts to improve patient safety and delivery of care.

For the leading not-for-profit hospitals and health systems allied in Premier, cost-effective quality improvement of care is not *solely* a priority—it is our mission and reason for being. Industry adoption of the bar code is a key component of an integrated, broad-based strategy to assist our hospitals achieve the highest quartile in care quality and lowest quartile in costs.

Premier believes the FDA ought to be commended for its thoughtful and balanced approach with respect to the proposed rule. Inasmuch as our comments address ways in which the regulation may be improved upon, we are cognizant and deeply appreciative of the lengths to which the agency has gone to seek out and incorporate input from all stakeholders, while maintaining a primary focus on the millions of patients whose care would be positively impacted by the implementation thereof.

Premier strongly believes that the bar code rule ought to be viewed as an important step—a stepping stone—in a larger, evolutionary process. For instance, while we support a three-year implementation window for the prescribed bar code labeling, inclusive of the NDC number, we believe that the FDA ought to promulgate additional rules, effective within five years, stipulating lot and expiration date as required elements of drug and biological product labels, as well. In addition, we believe that a compelling patient safety interest also lies in requiring certain medical devices to be similarly “bar coded.” We wish to reiterate, however, that our comments, even in their occasional departure from the letter of the proposed rule, are designed to provide further evidence in support of the agency's, and Premier's own, pursuit of sustained patient safety improvement.

We are also pleased to align ourselves with the vast majority of comments submitted by the National Alliance for Health Information Technology (NAHIT), of which Premier is a member. Premier has

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strived to work collaboratively with all stakeholders to reach consensus on as many issues as possible, with respect to the bar code rule. We believe NAHIT has achieved that goal. Premier's comments refer to sections/items/provisions/questions specified in the March 14 proposed rule, **Bar Code Label Requirement for Human Drug Products and Blood**, Docket No. 02N-0204, RIN 0910-AC26.

**1. FDA Question**

Should the rule require bar codes on prescription drug samples, and if so, what are the costs/benefits of their inclusion (reference the FDA Proposed Rule, Section II.B.2.a.)?

Premier believes that the bar code labeling of drug samples is critical. Such items are commonly dispensed in numerous hospital settings, including the Emergency Department (ED), hospital-operated and/or attached urgent care centers, and outpatient surgery and treatment (i.e., cancer, cardiovascular, pulmonary, dialysis) and diagnostic (i.e., gastrointestinal, radiology) centers. The very nature of treatment and medication administration in the ED presents unique challenges for which bar coding would prove instrumental.

Drug samples are so critical a component of care delivery that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) "requires a policy and procedure related to the control of drug samples throughout the institution which, in the case of organizations, includes all organization-owned clinics (even when off-site of the hospital campus), organization-owned physician practices, and the emergency room (ER)." JCAHO requires (and Premier supports) that "all recalled medications can be quickly retrieved from patients and removed from stock." Accordingly, hospitals must keep detailed records, often including lot and expiration date, of drug samples dispensed to patients. (See attached JCAHO fact sheet.)

**2. FDA Question**

What are the risks and benefits of including vaccines in the rule (reference the FDA Proposed Rule, Section II.B.2.a.)?

We concur with the proposed rule that vaccines ought to contain (i.e., be labeled with) bar codes. Further, we believe that requiring bar code labels on vaccines would *not* adversely impact vaccine manufacturers or suppliers. The three-year implementation period outlined in the proposed rule, with which Premier also concurs, would provide vaccine makers sufficient time to incorporate bar codes into the overall labeling process.

While numerous market factors impact vaccine production, including a lack of manufacturer diversity for some, we do *not* believe that a subsequent reduction in product would result from bar code incorporation. Further, we believe that the patient safety improvement potential inherent in bar coding is as appropriate and readily applicable to vaccines, as for pharmaceuticals, biologics, and certain medical devices. In particular, we believe that lot number and expiration date, as required bar code data components, may be even *more* critical for vaccines than for other drugs or biologics.

**3. FDA Question**

Are the terms used to describe the Over-the-Counter (OTC) drug product covered by the rule sufficient (reference the FDA Proposed Rule, Section II.B.2.b.)?

Premier supports the required bar code labeling of OTC drugs “sold to hospitals, packaged or labeled for institutional use, or marketed, promoted, or sold to hospitals through drug purchasing contracts or catalogues” at the manufacturing, repackaging, or re-labeling level. We believe that such language readily applies, as well, to other care settings like ambulatory surgery and dialysis centers, and long-term or step-down care facilities. For instance, ambulatory surgery centers, often connected to or affiliated with hospitals, are equipped similarly to inpatient hospital operating rooms; and, to be sure, similar medications are administered. From a patient safety perspective, and for the sake of consistent application, we believe it makes sense that any OTC drugs dispensed under an order, regardless of the care setting, to be bar coded.

#### 4. FDA Question

Should the Lot Number and Expiration Date be included in the rule, and if so, what is the data on the costs and benefits that would justify their inclusion (reference FDA Proposed Rule, Section II.C.2.)?

Premier agrees that the NDC number ought to be a required data component of the drug and/or biological bar code, as stipulated under the proposed rule. Premier, in fact, requires that all drugs and/or biologics for which group purchasing contracts are signed (as of Jan. 1, 2003) be bar-coded in this fashion. We believe, however, that the inclusion of the NDC number ought to be viewed as an *initial* step in a process by which lot and expiration date are also required in a rule to be promulgated by the FDA within five years.

Particularly compelling evidence of the utility of lot and expiration date as bar code data components can be found in the cases of medication recalls. The National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) included lot and expiration date as bar code components in its June 2001 recommendations. The council determined: “Inclusion of lot number within the bar code will ensure that those lots subject to a recall can be readily identified. Inclusion of the expiration date within the bar code will ensure that the patient does not receive a medication that is beyond its expiration date.”

We would also point to contemporary infectious outbreaks, as defined by the Centers for Disease Control and Prevention, in which lot numbers and expiration dates were *key factors* in agency inquiries. CDC investigators determined that *had* the products in question contained bar codes with lot and expiration date, investigations into the outbreaks would have greatly facilitated. The outbreaks in question (outlined below) involved a variety of microorganisms and/or endotoxins, and contaminated a wide variety of products, such as heparin sodium ampoules, an anesthetic; propofol (Diprivan) ampoules; peritoneal dialysis solutions; albumin vials; glucose and distilled water solutions; gentamicin vials, an antibiotic; and epoetin alfa vials, a medication. Several of these outbreaks had national implications, and that involving albumin necessitated a worldwide recall of 116,000 vials.

- Contamination of Heparin Sodium with *Pseudomonas putida*. Morb Mort Wkly Report 1986; 35(8):123-4.
- Postoperative infections traced to contamination of an intravenous anesthetic propofol. Bennett SN et al N Engl J Med 1995; 333(3) 147-54.
- Outbreak of sterile peritonitis among continuous cycling peritoneal dialysis patients. Mangram AJ et al. Kidney International 1998; 54(4):1367-71.
- *Enterobacter cloacae* bloodstream infections traced to contaminated human albumin. Wang SA et al. Clin Infect Dis 2000; 30(1):35-40.

- An outbreak of neonatal deaths in Brazil associated with contaminated intravenous fluids. Garrett DO et al. J Infect Dis 2002 186(1):81-6.
- Pyrogenic reactions associated with single daily dosing of intravenous gentamicin. Inf control Hosp Epidemiol 2000 21(2):771-4.
- *Serratia liquifaciens* bloodstream infections from contamination of epoetin alfa at a hemodialysis center. N Engl J Med 344(20):1491-7.

**5. FDA Question**

Should the rule refer to linear bar codes without mentioning any particular standard (reference FDA Proposed Rule, Section II.D.1.)?

Premier concurs with the NAHIT consensus that the FDA ought to remove its reference (in the proposed rule) to linear bar codes, and retain the requirement that such codes meet the Uniform Code Council's UCC/EAN standard. We believe the FDA ought to view the standards with maximum flexibility so as to allow the most advanced innovation. At the same time, reasonable parameters ought to ensure that hospitals may confidently purchase technology that will be applicable and allow for communication with other technologies.

We also concur with NAHIT's recommendation that, while not included under the purview of the current proposed rule, medical devices should meet either HIBCC or UCC/EAN standards when the FDA considers such auto identification requirements.

**6. FDA Question**

What is the current state of bar code scanners and their ability to read various symbologies (reference FDA Proposed Rule, Section II.D.1.)?

Premier is sensitive to the balance the FDA has worked to achieve with respect to code scanners and their ability to read various symbologies. On the one hand, hospitals need an achievable, predictable standard applicable to bar code use, and we are grateful that the FDA has maintained its view that such represents a critical component of any successful regulation. On the other hand, we believe patients are best served when the broadest scope of technological innovation is permitted. This way, as technology improves, more and perhaps better data can be captured in better, more efficient ways. Thus, improved patient safety, better information, and stronger opportunities for clinical research, would be facilitated.

It is in this context that we believe the FDA can promote innovation by requiring that bar codes meet UCC/EAN standards. As such, those standards may come to include other auto-identifiers allowing providers to migrate to this new technology.

**7. FDA Question**

Should the rule adopt a different format for the machine-readable code; what should that format be; how widely is it accepted by the industry; and will hospitals be able to read it with existing equipment or equipment under development (reference FDA Proposed Rule, Section II.D.1.)?

Premier agrees with NAHIT's recommendation that the FDA incorporate enough flexibility in the rule to encourage the adoption of improved auto-identification technology as it develops. By referencing a class of standards, such as UCC/EAN, rather than a particular technology or format, the FDA can provide for essential flexibility in the rule.

**8. FDA Question**

Should there be specific product exemptions from the rule and how should they be defined?

Premier agrees with the FDA that there should *not* be exemptions granted for specific products. It is worth noting that one of the real-world applications of bar-coded pharmaceuticals is an automated review of drug interactions. Any product that *ought* to be bar-coded, but is *not*, could have safety implications—a strong impetus, to be sure, for the promulgation of a rule.

**9. FDA Question**

Is the implementation timeframe of three years appropriate, or can it be shortened; should there be a different timeframe for new drug products (reference FDA Proposed Rule, Section II.G.)?

Premier supports a three-year implementation timeframe for the proposed rule. We believe that bar codes should be required for new drug product applications two months after the effective date of the final rule. Further, we maintain that lot and expiration date should be required bar code components within five years, as promulgated in a proposed rule.

**10. FDA Question**

Should the ISTB-128 standard be adopted for blood or should an UCC/EAN standard be required (reference FDA Proposed Rule, Section II.H.)?

Premier concurs with the NAHIT recommendation that the FDA ought to require a standard for the bar coding of blood products that is 1) recognized by the field, and 2) can be read by the same scanning technology employed in the medication use process utilizing the ISBT-128 standard. By adopting the standard—all the while recognizing that Codabar will continue to be necessary until existing inventory is completed, and requiring such within three years of the final rule—the FDA will advance the field in its compliance with standards for which voluntary consensus already exists.

**11. FDA Question**

How will the rule for blood affect hospitals' purchasing decisions for bar code technology given the requirements in the rest of the rule for drug products (reference FDA Proposed Rule, Section II.H.)?

Premier believes that scanners now used in hospitals can recognize both ISBT-128 and UCC/EAN standards. Therefore, we do not believe that the rule for blood products would greatly affect hospitals bar code technology purchasing decisions.

**12. FDA Question**

Are any of the alternatives discussed by the FDA in the economic impact section of the rule, of issuing no rule or requiring additional information in the code, viable (reference FDA Proposed Rule, Section II.O.)?

Premier believes that implementation of a final bar code rule would contribute significantly to sustained patient safety improvement. We believe the rule could be improved by requiring bar codes

on drug samples (question 1), requiring lot and expiration date within 5 years (questions 4 and 9), and requiring bar codes on appropriate medical devices (see below).

A compelling patient safety interest lies in requiring bar codes for certain medical devices, whether such are 'original,' reprocessed, repackaged, refurbished, or 'multiple-use.' These devices include implantable items like hip/knee prosthetics, stents, and CRM pacers. Bar coding would facilitate and improve upon the tracking of these devices, especially in the event of a recall or other safety concern. This argument was underscored by the testimony of Johns Hopkins at the FDA's July 26, 2002 public meeting on bar coding. In describing the challenges Johns Hopkins encountered with respect to successfully tracking and recalling a particular bronchoscope, the institution made an unimpeachable case for the bar coding of medical devices.

We would also return to our own June 18, 2002 comments submitted to the agency in advance of the July 26 public meeting. We stated that the medical devices for which bar code labeling ought to be required "are those with the strongest implications for patient safety and efficacy." This would include, for example, potentially high-risk medical devices, as identified by the FDA.

To reiterate and conclude, Premier believes that the bar coding of hospital-administered drugs and biologics, as well as most medical devices, would further industry efforts to sustainably improve patient safety and delivery of care. Further, we believe that the patient safety implications of bar coding go far beyond the point of administration. Bar coding systems, when used appropriately, can facilitate practitioners' and researchers' ability to identify and study improved patient treatment protocols. We would note that the reluctance of the medical device industry to embrace universal identifiers, like the proposed bar codes, seems particularly inconsistent, given that medical devices sold in the retail setting routinely contain bar codes. Again, we are deeply appreciative of the FDA's efforts in promulgating a bar code rule, and look forward to working with the agency toward implementation.

Sincerely,

A handwritten signature in black ink, appearing to read "Herb Kuhn", with a long horizontal flourish extending to the right.

Herb Kuhn  
Corporate Vice President

Attachment

## Hospital FAQs—Go to JCAHO home page and click on Top spot—Standards FAQ

<http://www.jcaho.org/accredited+organizations/hospitals/standards/hospital+faqs/care+of+patients/medication+use/drug+samples.htm>

June 1, 2000

### Drug Samples

**Q:** What exactly is required by JCAHO with regard to drug samples in the clinics and ER? What are the surveyors looking for?

**A:** There is only one standard that directly addresses drug samples (TX.3.3). This standard requires a policy and procedure related to the control of drug samples throughout the institution, which in the case of organizations includes all organization-owned clinics (even when off-site of the hospital campus), organization-owned physician practices, and the emergency room (ER).

However, it should be noted that all other standards applicable to medication use apply to drug samples to the same extent as they apply to regular prescription medications dispensed by the organization pharmacy. Furthermore, another standard (LD.1.6) requires a "uniform performance of patient care processes", including medication use processes, throughout the institution. Thus, the Joint Commission would expect that drug samples in ambulatory and other settings be handled with the same level of control, accountability, and security as other prescription drugs within the organization (i.e., floor stock). This is the key criterion that surveyors will use to determine compliance to our standards - specifically TX.3.5. As with all standards, however, the Joint Commission does not dictate the specific method or process to be used to control drug samples. This is left to the organization to determine.

Based on the above principles, the JCAHO surveyor will generally look for the following in evaluating compliance with the standards as related to drug samples:

There is a system (defined by policy and procedure) for the control, accountability and security of all drug samples throughout the organization. This process should adhere to FDA and other laws and regulations regarding distribution of drug samples, and should be consistent with other organization policies and procedures for medication use. The surveyor will also determine if the policies and procedures for drug samples are adhered to.

The drug samples are properly stored. Storage of drug samples are under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation and safety according to manufacturer's specifications and law and regulation (e.g., USP and OSHA requirements). Products that require refrigeration should be refrigerated. Stored drug samples should be organized to allow for easy retrieval yet segregated to prevent medication errors. All samples of the same drug should be stored together in the same sample storage area, although multiple storage areas for samples are allowed.

Although not required, it is recommended that samples be stored by therapeutic class rather than alphabetically, since the chances of a serious dispensing error are less likely. In any case, throwing all samples of various types into a drawer is not acceptable. Also, OSHA requires that cytotoxic agents (e.g. cancer chemotherapy, ganclivovir, etc.) be stored separately from non-cytotoxic drugs with special labeling of the storage area.

Drug sample storage areas are routinely inspected. This inspection checks for expired and deteriorated sample medications; samples stored in the wrong place; drugs which can no longer be identified for name, strength, and expiration date; and other medications that do not belong there. This process should be similar to and at the same frequency as medication checks of floor stock within the organization. That

is, if your organization conduct monthly inspections of floor stock, we would expect monthly inspections of the drug sample stock in the clinics and ER. There is no requirement that the pharmacy assume responsibility for the handling of drug samples (which is illegal in many states) or in conducting these inspections. However, the pharmacy should be involved in development of the system used, and in monitoring (i.e., random auditing) these processes for compliance to policies and procedures, and JCAHO standards for medication use.

Drug samples for prescription or legend drugs are secure. Drug samples should be kept in an area where unauthorized access is not allowed or which is under constant supervision or surveillance (e.g., behind the receptionist, in a locked room, in the physician's private office, etc.). If in areas not under constant surveillance by staff, and where visitors and patients are allowed (e.g., patient examination rooms), the drug samples must be locked in a drawer or cabinet. In determining compliance to security, the surveyor will determine if there is any possible way that a visitor, patient or unauthorized staff person (e.g. a janitor) can remove the sample drugs without being immediately noticed. If this can occur, your system is not secure. The surveyor will apply this same principle to other non-sample prescription drugs, syringes and prescription pads.

Drug samples for prescription drugs are labeled and dispensed according to the same standardized method that the organization uses for non-sample prescription medications. The organization's policies and procedures for dispensing medications to ambulatory patients should be followed. If the same system is not used, the same objectives and outcomes should be achieved. Handwritten and fill-in preprinted prescription labels are acceptable. If the organization normally provides written patient information with dispensed medications, the same should occur for samples.

Documentation requirements for sample drugs should be the same as other non-sample medications ordered and dispensed by the clinic or organization. At a minimum, all documentation requirements for prescription drugs in the medical record (e.g. inclusion on the summary list, progress notes, etc.) should be followed. There is no requirement to conduct a perpetual documented inventory of non-controlled substance sample medications, unless such a process is desired or required by organization policy and procedure.

There must be an effective recall mechanism for drug samples. There is no requirement to have a log of all dispensed sample medications and lot numbers, unless such a process is desired or required by organization policy and procedure (including pharmacy procedures for outpatient prescriptions). As long as all recalled medications can be quickly retrieved from patients and removed from stock, the process is acceptable. Thus, reviewing each patient's chart to determine who received the drug under recall, and calling all patients to remove the drug (irrespective of lot number) or verifying with the patient the lot number on the package at the time of calling the patient, is an acceptable method. Many organizations, however, do not want to alarm patients who did not receive the affected lot of drugs, and thus maintain a log of dispensed medications by lot number or document the lot number in the medical record. That way, only patients who received the affected lot of the recalled drug are contacted. However, this is not a JCAHO requirement.

As previously indicated, the Joint Commission does not prescribe any specific system, computerized or not, for the control and accountability of drug samples. Most organizations use a simple manual system for the control and accountability of drug samples that is inexpensive and easy to use. The basic premise is that the Joint Commission expects organizations to have the same level of accountability (documentation), control, and security for sample medications as it does for non-sample medication. As with other medications, we also expect that these process adhere to all organization policies and procedures for medication use, JCAHO standards for medication use, and all applicable laws and regulations. Any systems implemented for the handling of sample medications should be evaluated against this basic premise.



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**Q:** I was told that it is better to just eliminate drug samples than try to meet all the JCAHO requirements for sample drugs. Is this what JCAHO is trying to achieve?

**A:** No. The Joint Commission has never stated that drug samples be eliminated from organizations and clinics. We recognize the value of drug samples in treating indigent patients and as starter doses for patients receiving medications for the first time. Our requirements for sample drugs are no more than what we require for any other drug used or dispensed from the organization. Many organizations have received recommendations related to sample drugs, because their process for handling samples was often grossly below the level of control, accountability and security of non-sample medications.

Pharmacy directors who do not want to deal with medication issues in the clinics often take the approach of removing the problem altogether by eliminating all drug samples from the premises, and as justification for their actions blame JCAHO. While an organization can choose to remove samples from the institution for a variety of patient care reasons, blaming JCAHO is not recommended, since one call by the physician to JCAHO (as often happens) will result in the physician finding out that this is not a JCAHO requirement and the credibility of the pharmacist will be destroyed. In addition, the pharmacy director will still be held responsible for issues dealing with the control and handling of non-sample medications in the clinics, so a "head-in-the-sand" approach to medication use in the clinics will not help.

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**Q:** Must drug samples used within the clinics be only formulary drugs?

**A:** No. There is no specific requirement that drug samples dispensed from clinics be formulary drugs. However, we do require that the stocking and dispensing of sample drugs adhere to same policies and procedures of the formulary system for the institution as for non-sample drugs. Again, the principle is evoked that Joint Commission expects organizations to have the same level of control for sample medications as it does for non-sample medications.

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**Q:** When you say that the drug sample inventory should be "controlled", does this mean that there needs to be a perpetual inventory kept on samples so there can be accountability between what was received and dispensed or does it just mean that we have to lock up the samples. Please clarify.

**A:** No, unless this is stated in your policy and procedure for drug samples, or you require a perpetual inventory for all medication supplies in other areas of the organization (e.g. cardiac cath lab, inpatient floor stock, etc.). Most organizations do not require a perpetual inventory for drugs other than controlled substances. However, while it is not a requirement of our standards, we have found that many organizations utilize such an approach in the system for handling drug samples. We hope this is not under the mistaken belief that it is a JCAHO requirement.

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**Q:** We have been told that we must maintain a log of what samples each patient received with patient name, ID#, drug name, drug strength, amount dispensed, date dispensed, and lot number. Is all this required by JCAHO?

**A:** No. The Joint Commission does not require such specific documentation. The use of a separate log sheet has often been instituted because the organization believes that it make recalls easier. However,

the use of such log sheets is solely the discretion of the organization. It is perfectly acceptable for all documentation of the ordering and dispensing of the medication to be solely in the medical record, avoid duplication of effort. There is no requirement for the organization to record lot numbers for any medication (see the Standards Clarification on Lot Numbers), including sample medications.

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**Q:** Is the pharmacy responsible for the control of the supply of sample drugs.

**A:** No. In fact, direct pharmacist control of sample drugs is a violation of most state laws and regulations. However, many organization administrators hold the pharmacy department accountable for medication use issues throughout the institution. It would be wise (and is recommended by the Institute for Safe Medication Practices) for the pharmacy to help establish the control system and periodically (e.g. quarterly or semiannually) audit that it is working properly.

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**Q:** Are we required to identify, report and review significant medication errors and significant adverse drug reactions from sample drugs?

**A:** Yes. Again, all the medication-related standards (in this case, standard PI.4.3.) apply to sample medications dispensed from the clinics to the same extent as it does to regular prescription medications in the inpatient facility.

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**Q:** Are non-prescription sample medications required to be locked, and documented like prescription sample medications?

**A:** The process for documentation and dispensing of non-prescription sample medications should follow the same process for documentation and dispensing of non-prescription regular medications. In addition, the Joint Commission does not require that non-prescription medications (sample or non-sample) be locked or otherwise secure.

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**Q:** Can each physician maintain his own supply of sample medications in the clinic, or must it be a centralized storage area?

**A:** It is acceptable for each physician to maintain his or her own supply of sample medications for their own use. This may or may be in the physician's private office. However, all the requirements for medication storage, accountability and security still apply for each of the sample storage areas, as it would for just one.

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**Q:** Does the requirements for sample drugs apply to community health clinics that the organization has in remote cities?

**A:** The standards will apply to every site that is on the organization's application for survey. Based on our requirements of what must be on the application (determined by criteria for functional and organizational integration of services, and public perception of relatedness listed in the CAMH), most ambulatory sites

owned by the organization and reporting directly to the organization's administration, will be included in the scope of the accreditation. Hence, the standards will apply to those sites. I recommend that you speak to your organization's JCAHO coordinator to determine what is and is not on your application for survey.

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**Q:** Does these requirements apply only to organization-based clinics or to freestanding ambulatory clinics as well?

**A:** The standards for freestanding ambulatory organizations are the same as for organizations. The difference is that the "uniform performance of patient care processes" will be applied to the ambulatory organization only, and will not be tied to any performance of services or policies of the organization. Hence, more flexibility can occur.

## Ambulatory Care Manual

<http://www.jcaho.org/accredited+organizations/ambulatory+care/standards/faqs/faq+index.htm>

March 14, 2002

## Recording Medication Lot Numbers

**Q:** Must lot numbers for medication ampules or other dosage forms be recorded?

**A:** No. The Joint Commission does not require the recording of lot numbers for any drug.

Joint Commission standards require that the organization have an "effective medication recall mechanism." FDA medication recalls are always conducted by lot number.

***In the case of ampules, the lot number is not on the ampule itself; it appears only on the box in which ampules are shipped. In cases of recalls the organization must develop a procedure that allows all ampules from the recalled lot to be retrieved.***

If the organization can effectively retrieve all lots of the particular medication subjected to the FDA recall then the recall mechanism is acceptable.

The principle that recording of lot numbers is not a JCAHO requirement holds true for all dosage forms (pills, capsules, vials, etc.) of medications - including drug samples and therefore, it is not required for individual ampules to be re-labelled with the lot number or have lot numbers for any medication dosage form recorded for the purposes of a recall to meet Joint Commission standards.

*Effective 12/01/99*

*Updated 04/01/00*

*Revised 05/16/00*

*Updated 02/23/01*

*FAQ 03/14/02*

December 15, 2000

## Drug Samples

**Q:** I was told that it is better to just eliminate drug samples than try to meet all the JCAHO requirements for sample drugs. Is this what JCAHO is trying to achieve?

**A:** No. The Joint Commission has never stated that drug samples be eliminated from hospitals and clinics. We recognize the value of drug samples in treating indigent patients and as starter doses for patients receiving medications for the first time. Our requirements for sample drugs are no more than what we require for any other drug used or dispensed from the hospital. Many organizations have received recommendations related to sample drugs, because their process for handling samples was often grossly below the level of control, accountability and security of non-sample medications.

Pharmacy directors who do not want to deal with medication issues in the clinics often take the approach of removing the problem altogether by eliminating all drug samples from the premises, and as justification for their actions blame JCAHO. While an organization can choose to remove samples from the institution for a variety of patient care reasons, blaming JCAHO is not recommended, since one call by the physician to JCAHO (as often happens) will result in the physician finding out that this is not a JCAHO requirement and the credibility of the pharmacist will be destroyed. In addition, the pharmacy director will still be held responsible for issues dealing with the control and handling of non-sample medications in the clinics, so a "head-in-the-sand" approach to medication use in the clinics will not help.

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**A:** No, unless this is stated in your policy and procedure for drug samples, or you require a perpetual inventory for all medication supplies in other areas of the hospital (e.g. cardiac cath lab, inpatient floor stock, etc.). Most hospitals do not require a perpetual inventory for drugs other than controlled substances. However, while it is not a requirement of our standards, we have found that many hospitals utilize such an approach in the system for handling drug samples. We hope this is not under the mistaken belief that it is a JCAHO requirement.

**Q:** We have been told that we must maintain a log of what samples each patient received with patient name, ID#, drug name, drug strength, amount dispensed, date dispensed, and lot number. Is all this required by JCAHO?

**A:** No. The Joint Commission does not require such specific documentation. The use of a separate log sheet has often been instituted because the organization believes that it make recalls easier. However, the use of such log sheets is solely the discretion of the organization. It is perfectly acceptable for all documentation of the ordering and dispensing of the medication to be solely in the medical record, avoid duplication of effort. There is no requirement for the organization to record lot numbers for any medication (see the Standards Clarification on Lot Numbers), including sample medications.

**Q:** Is the pharmacy responsible for the control of the supply of sample drugs.

**A:** No. In fact, direct pharmacist control of sample drugs is a violation of most state laws and regulations. However, many hospital administrators hold the pharmacy department accountable for medication use issues throughout the institution. It would be wise (and is recommended by the Institute for Safe Medication Practices) for the pharmacy to help establish the control system and periodically (e.g. quarterly or semiannually) audit that it is working properly.

**Q:** Are we required to identify, report and review significant medication errors and significant adverse drug reactions from sample drugs?

**A:** Yes. Again, all the medication-related standards (in this case, standard PI.4.3.) apply to sample medications dispensed from the clinics to the same extent as it does to regular prescription medications in the inpatient facility.

**Q:** Are non-prescription sample medications required to be locked, and documented like prescription sample medications?

**A:** The process for documentation and dispensing of non-prescription sample medications should follow the same process for documentation and dispensing of non-prescription regular medications. In addition, the Joint Commission does not require that non-prescription medications (sample or non-sample) be locked or otherwise secure.

**Q:** Can each physician maintain his own supply of sample medications in the clinic, or must it be a centralized storage area?

**A:** It is acceptable for each physician to maintain his or her own supply of sample medications for their own use. This may or may be in the physician's private office. However, all the requirements for medication storage, accountability and security still apply for each of the sample storage areas, as it would for just one.

**Q:** Does these requirements apply only to hospital-based clinics or to freestanding ambulatory clinics as well?

**A:** The standards for freestanding ambulatory organizations are the same as for hospitals. The difference is that the "uniform performance of patient care processes" will be applied to the ambulatory organization only, and will not be tied to any performance of services or policies of the hospital. Hence, more flexibility can occur.

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