

Ask the Joint Commission

Security of Crash Carts and Medication Security in Other Areas: New Interpretation

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This column addresses questions from readers about any issue, process, standard, or future direction of the Joint Commission, whether it relates to home care, the hospital, or other practice environment. The objective is to give you a better insight into the Joint Commission accreditation process in your own practice site. Any question is fair game. Readers are encouraged to submit questions to Darryl S. Rich, PharmD, MBA, Joint Commission, Division of Accreditation Operations, One Renaissance Boulevard, Oakbrook Terrace, IL 60181. Fax: 630-792-5005 (be sure to include Darryl S. Rich's name and department on the cover sheet). E-mail: drich@jcaho.org. Please indicate that you are submitting your question for this Hospital Pharmacy feature.

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(1) We read your most recent column (August 2000), which indicated that plastic locks are not acceptable for the security of crash carts and that only a metal lock and key are acceptable. This would be a major inconvenience and could delay getting medications to the patient in an emergency situation. Is this interpretation correct?

You are correct. In several questions in that column, it was noted that plastic locks and seals used on crash carts do not meet the intent for security. However, based on numerous comments from the field, the Joint Commission re-evaluated that interpretation and has decided that

plastic breakaway locks or any type of seal (eg, heat-sealed plastic covers, etc) meet the intent for security of medications on crash carts.

Let us review some basics regarding control and security of crash carts based on this new interpretation:

1. Standard TX.3.5.5 requires that emergency medication (ie, the medications on crash carts) be "secure." The purposes of this requirement are to ensure that the medications are available when needed during an emergency and to prevent tampering. If a visitor removed a medication from the cart without staff knowledge, then—during an emergency—a patient could be negatively affect-

ed by the absence of a critical drug. The Joint Commission is *not* concerned about security of "used" crash carts (or medication trays/kits of the crash cart) that are on their way to the pharmacy for replacement or refilling, provided they are not "in use" for future emergencies. The security requirement can be met in one of three ways:

- a. Having the medications on the crash cart locked or sealed with a plastic breakaway lock. Alternatively, you can use plastic wrap or other types of seals to "seal" the contents.
 - b. Not locking or sealing the medications in the cart, but having the cart in a locked room
 - c. Not locking or sealing the medications in the cart, but having the cart in an area that is under constant surveillance or supervision, such as behind the nursing station.
2. Those plastic locks or other types of seal are also considered "control" devices for the purposes of determining that the contents are complete and within expiration date. A broken seal should signify that the contents have been removed or are expired. The use of a seal prevents the need for checking the contents of the cart

every shift or every day. If a seal is used, and the most recent expiration date of the medications in the cart is noted, then the cart does not need to be checked until the seal is broken or the expiration date occurs.

3. You don't need to attach a separate seal to indicate that products have been removed. If you are using seals to secure the medications, keep in mind (as stated before) that "used" crash carts (or medication trays/kits on the crash cart) on their way to the pharmacy for replacement or refilling do not need to be secure provided that they are not considered "in use" for future emergencies. However, many organizations use differently colored plastic locks to make it easier for the pharmacy (and other staff members) to identify a "used" cart that is not complete and needs replacement. This is acceptable.

4. Only the pharmacy should have control and access to the plastic locks used to seal the medication tray. The reason is that the pharmacy is solely responsible for replacing the missing medications and certifying that the cart is "complete" and within expiration date. By placing the seal on the tray, they validate to the nurses on the floor that it is complete and within expiration date.

The department that is responsible for replacement of medical supplies should have control of the seals for the medical supplies on the cart, for the same reason. It is possible for another nonpharmacy individual on the patient care unit to have access to the seals, if they replace the medications in the crash cart from another supply. Typically, we have limited such access to the nurse manager or a specifically designated individual. If all the nurses have

such access, it has been our experience that the locks will be replaced without the medication being restocked—and in such cases, the system collapses.

When the nurse manager has access to the plastic seals, the use of numbered plastic tabs is suggested, so that control of the seals remains with the pharmacy and that the pharmacy can determine if system is working or not. If the pharmacy is in total possession of the seals, then the plastic tabs do not need to be numbered. With the advent of automated dispensing devices, we have allowed one such seal to be in the machine. That way nursing can access medications in the device to replace the medications in the cart, but the pharmacy becomes immediately aware and can check to make sure the cart (and, if necessary the automated dispensing device) was restocked properly and a new expiration date has been properly assigned.

5. Medications need to be replaced by the pharmacy as soon as possible after the cart has been accessed. Once the cart has been accessed, nursing should call the pharmacy and the cart should be replaced or restocked by the pharmacy immediately. Once-a-day checking and restocking of the cart is inadequate, because emergency medications may be needed much sooner. This is why only one seal is permitted in the automated dispensing machine. It should not be the responsibility of nursing staff to replenish the emergency cart from the automated dispensing device, each time a product is used. This is pharmacy's responsibility.

If the cart contains both medical supplies and medications, coordination with another department (ie, central supply) might be need-

ed (see question below). Some organizations conduct shift checks of crash carts, in addition to regular replacement, as a double-check. This is perfectly acceptable.

To summarize, medications on crash carts do *not* need to be "secured" with a metal lock and key, *unless* the carts contain Schedule II drugs (narcotics). DEA regulations require that all Schedule II drugs be locked under a metal lock and key. However, I would recommend keeping narcotics out of your crash cart.

(2) Is it true that the crash carts themselves need to be secured with a metal lock and key?

No, not in all states. We are aware that there is at least one state (Utah) that requires crash carts to be so locked under hospital licensure regulations. Although the Joint Commission does not expect lock and key security of the crash carts, you may need to check for the existence of regulations in your state. JCAHO will accept plastic breakaway locks or other types of seals for crash carts.

(3) I was told that carts with medications cannot be stored in the Central Supply area, because the drugs are not secure. Is this true?

No, this is not true. If the the public (visitors) does not have access to the central supply area (as in most hospitals), then the area is considered secure. Thus, the carts within the central supply area should be secure.

(4) Is it true that JCAHO surveyors are looking for crash carts to be secured by breakaway locks after their use during a code?

No. The Joint Commission is more concerned about the security of crash carts prior to use than after. The purpose for the "security" component of the standard is to ensure that medications are available when

patients need them—more than to prevent diversion. For risk management purposes, simple measures (ie, placing the cart out of public access) should be taken to make sure that medications cannot be pilfered from the used cart. However, the addition of a plastic seal (breakaway lock) afterwards is not necessary. It should be noted, however, that many organizations add a different color seal afterwards to make it easier to identify the cart that has been used vs one that is patient-ready. There are some advantages to that approach, but it is not a Joint Commission requirement.

(5) Is it true that the Joint Commission has also revised its interpretation of medication security for non-crash cart medications?

Yes. The Joint Commission has recently revised its interpretation of medication security, from one of “strict” security of prescription medications to one of “reasonable” security, in an effort to get surveyors from focusing their survey process on this area, and addressing areas that have a higher impact on patient safety instead.

(6) Do all prescription and nonprescription drugs need to be secure?

Yes. How secure depends on the classification of the medication as a “controlled substance” or not. Certainly all Schedule II controlled substances (narcotics) need to be secure under lock and key based on DEA laws and regulations (standard TX.3.4). Although most states no longer require a “double-lock” system, these products must be stored in a “substantially constructed locked cabinet.” In addition, these drugs must be tightly controlled and accounted for, under law and regulation. For other drugs and products, we expect that the products be “reasonably secure” to prevent diversion or tampering with the products.

These products do not need to be locked; however, they should not be kept in areas that are readily accessible to the public and easily removed by visitors. For example, prescription medications left on a counter in a patient waiting area or patient examination room would not be considered secure.

However, if regular prescription medications are kept in a private office or other area where patients and visitors are not allowed without supervision or presence of a health care professional (eg, endoscopy, radiology, or operating rooms), they are considered secure even if not locked. All areas restricted to authorized personnel only are considered “secure” areas. The security of prescription medications should be addressed in your hospital’s security management plan (standard EC.1.4). As part of this plan, theft, pilferage, and tampering should be reported. If medication security becomes a problem, it is expected that the organization take additional steps to prevent it. Surveyors would score medication security issues only where there have been problems with diversion or tampering that has not been addressed, as documented in the security management program (EC.2.3), or the hospital’s system does not allow for such a determination.

(7) Does contrast media need to be locked up, or is OK to have it stored in rooms without a locked storage area?

Contrast media are considered prescription drugs (by both us and the FDA) and thus must be reasonably secure (see question above). However, in many hospitals the radiology suite is usually a restricted area where patients are only present with a health care worker. In such cases, we would consider this environment secure and the contrast media would not need to be locked. However, if the patient is left in the suite alone

for prolonged periods of time, then the contrast media in the room must be out of sight of the patient and thus be “reasonably secure.”

(8) I have two questions about medication security. On one of our nursing units, they keep syringes in an open area. This area is usually in view of nursing staff, but I cannot guarantee that 100% of the time. Do syringes need to be locked up, similar to medications? Secondly, we have developed an excellent policy regarding patient’s “own” medications and self-administration of medication in hospitalized patients. My question is, must medications that have been ordered by a physician—to be kept by the patient’s bedside—be locked up (ie, in a drawer or lock box)? Please clarify.

Syringes and needles have a high potential for diversion; thus they must be reasonably secure. Even though you cannot guarantee 100% surveillance, if they are under surveillance most of the time such that it would be unusual for any theft to occur without being noticed, we would consider them secure. However, if you found a problem with missing syringes and needles, we would expect you to take stronger measures. In addition, they should not be readily available during visiting hours out in the open in public hallways.

Patient’s medications do not need to be locked as long as they are in the patient’s room. Visitors are generally only allowed in the room when the patient is awake, and when awake, the medications are under constant surveillance of the patient.

(9) Do large volume parenterals on the patient care unit need to be secured? If so, what constitutes “secure”? Would the Joint Commission answer this question differently for: D5W 1000 mL; premixed D5W 1000 mL

with 20 mEq KCl; premixed heparin 25,000 units in 250 mL? You can assume that our State Regulations do not address this matter.

All IVs (regardless of the product) should be reasonably secure, like other prescription drugs. However, these are not small products that can be easily put in one's pocket or purse. So, the chances of diversion without being noticed are rare. The products have seals, so the potential for tampering without being noticed is low. As long as they are not located in a public area, or are located in a public area that is under surveillance most of the time, they would be considered reasonably secure.

(10) Manufacturer-prepared IV solutions are provided as floorstock to nursing units. These include premixed solutions containing potassium chloride such as D51/2 NS with 20 mEq potassium chloride and also "plain" solutions such as Dextrose 5%, Normal Saline, etc. Since these items require a prescription, does the pharmacy need to control these agents and distribute them as floor stock?

D5W, Normal Saline, and other plain IVs do not need to be under the control of the pharmacy. These are considered "medical supplies" and not "medications." However, when IVs are premixed with other drugs, for example, KCL or lidocaine, they are considered "prescription drugs" and should be under the control of the pharmacy.

(11) If Materials Management orders, stocks, and distributes IV solutions to the nursing units by utilizing material management personnel, does the pharmacy director have accountability for ensuring that these personnel are competent? How is this best accomplished if the individuals do not report to

the Pharmacy Director?

No, for plain IV solutions. However, premixed IV medications should not be handled by Materials Management and should be under the control of the pharmacy.

(12) If state law requires that a pharmacist directly supervise and verify pharmacy technician functions, but does not address technicians from other departments (such as Materials Management) who also order, deliver, and distribute prescription products (such as IV solutions), would this require the Materials Management technicians to report to pharmacy director?

Check with your state board of pharmacy.

(13) If Materials Management is distributing IVs to nursing units and there is no pharmacist verifying accuracy, what JCAHO standards would address this?

See answers above; however, there are no related JCAHO standards.

(14) Can Materials Management have access to the locked medication room to stock these agents without having accountability to the Pharmacy Director (patient-specific medications are not locked within the locked Medication room)? If yes, can this access be unsupervised by a licensed person?

Generally, yes. Nonlicensed staff can as part of their job responsibility (as defined in their job description) transport, store, and have access to medications without a pharmacist being present or involved. The Joint Commission would have no problem with these individuals accessing the locked medication room, unless there was a documented diversion problem in your institution. These individuals need not report to the Director

of Pharmacy, unless required by pharmacy law and regulation. However, a basic point needs to be made. The state considers the Director of Pharmacy responsible for all medications throughout the hospital. If a diversion problem became apparent, the Director of Pharmacy would have to resolve the problem.

(15) We have anesthesia trays (that contain various medications) in our C-section rooms in the Labor and Delivery area. Environmental folks have access to these rooms for obvious reasons. Do these trays need to be locked or just controlled? If locked, what standard requires them to be locked? If controlled, does that mean that a licensed person needs to be in the room at all times while the nonlicensed person is there?

Usually anesthesia trays contain narcotics, and hence narcotics must be secure (as required by DEA regulations). Secure includes "under constant surveillance" by a licensed health professional. So they must either be locked or a licensed person needs to be in the area at the same time. For noncontrolled substances, the products need to be reasonably secure, that is, not out in open public areas—but they do not need to be locked.

(16) How will surveyors now survey prescription medications, syringes, needles, IVs, etc, that are not in the crash cart as being "reasonably secure"?

For medications, the surveyor will no longer look at medication security in most areas and will not require any medications, except Schedule II controlled substances, to be locked or under constant surveillance. Reasonably secure includes items located in nonpublic areas (areas where the public is not authorized to go), out of sight in a drawer or opaque cabinet, or where the med-

ications are under surveillance most of the time. If the surveyors finds a situation where medications are “grossly” insecure, that is, in plain sight in a public area with no supervision, or in violation of the organization’s own security management plan, they may score this as a security issue at EC.2.3.

In addition, if the surveyor finds something that he or she feels is not grossly insecure, but on the other hand is not reasonably secure, the surveyor will ask for documentation of any diversion problems or security problems with the way the medications are stored. If the organization has had problems in the past, or does not have a process to identify such issues, then the same recommendation at EC.2.3 will be made. However, if there have been no documented problems, a recommendation will not be made. Security of crash carts is scored at TX.3.5.5, and we would expect these medications to be locked (plastic locks or other seals are acceptable), or in a locked area, or under constant surveillance, when “in use” or “ready for use.” We would only expect that they be “reasonably secure” once used and on the way to the pharmacy for replacement, or otherwise designated as “not be used

in an emergency.”

Missing medications in a “ready-to-use” emergency cart, which could negatively affect patient safety in an emergency situation, is a more serious issue than missing medications in other areas of the hospital, which often can be obtained from other areas without resulting in patient harm. This is the reason for the heightened security requirement for crash carts that are “ready-to-use.”

(17) My question relates to your response to a question in the August 2000 issue to the effect that needles and syringes must be secured or locked like medications. I can't find any JCAHO standard or intent statement that requires this. Can you identify the specific standard that requires this?

Standards EC.1.4 and EC.2.3 require that “high risk” items be secure. We define high risk to include “patient care supplies with a high potential for theft,” although this is not clearly defined in the intent or glossary. According to NABP, most states require that “reasonable” steps be taken to prevent diversion of syringes and needles. So, it is also a law and regulation issue, and our standard MA.2 requires adherence to

all laws, regulations, and standards of practice. Thus, we would expect that *reasonable* steps be taken to prevent theft of “abusable” syringes and needles. This was published in the April 1999 issue of *Inside Perspectives*, which is an official update to standards interpretation, and is posted on our website.

Please be advised that this is not a high-priority survey issue. You would *only* receive a type I recommendation if you had reports of theft of syringes/needles in the past (ie, a documented problem) and the problem remained unresolved. You would also get a Type I recommendation if you had no system for reporting such thefts, or could not determine if this was a problem (the intent of the same standards require reporting, documentation, and evaluation of all security events). We have not seen any type I recommendations from hospitals related to unsecured syringes and needles in the entire US in the past year.

(18) When will this “looser” interpretation on medication security take effect?

January 1, 2001. We cannot go back and correct reports for surveys conducted before 2001. ■