

PHARMACY NEWSCAPSULE

Wisconsin Department of Health and Family Services
Division of Quality Assurance
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Medication Security in Hospitals *By Doug Englebert, R.Ph.*

The November 27, 2006 Federal Register published a specific regulatory change in regards to securing or locking medications. The old regulation stated:

42 §482.25(b)(2) Drugs and biologicals must be kept in a locked storage area.

The new regulation now states:

42§482.25(b)(2)(i) All drugs and biologicals must be kept in a secure area, and locked when appropriate. (ii) Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area. (iii) Only authorized personnel may have access to locked areas.

This change is significant in that it allows uncontrolled medications to be unlocked under some circumstances.

As surveyors, we have been applying the new regulations throughout 2007. The change that recently occurred, however, is that, on April 11, 2008, CMS issued Survey and Certification letter 08-18 that provided updated guidance to surveyors. Prior to this letter, except for the Federal Register, there was no guidance as to when unlocked medications would be appropriate.

Following is a sample of some of the guidance that we have received in the past.

What is a “secure area?” A secure area is defined as an area where drugs and biologicals are stored in a manner that prevents unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. If an

area is “unsecured,” it means that an area is unmonitored and has unlocked medications that anyone can access; a situation that would lead to a violation of medication security.

When is locking the medication appropriate? As specified in the regulations, **ALL** controlled substances must be locked. There is some security flexibility involving the storage of non-controlled drugs and biologicals. This flexibility involves situations where staff are actively providing care to patients or preparing to receive patients, i.e., when setting up for procedures before the arrival of a patient, to have medications unlocked but still secure. When that patient care area is not staffed, **both** controlled and non-controlled substances should be locked.

What about areas like the operating room? The operating room suite is considered secure when the suite is staffed and staff members are actively providing patient care. When the suite is not in use, e.g., weekends, holidays, after hours, it would not be considered secure. A hospital may choose to lock the entire suite, lock non-mobile carts containing drugs and biologicals, place mobile carts in a locked room, or otherwise lock drugs and biologicals in a secure area. If an individual operating room is not in use, the hospital is expected to lock non-mobile carts and ensure that mobile carts are in a locked room.

What about automated machines like Pyxis? Medication automated distribution units with security features, such as logon and password or biometric identification, are considered to be locked; since they can only be accessed by authorized personnel who are permitted access to the medications. Such units must be stored in a secure area.

Who are “authorized personnel?” A hospital has the flexibility to define which personnel have access to locked areas, based on the hospital’s needs, as well as State and local law. For example, a hospital could include within its definition of “authorized personnel;” ancillary support personnel such as engineering, housekeeping staff, orderlies, and security personnel – such access being necessary to the performance of their assigned duties

In conclusion, please remember that **ALL** controlled substances must be locked. All other medications do not need to be locked; however, these medications must be in an area that is monitored. If the medication is not locked, it must be secured via monitoring.

Medication Waste By Doug Englebert, R.Ph.

The Division of Quality Assurance continues to address the issue of medication disposal. The DQA has issued three recent memos (06-022, 07-008, and 08-003) on this topic in an attempt to provide some guidance for facilities. In general, DQA-regulated facility regulations do not define a specific method of disposal. Facilities should be following other waste regulations that may apply, such as those issued by the Department of Natural Resources, the Environmental Protection Agency, and other governmental agencies.

The difficult issue for facilities is that the disposal of medications can be complicated.

One such complication is that some medications are considered as hazardous as some toxic chemicals such as lead and mercury. Currently, there is no low-cost and simple method to identify which medications are hazardous.

Many nursing home, assisted living, and surveyor staff members have asked if there is a simple list that could be of assistance. Attached is a short list of medications that are considered hazardous. Although THIS LIST IS NOT ALL INCLUSIVE, it can be a starting point in determining whether a facility has hazardous waste requiring specific methods for destruction. To locate an available contractor who can remove hazardous waste, a facility should contact the local DNR hazardous waste contact through the links provided in previous DQA memos.



New Medications

Brand Name	Generic Name	Use
Cimzia	Certolizumab	A tumor necrosis factor for treating Crohn's disease.
Intelence	Entravirine	For treatment of advanced HIV-1 infection.
Relistor	Methylnaltrexone	A peripherally-acting opioid antagonist for severe opioid-induced constipation.
Patanase	Olopatadine	New nasal spray formulation for seasonal allergic rhinitis.

Medication Stability in Food By Doug Englebert, R.Ph.

Recently, DQA memo 07-012 was released that addresses involuntary administration of psychotropic medications. The memo states that the mixing of medication with food in some cases can be considered involuntary administration. This statement has generated a subsequent discussion about the effect of mixing food with medication on medication stability and absorption. Some medications cannot be given with food, and therefore, the mixing of such medications with applesauce or any food becomes an issue.

Other than those medications with specific warnings regarding their administration with food, medication generally can be mixed with food, and if the mixture is taken immediately, stability is minimally affected. However, in some cases, crushed medication is mixed with applesauce or other foods that are then set aside for a period of time. Applesauce and other foods may have a low pH which will begin the breakdown of a medication and which may affect its stability and effectiveness.

It is advisable to avoid mixing medication in food, setting it aside, and/or storing it for later use. If medication is mixed with food, staff should be directed to use it immediately. If medications

and food mixture does need to be set aside or stored, staff should contact their pharmacist for guidance.

In some cases, facilities will crush medication in a bag or some other container. If, for some reason, the crushed medication cannot be given at that time, and is not mixed with food, it is possible to set aside the crushed mixture until the patient is ready to take the medication. However, a procedure to identify (resident name and medication name) the bag of crushed medication must be in place.

Consultant Corner By Doug Englebert, R.Ph.

1) What if a resident is on two psychotropic medications that, according to the surveyor guidance, need dosage reduction; do we need to reduce both medications at the same time in order to meet the time frames?

The rationale for conducting dose reduction is to determine if the medication is still needed, or if the correct dose is being used. If both medications are reduced at the same time, you may not be able to answer those questions. Therefore, only one medication should be reduced at a time. The clinical contraindication or justification for not reducing one of the medications is that you are reducing the other.

2) Do we need an order to crush medications in assisted living and in nursing homes?

The Division of Quality Assurance issued a memo on crushing medication in nursing homes. In a nursing home, an order can be used, but is not necessary. Please see DQA memo 04-023 (http://dhfs.wisconsin.gov/rl_dsl/NHs/nh04023.htm). Many assisted living facilities will request an order to be in place, but such an order may not be necessary.

When staff members at a facility administer a medication, they need to know the restrictions governing the manipulation of that medication. Can it be given with food? With water? Can it be chewed? Can it be crushed? A physician order is one way to provide information to staff on specific medication restrictions. Often, however, medications orders from a physician do not consider every medication in a resident profile and are simply blanket orders that include the language “may crush meds.” A pharmacist consultant plays a vital role in looking at each medication individually, and providing the appropriate guidance to facility staff.

3) When do injectable medications in multidose vials expire?

In some cases, manufacturers provide specific expiration dates once a vial of medication is opened. In other cases, manufacturer’s information or other research data is not available to provide a definitive expiration date once a vial is opened and partially used. Currently, the United States Pharmacopeia General, Chapter 797, indicates that unless the manufacturer has stated otherwise, the expiration date or beyond-use-date for a vial is 28 days once opened. In some instances, other data may be available that indicates that medication may be stored for a longer period of time.

[Attachment](#)

