

Hospital Pharmacy Update

Medication Security

The November 27, 2006 Federal Register published a specific regulation 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.

The following are some highlights from the guidance that have come up previously in Wisconsin.

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? ALL controlled substances must be locked as specified in the regulations. Flexibility of security involves the storage of non-controlled drugs and biologicals. This flexibility allows 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 are expected to be locked.

What about areas like the operating room? The operating room suite is considered secure when the suite is staffed and staff 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 as necessary to perform their assigned duties

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

Medication Storage: Refrigerator Monitoring

The standard is fast becoming continuous monitoring and alarms. Especially in situations where there are medications that have short shelf lives at room temperature, like, vaccines. Weekly, monthly and in some cases even the once daily check and recording may not be enough.