



MEDICATION CART STORAGE: SECURED AND LOCKED

Division of Quality Assurance / Bureau of Education Services and Technology

P-01744 (02/2017)

Background

In 2006, the regulations for hospitals related to medication security were updated. This update relaxed the requirements for all medications to be locked at all times. The new regulations do allow medications to be secure without being locked. In February 2008, along with the regulation update, The Centers for Medicare and Medicaid Services (CMS) issued the following guidance related to locking and securing medications:

“A secure area means that drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional (e.g., ambulatory infusion), they are considered secure. Areas restricted to authorized personnel only would generally be considered “secure areas.” If there is evidence of tampering or diversion, or if medication security otherwise becomes a problem, the hospital is expected to evaluate its current medication control policies and procedures, and implement the necessary systems and processes to ensure that the problem is corrected, and that patient health and safety are maintained. (71 FR 68689)

All controlled substances must be locked. Hospitals are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. An area in which staff is actively providing care to patients or preparing to receive patients, i.e., setting up for procedures before the arrival of a patient, would generally be considered a secure area. When a patient care area is not staffed, both controlled and non-controlled substances are expected to be locked.

Generally labor and delivery suites and critical care units are staffed and actively providing patient care around the clock, and, therefore, considered secure. However, hospital policies and procedures are expected to ensure that these areas are secure, with entry and exit limited to appropriate staff, patients, and visitors.

The operating room suite is considered secure when the suite is staffed and staff is actively providing patient care. When the suite is not in use (e.g., weekends, holidays and after hours), it is not 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 mobile carts are in a locked room. (71 FR 68689)

Due to their mobility, mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing drugs or biologicals (hereafter, all referred to as “carts”) must be locked in a secure area when not in use. Hospital policies and procedures are expected to address the security and monitoring of carts, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage and to ensure patient safety. (71 FR 68689)

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.”

The guidance spends a good portion of time talking specifically about medication carts which would include crash carts and anesthesia carts. The guidance and previous CMS comments published in the Federal Register recognize that, during patient care activities, the carts will not be locked. In addition, due to patient care needs,

it would be inappropriate for carts to have a traditional key lock for fear that the key was not available when a patient would emergently need the medications stored in the cart. However, the guidance is clear that, when the cart is not in a secure situation, the medication carts must be locked. There is recognition to meet patient safety concerns by having immediate access; however, that concern needs to be balanced against potential access to unsecured medications where the medications that are needed for an emergency are no longer present or have been tampered with, making them unusable and putting the patient at risk.

Position

A plastic breakaway lock is not a locked medication cart. For these carts to be secured they must meet **one** of the following:

1. A permanent key lock, key pad, biometric or similar permanent locking system must be used, or
2. The cart can be placed in a locked room when authorized staff are not present, or
3. The cart can be placed in a secure area where staff is present.

In most areas where crash carts are stored, staff is present and can actively provide patient care and monitor the crash carts in a manner that meets the requirement of a secured medication cart. However, this requirement is not met when crash carts and other medication carts are pushed into alcoves, stored in patient rooms, or stored in departments where staff are not present (operating room suites, radiology, etc.). Unsecured medication carts include carts in patient exam rooms where patients are left unattended or unsupervised for a period of time. In these instances, the carts are not permanently locked, not in a locked room and, since staff is not present, the medications are not secured.

The use of breakaway locks, exchangeable trays with sealed plastic, and other tamper-proof devices are valuable tools to alert staff to tampered medication carts. However, these devices do not ensure secured medications.