



DEPARTMENT OF HEALTH SERVICES / DIVISION OF QUALITY ASSURANCE

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MOBILE CARTS IN HOSPITALS AND MEDICATION STORAGE

In 2006, hospital regulations related to medication security were updated. This update relaxed the requirements for all medications to be locked at all times, allowing medications to be kept in a secure area and locked when appropriate.

The Centers for Medicare and Medicaid Services (CMS) subsequently issued guidance related to locking and securing medications, incorporating guidance on mobile carts (including crash carts and anesthesia carts) that may have medications. The guidance and CMS comments published in the Federal Register relating to this issue recognize that the carts will likely not be locked during patient care activities. In addition, due to patient care needs, it would be inappropriate for crash carts and anesthesia carts to have a traditional key lock as the key would not be available when a patient urgently needed the medications stored in the cart.

However, the guidance is clear that when a medication cart is not in a secure location, the cart must be locked. While the regulations recognize that immediate access is necessary to meet patient safety needs, accessibility must be balanced against potential access to unsecured medications. Patients are placed at risk when the medications needed for an emergency have been removed or are unusable due to tampering.

(continued)

APP FOR THAT



Prognosis Your Diagnosis

This app can be considered a game as you test your diagnostic ability with simulated clinical cases. Each case has a short, but in-depth analysis of the diagnostic process, followed by an up-to-date discussion on the specific condition. New cases are added all the time. Test it out!

In 2009, the Division of Quality Assurance (DQA) issued a memo (no longer available online) with the following position:

There have been a number of citations for unsecured medications. In these situations, a plastic breakaway lock was utilized to lock medication carts stored in unsecure areas. A plastic breakaway lock does not adequately lock a medication cart.

A properly secured medication cart must meet one of the following conditions:

- 1) A permanent key lock, such as 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 and anesthesia carts are stored, staff is present and actively providing patient care. In these situations staff can monitor the cart, thereby meeting the requirement for a secured medication cart. Crash carts and other medication carts pushed into alcoves, stored in patient rooms, or stored in unlocked departments where staff are not present (operating room suites, radiology, etc.) are not considered secured and need to be locked. Unlocked medication carts in exam rooms where patients are left unattended or unsupervised for any period of time is another example of an unsecured medication cart. In these instances, the carts are not permanently locked, not in a locked room, and as staff is not present, the medications are not secure.

Recently, questions have come up about “secured departments” and medication storage and whether medications stored in cabinets in these secured departments need to be locked. Secured departments are areas in the hospital where staff entrance requires the use of a badge and where all patients and guests require an escort (e.g., medical intensive care units, neonatal units, or radiology departments).

The regulations and standards are clear that medications are required to be secured at all times and controlled substances locked at all times. The only exceptions would be when medications are in use and authorized persons are present. In the “secured department” scenario, controlled substances must be locked at all times and the cabinet or drawer in which the controlled substances are stored must be locked at all times, even in a department deemed “secured.” If medications that are not controlled substances are in an unlocked cabinet in a “secured department,” the medications could be considered secure when authorized staff are present.

NEW MEDICATION TO COMBAT SUBSTANCE ABUSE

The U.S. Food and Drug Administration approved Probuphine, the first buprenorphine implant for the maintenance treatment of opioid dependence. Probuphine is designed to provide a constant, low-level dose of buprenorphine for six months in patients who are already stable on low-to-moderate doses of other forms of buprenorphine, as part of a complete treatment program.

Until today, buprenorphine for the treatment of opioid dependence was only approved as a pill or a film placed under the tongue or on the inside of a person’s cheek until it dissolved. While effective, a pill or film may be lost, forgotten, or stolen. However, as an implant, Probuphine provides a new treatment option for people in recovery who may value the unique benefits of a six-month implant compared to other forms of buprenorphine, such as the convenience of not taking medication on a daily basis.

Probuphine should be used as part of a complete treatment program that includes counseling and psychosocial support. Probuphine consists of four, one-inch-long rods that are implanted under the skin on the inside of the upper arm that provide treatment for six months. Administering Probuphine requires specific training because it must be surgically inserted and removed. Only a health care provider who has completed the training and become certified through a restricted program called the Probuphine Risk Evaluation and Mitigation Strategy (REMS) program should insert and remove the implants. If further treatment is needed, new implants may be inserted in the opposite arm for one additional course of treatment. The FDA is requiring post-marketing studies to establish the safety and feasibility of placing the Probuphine implants for additional courses of treatment.

The most common side effects from treatment with Probuphine include implant-site pain, itching, and redness, as well as headache, depression, constipation, nausea, vomiting, back pain, toothache, and oropharyngeal pain. Clinical studies of Probuphine did not include participants over the age of 65.

Probuphine includes a boxed warning that provides important safety information for health care professionals, including a warning that insertion and removal of Probuphine are associated with the risk of implant migration, protrusion, expulsion, and nerve damage as a result of the procedure. Probuphine must only be prescribed and dispensed according to the Probuphine REMS program due to the risks of surgical complications, the risk of accidental overdose, and the possible risk of misuse and abuse if an implant comes out or protrudes from the skin. As part of this program, Probuphine can only be prescribed and dispensed by health care providers who are certified with the REMS program and have, among other requirements, completed live training.

Probuphine implants contain a significant amount of drug that can potentially be expelled or removed, resulting in the potential for accidental exposure or intentional misuse and abuse if the implant comes out of the skin. Patients should be seen by their health care provider during the first week after insertion and additionally, a visit schedule of no less than once a month is recommended for continued counseling and psychosocial support.

CONSULTANT CORNER *by Doug Englebort, R.Ph.*



In a CBRF with minimal registered nurse (RN) coverage and oral morphine concentrate is ordered for a hospice patient: If the patient is near end-of-life and the pharmacy provides a 30 ml bottle of morphine oral concentrate 20 mg/1ml per prescription order, can the hospice RN come in and draw up a small supply (approximately 10 syringes) for a caregiver to administer as needed for a short period of time (24-48 hours)?

The short answer is “yes.” The RN for the hospice can come to the facility and draw up the oral liquid morphine. However the following requirements need to be considered:

- A CBRF that does not have an RN who meets supervision requirements must have all medications in unit-of-use packaging, unless the medication physically cannot be packaged in unit-of-use (i.e., inhaler).
- If the CBRF does have an RN who meets supervision requirements, the pharmacy can then provide a bulk bottle of the liquid morphine. The CBRF rules allow the RN to repackage medications (see below). However, if that RN is not able to repackage medications and, instead, the hospice RN is going to repackage it, the hospice RN will need to follow repackage regulation and label the oral syringes appropriately. Surveyors should be aware that liquid morphine and repackaging is an area

of high risk and can result in frequent errors. If possible, it is always best for the pharmacy to package the liquid morphine in unit-of-use packaging to minimize repackaging at the facility.

Wisconsin Adm. Code ch. DHS 83 states the following regarding medication administration:

- DHS 83.37(2)(c) Medication administration not supervised by a registered nurse, practitioner, or pharmacist. When medication administration is not supervised by a registered nurse, practitioner, or pharmacist, the CBRF shall arrange for a pharmacist to package and label a resident's prescription medications in unit dose. Over-the-counter medications may be excluded from unit dose packaging requirements, unless the physician specifies unit dose.
- DHS 83.37(3) MEDICATION STORAGE. (a) Original containers. The CBRF shall keep medications in the original containers and not transfer medications to another container unless the CBRF complies with all of the following:
 - Transfer of medications from the original container to another container shall be done by a practitioner, registered nurse, or pharmacist. Transfer of medication to another container may be delegated to other personnel by a practitioner, registered nurse, or pharmacist.
 - If a medication is administered by CBRF employees and the medication is transferred from the original container by a registered nurse or practitioner or other personnel who were delegated the task, the CBRF shall have a legible label on the new container that includes, at a minimum, the resident's name, medication name, dose, and instructions for use. The CBRF shall maintain the original pharmacy container until the transferred medication is gone.