A-0503(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08) §482.25(b)(2)(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.

Interpretive Guidelines §482.25(b)(2)(ii)

All Schedule II, III, IV, and V drugs must be kept locked within a secure area. A secure area means the drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. Medication automated distribution units with logon and password/biometric identification are considered to be locked, since they can only be accessed by authorized personnel who are permitted access to Schedule II – V medications.

Mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing Schedule II, III, IV, and V drugs must be locked within a secure area.

Survey Procedures §482.25(b)(2)(ii)

- Determine whether there is a hospital policy and procedure that requires Schedule II, III, IV, and V drugs to be kept in a locked storage area.
- Observe in various parts of the hospital whether Schedule II, III, IV and V drugs are locked and stored in a secure area..
- Determine whether security features in automated medication distribution units are implemented and actively maintained, e.g., that access authorizations are regularly updated to reflect changes in personnel, assignments, etc.
- Interview staff to determine whether policies and procedures to restrict access to authorized personnel are implemented and effective.