

§482.25(b)(4) - When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

Interpretive Guidelines §482.25(b)(4)

Routine after-hours access to the pharmacy by non-pharmacists for access to medication should be minimized and eliminated as much as possible. The use of well-designed night cabinets, after-hours medication carts, and other methods may preclude the need for non-pharmacist to enter the pharmacy. Policies and procedures should be consistent with Federal and State Law.

If an urgent or emergent patient need occurs, the hospital must be able to provide medications to the patients in its facility.

The hospital must have a process for providing medications to meet patient needs when the pharmacy is closed.

When non-pharmacist health care professionals are allowed by law and regulation to obtain medications after the pharmacy is closed, the following safeguards are applied:

- Access is limited to a set of medications that has been approved by the hospital. These medications can be stored in a night cabinet, automated storage and distribution device, or a limited section of the pharmacy.
- Only trained, designated prescribers and nurses are permitted access to medications.
- Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system, such as bar coding) are in place to prevent medication retrieval errors.
- The hospital arranges for a qualified pharmacist to be available either on-call or at another location (for example, at another organization that has 24-hour pharmacy service) to answer questions or provides medications beyond those accessible to

non-pharmacy staff.

- This process is evaluated on an on-going basis to determine the medications accessed routinely and the causes of accessing the pharmacy after hours.
- Changes are implemented as appropriate to reduce the amount of times non-pharmacist health care professionals are obtaining medications after the pharmacy is closed.

Survey Procedures §482.25(b)(4)

- Determine through pharmacy records that when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law if applicable) and only in amounts sufficient for immediate therapeutic needs.
- Review policies and procedures to determine who is designated to remove drugs and biologicals from the pharmacy or storage area and the amount a non-pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and qualifications.
- Determine that a system is in place that accurately documents the removal of medications (type and quantity) from either the pharmacy or the after hours supply.
- Determine that the pharmacist reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile.
- Determine if the pharmacist routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the hospital.