

7-21-2025 Weekly Clinical Update

F761 Labeling and Storing Drugs and Biologicals has again surged to the third most frequently cited deficiency nationally. This requirement is deceptively straightforward so it is curious that it has become a pitfall during surveys.

The regulation requirements are pretty simple. The facility must ensure:

- Labeling
 - All drugs & biologicals must be labeled per professional standards including:
 - Medication name, strength, dosage
 - Resident's name
 - Expiration date
 - Accessory and cautionary instructions (such as “shake well”, “do not crush”, etc.)
 - For any biological that is not packaged in unit dose, the pen, flex pen, vial, tube, or bottle must be labeled in addition to the required dispensing information with:
 - Date opened
 - Use-by date
 - Initials of person opening the container
- Storage
 - Medications, biologicals must be kept in locked compartments with proper temperature controls
 - Controlled substances (Schedule II-V) must be stored in separately locked, permanently affixed compartments
 - Only authorized personnel may access medications
- Common deficiency findings include:
 - Improper labeling
 - Expired meds on carts; missing cautionary instructions; insulin pens not labeled with resident identifiers
 - Unsecured storage
 - Med carts left unlocked & unattended
 - Controlled substances not stored in affixed compartments including controlled substances in E-kits not stored in permanently affixed compartments or controlled substances that require refrigeration not stored in permanently affixed refrigerated units
 - Discontinued controlled substances:
 - ❖ Not stored in affixed compartments

- ❖ Access provided after controlled substances placed in med room without double locks
 - Controlled substances not reconciled with signatures of on-coming and off-going shift personnel every opportunity
 - ❖ Findings when keys are given to different person that reconciled drugs for breaktimes and not reconciled when keys transferred
- Multi-Dose Vial Misuse
 - Vials not dated upon opening
 - Vials used across multiple residents
 - Vials stored improperly
- Refrigeration Violations
 - No temperature logs or missing temps on logs
 - Controlled substances not stored in locked boxes inside refrigerators
- Immediate Jeopardy tags:
 - Resident accessed unsecured meds leading to overdose & hospitalization
- Strategies for Compliance
 - Assign medication room and cart inventory weekly by licensed nurse to check for expired meds
 - Engage consulting pharmacist for monthly medication room/med cart audit for appropriate labeling and removal of expired medications; and appropriate storage & documentation of controlled medications
 - Conduct routine audits using CMS Medication Storage & Labeling Critical Element Pathway
 - Conduct random & routine audits of controlled substances reconciliation
 - Ensure staff training and competency training including labeling/storage protocols and competency checks
 - Implement QAPI reviews of med room/cart inspections & incident reports
 - Use visual cues & signage to reinforce secure handling practices

F761 deficiencies aren't just regulatory missteps. They pose serious risks to resident safety including medication errors, drug diversion, and adverse drug events or ineffective drug administration. With its high citation rate and broad scope, the regulation requires attention from facility leadership, clinical staff and pharmacy partners