

# COMPLIANCE CUE

F761

## \*Labeling and Storage of Drugs and Biologicals

### BACKGROUND

F761 of the CMS State Operations Manual Appendix PP provides guidance to Long Term Care Facility (LTCF) surveyors regarding **Appropriate Labeling and Storage of Drugs and Biologicals**.

### REQUIREMENT

**§483.45(g) Labeling of Drugs and Biologicals:** Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.”

**§483.45(h) Storage of Drugs and Biologicals**

- (1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls and permit only authorized personnel to have access to the keys.
- (2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II [through Schedule V] of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

### KEY INFORMATION TO MANAGE SURVEY RISK

#### PHARMERICA'S CONSULTANT PHARMACISTS NOTE THE FOLLOWING INFORMATION AS KEY FOR REGULATORY COMPLIANCE

##### General

- The referenced “Drugs and Biologicals” account for all pharmacotherapeutic substances that might be stored and used at a facility to treat, prevent, or diagnose diseases and medical conditions: small molecule drug products, vaccines, blood components, allergenics, gene therapies, and recombinant therapeutic proteins.
- CMS recognizes that pharmacies are responsible for labeling dispensed products, but places corresponding responsibility on nursing facilities to ensure compliance with currently accepted labeling requirements for products at the facility.

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- **Minimum Labeling Requirements:**
  - Medication name (generic and/or brand)
  - Prescribed dose
  - Strength
  - Expiration date (when applicable)
  - Resident's name
  - Route of administration

\*Medication *should* also be labeled with or accompanied by appropriate instructions and precautions (such as shake well, take with meals, do not crush, special storage instructions)
- A facility is required to secure all medications in a locked storage area and to limit access to authorized personnel consistent with state or federal requirements and professional standards of practice.
  - **Storage areas** may include, but are not limited to:
    - Cabinets
    - Carts
    - Drawers
    - Medication rooms
    - [Refrigerators](#) (read [CMS Clarification on Storing Refrigerated Controlled Substances](#) on page 5)
  - **Authorized personnel** would include, for example, pharmacy technicians or assistants who have been delegated access to medications by the facility's pharmacist as a function of their jobs.

### Labeling of Medications and Biologics

Although medication delivery and labeling systems may vary, the facility must ensure compliance with applicable federal and state requirements and currently accepted pharmaceutical principles and practices.

- The medication label must accurately **display all components of the minimum labeling requirements**
- The medication must be **labeled with or accompanied by appropriate instructions and precautions**
  - E.g., shake well, take with meals, do not crush

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- For medications designed for multiple administrations (e.g., inhalers, eye drops), the **label must identify the specific resident for whom it was prescribed.**
- IV medications prepared or compounded must display **labels for intravenous infusions** that include:
  - Name and volume of the solution
  - Resident's name
  - Infusion rate
  - Name and quantity of each additive
  - Date of preparation
  - Initials of the compounder
  - Date and time of administration
  - Initials of the person administering the medication
  - Date for which the mixture must no longer be used
  - Ancillary precautions as applicable
- **For OTC medications** in bulk containers, the label must contain the original manufacturer's or pharmacy-applied label indicating:
  - Medication name
  - Strength
  - Quantity
  - Accessory instructions
  - Lot number
  - Expiration Date
- Facility staff should **date labels of any multi-use vial when the vial is first accessed.**
  - If a multi-dose vial has been opened or accessed (e.g., needle-punctured), the vial should be **dated and discarded within 28 days unless the manufacturer specifies a different date** for that opened vial.
    - See PharMerica's [Abridged List of Medications with Shortened Expiration Dates](#).
  - If a multi-dose vial has not been opened or accessed, it should be discarded according to the manufacturer's expiration date.

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### Medication Access and Storage

A facility is required to secure all medications in a locked storage area and to limit access to authorized personnel consistent with state or federal requirements and professional standards of practice.

- When medications are **not stored in separately locked compartments within a storage area, only appropriately authorized staff may have access to the storage area.**
- **Access to medications can be controlled by keys, security codes or cards, or other technology such as fingerprints**
- **Schedule II-V medications must be maintained in separately locked, permanently affixed compartments.**
  - The access system (e.g., key, security codes) used to lock Schedule II-V medications, and other medications subject to abuse, **cannot be the same access system used to obtain the non-scheduled medications.**
  - **Exception:** Controlled medications and those medications subject to abuse may be stored with non-controlled medications as part of a single unit package medication distribution system if the supply of the medication(s) is minimal and a shortage is readily detectable.
- **During a medication pass, medications must be under the direct observation of the person administering the medications or locked in the medication storage area/cart.**
- The facility should have **procedures for the control and safe storage of medications for those residents who can self-administer medications.**
- Safe medication storage should include the provision of appropriate environmental controls. **The facility is to implement procedures that address and monitor the safe storage and handling of medications in accordance with manufacturers' specifications, state requirements and standards of practice.**
- Federal surveyors have demonstrated drastic changes in their perceptions of levels of concern related to unlocked medication carts/rooms, having recently issued IJ templates (specifically in North Carolina). Albeit, these issues were cited at F689 (the facility must ensure that the resident environment remains as free of accident hazards), facility leadership should be aware of this increased scrutiny.

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## CMS Clarification on Storing Refrigerated Controlled Substances

**Question:** How does the requirement for controlled substance storage within “permanently affixed compartments” apply to controlled substances that require refrigeration?

**CMS Response:** To meet the requirement of storage within a permanently affixed compartment for refrigerated controlled substances, facilities may choose one of the following options:

1. Store controlled substances in a locked refrigerator within a locked room.
2. Store controlled substances within a lock box that is permanently affixed inside an unlocked refrigerator, which is located within a locked medication room.

## When is F761 Cited?

To cite F761, a CMS surveyor’s investigation will show:

- **Failure to ensure that all drugs and biologicals are labeled in accordance with professional standards**, including expiration dates and with appropriate accessory and cautionary instructions.
- **Failure to store all drugs and biologicals in locked compartments, including schedule II-V medications in separately locked, permanently affixed compartments.**
  - With the *exception* that the facility uses single unit medication distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.
- **Failure to store medications at proper temperatures and other appropriate environmental controls** to preserve their integrity.

## Examples of Noncompliance

- **Level 4 Severity:** Facility staff failed to identify an incorrect medication label, resulting in administration of the wrong dose of medication to the resident and potential for significant adverse consequences.
- **Level 3 Severity:** Facility staff failed to identify that a medication label lacked the instructions to take with food, altering absorption and effectiveness of the medication and worsening the resident’s symptoms, requiring medical intervention.
- **Level 2 Severity:** The facility’s medication cart was not locked or under direct observation of authorized staff while in an area where residents could access it. No medications were stolen, but the potential for harm exists.

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## KEY QUESTIONS FOR SURVEYORS

Does the facility appropriately label and store drugs and biologicals in accordance with currently accepted professional principles?  Yes  No F761

Does the facility ensure that all drugs and biologicals are in locked compartments under proper temperature controls, and permit only authorized personnel to have access?  Yes  No F761

Does the facility ensure that controlled substances and other drugs subject to abuse are stored in separately locked, permanently affixed compartments?  Yes  No F761

## STEPS TO FACILITY COMPLIANCE

- ✓ Review (1) this **Compliance Cue** and (2) the [CMS SOM section on F761](#) (pg. 603-608) with all relevant staff.
- ✓ Perform periodic reassessment and discussion regarding facility policy and procedures compared against CMS regulations to assess opportunities for improvement and if prior recommendations have been effectively implemented.
- ✓ Leverage your PharMerica pharmacist to educate staff as needed.

## HOW PHARMERICA CAN HELP

- ✓ Experienced and knowledgeable nurse consultants and consultant pharmacists available for mock internal audits to help your facility **Be Survey Ready!** This includes a specific Pharmacy Services Review Checklist that covers elements essential to F761 compliance.
- ✓ Numerous drug information resources maintained, including the [Expired Medication Inventory Audit](#), [Abridged List of Medications with Shortened Expiration Dates](#), and [Medication Storage: Abridged Guidance for Select \(Non-Insulin Injectable\) Medications](#).

## RESOURCES

Be familiar with the [Medication Administration Observation Critical Elements Pathway](#) [LTC Survey Pathways ⇨ CMS-20056] that surveyors are encouraged to use when investigating concerns related to medication errors.