

F431

(Rev. 22, Issued: 12-15-06, Effective/Implementation: 12-18-06)

§483.60(b) Service Consultation. The facility must employ or obtain the services of a licensed pharmacist who--

- (2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and*
- (3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.*

§483.60(d) 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.

(e) 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 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.*

INTENT (F431) 42 CFR 483.60(b)(2)(3)(d) Labeling of Drugs and Biologicals & (e) Storage of Drugs and Biologicals

The intent of this requirement is that the facility, in coordination with the licensed pharmacist, provides for:

- *Safe and secure storage (including proper temperature controls, limited access, and mechanisms to minimize loss or diversion) and safe handling (including disposition) of all medication;*
- *Accurate labeling to facilitate consideration of precautions and safe administration of medications;*
- *A system of medication records that enables periodic accurate reconciliation and accounting of all controlled medications; and*
- *Identification of loss or diversion of controlled medications so as to minimize the time between actual loss or diversion and the detection and determination of the extent of loss or diversion.*

NOTE: *For purposes of this guidance, references to “the pharmacist” mean the licensed pharmacist, whether employed directly by the facility or through arrangement.*

DEFINITIONS (refer to F425 and F428 for additional definitions)

- *“Adverse consequence” refers to an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in an individual’s mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease).*
- *“Clinically significant” refers to effects, results, or consequences that materially affect or are likely to affect an individual’s physical, mental, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.*

OVERVIEW

Due to the number and types of medications that may be used and the vulnerable populations being served, the regulations require a long term care facility to have formal mechanisms to safely handle and control medications, and to maintain accurate and timely medication records. These regulations also require the facility to use a pharmacist to help establish and evaluate these mechanisms or systems. This guidance addresses those portions of the facility’s pharmaceutical services related to medication access and

storage, appropriate security and safeguarding of controlled medications, and labeling of medications to assure that they are stored safely and are provided to the residents accurately and in accordance with the prescriber's instructions.

MEDICATION ACCESS AND STORAGE

A facility is required to secure all medications in a locked storage area and to limit access to authorized personnel (for example, pharmacy technicians or assistants who have been delegated access to medications by the facility's pharmacist as a function of their jobs) consistent with state or federal requirements and professional standards of practice.

Storage areas may include, but are not limited to, drawers, cabinets, medication rooms, refrigerators, and carts. Depending on how the facility locks and stores medications, access to a medication room may not necessarily provide access to the medications (for example, medications stored in a locked cart, locked cabinets, a locked refrigerator, or locked drawers within the medication room). 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 medications must be maintained in separately locked, permanently affixed compartments. The access system (e.g. key, security codes) used to lock Schedule II medications and other medications subject to abuse, cannot be the same access system used to obtain the non-scheduled medications. The facility must have a system to limit who has security access and when access is used. Exception: Controlled medications and those 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. In addition, the facility should have procedures for the control and safe storage of medications for those residents who can self-administer medications.

Safe medication storage includes the provision of appropriate environmental controls. Because many medications can be altered by exposure to improper temperature, light, or humidity, it is important that the facility implement procedures that address and monitor the safe storage and handling of medications in accordance with manufacturers' specifications, State requirements and standards of practice (e.g., United States Pharmacopeia (USP) standards).

CONTROLLED MEDICATIONS

Regulations require that the facility have a system to account for the receipt, usage, disposition, and reconciliation of all controlled medications. This system includes, but is not limited to:

- *Record of receipt of all controlled medications with sufficient detail to allow reconciliation (e.g., specifying the name and strength of the medication, the quantity and date received, and the resident's name). However, in some delivery systems (e.g., single unit package medication delivery system or automated dispensing systems utilizing single-unit packages of medications that are not dispensed pursuant to a specific order), the resident's name may not be applicable;*

NOTE: The facility may store some controlled medications in an emergency medication supply in accordance with state requirements. The facility's policies and procedures must address the reconciliation and monitoring of this supply.

- *Records of usage and disposition of all controlled medications with sufficient detail to allow reconciliation (e.g., the medication administration record [MAR], proof-of-use sheets, or declining inventory sheets), including destruction, wastage, return to the pharmacy/manufacturer, or disposal in accordance with applicable State requirements;*
- *Periodic reconciliation of records of receipt, disposition and inventory for all controlled medications (monthly or more frequently as defined by facility procedures or when loss is identified). The reconciliation identifies loss or diversion of controlled medications so as to minimize the time between the actual loss or diversion and the time of detection and follow-up to determine the extent of loss. Because diversion can occur at any time, the reconciliation should be done often enough to identify problems. Some State or other federal requirements may specify the frequency of reconciliation.*
 - *If discrepancies are identified during the reconciliation, the pharmacist and the facility develop and implement recommendations for resolving them.*
 - *If the systems have not been effective in preventing or identifying diversion or loss, it is important that the pharmacist and the facility review and revise related controls and procedures, as necessary, such as increasing the frequency of monitoring or the amount of detail used to document controlled substances.*

NOTE: The pharmacist is not required by these regulations to perform the reconciliation, but rather to evaluate and determine that the facility maintains an account of all controlled medications and completes the reconciliation according to its procedures, consistent with State and federal requirements.

LABELING OF MEDICATIONS AND BIOLOGICALS

This section requires facility compliance with currently accepted labeling requirements, even though the pharmacies are responsible for the actual labeling. Labeling of medications and biologicals dispensed by the pharmacy must be consistent with applicable federal and State requirements and currently accepted pharmaceutical principles and practices. Although medication delivery systems may vary, the medication label at a minimum includes the medication name (generic and/or brand) and strength, the expiration date when applicable, and typically includes the resident's name, route of administration, appropriate instructions and precautions (such as shake well, with meals, do not crush, special storage instructions).

For medications designed for multiple administrations (e.g., inhalers, eye drops), the label is affixed in a manner to promote administration to the resident for whom it was prescribed.

When medications are prepared or compounded for intravenous infusion, the label contains the name and volume of the solution, resident's name, infusion rate, name and quantity of each additive, date of preparation, initials of compounder, date and time of administration, initials of person administering medication if different than compounder, ancillary precautions as applicable, and date after which the mixture must not be used.

For over-the-counter (OTC) medications in bulk containers (e.g., in states that permit bulk OTC medications to be stocked in the facility), the label contains the original manufacturer's or pharmacy-applied label indicating the medication name, strength, quantity, accessory instructions, lot number, and expiration date when applicable. If supplies of bulk OTC medications are used for a specific resident, the container identifies that resident by name and must contain the original manufacturer's or pharmacy-applied label.

The facility ensures that medication labeling in response to order changes is accurate and consistent with applicable state requirements.

INVESTIGATIVE PROTOCOL

For investigating compliance with the requirement at 483.60(d) & (e), see State Operations Manual, Appendix P, II.B. The Traditional Standard Survey, Task 5, Sub-Task 5E Investigative Protocol: Medication Pass and Pharmacy Services.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of regulation (F431)

This requirement has several aspects. The pharmaceutical services must:

- *Provide for the safe and secure storage of medications, i.e., medications must be stored at proper temperatures and locked at all times (except when under direct staff observation);*
- *Limit access to medications only to authorized staff;*
- *Label medications in accordance with Federal and State labeling requirements and accepted standards of practice; and*
- *Have safeguards and systems in place to control, account for, and periodically reconcile controlled medications.*

Criteria for Compliance

Compliance with 42 CFR 483.60(b)(2)(3)(d)(e), F431, Labeling, Storage, and Controlled Medications

The facility is in compliance if:

- *The facility safeguards medications by locking the medications, limiting access, and disposing of medications appropriately;*
- *Medications are stored under proper temperature controls and in accordance with manufacturers' specifications;*
- *Medication labeling identifies, at a minimum, the medication's name, strength, expiration date when applicable, and lot number, and provides instructions as necessary for safe administration;*
- *Schedule II medications are stored in separately locked, permanently affixed compartments, except when the facility uses single unit medication distribution systems in which the quantity stored is minimal and a missing dose can be readily detected; and*
- *Controlled medications are reconciled accurately.*

If not, cite F431.

Noncompliance for F431

After completing the investigation, determine whether compliance with the regulation exists. Noncompliance for F431 may include (but is not limited to) facility failure to:

- *Store medications to preserve their integrity, for example allowing medications that should be stored between 40 and 86 degrees Fahrenheit to either reach temperatures below 32 degrees or above 100 degrees;*

- *Provide accurate labeling with appropriate accessory and cautionary instructions, thereby creating a potential for the wrong medication to be administered or for the correct medications to be given by the wrong route; and*
- *Accurately reconcile controlled medications.*

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The key elements for severity determination for F431 are as follows:

1. Presence of actual or potential harm/negative outcome(s) due to a facility failure related to storage, labeling, or reconciliation of controlled medications.

Identify actual or potential harm/negative outcomes for F431 which may include, but are not limited to:

- *Accidental ingestion of medication(s) by a resident(s) as a result of failure to lock medications;*
- *One or more residents received (or had the potential to receive) the wrong medication or dose or the correct medication by the wrong route as a result of inaccurate or incomplete labeling; or*
- *Potential for a resident(s) to receive potentially ineffective medication(s) as a result of storing medications or vaccines at wrong temperatures, resulting in their potential inactivation.*

2. Degree of actual or potential harm/negative outcome(s) due to a facility failure related to storage, labeling, or reconciliation of controlled medications.

Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:

- *If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or*
- *If harm has not yet occurred, determine the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.*

3. The immediacy of correction required.

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F431. First, the team must rule out whether Severity Level 4, Immediate Jeopardy, to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Guidelines for Determining Immediate Jeopardy.)

NOTE: *The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance which allowed or caused the immediate jeopardy.*

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has caused/resulted in, or is likely to cause, serious injury, harm, impairment, or death to a resident; and*
- Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.*

Examples may include, but are not limited to:

- The facility failed to restrict access to medications resulting in serious injury or harm or death from ingestion of the medications (e.g., warfarin, digoxin, antibiotics, opioids, anticonvulsants, antipsychotics) or posed a significant risk to the health of the residents resulting in the potential for clinically significant adverse consequences such as kidney or liver failure, anaphylaxis, cardiac arrest, or death; or*
- As a result of an incorrect label on the package, staff administered the wrong medication or wrong dose(s) of a medication (e.g., anticonvulsant, antihyperglycemic, benzodiazepine) with a potential for clinically significant adverse consequences, which resulted in or had the potential for serious harm or death (e.g., toxic levels of the medication, unresponsiveness, uncontrolled seizures).*

NOTE: *If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.*

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Level 3 indicates noncompliance that resulted in actual harm, and can include but may not be limited to compromise, decline, or interference with the resident's ability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:

- Medication labeling was incomplete and lacked instructions that the medication was not to be given with specific foods (e.g., milk or milk-based products) resulting in altered effectiveness of the medication and worsening of the residents' symptoms, requiring medical intervention; or*
- The facility failed to implement a system to reconcile controlled medications. As a result, medications were unavailable for residents for whom the medications were prescribed. Residents experienced moderate pain that compromised their ability to perform ADLs.*

NOTE: *If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.*

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided. Examples may include, but are not limited to:

- The facility's medication cart was not kept locked or under direct observation of authorized staff and a wandering resident with dementia ingested a medication that he/she had taken off the cart but did not suffer any adverse consequences; or*
- As a result of inaccurate labeling, the resident received the wrong medication or dose or the correct medication by the wrong route and experienced discomfort but did not require any interventions.*

NOTE: *If Severity Level 2 (no actual harm with potential for more than minimal harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 1 (no actual harm with the potential for minimal harm) exists.*

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm

Level 1 indicates noncompliance that resulted in no harm to the resident, and the potential for no more than minimal harm. Examples may include, but are not limited to:

- The facility failed to reconcile controlled medications but there was no negative resident outcome and no potential for more than minimal harm.*

F441

§483.65 Infection Control

The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.

§483.65(a) Infection Control Program

The facility must establish an infection control program under which it--

- (1) Investigates, controls, and prevents infections in the facility;**
- (2) Decides what procedures, such as isolation should be applied to an individual resident; and**
- (3) Maintains a record of incidents and corrective actions related to infections.**

Intent §483.65(a)

The intent of this regulation is to assure that the facility has an infection control program which is effective for investigating, controlling, and preventing infections. If infection control has been identified as an area of concern during Phase 1 of the survey, investigate aspects of the program, as appropriate, during Phase 2.

Interpretive Guidelines §483.65(a)

The facility's infection control program must have a system to monitor and investigate causes of infection (nosocomial and community acquired) and manner of spread. A facility should, for example, maintain a separate record on infection that identifies each resident with an infection, states the date of infection, the causative agent, the origin or site of infection, and describes what cautionary measures were taken to prevent the spread of the infection within the facility. The system must enable the facility to analyze