

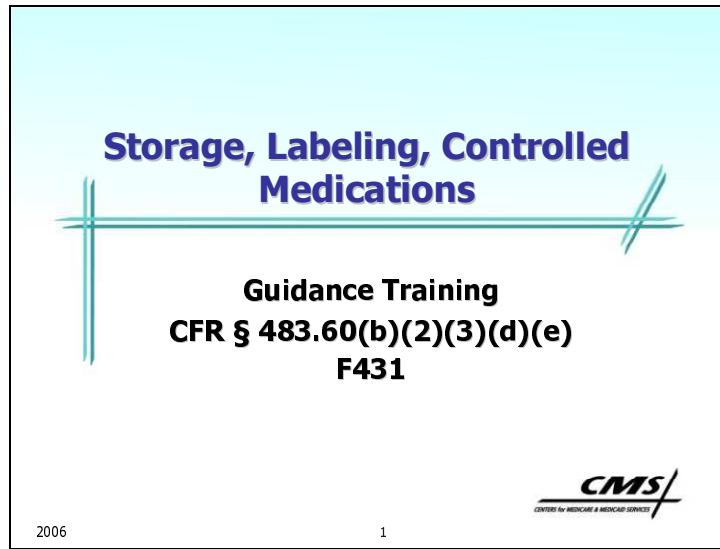


Centers for Medicare & Medicaid Services (CMS)

**Storage, Labeling, Controlled Medications
Instructor's Guide
CFR § 483.60(b)(2)(3)(d)(e)
F431**

2006

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Guidance Training

Notes:

- Introduce yourself and the other presenters
- Welcome the participants
- Provide logistical information such as anticipated length of presentation, location of restrooms, vending machines, etc., as appropriate.

F431 Storage, Labeling, Controlled Medications

Training Objectives

After today's session, you should be able to:

- Describe the intent of the regulation
- Identify triggers leading to an investigation of F431
- Utilize the components of the investigative protocol
- Identify compliance with the regulation
- Appropriately categorize the severity of noncompliance

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Training Objectives

Message: Today, we'll review the text of the regulation and the intent, the interpretive guidelines, investigative protocol, determination of compliance and deficiency categorization.

F431 Storage, Labeling, Controlled Medications

Regulatory Language

(F431) 42 CFR 483.60(b)(2)(3)

[The pharmacist]

(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.

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Regulatory Language

Message: The text of the regulation and the guidance for 483.60(b)(2) and (3) that addresses records for controlled medications had been previously at tag F427, but is now merged into F431 with the other regulatory language and guidance addressing controlled medications.

F431 Storage, Labeling, Controlled Medications

Regulatory Language (F431) 42 CFR 483.60(d)

(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.

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Message: It is important to note that this requirement addresses the accurate labeling of medications.

This tag requires the expiration date to be on the medication label. The quality and integrity of a medication's properties cannot be assured for a medication that is expired.

To address the use of expired medications, refer to F425 for issues related to the availability of medications to meet the need of the resident. Expired medications may be identified during the survey in areas or situations such as during the medication pass, or in an emergency supply of medications, if the facility has one.

F431 Storage, Labeling, Controlled Medications

Regulatory Language (F431) 42 CFR 483.60(e)

(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.

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Message: The regulatory language and guidance regarding storage of medications and biologicals was previously at tag F432, but has now been merged into F431.

It is important that medications be stored in accordance with the manufacturer's recommendations to maintain the integrity of the medication and to limit access to the medications by authorized personnel only in order to prevent diversion, to the extent possible, and help keep medications secure from resident access.

F431 Storage, Labeling, Controlled Medications

Regulatory Language (F431) 42 CFR 483.60(e)

(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.

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Message: Delivery systems and packaging for medications are becoming increasingly sophisticated. The thrust of this regulatory language is that the facility must have a system in place that will limit access to the Schedule II medications, diminish losses of Schedule II's and will allow for rapid identification of loss, if it occurs.



Interpretive Guidelines

F431 Storage, Labeling, Controlled Medications

Interpretive Guidelines

Components

- Intent
- Definitions
- Overview
- Medication Access and Storage
- Controlled Medications
- Labeling of Medications and Biologicals
- Investigative Protocol (SubTask 5E)
- Determination of Compliance
- Deficiency Categorization

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Components

Message: We will discuss all of these components of the Interpretive Guidelines. Some will be covered in greater detail than others.

F431 Storage, Labeling, Controlled Medications

Interpretive Guidelines

Intent

The facility, in coordination with the pharmacist, provides:

- Safe and secure storage and handling of all medication
- Accurate labeling to facilitate safe administration
- A system of records enabling reconciliation and accounting of controlled medications
- Identification of loss or diversion of controlled medications minimizing the time between actual loss and the detection of the extent of loss

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Intent

Message: The safe and secure storage and handling of medications includes:

- Accurate labeling
- Storage of medications in accordance with the manufacturer's recommendations such as proper temperature controls
- Secure storage including limiting access to the medications and safe disposition, of medications; and
- A system in place to account for and to minimize loss or diversion of all controlled medications and other medications subject to abuse.

F431 Storage, Labeling, Controlled Medications

Interpretive Guidelines

Definitions

Adverse Consequence - 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).

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Definitions

Message: In earlier guidance, the terms adverse drug reaction and side effects were frequently used. The regulatory language at F329 uses the term adverse consequence which is a broader term and encompasses both an Adverse Drug Reaction and side effect.

This definition is included in this guidance because of the effects or consequences that might occur to a resident as a result of non compliance with storage, labeling and access requirements. You will see these terms used in the severity examples.

F431 Storage, Labeling, Controlled Medications

Interpretive Guidelines

Definitions

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.

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Definitions

Message: This definition is also included in this guidance because of the clinically significant effects or consequences that might occur to a resident as a result of non compliance with storage, labeling and access requirements. You will see this term used in the severity examples.

We felt it was important to define clinically significant because of the potential impact that medications have on the resident's function and well-being. Clinically significant provides some measure of that potential impact on the resident.

F431 Storage, Labeling, Controlled Medications

Interpretive Guidelines Overview

The guidance addresses:

- medication access and storage
- security and safeguarding of controlled medications
- Labeling of medications to assure that they are provided:
 - Safely
 - Accurately and
 - In accordance with prescriber's instructions

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Overview

Message: Due to the vulnerable populations residing in nursing facilities, it is important that the facility have effective systems in place to safeguard medications.

The facility must have a licensed pharmacist who helps to establish and evaluate the mechanisms or systems that support the safe handling, labeling, and control of medications and to provide for accurate medication records.

F431 Storage, Labeling, Controlled Medications

Interpretive Guidelines

Medication Access and Storage

- Facility must secure all medications and limit access to authorized personnel
- Storage in accordance with manufacturers' guidelines
 - Draws
 - Cabinets
 - Medication rooms
 - Carts

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Medication Access and Storage

Discussion Question: Is it a negative finding or an issue if you observe staff, such as housekeeping staff, obtain the medication room key and enter the room, even though they are not authorized to administer or have access to medications?

Answer: It depends. Certainly, you would want to investigate further. The key used to access the medication room, should not be the same key that allows access to the locked medications. If, however, medications are not accessible and are secured in locked areas within the medication room, such locked drawers, compartments, cabinets, medication carts, or refrigerators, access to the room by non authorized staff would not be a problem. However, when medications are not stored in separately locked compartments within a storage area such as a medication room, access, in these situations, needs to be limited to authorized personnel, or direct observation must be provided by the authorized personnel.

Message: Other access and security issues may include some of the following situations:

- During a medication pass, medications must be either under the direct observation of the person administering the medications or be locked in the medication storage area, such as the med cart.
- If a resident is allowed to self-administer medications, the facility must have mechanisms for the control and safe storage of the medications for the resident.

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.

F431 Storage, Labeling, Controlled Medications

Interpretive Guidelines

Controlled Medications

- Schedule II medications, separately locked, permanently affixed
- Facility must have a system to account for
 - Receipt
 - Usage
 - Disposition
 - Reconciliation of all controlled medications

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Controlled Medications

Message: You may see the facility secure medications in any of several different types of security systems or mechanisms, such as with keys, touch pads, or voice recognition. However, the facility can't use the same key or code to access Schedule II medications. These medications must have a separate code or key than those used to access other medications.

There is an exception, however. Scheduled II medications and those subject to abuse may be stored with non-scheduled 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.

F431 Storage, Labeling, Controlled Medications

Interpretive Guidelines Controlled Medications

The facility's system includes:

- Record receipt to allow for reconciliation
- Records of usage and disposition to allow for reconciliation
- Periodic reconciliation of records of receipt, disposition and inventory (at least monthly)

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Controlled Medications

Message: The facility should have a system in place to identify how receipt of controlled medications will take place, including recording the name and strength of the medication, the quantity and date received, and the resident's name. However, in some delivery systems the resident's name may not be applicable. You may see that the facility in accordance with state requirements has an emergency supply of medications including controlled medications. The facility's procedures must address the reconciliation and monitoring of this supply.

Discussion Question: How have you seen the disposition of controlled medications handled?

Answer: The requirement regarding the reconciliation of controlled medications includes the disposition of controlled medications. This means the facility has the ability to track what happened to a medication from receipt, storage, administration and disposition, which may include destruction, wastage, return to the pharmacy or manufacturer, all in accordance with applicable state requirements.

Message: The facilities pharmacist in collaboration with the staff, must provide for reconciliation of controlled medications with sufficient frequency to identify loss or diversion. This is necessary so that the time is minimized 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.

The regulation does not mandate either a specific method or system for reconciling and accounting for controlled medications or the frequency with which it must be done, but it does require that systems and records are in place to detect diversion and to reconcile and account for controlled medications.

F431 Storage, Labeling, Controlled Medications

Interpretive Guidelines

Labeling of Medications and Biologicals

Label includes:

- Medication name
- Strength
- Expiration date when applicable
- When applicable accessory and cautionary instructions

Typically also, depending on the medication system:

- Resident's name
- Route of administration

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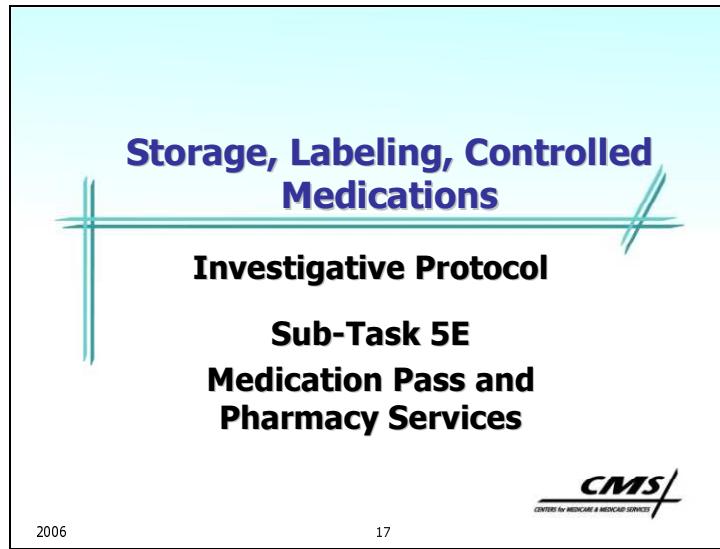
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Labeling of Medications and Biologicals

Message: Although the pharmacy is responsible for labeling medications, the facility must be in compliance with current labeling requirements. 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.

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 the compounder, date and time of administration, initials of person administering medication if different than the compounder, ancillary precautions as applicable, and date after which the mixture must not be used.

Some states allow the use of over-the-counter (OTC) medications in bulk containers to be stocked in the facility. In these situations, 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.



Sub-Task 5E

Message: For investigating compliance with components of F431, use the revised Sub-Task 5E - Medication Pass and Pharmacy Services.

F431 Storage, Labeling, Controlled Medications

Use of Sub-Task 5E: Medication Pass and Pharmacy Services

- Labeling

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Use of Sub-Task 5E

Message: During the medication pass, you will record the name, dose or concentration and route of administration, if other than oral, of each medication administered.

F431 Storage, Labeling, Controlled Medications

Use of Sub-Task 5E: Medication Pass and Pharmacy Services

- Storage (includes labeling and access)
- Controlled Substances

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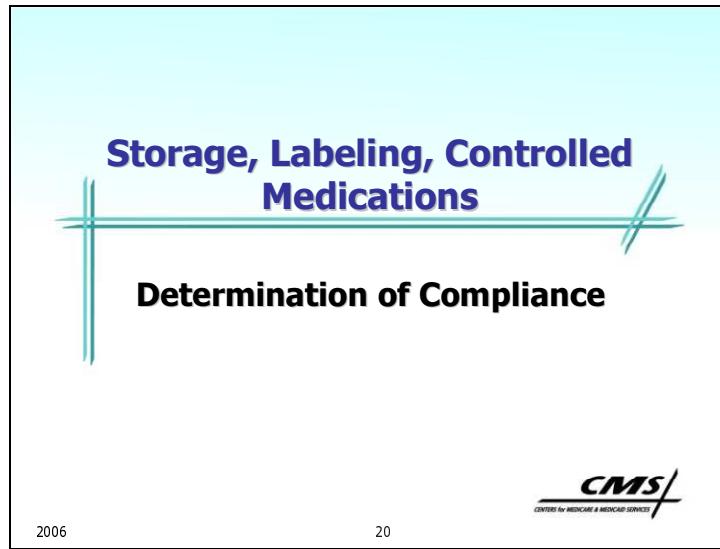
Use of Sub-Task 5E

Message: A review for the storage, including all areas where medications are stored, and access to these medications must be conducted on every survey.

Use CMS form 803 for documentation regarding issues of drug storage, such as whether the medications are secured appropriately and stored at temperatures consistent with manufacturer's specifications.

In addition, record issues, if any, in regard to labeling.

For controlled medications, if a potential problem has been identified regarding the lack of reconciliation or loss of controlled medications, investigate for storage, access, and reconciliation. Interviews with the director of nursing and the licensed pharmacist may be necessary to follow up on these concerns.



Determination of Compliance

Message: This requirement is not a resident specific outcome requirement, but rather addresses facility structures and processes. There does not need to be a specific negative resident outcome to determine and cite non-compliance with this requirement.

F431 Storage, Labeling, Controlled Medications

Determination of Compliance

- Synopsis of regulation
- Criteria for compliance
- Noncompliance for F431

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Determination of Compliance

Message: The guidance for the determination of compliance discusses the aspects of the regulation that address labeling, storage, and controlled medications and defines the criteria that the facility must meet to be determined to be in compliance. This guidance also provides some examples of possible non-compliance.

F431 Storage, Labeling, Controlled Medications

Determination of Compliance

Synopsis of Regulation

Pharmaceutical services must:

- Provide for the safe and secure storage of medications
- Limit access to medications only to authorized staff
- Label medications in accordance with labeling requirements
- Have safeguards and systems in place to control, account for, and periodically reconcile controlled medications

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Determination of Compliance

Message: There are several aspects to the requirements grouped under F431. Medications must be stored at proper temperatures and be locked at all times except when they are under direct staff observation, such as during medication passes.

Access to medications is limited to only those staff who are authorized by state law and facility policy to have access.

Medications must be labeled in accordance with federal and state labeling requirement and accepted standards of practice, and the facility must have safeguards and systems in place to control, account for, and periodically reconcile controlled medications.

F431 Storage, Labeling, Controlled Medications

Determination of Compliance

Criteria for Compliance

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

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Determination of Compliance

Message: In order for the facility to be considered in compliance with this regulation, the facility must demonstrate compliance with each one of these criteria.

Note: *Continued on next slide*

F431 Storage, Labeling, Controlled Medications

Determination of Compliance

Criteria for Compliance

(con't)

- 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
- Controlled medications are reconciled accurately

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Determination of Compliance

Message: If the facility does not meet any of these criteria, cite F431.

F431 Storage, Labeling, Controlled Medications

Determination of Compliance

Noncompliance for F431

Noncompliance for F431 may include failure to:

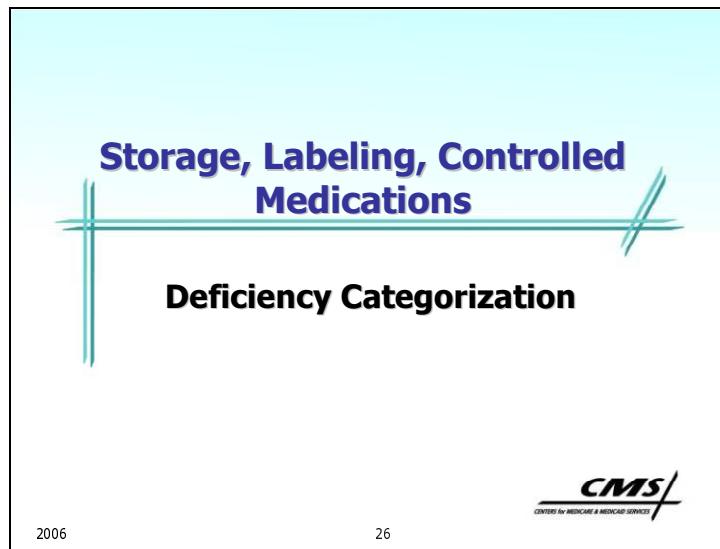
- Store medications to preserve their integrity
- Provide accurate labeling with appropriate accessory and cautionary instructions, thereby creating a potential for the wrong medication to be administered or for the correct medications to be given by the wrong route.
- Accurately reconcile controlled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

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Determination of Compliance

Message: These are some examples of non compliance, another example, could be regarding issues related to access to medications, such as one or more residents having access to medications on top of a medication cart not under observation or supervision of authorized staff.



Deficiency Categorization

Message: We will now address the key elements for severity determination.

F431 Storage, Labeling, Controlled Medications

Deficiency Categorization Severity Determination

The key elements for severity determination are:

- Presence of harm or potential for negative outcomes
- Degree of harm or potential harm related to noncompliance
- Immediacy of correction required

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Deficiency Categorization

Message: There are three key elements to apply when determining severity of non compliance.

The first key element is the presence of actual or potential harm or negative outcome(s) due to a facility failure related to medication storage or labeling or reconciliation of controlled medications.

The identification of actual or potential harm or negative outcomes for F431 which may include examples such as:

- The accidental ingestion of medication by a resident as a result of failure to lock medications or
- 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
- The potential for a resident(s) to receive potentially ineffective medication as a result of storing medications or vaccines at wrong temperatures, resulting in their potential inactivation.

The second key element is the degree of actual or potential harm/ or negative outcome(s) due to a facility failure related to storage, labeling, or reconciliation of controlled medications.

This includes determining 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.

And the third key element is the immediacy of correction required.

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

F431 Storage, Labeling, Controlled Medications

Deficiency Categorization

Severity Determination Levels

- **Level 4:** Immediate Jeopardy to resident health or safety
- **Level 3:** Actual harm that is not immediate jeopardy
- **Level 2:** No actual harm with potential for more than minimal harm that is not immediate jeopardy
- **Level 1:** No actual harm with potential for minimal harm

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Deficiency Categorization

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

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.

F431 Storage, Labeling, Controlled Medications

Deficiency Categorization

Severity Level 4: Immediate Jeopardy

Level 4: Immediate Jeopardy to resident health or safety

- Noncompliance with one or more requirements of participation:
 - Has resulted in or is likely to cause serious injury, harm, impairment, or death to a resident
 - Requires immediate correction

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Deficiency Categorization

Message: Let's discuss some examples of non compliance which would come under level 4 Severity.

One example of non compliance was if the facility failed to restrict access to medications and a resident ingested medications such as warfarin, digoxin, antibiotics, opioids, anticonvulsants, or antipsychotics. These medications may pose the risk for clinically significant adverse consequences, such as kidney or liver failure, anaphylaxis, cardiac arrest or death.

Another example is that as a result of an incorrect label on the package and staff administered the wrong medication or wrong dose of a medication such as an anticonvulsant, antihyperglycemic medication, or a benzodiazepine that had a potential for clinically significant adverse consequences. This resulted in or had the potential for serious harm or death, such as toxic levels of the medication or unresponsiveness or uncontrolled seizures.

F431 Storage, Labeling, Controlled Medications

Deficiency Categorization

Severity Level 3: Actual Harm

Level 3: Actual harm that is not immediate jeopardy

- Noncompliance resulted in actual harm
- May include clinical compromise, decline, or resident's inability to maintain and/or reach his/her highest practicable level of well-being

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Deficiency Categorization

Message: Here is an example of non compliance which would come under level 3 Severity.

One example of Severity Level 3 harm is that medication labeling was incomplete and lacked instructions that the medication was not to be given with specific foods, such as, milk or milk-based products. The medication was routinely administered with milk, which resulted in the altered effectiveness of the medication and worsening of the residents' symptoms, requiring medical intervention.

F431 Storage, Labeling, Controlled Medications

Deficiency Categorization

Severity Level 2: Potential for Harm

Level 2: No actual harm with potential for more than minimal harm that is not immediate jeopardy

Noncompliance resulted in:

- No more than minimal discomfort to resident; and/or
- Potential to compromise resident's ability to maintain or reach his/her highest practicable level of well-being

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Deficiency Categorization

Message: An example of Severity Level 2 includes:

The facility's medication cart was not kept locked or under direct observation of authorized staff and a resident ingested a medication that he had taken off the cart but he 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 some discomfort, but he or she did not require any interventions.

F431 Storage, Labeling, Controlled Medications

Deficiency Categorization

Severity Level 1: Potential for Minimal Harm

Level 1: No actual harm with potential for minimal harm

- Verify that no resident harm or potential for more than minimal harm is identified

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Deficiency Categorization

Message: An example of Severity Level 1 might be that the facility failed to reconcile controlled medications, but there was no negative resident outcome and no potential for more than minimal harm as the controlled medications were in the facility and available for resident use.