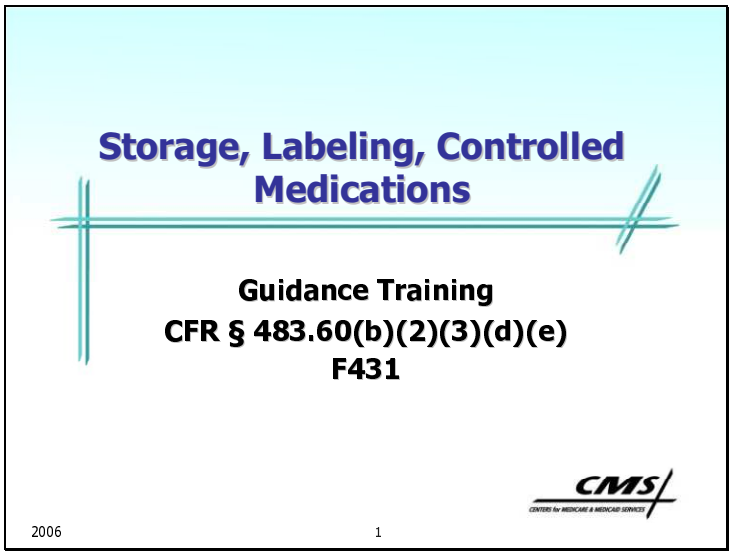
Centers for Medicare & Medicaid Services (CMS)

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

2006

Prepared by:
American Institutes for Research
1000 Thomas Jefferson St, NW
Washington, DC 20007

Slide 1



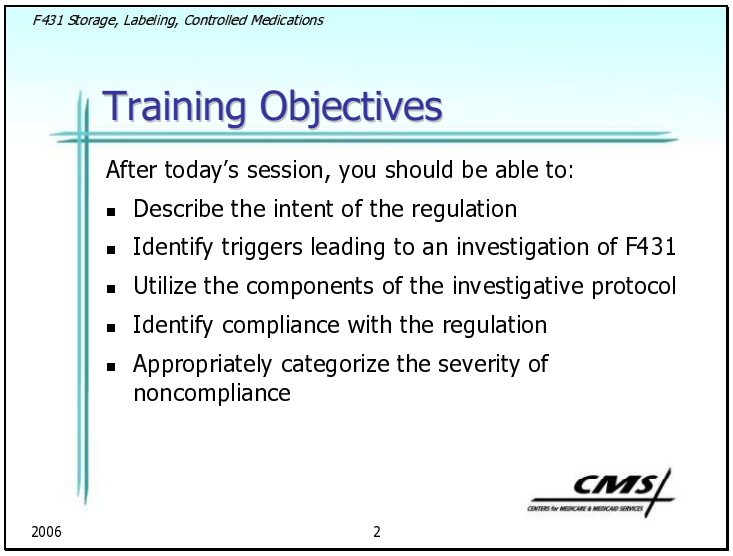
Guidance Training

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.

.

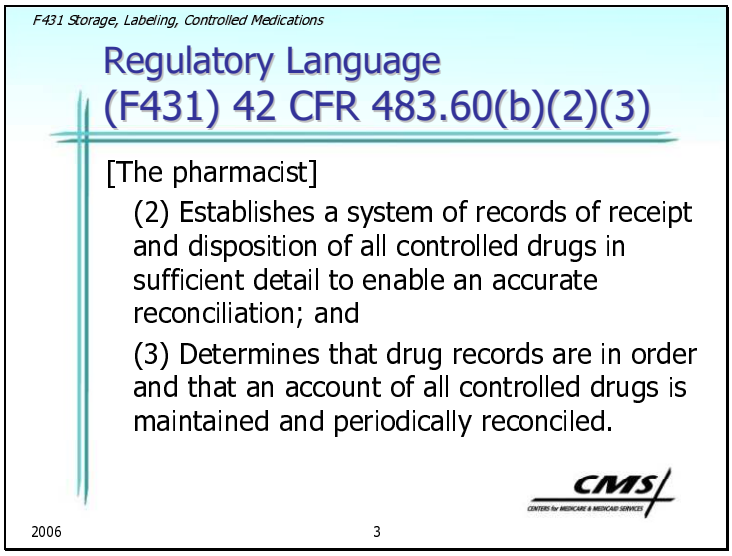
Slide 2



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.

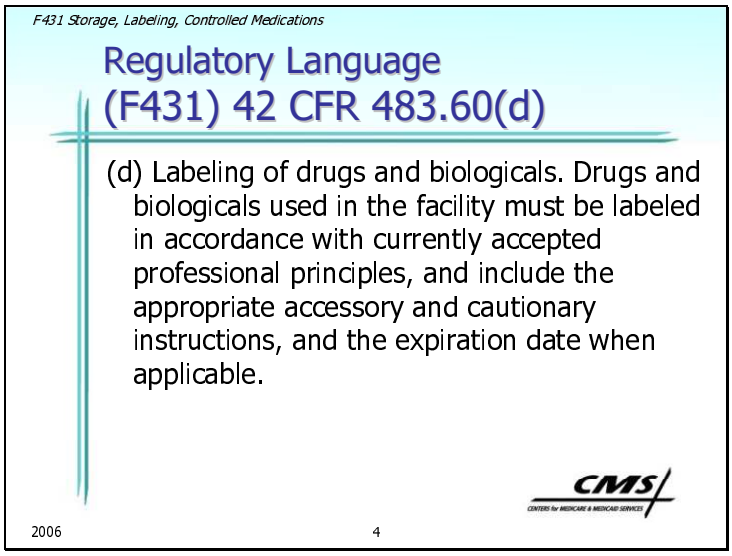
Slide 3



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 F431with the other regulatory language and guidance addressing controlled medications.

Slide 4

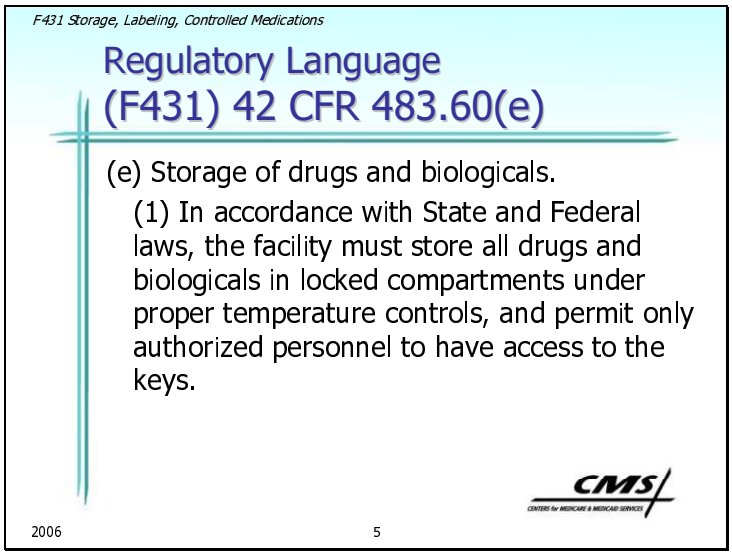


Message: It is important to note that this requirement addresses the accurate labeling of medications.

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.

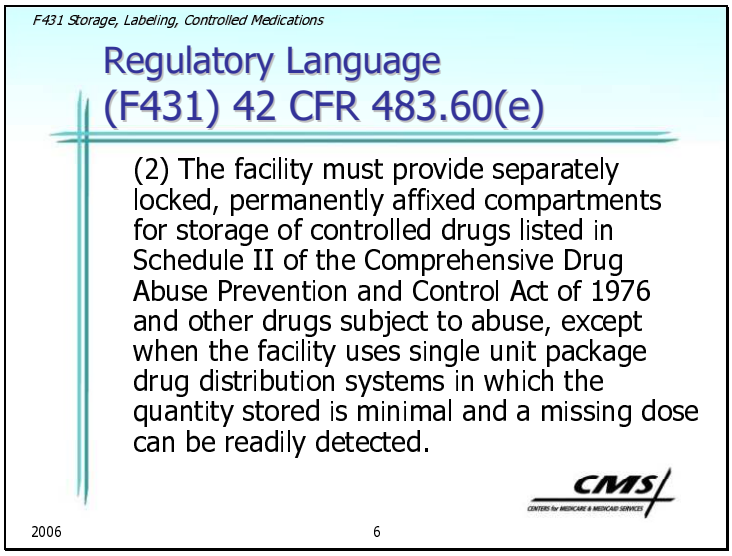
Slide 5



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

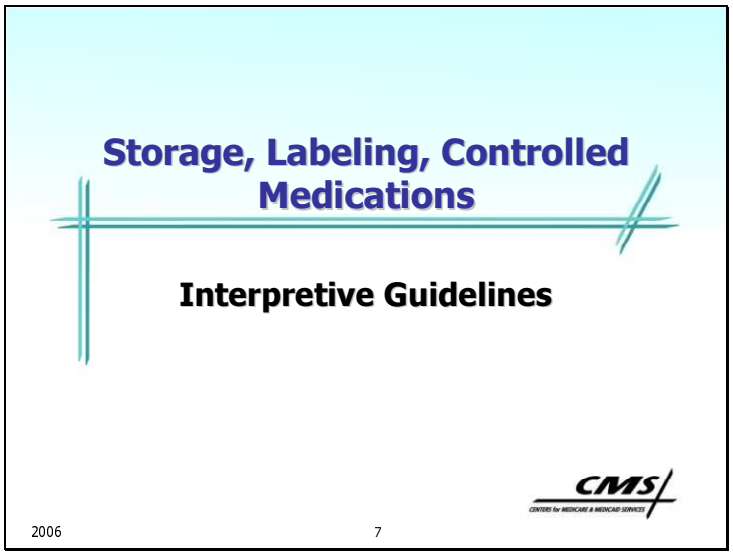
It is important that medications be stored in accordance with the manufacturer's recommendations to maintain the integrity of the medication and to limit access to the medications by authorized personnel only in order to prevent diversion, to the extent possible, and help keep medications secure from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

Slide 6



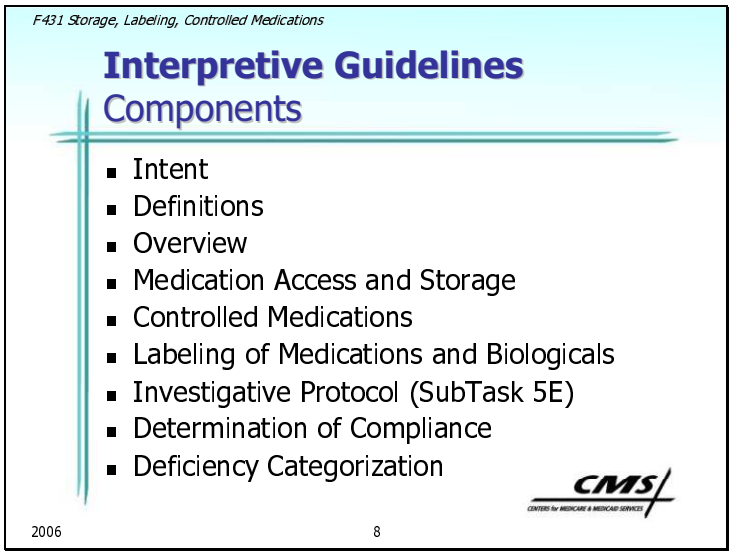
Message: Delivery systems and packaging for medications are becoming increasingly sophisticated. The thrust of this regulatory language is that the facility must have a system in place that will limit access to the Schedule II medications, diminish losses of Schedule II's and will allow for rapid identification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

Slide 7



Interpretive Guidelines

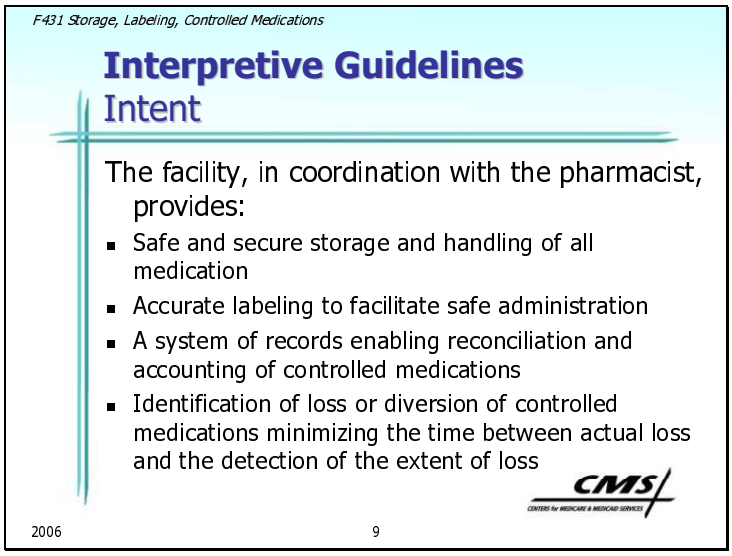
Slide 8



Components

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

Slide 9

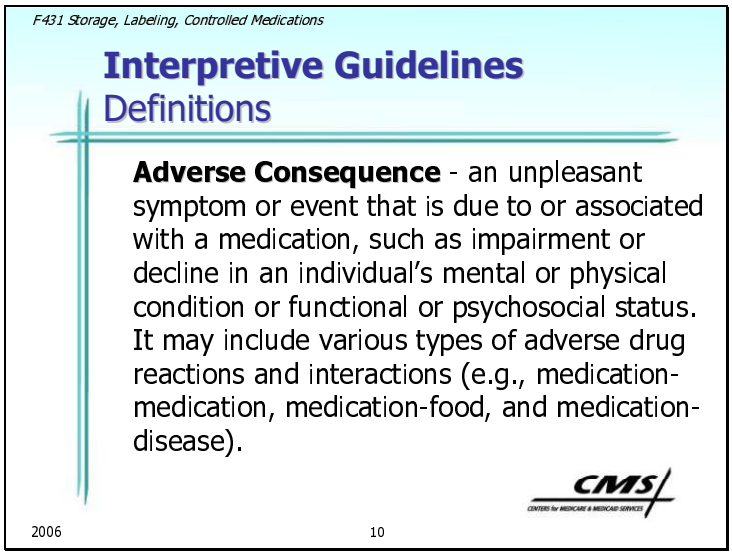


Intent

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.

Slide 10

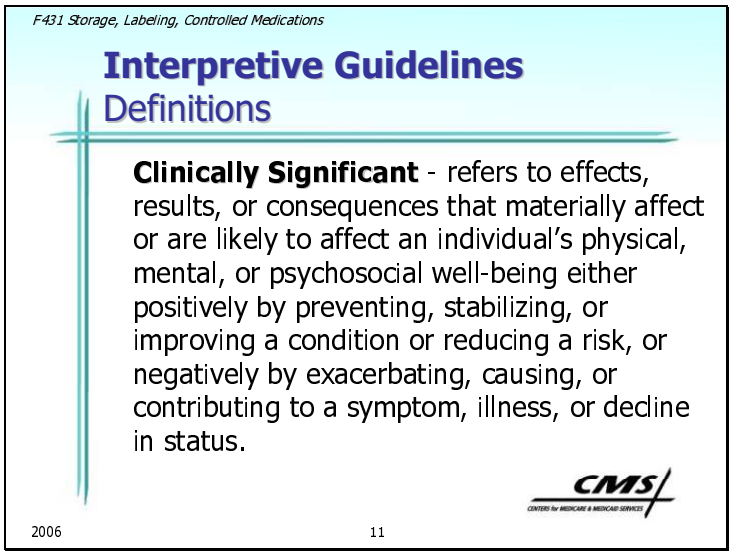


Definitions

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.

Slide 11

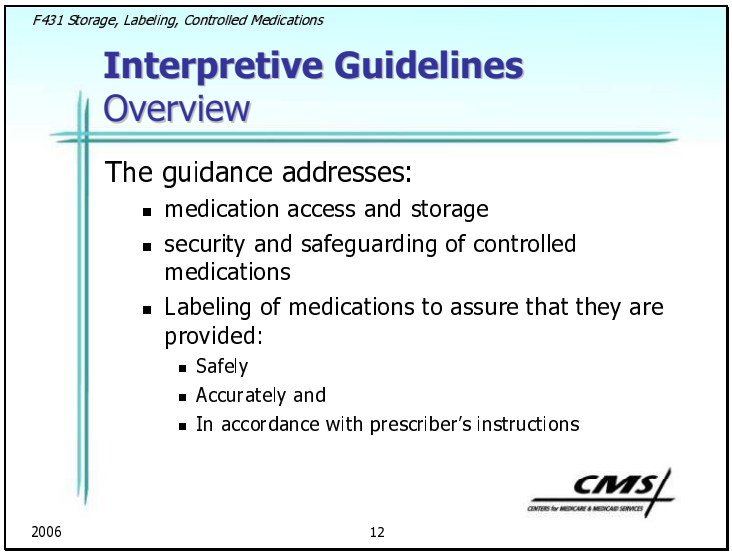


Definitions

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.

Slide 12

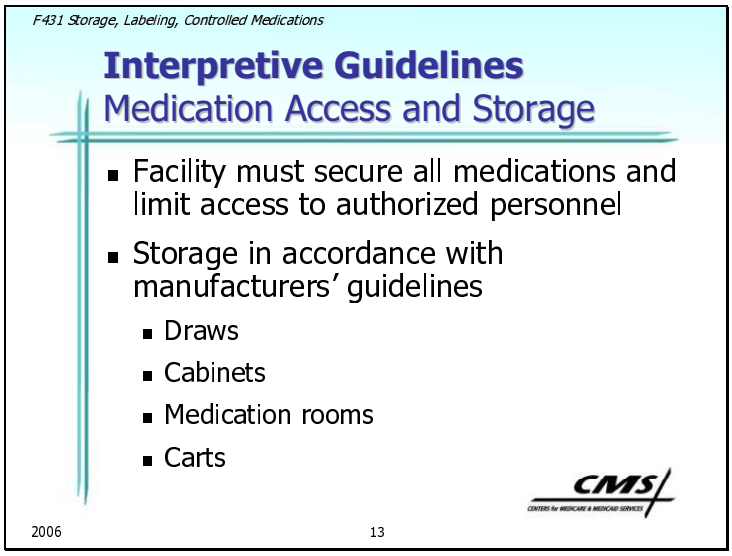


Overview

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.

Slide 13



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?

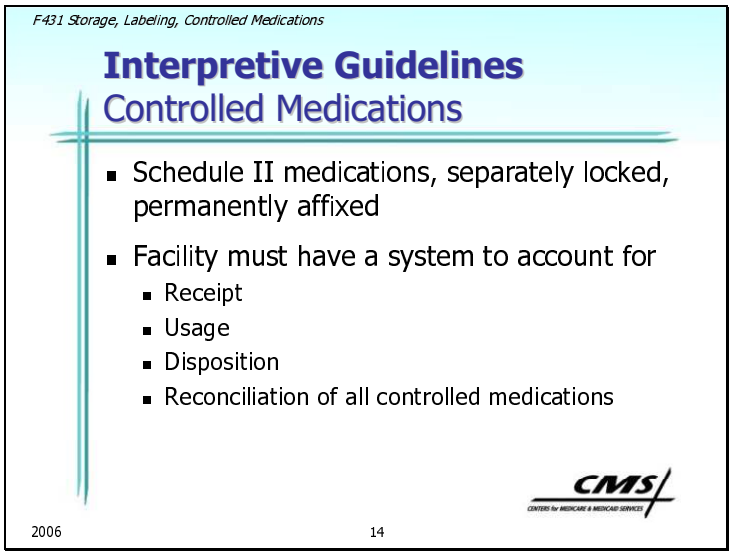
Answer: It depends. Certainly, you would want to investigate further. The key used to access the medication room, should not be the same key that allows access to the locked medications. If, however, medications are not accessible and are secured in locked areas within the medication room, such locked 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.

Slide 14

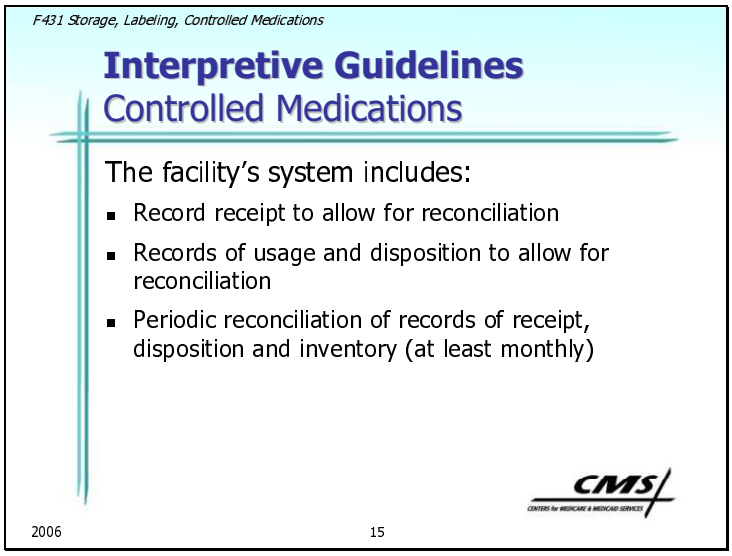


Controlled Medications

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.

Slide 15



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.

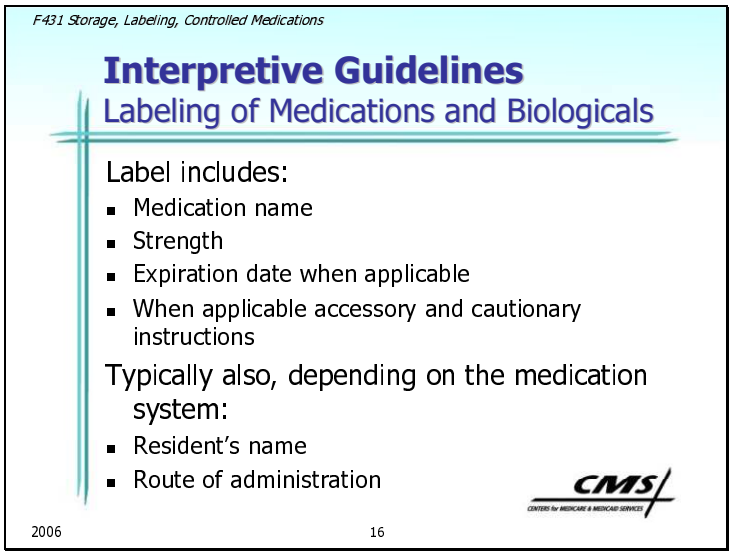
Discussion Question: How have you seen the disposition of controlled medications handled?

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.

Slide 16



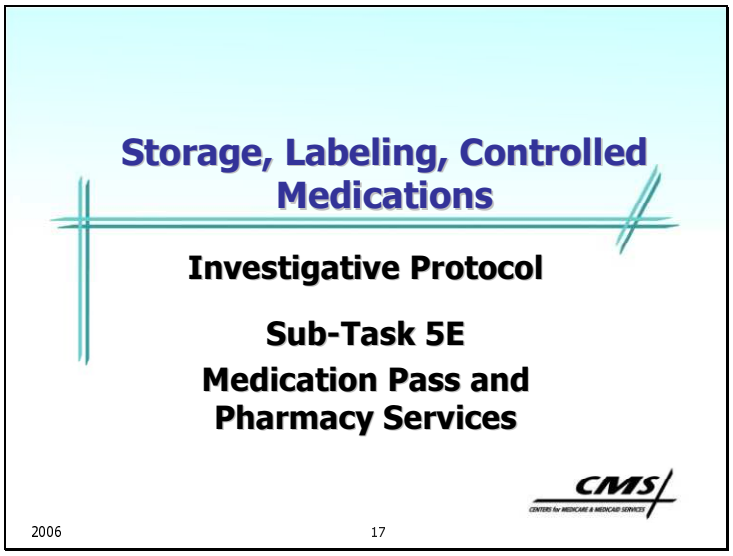
Labeling of Medications and Biologicals

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.

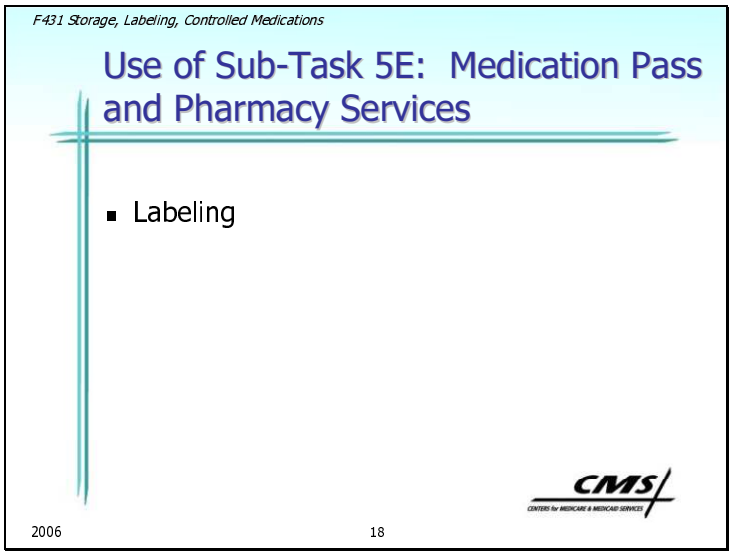
Slide 17



Sub-Task 5E

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

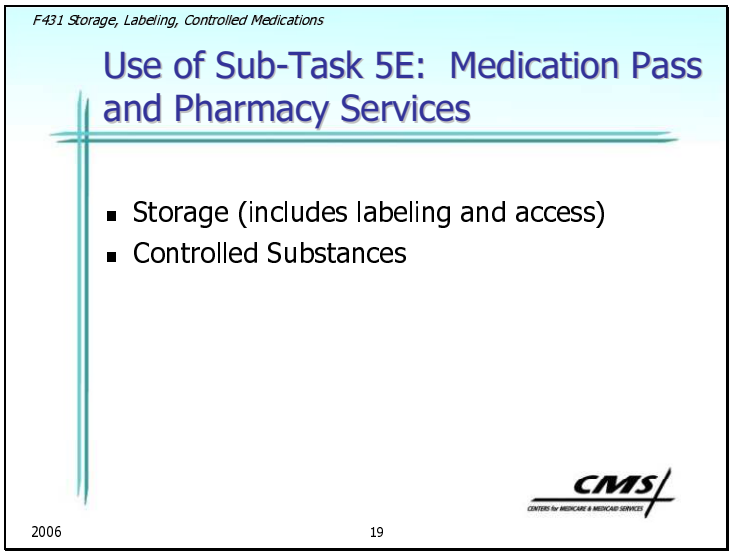
Slide 18



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.

Slide 19



Use of Sub-Task 5E

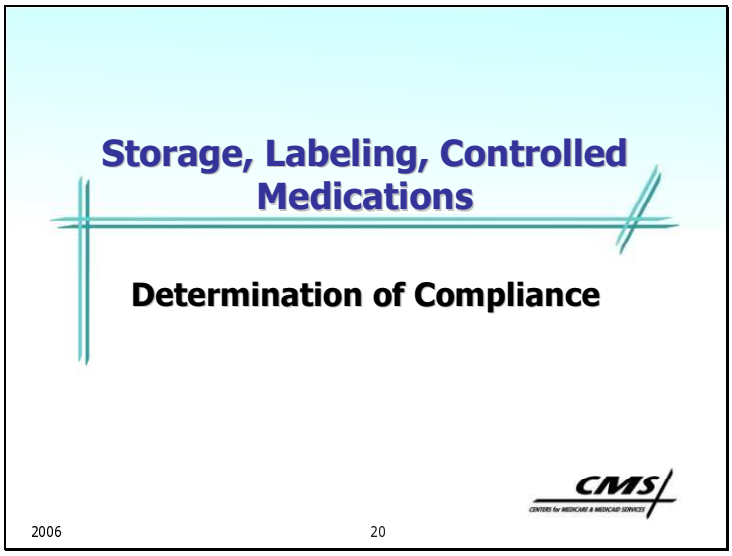
Message: A review for the storage, including all areas where medications are stored, and access to these medications must be conducted on every survey.

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.

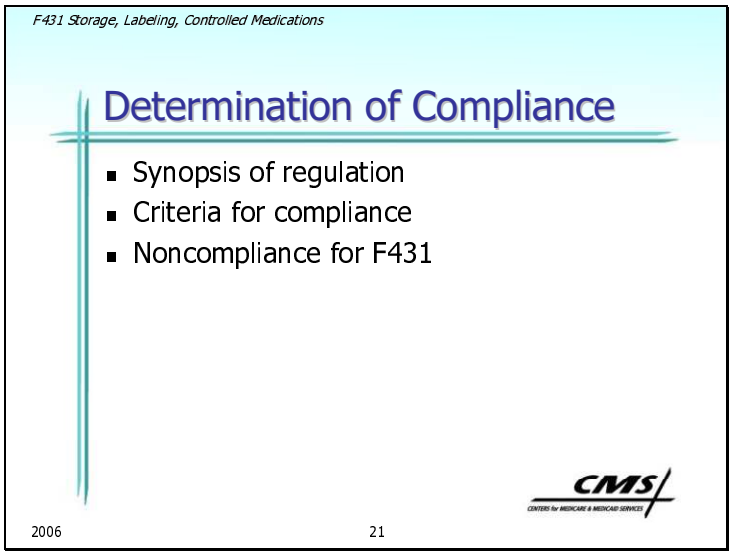
Slide 20



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.

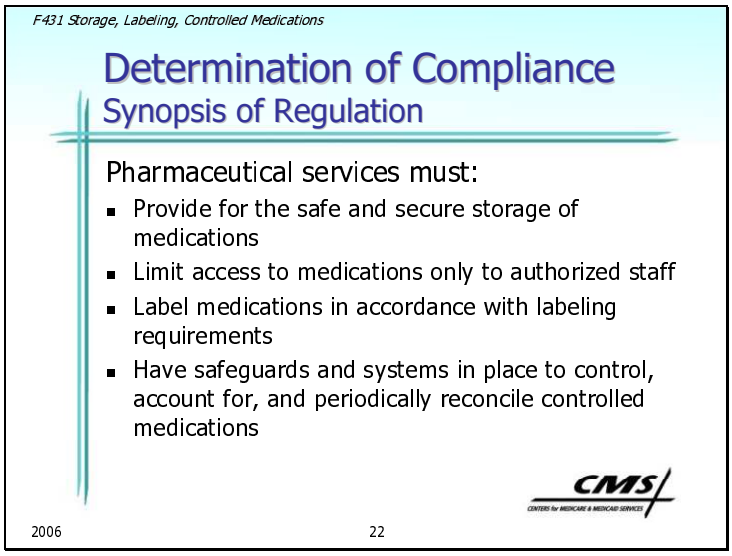
Slide 21



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.

Slide 22



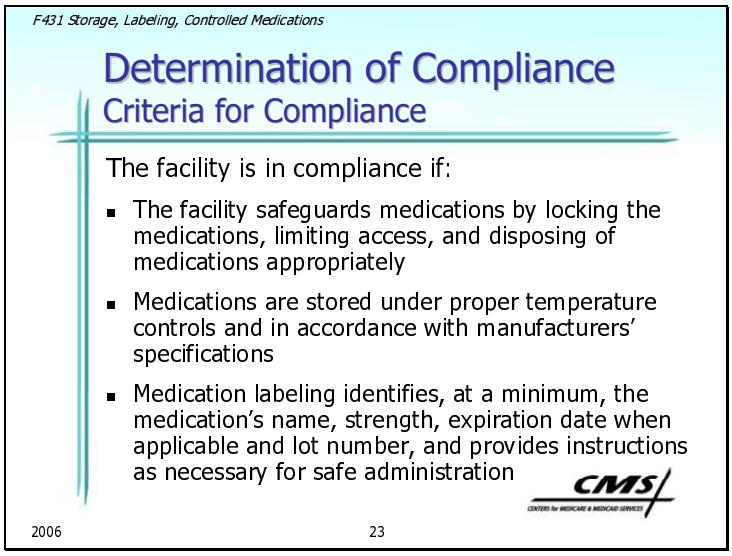
Determination of Compliance

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.

Slide 23

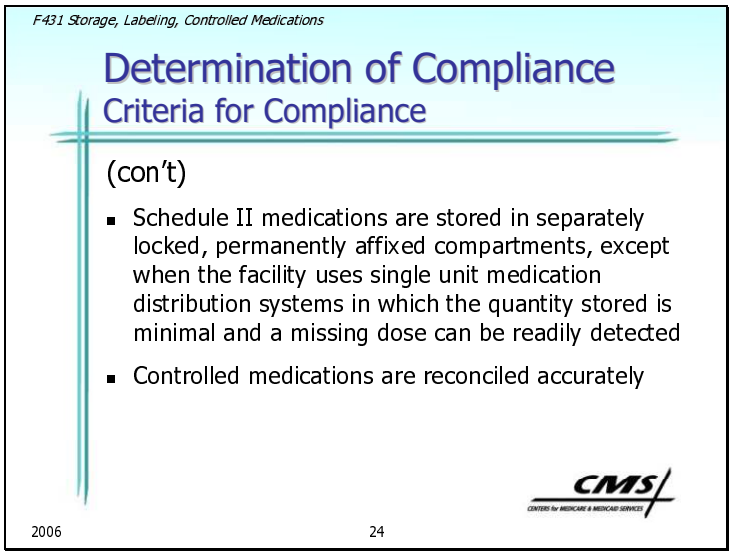


Determination of Compliance

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*

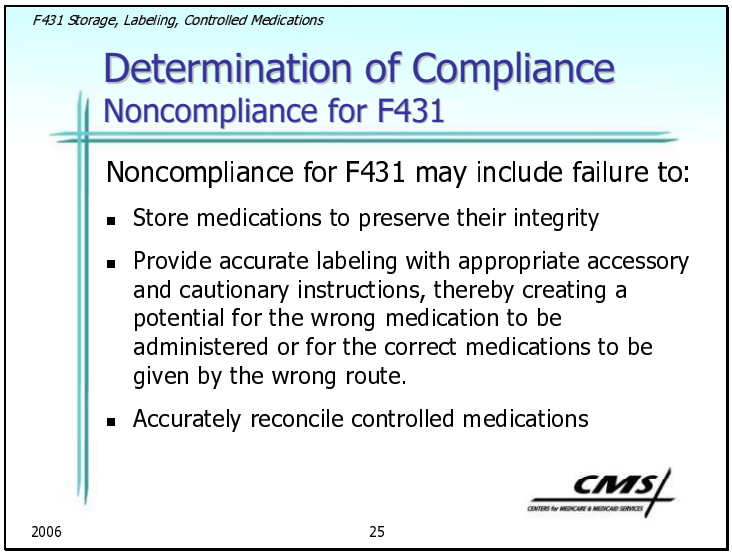
Slide 24



Determination of Compliance

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

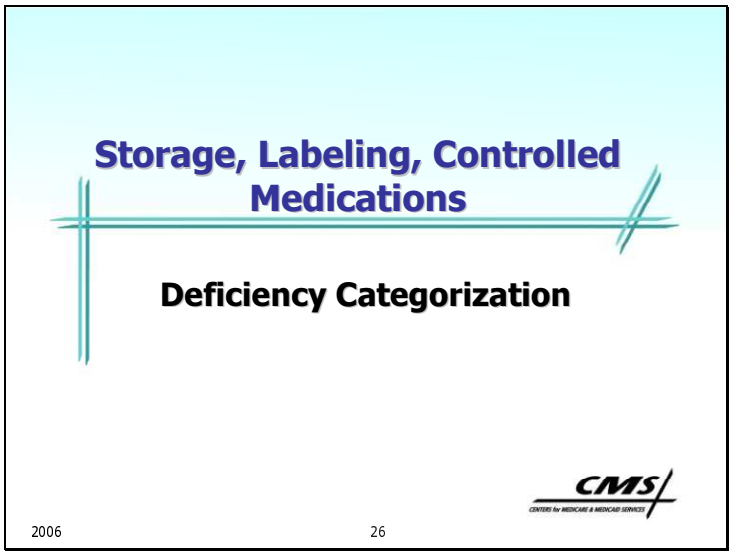
Slide 25



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.

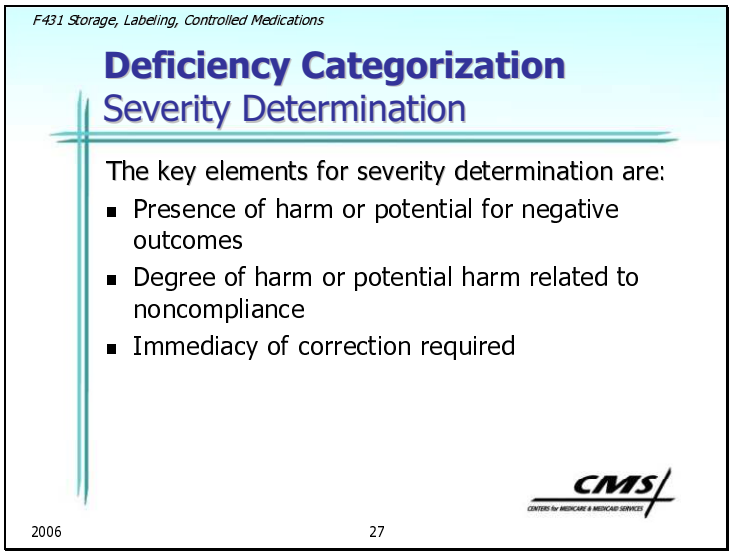
Slide 26



Deficiency Categorization

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

Slide 27



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:

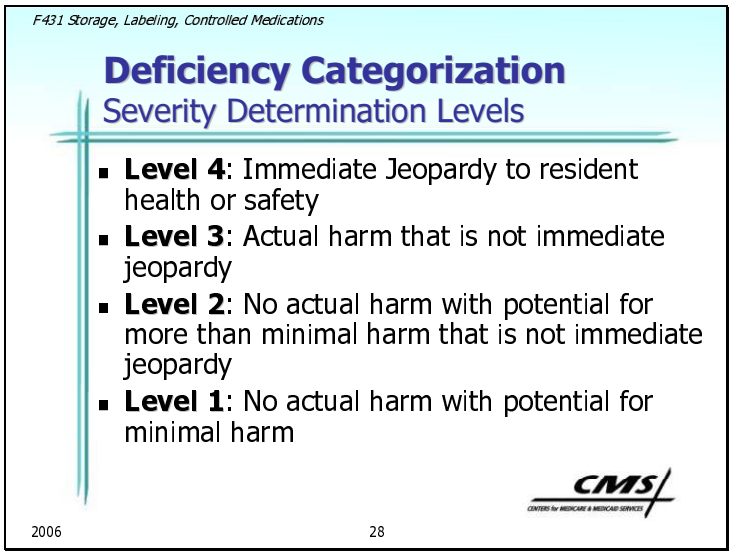
- The accidental ingestion of medication by a resident as a result of failure to lock medications or
- One or more residents received (or had the potential to receive) the wrong medication or dose or the correct medication by the wrong route as a result of inaccurate or incomplete labeling, or
- The 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.

Slide 28

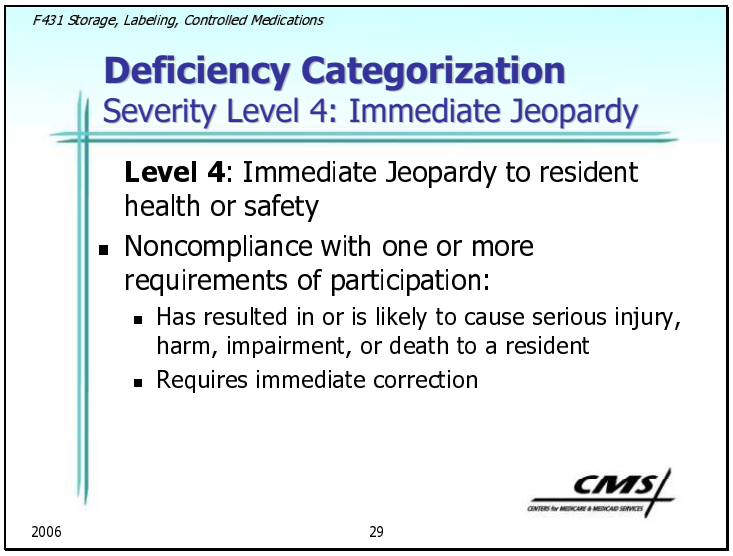


Deficiency Categorization

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.

Slide 29



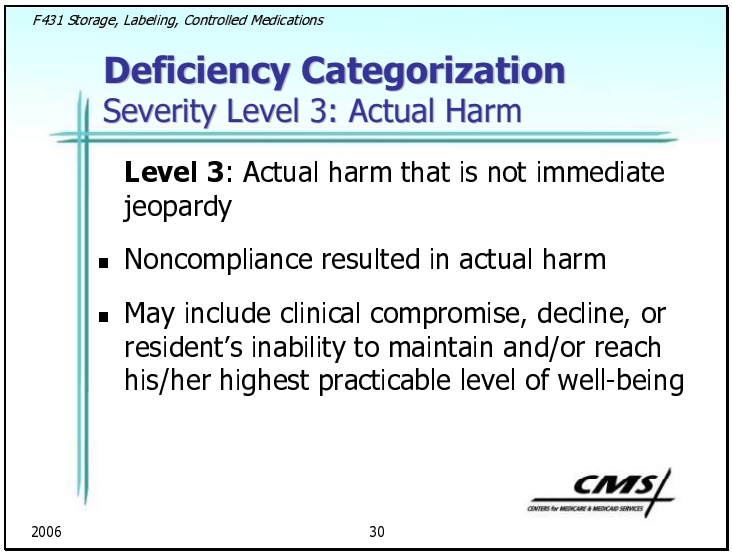
Deficiency Categorization

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.

Slide 30

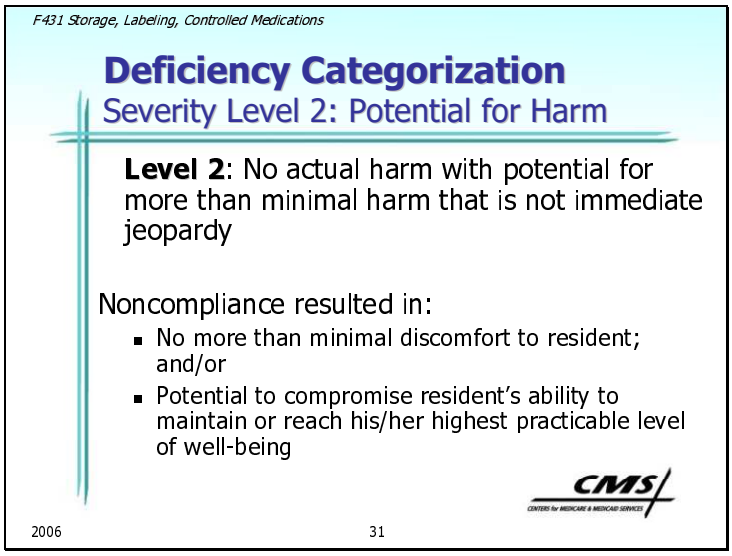


Deficiency Categorization

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.

Slide 31



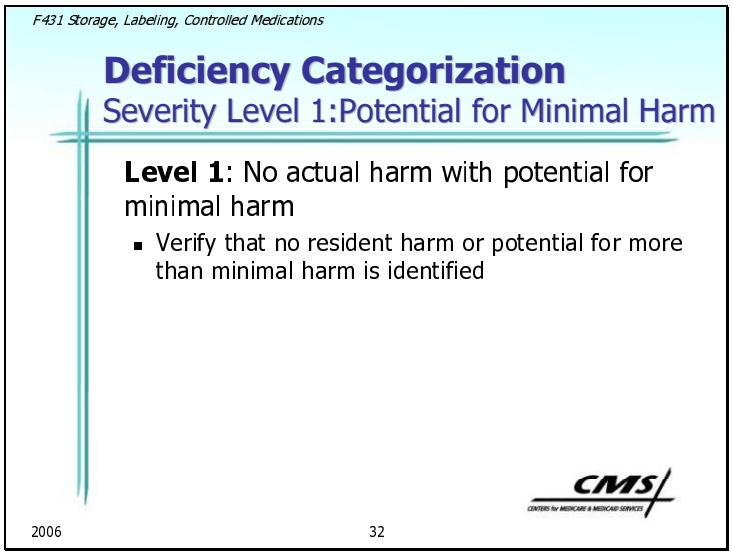
Deficiency Categorization

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.

Slide 32



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.