

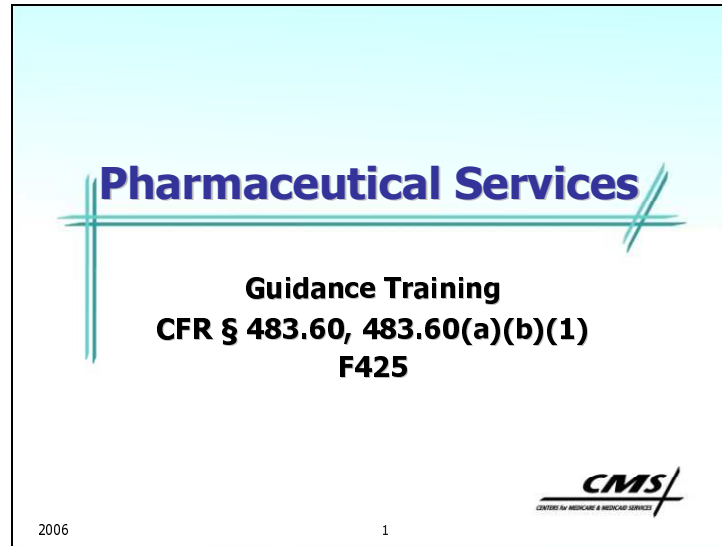


Centers for Medicare & Medicaid Services (CMS)

**Pharmaceutical Services
Instructor's Guide
CFR § 483.60, 483.60(a)(b)(1)
F425**

2006

Prepared by:
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Washington, DC 20007



Guidance Training

Message:

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


F425 Pharmaceutical Services

Training Objectives

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

- Describe the intent of the regulation
- Explain the regulatory components incorporated into F425
- 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 will discuss the regulation and the intent. We will cover:
- The guidance for F425,
 - the investigative protocol as reflected in sub task 5E,
 - what is required to be in compliance with the requirement, and
 - The assignment of an appropriate level of severity to a deficiency

F425 Pharmaceutical Services

Regulatory Language (F425) 42 CFR 483.60

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in Sec. 483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

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Regulatory Language

Message: The regulatory language at F425 lays out the framework for the facility's pharmaceutical services with the goal being to safely and accurately provide medications to meet the resident's needs.

F425 Pharmaceutical Services


Regulatory Language *Continued*

(F425) 42 CFR 483.60(a)(b)(1)

(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident. (b) Service consultation. The facility must employ or obtain the services of a licensed pharmacist who—(1) Provides consultation on all aspects of the provision of pharmacy services in the facility.

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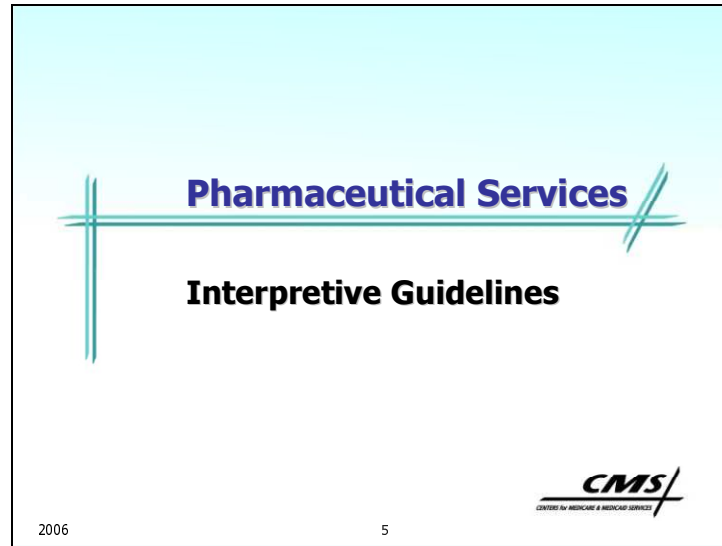

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Regulatory Language

Message: The regulatory language and guidance for the previous tags of F425, F426, and 483.60 (b)(1) which was the first portion of F427, has now been merged into F425.

In the guidance for the unnecessary medications and pharmacy requirements, we have used the term medications rather than drugs, except when the term drugs has become part of an accepted nomenclature such as Adverse Drug Event.

Slide 5



Pharmaceutical Services

Interpretive Guidelines

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The slide features a light blue header with the title 'Pharmaceutical Services' in bold blue text. Below the header, the subtitle 'Interpretive Guidelines' is centered in bold black text. A decorative graphic of three intersecting lines (two vertical, one horizontal) is positioned to the left of the title. The CMS logo is in the bottom right corner, and the year '2006' and slide number '5' are in the bottom left corner.

Interpretive Guidelines

F425 Pharmaceutical Services

Interpretive Guidelines Components

- Intent
- Definitions
- Overview
- Provision of Routine and/or Emergency Medications
- Services of a Licensed Pharmacist
- Pharmaceutical Services Procedures
- Investigative Protocol (Sub-Task 5E)
- Determination of Compliance
- Deficiency Categorization

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Interpretive Guidelines

Message: These are the components of the Interpretive Guidelines.
All of these areas will be discussed, to varying degrees.


F425 Pharmaceutical Services

Interpretive Guidelines

Intent

- Facility provides pharmaceutical services to meet the needs to residents
 - Medications and biologicals
 - Services of licensed pharmacist
- Pharmaceutical services are coordinated within the facility
 - Procedures developed and implementation evaluated
- Pharmaceutical concerns and issues affecting residents and care are identified and evaluated
- Only persons authorized under state requirements administer medications

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Intent

Message: The intent of this requirement is that:

- In order to meet the needs of each resident, the facility accurately and safely provides or obtains pharmaceutical services, including the provision of routine and emergency medications and biologicals and the services of a licensed pharmacist;
- The licensed pharmacist collaborates with facility leadership and staff to coordinate pharmaceutical services within the facility, and to guide development and evaluation of the implementation of pharmaceutical services procedures;
- The licensed pharmacist helps the facility identify, evaluate, and address/resolve pharmaceutical concerns and issues that affect resident care, medical care or quality of life such as the:
 - Provision of consultative services by a licensed pharmacist between the monthly pharmacist's visits, as necessary; and
 - Coordination of the pharmaceutical services if multiple pharmaceutical service providers are utilized such as the vendor pharmacy, infusion services, prescription drug plans (PDP) or hospices.

The intent of this requirement also provides for the facility to utilize only persons authorized under state requirements to administer medications.

F425 Pharmaceutical Services

Interpretive Guidelines

Definitions

- Acquiring medication
- Administering medication
- Biologicals
- Current standards of practice
- Dispensing
- Disposition
- Pharmaceutical Services
- Pharmacy assistant or technician
- Receiving Medication

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Definitions

Message: The guidelines include numerous definitions. These definitions are provided to clarify terminology related to pharmaceutical services and the management of each resident's medication regimen for effectiveness and safety. For this discussion, we will discuss biologicals, dispensing medications, and the definition of Pharmaceutical Services.


F425 Pharmaceutical Services

Interpretive Guidelines

Definitions

Dispensing - a process that includes the interpretation of a prescription; selection, measurement, and packaging or repackaging of the product (as necessary); and labeling of the medication or device pursuant to a prescription/order.

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Definitions

Message: Some people may have used the term “dispensing” to mean the act of administering a medication. The definition identifies that dispensing is actually a function of a pharmacy and is generally one of the specific functions included in a state’s pharmacy practice act.


F425 Pharmaceutical Services

Interpretive Guidelines

Definitions

Biologicals - are products isolated from a variety of natural sources—human, animal, or microorganism—or produced by biotechnology methods and other cutting-edge technologies. They may include a wide range of products such as vaccine, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

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Definitions

Message: There has been confusion as to what the term “biologicals” actually means. As you can see from the definition, the term biologicals does not include environmental cleansers or germicides, such as bleach or quaternary compounds, or skin antiseptics such as povidone iodines or hydrogen peroxide, and it does not refer to the use of herbals or nutritional supplements.

F425 Pharmaceutical Services

Interpretive Guidelines

Definitions

*What is included in the concept of
Pharmaceutical Services?*

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Definitions

Discussion Question: What does the concept of Pharmaceutical Services include?

Note: Note to the instructor: Attempt to draw out responses that demonstrate that the participants understand that the breadth of pharmaceutical services is more than getting the medications from the pharmacy and administering them to the resident, or the provision of the monthly medication regimen review by the pharmacist.

Answer on next slide.

F425 Pharmaceutical Services

Interpretive Guidelines

Definitions

Pharmaceutical Services

- The process of receiving and interpreting prescriber's orders; acquiring, receiving, storing, controlling, reconciling, compounding (e.g., intravenous antibiotics), dispensing, packaging, labeling, distributing, administering, monitoring responses to, using and/or disposing of all medications, biologicals, chemicals;
- The provision of medication-related information to health care professionals and residents;
- The process of identifying, evaluating and addressing medication-related issues including the prevention and reporting of medication errors; and
- The provision, monitoring and/or the use of medication-related devices.

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Definitions

Question: What is included in the concept of Pharmaceutical Services?

Answer: As you can see, the definition of pharmaceutical services involves not only the processes of medication administration, but the development of procedures that provide direction to facility staff in all aspects of handling and managing medications and medication related equipment. It also includes the pharmacist's consultation regarding all aspects of pharmaceutical services within the facility.

F425 Pharmaceutical Services

Interpretive Guidelines Overview

- Overall goal is to ensure safe and effective use of medications for each resident
- Risk of adverse consequences increases with:
 - Complex medication regimens
 - Numbers and types of medications used
 - Physiological changes associated with aging
 - Multiple comorbidities
- Medication-related adverse consequences leading to death and serious events are too common and are often preventable

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Overview

Message: The provision of pharmaceutical services is an integral part of the care provided to a resident. It is important that the facility have a goal of safe use of medications. Preventable medication-related adverse consequences and events are a major concern in nursing homes. This was reflected in a study published by Gurwitz and colleagues, in which they evaluated the incidence and preventability of adverse drug events in 18 nursing homes in Massachusetts. The report noted that 51% of the adverse drug events in the 18 nursing homes were judged to be preventable including 171 or 72% of the 238 fatal, life threatening or serious events and 105 or 34% of the 308 significant events. If these findings were extrapolated to all US nursing homes, approximately 350,000 adverse drug events could occur annually including 20,000 fatal or life-threatening events.

Many factors in a nursing facility increase the risk of adverse consequences associated with medication use, such as complex medication regimens, the numbers and types of medications used, physiological changes associated with aging, as well as multiple comorbidities.

There are several ways that surveyors evaluate the safe use of medications in a facility during the survey process, including medication passes, observation of medication storage and access to medications, as well as review of a sampled resident's medication regimen.


F425 Pharmaceutical Services

Interpretive Guidelines

Provision of Routine and/or Emergency Medications

- Facility must provide or obtain routine and emergency medications and biologicals to meet needs of each resident
- Meeting needs includes timeliness
- Factors affecting timeliness:
 - Resident condition and risk factors
 - Category of medication
 - Ordered start time
 - Availability of medications

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Provision of Routine and/or Emergency Medications

Message: The facility is expected to be able to provide medications on a timely basis to meet the needs of each resident including a newly admitted resident. Whether prescribed on a routine, emergency, or on an “as needed” basis, medications should be administered in a timely manner.

Timeliness may be affected by the resident’s condition, the category of medication, such as pain medication or antibiotics, by the ordered start time and by the availability of the medications.

For example, if a resident has an acute change in condition requiring the immediate administration of an antibiotic, it is expected that the medication is available or can be readily obtained. If allowed by state law, a facility may maintain a limited supply of medications for use during an emergency or after-hours situation.


Delayed acquisition of a medication may impede timely administration and adversely affect a resident’s condition. If there is a delay, this information should be communicated to the prescriber so that he or she may decide what intervention will best meet the resident’s needs, such as ordering another medication that may be more immediately available.

F425 Pharmaceutical Services

Interpretive Guidelines Services of a Licensed Pharmacist

- Facility is responsible for employing or contracting pharmacist
- Pharmacist collaborates with staff to:
 - Provide feedback about medication administration practices and medical errors
 - Develop, implement, evaluate and revise procedures
 - Coordinate pharmaceutical services
 - Develop intravenous therapy procedures
 - Determining contents of supply of medications

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Services of a Licensed Pharmacist

Message: The regulation requires the facility to employ or obtain the services of a licensed pharmacist, but it does not specify any particular arrangement. The pharmacist has an important role in identifying, communicating, addressing, and resolving concerns and issues related to the provision of pharmaceutical services. This includes collaborating with the facility to develop procedures for the provision of pharmaceutical services within the facility, such as preventing and analyzing medication errors; procedures for medication-related documentation (including a facility-approved list of abbreviations), and intravenous (IV) therapy procedures, if IV's are used within the facility. This may also involve evaluating staff practices for preparing and administering the IVs and assuring that procedures are consistent with state requirements.

Other aspects of pharmaceutical services for which the pharmacist may provide consultation or be involved in, include:

- Processes for receiving, transcribing and recapitulating medication orders
- Medication delivery systems and packaging including the use of automated medication delivery devices;
- Participation with the Quality Assessment and Assurance Committee, as needed;
- The identification of resources to help staff identify medications and information on contraindications, side effects, dosage and other information; and
- Helping identify facility educational needs related to medication use.

The pharmacist may also participate as a member of the interdisciplinary team to help identify and address a resident's medication related needs.

F425 Pharmaceutical Services


Interpretive Guidelines **Services of a Licensed Pharmacist**

Pharmacist collaborates to establish procedures for:

- Conducting monthly MRR for each resident
- Addressing time frames
- Addressing irregularities
- Documenting and reporting results of review

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Services of a Licensed Pharmacist

Message: The pharmacist collaborates with the facility and medical director to establish procedures including the conduct of the medication regimen review. These procedures should include how the pharmacist could be notified about a resident with an anticipated stay of less than 30 days or how the staff could communicate a request for a medication review for a resident who has experienced a change of condition that may be medication related; and how and when the reviews could be conducted.

F425 Pharmaceutical Services

Interpretive Guidelines

Pharmaceutical Services Procedures

- Acquiring
- Receiving
- Dispensing
- Administering
- Disposition
- Labeling and storage of medications

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Pharmaceutical Services Procedures

Message: The pharmacist collaborates with the facility to develop and evaluate the implementation of pharmaceutical services procedures. We will address each of these aspects, beginning with the acquisition of medications.

F425 Pharmaceutical Services

Interpretive Guidelines Pharmaceutical Services Procedures

Acquisition of Medications - Examples

- Availability of supply (emergency or otherwise)
- When, how to and who may contact pharmacy
- Verification or clarification of orders
- Actions in response to delayed delivery or unavailability of medication
- Transportation of medications to prevent contamination, degradation, and diversion of medications

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Pharmaceutical Services Procedures

Message: Examples of procedures addressing acquisition of medications include:

- In accordance with state law, which staff may contact the pharmacy for medication order changes; and
- Procedures that address the availability of medications when needed, that is, either the medication is included in the facility's emergency supply, if allowed by state law, or it is obtained from a pharmacy that can be reached 24 hours a day, seven days a week.

F425 Pharmaceutical Services

Interpretive Guidelines Pharmaceutical Services Procedures

Receiving Medications - Examples

- Receipt of medication and reconciliation with order and requisition for medication
- Staff identified and authorized to receive and deliver medication to secured area
- Staff responsible for assuring that medications are incorporated into resident's specific allocation/storage area

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Pharmaceutical Services Procedures

Note to Instructor: Ask participants to discuss concerns they may have identified regarding the receipt of medications:

Answers: (for example)

- Leaving medications at the nurses station unattended; or
- Delivery of medications to a staff person not authorized to receive medications

Message: Some examples of procedures addressing receipt of medications that a facility may have include, but are not limited to:

- The process for receiving medications from dispensing pharmacies or family members (where permitted by state law);
- How they will reconcile medications received with the medication order and requisition for the medication;
- How they will control medications after receipt until the medication can be delivered to the secured medication storage area, and which staff will be responsible for assuring that medications are incorporated into the correct resident's medication storage area.

F425 Pharmaceutical Services

Interpretive Guidelines Pharmaceutical Services Procedures

Dispensing Medications - Examples

- Delivery and receipt
- Labeling
- Types of medication packing

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Pharmaceutical Services Procedures

Message: As we discussed earlier, dispensing is the process that includes the interpretation of a prescription, the selection, measurement, and packaging or repackaging of the product as necessary, and the labeling of the medication or device pursuant to a prescription order.

The facility develops procedures to assure safe medication delivery, to minimize the potential for medication administration errors, and to address their expectations of an in-house pharmacy or outside dispensing pharmacies. Procedures would address dispensing medications in a way to assure compatibility of the packaging with existing facility systems to administer the medications. This would include methods such as, unit dose, or blister card type systems.

F425 Pharmaceutical Services

Interpretive Guidelines Pharmaceutical Services Procedures

Administering Medications – Examples

- Preventing unnecessary interruptions during the medication pass
- Reporting of errors
- Using only authorized personnel to administer medications
- Assuring correct medication and dose given to correct person
- Defining schedules for administration
- Defining guidelines for specific monitoring related to medications
- Defining techniques and precautions for administration

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Pharmaceutical Services Procedures

Message: As you can see, there is more to administering medications than simply passing the medication to the resident. This is a sample of some types of procedures that address administration. Let's discuss a few of these:

- The procedure for defining schedules for administering medications would identify the specific times for giving a medication that is ordered 4 times a day. This would include consideration of the type of medication, such as antibiotics that may need to be equally spaced over a 24 hour time period
- Other considerations for scheduling would be to define time frames for administering medications such as before, during or after meals {NOTE: Previous content is repeated below}

Other procedures may include:

- Mechanisms and approaches to prevent medication errors such as how to minimize or prevent interruptions for staff passing medications,
- Reporting medication errors; or to whom to report concerns about factors that could contribute to an error in administering medications
- Assuring that only authorized staff administer medications.


F425 Pharmaceutical Services

Interpretive Guidelines Pharmaceutical Services Procedures

Disposition of Medications – Examples

- Removal of medications for disposition
- Storage method for medications awaiting final disposition
- Control and accountability of medications awaiting final disposition
- Method of disposition consistent with applicable state and federal requirements, local ordinances, and standards of practice

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Pharmaceutical Services Procedures

Message: Examples of procedures addressing the disposition of medications include:

- A procedure defining when discontinued or expired medications should be removed from the individual resident's storage; and
- Where medications should be stored prior to disposal to assure resident safety and prevent misappropriation of medication, and how these medications will be accounted for while awaiting disposition

Documentation of disposition of medications may be affected by applicable state law and may include:

- resident name
- medication name
- strength
- prescription number (as applicable)
- quantity
- date of disposition, and
- involved facility staff, consultant(s) or other applicable individuals.

F425 Pharmaceutical Services

Interpretive Guidelines


Pharmaceutical Services Procedures

Labeling – Examples

- Requirements for labeling medications not labeled by a pharmacy, such as bulk supplies or IV solutions prepared or hung by facility staff
- Modifying labels due to changes in the medication orders or directions
- Labeling multi-dose vials to assure product integrity (e.g., modified expiration dates upon opening the multi-dose vial)

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Pharmaceutical Services Procedures

Message: Procedures addressing accurate labeling of medications should, at a minimum, reflect the state and federal requirements.

F425 Pharmaceutical Services

Interpretive Guidelines Pharmaceutical Services Procedures

Storage of Medications – Examples

- Location, security (locking), and authorized access to the medication rooms, carts and other storage areas
- Temperatures and other environmental considerations of medication storage area(s)
- Location, access, and security for discontinued medications awaiting disposal

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Pharmaceutical Services Procedures

Message: These are just some of the examples of procedures addressing the safe storage of medications.

Question: Discuss some procedures that you might see in relation to temperatures or other environmental considerations?

Answer:

- How to monitor for the correct temperature for medications requiring refrigeration;
- How to monitor for room temperatures in medication storage area; and
- Where to store light sensitive medications

F425 Pharmaceutical Services

Interpretive Guidelines


Pharmaceutical Services Procedures

Controlled Medications – Examples

- Location, access, and security for controlled medications
- A system of records of receipt and disposition of all controlled medications that accounts for all controlled medications
- Periodic reconciliation of controlled medications

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Pharmaceutical Services Procedures

Message: Procedures addressing controlled medications would include, for example:

- The entire process of receipt, storage, security, access, disposition of controlled substances
- The process for the reconciliation of controlled medications, including who is responsible, the frequency and methods
- Storage, security and access for preparations containing Schedule II medications needing refrigeration


F425 Pharmaceutical Services

Interpretive Guidelines Pharmaceutical Services Procedures

Authorized Personnel – Examples

- Assuring ongoing competency of staff
- Training on operation, limitations, monitoring, and precautions associated with medication administration
- Identifying personnel in addition to the pharmacist (e.g., pharmacy technicians, pharmacist assistants) who are authorized under state and federal requirements to access medications and biologicals.

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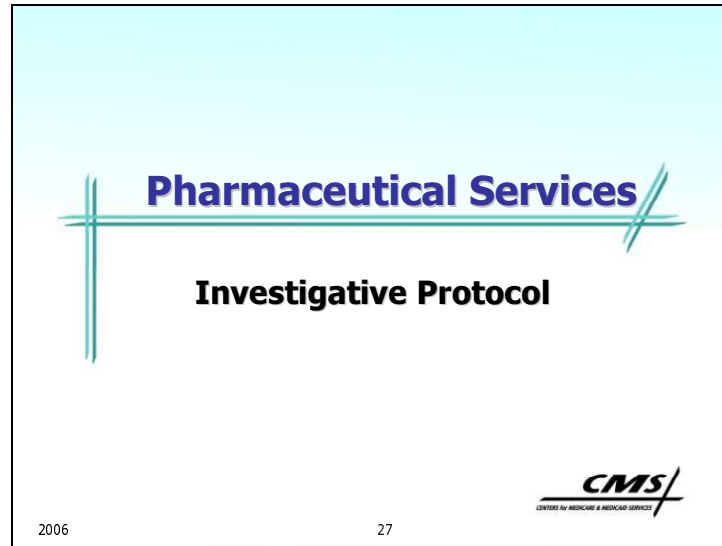
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Pharmaceutical Services Procedures

Message: Procedures for assuring that the facility utilizes only authorized staff and assures the ongoing competency of staff may include:

- For those facilities that use temporary, agency or on-call staff, how they orient those staff to the facility's procedures;
- For all medication administration staff, how the facility provides access to current information regarding medications being used within the facility, including side effects of medications, contraindications, doses and other medication related information;
- How the facility assures that the staff are competent in the use of medication administration devices or other equipment such as
 - If the facility provides IV services, how to use the IV pumps or other IV delivery systems including calculating dosage, infusion rates, and compatibility of medications to be added to the IV;
 - How to use blood glucose meters, including calibration and cleaning between individual residents;
 - How to use, maintain, clean, and dispose of the various devices for administration including nebulizers, inhalers, syringes, medication cups, spoons, and pill crushers; and assuring resident-specific equipment or devices remain identified as belonging to that resident

Slide 27



The slide features a light blue header with the text "Pharmaceutical Services" in a bold, dark blue font. Below this, the title "Investigative Protocol" is centered in a bold, black font. The slide is framed by a thin black border. In the bottom left corner, the year "2006" is displayed. In the bottom right corner, the CMS logo is shown, consisting of the letters "CMS" in a stylized font with a diagonal line through them, and the text "CENTERS FOR MEDICARE & MEDICAID SERVICES" in a smaller font below it.

Pharmaceutical Services

Investigative Protocol

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Investigative Protocol

F425 Pharmaceutical Services

Pharmaceutical Services Investigative Protocol

Use Sub-Task 5E – Medication Pass and
Pharmacy Services

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Investigative Protocol

Message: For investigating compliance with components of F425, use the revised Sub-Task 5E - Medication Pass and Pharmacy Services.

F425 Pharmaceutical Services

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

- Services of licensed pharmacist
- Provision of pharmaceutical services

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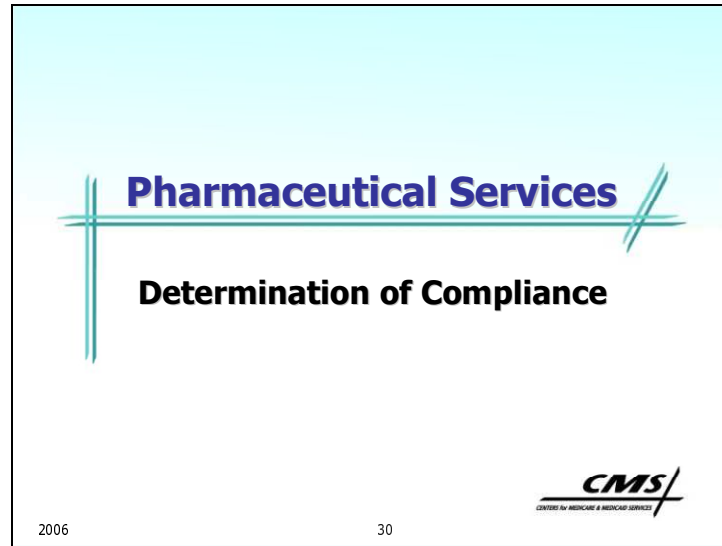
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Use of Sub-Task 5E

Message: During the survey, review for the provision of services by a licensed pharmacist if concerns have been identified that indicate that the facility does not have a licensed pharmacist or that the pharmacist may not have performed his or her functions related to the provision of pharmaceutical services.

If during the survey, concerns have been identified regarding the provision of pharmaceutical services, review for the development and implementation of pharmaceutical procedures specific to the concerns that have been identified. This could include concerns in areas such as: the availability of medications, the accurate and timely acquisition of medications; or for other concerns such as the receiving, dispensing, administering, labeling or storage of medications.

Conduct interviews, observations and record reviews as necessary for the identified concerns as described in Sub-Task 5E.



Determination of Compliance

Message: These requirements address both facility structures and processes and provision of pharmaceutical services to meet each resident's needs. Because there are structure and processes in this requirement, there does not need to be a specific negative resident outcome to determine and cite non-compliance with this requirement.


F425 Pharmaceutical Services

Determination of Compliance

Synopsis of Regulation

1. Facility must provide routine and or emergency medications and biologicals or obtain them
2. Facility must have pharmaceutical procedures to meet the resident's needs
3. Facility must have a licensed pharmacist who provides consultation and oversees service
4. Facility must follow laws about who may administer medications

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Determination of Compliance

Message: The pharmaceutical services, procedures, and consultation requirement has 4 aspects:


- Routine and emergency medications must be provided to meet resident's needs
- The facility must have procedures that assure accurate acquisition, receipt, dispensing, and administration of all medications and biologicals
- The facility must have a licensed pharmacist who provides consultation and oversees all aspects of the pharmaceutical services
- The facility must follow applicable laws and regulations about who may administer medications.

F425 Pharmaceutical Services

Determination of Compliance Criteria for Compliance

The facility is in compliance if they provide:

- Medications and/or biologicals for each resident as ordered by the prescriber
- Development and implementation of procedures for the pharmaceutical services
- A pharmacist who provides consultation regarding all aspects of pharmaceutical services
- Personnel to administer medications, consistent with applicable state law and regulations

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Determination of Compliance


Message: The facility is in compliance, if they have collaborated with the pharmacist to meet each of these aspects of the requirement. If not, cite at F425.

F425 Pharmaceutical Services

Determination of Compliance Noncompliance for F425

Noncompliance may include the facility failure to:

- Utilize the services of a pharmacist
- Ensure that only appropriate personnel administer medications
- Provide medications and/or biologicals to meet the needs of the resident
- Develop or implement procedures for any of the following: acquiring, receiving, dispensing or accurately administering medications

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Determination of Compliance

Message: After completing the Investigative Protocol, analyze the data and review the regulatory requirement in order to determine whether or not compliance with F425 exists.

These requirements at F425 address both facility structures and processes and provision of pharmaceutical services to meet each resident's needs. Because there are structure and processes in this requirement, there does not need to be a specific negative resident outcome to determine and cite non-compliance with this requirement.

If the survey team identifies noncompliance at other tags that may be related to the roles and responsibilities of the pharmacist or the provision of pharmaceutical services, the team must also investigate the concerns in order to determine whether there is noncompliance with this requirement.

F425 Pharmaceutical Services

Determination of Compliance Potential Tags for Additional Investigation

- F353 Sufficient Staff
- F501 Medical Director
- F520 Quality Assessment and Assurance
- F514 Clinical Records

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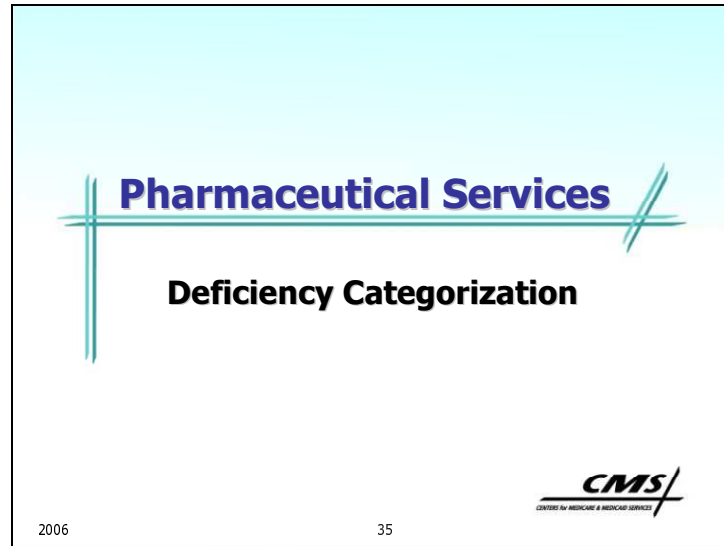
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Determination of Compliance

Message: If noncompliance with 483.60, 483.60(a)(b)(1) has been identified, then concerns with additional requirements may also have been identified. The surveyor is cautioned to investigate these related additional requirements before determining whether noncompliance with the additional requirements may be present.

Examples of some of the related requirements that may be considered when noncompliance has been identified include the sufficiency of qualified nursing staff to provide medications to the residents as needed on a 24 hour a day basis, the medical director's role in developing pharmaceutical procedures for safe and accurate provision of medications; whether concerns related to pharmaceutical services or medication administration have been addressed by the QAA committee, or if there are concerns with the accuracy or content of clinical records in relation to medication use.



Deficiency Categorization

Message: Once the survey team has completed its investigation, 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.


F425 Pharmaceutical Services

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: The three key elements for severity determination include the following:

- 1. The presence of actual or potential harm or negative outcome(s) due to a facility failure related to pharmaceutical services.**

Actual or potential harm or negative outcomes for F425 may include:

- The facility's failure to involve a pharmacist in developing, implementing, and evaluating pharmaceutical procedures including procedures for accurately acquiring, receiving, storing, controlling, dispensing, and administering routine and emergency medications and biologicals resulted in the lack of specific procedures or in procedures that were not consistent with current standards of practice; or
 - The facility's failure to provide medications needed by a resident in a timely manner resulted in continued pain or worsening symptoms; or
 - The use of unauthorized personnel to administer medications created the potential for harm.
- 2. The second element is the degree of actual or potential harm/ or negative outcome(s) due to a facility failure related to pharmaceutical services and to what degree 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. 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.

F425 Pharmaceutical Services

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 based upon the following levels of severity for tag F425. 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.)

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.


F425 Pharmaceutical Services

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 that would come under level 4 Severity.

You may have severity level 4 at this tag if you have identified non compliance at severity Level 4 (Immediate Jeopardy) at another tag such as F309 - Quality of Care, F329 - Unnecessary Medications, F332 and F333 - Medication Errors, and F428 - Medication Regimen Review, and the noncompliance is related to a failure of the facility to:

- Provide or obtain the service of a pharmacist; or
- To collaborate with the pharmacist to establish and implement procedures for using medications, resulting in the potential for significant adverse consequences.

Other Severity level 4 examples could include the facility, in collaboration with the pharmacist, failed to establish effective procedures to meet the needs of the residents, such as:

- Lack of procedures to assure availability of pain medication for a recently admitted resident resulting in the resident complaining of excruciating pain; or
- Lack of procedures to assure that devices used to administer medications, such as IV pumps, were working properly, leading to an adverse consequence at the immediate jeopardy level as a result of improperly calibrated equipment; or
- A failure to identify medication errors. For example, medications were dispensed without a valid prescriber's order, resulting in a resident incorrectly receiving three medications over two consecutive months, which ultimately resulted in hospitalization due to the medication errors.

F425 Pharmaceutical Services


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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 CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Deficiency Categorization

Message: Let's discuss some examples of non compliance that would come under Severity level 3.

You may have Severity level 3 at this tag if you have identified non compliance at Severity Level 3 at another tag such as F309 - Quality of Care, F329 - Unnecessary Medications, F332 and F333 - Medication Errors, and F428 Medication Regimen Review, **and** the noncompliance is related to a failure of the facility to:

- Provide or obtain the service of a pharmacist; or
- Collaborate with the pharmacist to develop and implement procedures for monitoring medication therapy, resulting in a failure to monitor treatment and the resident experiencing actual harm.

Other Severity level 3 examples could include the facility's failure to collaborate with the pharmacist to assure that procedures were developed and implemented, such as:

- Failure to have an effective procedure or mechanism to assure that all medication orders were processed consistently and accurately through the stages of ordering, receiving, and administering medications (including transfer orders, admission orders, telephone orders, order renewals, and the MAR). For example, a transcription error led to an incorrect dose of a medication being administered and the resident experienced spontaneous bruising or bleeding requiring medical intervention.
- Failure to assure that staff were trained or competent to use medication-related devices such as an intravenous pump. This resulted in a resident receiving an excessive dose of medication requiring subsequent hospitalization or receiving a sub-therapeutic dose of medication with consequential exacerbation of a condition such as an infection, continuation of treatment beyond the expected time frame, and subsequent functional decline.

F425 Pharmaceutical Services

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
- Has 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: Let's discuss some examples of non compliance that would come under Severity Level 2.

You may have severity level 2 at this tag if you have identified non compliance at Severity Level 2 at another tag such as F309 - Quality of Care, F329 - Unnecessary Medications, F332 and F333 Medication Errors, and F428 - Medication regimen Review, **and** the noncompliance is related to:

A failure of the facility to implement established medication administration procedures. For example, as a result of failure of licensed staff to supervise medication administration by authorized unlicensed personnel, errors occurred in providing timely oral antibiotic therapy

Another Severity level 2 example could include:

The facility failed to obtain or provide the services of a pharmacist or to collaborate with the pharmacist to assure that effective policies and procedures were established and implemented, including, for example:

As a result of not reordering medications often enough to maintain an adequate supply, a resident did not receive medication for heartburn for seven days and had difficulty sleeping due to nocturnal heartburn. The level of discomfort did not interfere with the resident's participation in activities or performing activities of daily living.

F425 Pharmaceutical Services


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 identified at other requirements was related to:
 - Lack of pharmaceutical services
 - Absence of or failure to implement pharmaceutical procedures
 - Absence of or oversight by pharmacist

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Deficiency Categorization

- Message:**
- The facility and the pharmacist failed to collaborate to:
 - Implement pharmaceutical procedures, but there were no negative resident outcomes or potential for more than minimal negative outcomes as a result of that deficient practice
 - Or
 - There is no pharmacist; and
 - There were no negative resident outcomes or potential for more than minimal negative outcomes related to pharmaceutical services; **and**
 - Pharmaceutical procedures were in place; **and**
 - The facility was actively seeking a new pharmacist.

NOTE:

- If there is no pharmacist **and**
- There WERE negative outcomes; **or**
- Procedures were NOT in place; **or**
- If the facility was not looking for a replacement,
- cite at a Severity Level 2 or higher.