§483.60 Pharmacy Services

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §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.

(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;

INTENT (F425) 42 CFR 483.60, 483.60(a) & (b)(1)

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:
  o Provision of consultative services by a licensed pharmacist between the pharmacist’s visits, as necessary; and
  o Coordination of the pharmaceutical services if multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP]); and
• The facility utilizes only persons authorized under state requirements to administer medications.

NOTE: Although the regulatory language refers to “drugs,” the guidance in this document generally will refer to “medications,” except in those situations where the term “drug” has become part of an established pharmaceutical term (e.g., adverse drug event, adverse drug reaction or consequence).

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

DEFINITIONS

Definitions are provided to clarify terminology related to pharmaceutical services and the management of each resident’s medication regimen for effectiveness and safety.

• “Acquiring medication” is the process by which a facility requests and obtains a medication.
• “Administering medication” is the process of giving medication(s) to a resident.
• “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.
• “Current standards of practice” refers to approaches to care, procedures, techniques, treatments, etc., that are based on research and/or expert consensus and that are contained in current manuals, textbooks, or publications, or that are accepted, adopted or promulgated by recognized professional organizations or national accrediting bodies.
• “Dispensing” is 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.
• “Disposition” is the process of returning, releasing and/or destroying discontinued or expired medications.
• “Pharmaceutical Services” refers to:
  o The process (including documentation, as applicable) 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 (e.g., povidone iodine, hydrogen peroxide);
  o The provision of medication-related information to health care professionals and residents;
  o The process of identifying, evaluating and addressing medication-related issues including the prevention and reporting of medication errors; and
  o The provision, monitoring and/or the use of medication-related devices.
• “Pharmacy assistant or technician” refers to the ancillary personnel who work under the supervision and delegation of the pharmacist, consistent with state requirements.
• “Receiving medication”—for the purpose of this guidance—is the process of accepting a medication from the facility’s pharmacy or an outside source (e.g., vending pharmacy delivery agent, Veterans Administration, family member).

OVERVIEW
The provision of pharmaceutical services is an integral part of the care provided to nursing home residents. The management of complex medication regimens is challenging and requires diverse pharmaceutical services to minimize medication-related adverse consequences or events. The overall goal of the pharmaceutical services system within a facility is to ensure the safe and effective use of medications.

Preventable medication-related adverse consequences and events are a serious concern in nursing homes. Gurwitz and colleagues evaluated the incidence and preventability of adverse drug events in 18 nursing homes in Massachusetts noting that 51% of the adverse drug events were judged to be preventable including 171 (72%) of the 238 fatal, life threatening or serious events and 105 (34%) of the 308 significant events. If these findings are extrapolated to all US nursing homes, approximately 350,000 adverse drug events may occur annually among this patient population, including 20,000 fatal or life threatening events.63,64

Factors that increase the risk of adverse consequences associated with medication use in the nursing home setting include complex medication regimens, numbers and types of medication used, physiological changes accompanying the aging process, as well as multiple comorbidities. The consultative services of a pharmacist can promote safe and effective medication use. A pharmacist evaluates and coordinates all aspects of pharmaceutical services provided to all residents within a facility by all providers (e.g., pharmacy, prescription drug plan, prescribers). A pharmacist can also help in the development of medication-related documentation procedures, such as identification of abbreviations approved for use in the facility and can help guide the selection and use of medications in accordance with the authorized prescriber’s orders,
applicable state and federal requirements, manufacturers’ specifications, characteristics of the resident population, and individual resident conditions.

Providing pharmaceutical consultation is an ongoing, interactive process with prospective, concurrent, and retrospective components. To accomplish some of these consultative responsibilities, pharmacists can use various methods and resources, such as technology, additional personnel (e.g., dispensing pharmacists, pharmacy technicians), and related policies and procedures.

Numerous recognized resources address different aspects of pharmaceutical services and medication utilization, such as:

• The American Society of Consultant Pharmacists (ASCP) www.ascp.com;
• The American Society of Health System Pharmacists (ASHP) www.ashp.com;
• The American Medical Directors Association (AMDA) www.amda.com;
• The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) www.nccmerp.org;
• US Department of Health and Human Services (DHHS), Food and Drug Administration (FDA) www.fda.gov/cder; and
• The DHHS, CMS Sharing Innovations in Quality website at: http://siq.air.org.

NOTE: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

**PROVISION OF ROUTINE AND/OR EMERGENCY MEDICATIONS**

The regulation at 42 CFR 483.60 (F425) requires that the facility provide or obtain routine and emergency medications and biologicals in order to meet the needs of each resident. Facility procedures and applicable state laws may allow the facility to maintain a limited supply of medications in the facility for use during emergency or after-hours situations. Whether prescribed on a routine, emergency, or as needed basis, medications should be administered in a timely manner. Delayed acquisition of a medication may impede timely administration and adversely affect a resident’s condition. Factors that may help determine timeliness and guide acquisition procedures include:

• Availability of medications to enable continuity of care for an anticipated admission or transfer of a resident from acute care or other institutional settings;
• Condition of the resident including the severity or instability of his/her condition, a significant change in condition, discomfort, risk factors, current signs and symptoms, and the potential impact of any delay in acquiring the medications;
• Category of medication, such as antibiotics or analgesics;
• Availability of medications in emergency supply, if applicable; and
• Ordered start time for a medication.

**SERVICES OF A LICENSED PHARMACIST**

The facility is responsible for employing or contracting for the services of a pharmacist to provide consultation on all aspects of pharmaceutical services. The facility may provide for this service through any of several methods (in accordance with state requirements) such as direct employment or contractual agreement with a pharmacist. Whatever the arrangement or method employed, the facility and the pharmacist identify how they will collaborate for effective consultation regarding pharmaceutical services. The pharmacist reviews and evaluates the
pharmaceutical services by helping the facility identify, evaluate, and address medication issues that may affect resident care, medical care, and quality of life. The pharmacist is responsible for helping the facility obtain and maintain timely and appropriate pharmaceutical services that support residents’ healthcare needs, that are consistent with current standards of practice, and that meet state and federal requirements. This includes, but is not limited to, collaborating with the facility and medical director to:

- Develop, implement, evaluate, and revise (as necessary) the procedures for the provision of all aspects of pharmaceutical services;
- Coordinate pharmaceutical services if and when multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP])
- Develop intravenous (IV) therapy procedures if used within the facility (consistent with state requirements) may include determining competency of staff, facility-based IV admixture procedures that address sterile compounding, dosage calculations, IV pump use, and flushing procedures;
- Determine (in accordance with or as permitted by state law) the contents of the emergency supply of medications and monitor the use, replacement, and disposition of the supply;
- Develop mechanisms for communicating, addressing, and resolving issues related to pharmaceutical services;
- Strive to assure that medications are requested, received, and administered in a timely manner as ordered by the authorized prescriber (in accordance with state requirements), including physicians, advanced practice nurses, pharmacists, and physician assistants;
- Provide feedback about performance and practices related to medication administration and medication errors;
- Participate on the interdisciplinary team to address and resolve medication-related needs or problems;
- Establish procedures for:
  - conducting the monthly medication regimen review (MRR) for each resident in the facility,
  - addressing the expected time frames for conducting the review and reporting the findings,
  - addressing the irregularities,
  - documenting and reporting the results of the review (See F428 for provision of the review.);

  and
- Establish procedures that address medication regimen reviews for residents who are anticipated to stay less than 30 days or when the resident experiences an acute change of condition as identified by facility staff.

**NOTE:** Facility procedures should address how and when the need for a consultation will be communicated, how the medication review will be handled if the pharmacist is off-site, how the results or report of their findings will be communicated to the physician, expectations for the physician’s response and follow up, and how and where this information will be documented. In addition, the pharmacist may collaborate with the facility and medical director on other aspects of pharmaceutical services including, but not limited to:

- Developing procedures and guidance regarding when to contact a prescriber about a medication issue and/or adverse effects, including what information to gather before contacting the prescriber;
- Developing the process for receiving, transcribing, and recapitulating medication orders;
- Recommending the type(s) of medication delivery system(s) to standardize packaging, such as bottles, bubble packs, tear strips, in an effort to minimize medication errors;
• Developing and implementing procedures regarding automated medication delivery devices or cabinets, if automated devices or cabinets are used, including: the types or categories of medications, amounts stored, location of supply, personnel authorized to access the supply, record keeping, monitoring for expiration dates, method to ensure accurate removal of medications and the steps for replacing the supply when dosages are used, and monitoring the availability of medications within the system;
• Interacting with the quality assessment and assurance committee to develop procedures and evaluate pharmaceutical services including delivery and storage systems within the various locations of the facility in order to prevent, to the degree possible, loss or tampering with the medication supplies, and to define and monitor corrective actions for problems related to pharmaceutical services and medications, including medication errors;
• Recommending current resources to help staff identify medications and information on contraindications, side effects and/or adverse effects, dosage levels, and other pertinent information; and
• Identifying facility educational and informational needs about medications and providing information from sources such as nationally recognized organizations to the facility staff, practitioners, residents, and families.

NOTE: This does not imply that the pharmacist must personally present educational programs.

PHARMACEUTICAL SERVICES PROCEDURES
The pharmacist, in collaboration with the facility and medical director helps develop and evaluate the implementation of pharmaceutical services procedures that address the needs of the residents, are consistent with state and federal requirements, and reflect current standards of practice. These procedures address, but are not limited to, acquiring; receiving; dispensing; administering; disposing; labeling and storage of medications; and personnel authorized to access or administer medications.

Acquisition of Medications
Examples of procedures addressing acquisition of medications include:
• Availability of an emergency supply of medications, if allowed by state law, including the types or categories of medications; amounts, dosages/strengths to be provided; location of the supply; personnel authorized to access the supply; record keeping; monitoring for expiration dates; and the steps for replacing the supply when medications are used;
• When, how to, and who may contact the pharmacy regarding acquisition of medications and the steps to follow for contacting the pharmacy for an original routine medication order, emergency medication order, and refills;
• The availability of medications when needed, that is, the medication is either in the facility (in the emergency supply) or obtained from a pharmacy that can be reached 24 hours a day, seven days a week;
• The receipt, labeling, storage, and administration of medications dispensed by the physician, if allowed by state requirements;
• Verification or clarification of an order to facilitate accurate acquisition of a medication when necessary (e.g., clarification when the resident has allergies to, or there are contraindications to the medication being ordered);
• Procedure when delivery of a medication will be delayed or the medication is not or will not be available; and
• Transportation of medications from the dispensing pharmacy or vendor to the facility consistent with manufacturer’s specifications, state and federal requirements, and standards of professional practice to prevent contamination, degradation, and diversion of medications.

Receiving Medication(s)
Examples of procedures addressing receipt of medications include:
• How the receipt of medications from dispensing pharmacies (and family members or others, where permitted by state requirements) will occur and how it will be reconciled with the prescriber’s order and the requisition for the medication;
• How staff will be identified and authorized in accordance with applicable laws and requirements to receive the medications and how access to the medications will be controlled until the medications are delivered to the secured storage area; and
• Which staff will be responsible for assuring that medications are incorporated into the resident’s specific allocation/storage area.

Dispensing Medication(s)
Examples of procedures to assure compatible and safe medication delivery, to minimize medication administration errors, and to address the facility’s expectations of the in-house pharmacy and/or outside dispensing pharmacies include:
• Delivery and receipt;
• Labeling; and
• The types of medication packaging (e.g., unit dose, multi-dose vial, blister cards).

Administering Medications
Examples of procedures addressing administration of medications include:
• Providing continuity of staff to ensure that medications are administered without unnecessary interruptions;
• Reporting medication administration errors, including how and to whom to report;
• Authorizing personnel, consistent with state requirements, to administer the medications, including medications needing intravenous administration (see Authorized Personnel and Staff Qualifications section within this document);
• Assuring that the correct medication is administered in the correct dose, in accordance with manufacturer’s specifications and with standards of practice, to the correct person via the correct route in the correct dosage form and at the correct time;
• Defining the schedules for administering medications to:
  o Maximize the effectiveness (optimal therapeutic effect) of the medication (for example, antibiotics, antihypertensives, insulins, pain medications);
  o Avoid potential significant medication interactions such as medication-food or medication-medication interactions; and
  o Recognize resident choices and activities, to the degree possible, consistent with the medical plan of care;
• Defining general guidelines for specific monitoring related to medications, when ordered or indicated, including specific item(s) to monitor (e.g., blood pressure, pulse, blood sugar, weight), frequency (e.g., weekly, daily), timing (e.g., before or after administering the medication), and parameters for notifying the prescriber;
• Defining pertinent techniques and precautions for administering medications through alternate routes such as eye, ear, buccal, injection, intravenous, atomizer/aerosol/inhalation therapy, or enteral tubes;
• Documenting the administration of medications, including:
The administration of routine medication(s), and if not administered, an explanation of why not;
- The administration of “as-needed” medications including the justification and response;
- The route, if other than oral (intended route may be preprinted on MAR); and
- Location of administration sites such as transdermal patches and injections;
  - Providing accessible current information about medications (e.g., medication information references) and medication-related devices and equipment (e.g., user’s manual);
  - Clarifying any order that is incomplete, illegible, or presents any other concerns, prior to administering the medication; and
  - Reconciling medication orders including telephone orders, monthly or other periodic recapitulations, medication orders to the pharmacy, and medication administration record (MAR), including who may transcribe prescriber’s orders and enter the orders onto the MAR.

Disposition of Medications
Examples of procedures addressing the disposition of medications include:
- Timely identification and removal (from current medication supply) of medications for disposition;
- Identification of storage method for medications awaiting final disposition;
- Control and accountability of medications awaiting final disposition consistent with standards of practice;
- Documentation of actual disposition of medications to include: resident name, medication name, strength, prescription number (as applicable), quantity, date of disposition, and involved facility staff, consultant(s) or other applicable individuals; and
- Method of disposition consistent with applicable state and federal requirements, local ordinances, and standards of practice.

Labeling and Storage of Medications, including Controlled Substances
Examples of procedures addressing accurate labeling of the medications (including appropriate accessory and cautionary instructions) include:
- Labeling medications prepared by facility staff, such as IV solutions prepared in the facility;
- Requirements for labeling medications not labeled by a pharmacy, such as bulk supplies/bottles of over-the-counter (OTC) medications (as permitted);
- Modifying labels due to changes in the medication orders or directions, in accordance with state and federal requirements; and
- Labeling multi-dose vials to assure product integrity, considering the manufacturer’s specifications (e.g., modified expiration dates upon opening the multi-dose vial).
Examples of procedures addressing the safe storage of medications include:
- 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) such as the medication room(s) and refrigerators; and
- Location, access, and security for discontinued medications awaiting disposal.
Examples of procedures addressing controlled medications include:
- Location, access, and security for controlled medications, including the separately locked permanently affixed compartment for those Schedule II medications or preparations with Schedule II medications needing refrigeration;
- A system of records of receipt and disposition of all controlled medications that accounts for all controlled medications; and
• Periodic reconciliation of controlled medications including the frequency, method, by whom, and pertinent documentation.

**Authorized Personnel**
The facility may permit unlicensed personnel to administer medications if state law permits, but only under the general supervision of a licensed nurse.
The facility assures that all persons administering medications are authorized according to state and federal requirements, oriented to the facility’s procedures, and have access to current information regarding medications being used within the facility, including side effects of medications, contraindications, doses, etc.

Examples of procedures addressing authorized personnel include:
• How the facility assures ongoing competency of all staff (including temporary, agency, or on-call staff) authorized to administer medications and biologicals;
• Training regarding the operation, limitations, monitoring, and precautions associated with medication administration devices or other equipment, if used, such as:
  o IV pumps or other IV delivery systems including calculating dosage, infusion rates, and compatibility of medications to be added to the IV;
  o Blood glucose meters, including calibration and cleaning between individual residents; and
  o Using, maintaining, cleaning, and disposing of the various types of devices for administration including nebulizers, inhalers, syringes, medication cups, spoons, and pill crushers;
• Identifying pharmacy 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.

**INVESTIGATIVE PROTOCOL**
For investigating compliance with the requirements at 42 CFR 483.60 and 483.60(a) & (b), see State Operations Manual, Appendix P, II.B., The Traditional Standard Survey, Task 5, Sub-Task 5E Investigative Protocol: Medication Pass and Pharmacy Services.

**DETERMINATION OF COMPLIANCE (Task 6, Appendix P)**
**Synopsis of Regulation (F425)**
The Pharmaceutical Services, Procedures and Consultation requirement has four aspects. First, the facility must provide routine and/or emergency medications and biologicals or obtain them under an agreement described in 42 CFR 483.75(h). Second, the facility must have procedures for pharmaceutical services to meet the resident’s needs. The procedures must assure accurate acquisition, receipt, dispensing, and administration of all medications and biologicals. Third, the facility must have a licensed pharmacist who provides consultation and oversees all aspects of the pharmaceutical services. Fourth, the facility must follow applicable laws and regulations about who may administer medications.

**Criteria for Compliance**
Compliance with 42 CFR 483.60, F425, Pharmaceutical Services
The facility is in compliance with this requirement, if they provide or arrange for:
• Each resident to receive medications and/or biologicals as ordered by the prescriber;
• The development and implementation of procedures for the pharmaceutical services;
• The services of a pharmacist who provides consultation regarding all aspects of pharmaceutical services; and
• Personnel to administer medications, consistent with applicable state law and regulations. If not, cite F425.

**Noncompliance for F425**
After completing the Investigative Protocol, analyze the data and review the regulatory requirement in order to determine whether or not compliance with F425 exists. As the requirements for F425 include both process and structural components, a determination of noncompliance with F425 does not require a finding of harm to the resident. If the survey team identifies noncompliance at other tags which may be related to the roles and responsibilities of the pharmacist or the provision of pharmaceutical services, the team must also decide whether there is noncompliance with this requirement. Noncompliance for F425 may include (but is not limited to) 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; and
• Develop or implement procedures for any of the following: acquiring, receiving, dispensing or accurately administering medications.

Potential Tags for Additional Investigation
If noncompliance with 42 CFR 483.60 and 483.60(a) & (b) 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 should be considered when noncompliance has been identified include the following:

• 42 CFR 483.30(a), F353, Sufficient Staff
  o Determine if the facility had qualified staff in sufficient numbers to provide medications on a 24-hour basis to meet the needs of the residents, based upon the comprehensive assessment and care plan.
• 42 CFR 483.75(i)(2), F501, Medical Director
  o Determine whether the medical director, in collaboration with the facility and the pharmacist, and based on current standards of practice, helped the facility develop procedures for the safe and accurate provision of medications to meet the needs of the residents.
• 42 CFR 483.75(o), F520, Quality Assessment and Assurance
  o Determine whether the quality assessment and assurance committee, if concerns regarding pharmaceutical services have been identified, has identified those concerns, responded to the concerns and, as appropriate, has developed, implemented, and monitored appropriate plans of action to correct identified quality deficiencies.
• 42 CFR 483.75(l)(1), F514, Clinical Records
  o Determine whether the facility has maintained clinical records, including medication administration, in accordance with accepted professional standards and practices that are complete, accurately documented, and readily accessible.

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)
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.

The key elements for severity determination for F425 are as follows:

1. Presence of potential or actual harm/negative outcome(s) due to a facility failure related to pharmaceutical services.

Identify actual or potential harm/negative outcomes for F425 which may include, but are not limited to:
• 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, for example:
  o Absent or inadequate IV infusion procedures led to a resident developing congestive heart failure as a result of an IV infusing too quickly.
• The facility’s failure to provide medications needed by a resident in a timely manner resulted in continued pain or worsening symptoms.
• The use of unauthorized personnel to administer medications created the potential for harm.

2. Degree of potential or actual harm/negative outcome(s) due to a facility failure related to pharmaceutical services.
Identify how the facility’s 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.
• If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.

3. The immediacy of correction required.
Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.
The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag 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, Guidelines for Determining Immediate Jeopardy.)

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

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety
Immediate Jeopardy is a situation in which the facility’s noncompliance with one or more requirements of participation:
• Has caused/resulted in, or is likely to cause, serious injury, harm, impairment, or death to a resident; and
• Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.
Examples may include, but are not limited to:
• Severity Level 4 (Immediate Jeopardy) deficiency at another tag (e.g., F309, F329, F332, F333, F428) 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.
• The facility, in collaboration with the pharmacist, failed to establish effective procedures to meet the needs of the residents, such as:
Assuring that pain medications were available to meet the needs of the resident. For example, failure to assure availability of pain medication for a recently admitted resident resulting in the resident complaining of excruciating pain (e.g., a pain score of 9 on a 10-point scale).

Assuring that devices used to administer medications (such as IV pumps) were working properly, leading to an adverse consequence at the immediate jeopardy level.

Identifying medication errors, for example, medications were being dispensed without a valid prescriber’s order, resulting in a resident incorrectly receiving three medications over two consecutive months.

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

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

Level 3 indicates noncompliance that results in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident’s inability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:

• Severity Level 3 deficiency at another tag (e.g., F309, F329, F332, F333, F428) and the noncompliance is related to a failure of the facility to provide or obtain the services of a pharmacist or to 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.

• The facility in collaboration with the pharmacist failed to assure that procedures were developed and implemented, such as:
  o An effective procedure/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 experiencing spontaneous bruising and epistaxis requiring medical intervention.
  o Provisions to assure that staff were trained or competent to use new medication-related devices (e.g., 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 (e.g., infection), continuation of treatment beyond the expected time frame, and subsequent functional decline.

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

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

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

• A Severity Level 2 deficiency at another tag (e.g., F309, F329, F332, F333, F428) 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.
• 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:
  o 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 participating in activities or performing activities of daily living.
  o As a result of failure to identify medications that should not be crushed for administration, a resident received a medication that was crushed, contrary to the manufacturer’s specifications (e.g., an enteric coated aspirin). While the resident did not experience any harm, the potential for harm was present.

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

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm
In order to cite no actual harm with potential for minimal harm at this tag, the surveyor must 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, or absence of oversight by the pharmacist. Examples of noncompliance for Severity Level 1 may include:
• The facility and the pharmacist failed to collaborate to:
  o 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.
• There is no pharmacist; and
  o There were no negative resident outcomes or potential for more than minimal negative outcomes related to pharmaceutical services; and
  o Pharmaceutical procedures were in place; and
  o 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 severity.
• There was a short term failure to provide medications that posed minimal risk to the resident, such as a routine order for a daily multivitamin.

F428
(Rev. 22, Issued: 12-15-06, Effective/Implementation: 12-18-06)
§483.60(c) Drug Regimen Review
(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.
(2) The pharmacist must report any irregularities to the attending physician, and the director of nursing, and these reports must be acted upon.

INTENT (F428) 42 CFR 483.60(c)(1)(2) Medication Regimen Review
The intent of this requirement is that the facility maintains the resident’s highest practicable level of functioning and prevents or minimizes adverse consequences related to medication therapy to the extent possible, by providing:
• A licensed pharmacist’s review of each resident’s regimen of medications at least monthly; or
A more frequent review of the regimen depending upon the resident’s condition and the risks or adverse consequences related to current medication(s);

- The identification and reporting of irregularities to the attending physician and the director of nursing; and
- Action taken in response to the irregularities identified.

**NOTE:** Although the regulatory language refers to “drugs,” the guidance in this document generally will refer to “medications,” except in those situations where the term “drug” has become part of an established pharmaceutical term (e.g., adverse drug event, and adverse drug reaction or consequence).

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

### DEFINITIONS

Definitions are provided to clarify terminology related to pharmaceutical services and the management of each resident’s medication regimen for effectiveness and safety.

- **“Adverse consequence”** refers to an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in an individual’s mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medications, medication-food, and medication-disease).

**NOTE:** Adverse drug reaction (ADR) is a form of adverse consequence. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic and helpful effects of the medication or any response to a medication that is noxious and unintended and occurs in doses used for prophylaxis, diagnosis, or therapy. The term “side effect” is often used interchangeably with ADR; however, side effects are but one of five ADR categories. The others are hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not rise to the level of being an adverse consequence.

- **“Clinically significant”** means effects, results, or consequences that materially affect or are likely to affect an individual’s mental, physical, 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.

- **“Dose”** is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.

  - “Excessive dose” (including duplicate therapy) means the total amount of any medication given at one time or over a period of time that is greater than the amount recommended by the manufacturer’s label, package insert, or current standards of practice for a resident’s age and condition; without evidence of a review for the continued necessity of the dose or of attempts at, or consideration of the possibility of, tapering a medication; and there is no documented clinical rationale for the benefit of, or necessity for the dose or for the use of multiple medications from the same class.

- **“Duration”** is the total length of time the medication is being received.

  - “Excessive Duration” means the medication is administered beyond the manufacturer’s recommended time frames or facility-established stop order policies, beyond the length of time advised by current standards of practice, and/or without either evidence of additional therapeutic
benefit for the resident or clear clinical factors that would warrant the continued use of the medication.

- “Irregularity” refers to any event that is inconsistent with usual, proper, accepted, or right approaches to providing pharmaceutical services (see definition in F425), or that impedes or interferes with achieving the intended outcomes of those services.
- “Medication Interaction” is the impact of another substance (such as another medication, herbal product, food or substances used in diagnostic studies) upon a medication. The interactions may alter absorption, distribution, metabolism, or elimination. These interactions may decrease the effectiveness of the medication or increase the potential for adverse consequences.
- “Medication Regimen Review” (MRR) is a thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication. The review includes preventing, identifying, reporting, and resolving medication-related problems, medication errors, or other irregularities, and collaborating with other members of the interdisciplinary team.
- “Monitoring” is the ongoing collection and analysis of information (such as observations and diagnostic test results) and comparison to baseline data in order to:
  - Ascertain the individual’s response to treatment and care, including progress or lack of progress toward a therapeutic goal;
  - Detect any complications or adverse consequences of the condition or of the treatments; and
  - Support decisions about modifying, discontinuing, or continuing any interventions.
- “Pharmacy Assistant or Technician” refers to ancillary personnel who work under the supervision and delegation of the pharmacist as consistent with state requirements.

OVERVIEW

Many nursing home residents require multiple medications to address their conditions, leading to complex medication regimens. Medications are used for their therapeutic benefits in diagnosing, managing, and treating acute and/or chronic conditions, for maintaining and/or improving a resident’s functional status, and for improving or sustaining the resident’s quality of life. The nursing home population may be quite diverse and may include geriatric residents as well as individuals of any age with special needs, such as those who are immunocompromised or who have end stage renal disease or spinal cord or closed head injuries. Regardless, this population has been identified as being at high risk for adverse consequences related to medications. Some adverse consequences may mimic symptoms of chronic conditions, the aging process, or a newly emerging condition.

Transitions in care such as a move from home or hospital to the nursing home, or vice versa, increases the risk of medication-related issues. Medications may be added, discontinued, omitted, or changed. It is important, therefore, to review the medications. Currently, safeguards to help identify medication issues include:

- The physician providing and reviewing the orders and total program of care on admission and the prescriber reviewing at each visit;
- The nurse reviewing medications when transmitting the orders to the pharmacy and/or prior to administering medications;
- The interdisciplinary team reviewing the medications as part of the comprehensive assessment for the Resident Assessment Instrument (RAI) and/or care plan;
- The pharmacist reviewing the prescriptions prior to dispensing; and
• The pharmacist performing the medication regimen review at least monthly. During the MRR, the pharmacist applies his/her understanding of medications and related cautions, actions and interactions as well as current medication advisories and information. The pharmacist provides consultation to the facility and the attending physician(s) regarding the medication regimen and is an important member of the interdisciplinary team. Regulations prohibit the pharmacist from delegating the medication regimen reviews to ancillary staff. Some resources are available to facilitate evaluating medication concerns related to the performance of the MRR, such as:
  • American Society of Consultant Pharmacists (ASCP) www.ascp.com;
  • American Medical Directors Association (AMDA) www.amda.com;
  • National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) www.nccmerp.org;
  • American Geriatrics Society (AGS) www.americangeriatrics.org;
  • U.S. Department of Health and Human Services, Food and Drug Administration (FDA) http://www.fda.gov/medwatch/safety.htm; and

**NOTE:** References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication. This guidance is not intended to imply that all adverse consequences related to medications are preventable, but rather to specify that a system exists to assure that medication usage is evaluated on an ongoing basis, that risks and problems are identified and acted upon, and that medication-related problems are considered when the resident has a change in condition. This guidance will discuss the following aspects of the facility’s MRR component of the pharmaceutical services systems:
  • A pharmacist’s review of the resident’s medication regimen to identify and report irregularities; and
  • Acting upon identified irregularities in order to minimize or prevent adverse consequences, to the extent possible.

**NOTE:** The surveyor’s review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.

**MEDICATION REGIMEN REVIEW (MRR)**
The MRR is an important component of the overall management and monitoring of a resident’s medication regimen. The pharmacist must review each resident’s medication regimen at least once a month in order to identify irregularities; and to identify clinically significant risks and/or adverse consequences resulting from or associated with medications. It may be necessary for the pharmacist to conduct the MRR more frequently, for example weekly, depending on the resident’s condition and the risks for adverse consequences related to current medications. Generally, MRRs are conducted in the facility because important information about indications for use, potential medication irregularities or adverse consequences (such as symptoms of tardive dyskinesia, dizziness, anorexia, or falls) may be attainable only by talking to the staff, reviewing the medical record, and observing and speaking with the resident. However, electronic health and medication records and other available technology may permit the pharmacist to conduct some components of the review outside the facility.
Important aspects of the MRR include identification of irregularities, including medication-related errors and adverse consequences, location and notification of MRR findings, and response to identified irregularities. This guidance discusses these aspects and also provides some examples of clinically significant medication interactions.

**Identification of Irregularities**

An objective of the MRR is to try to minimize or prevent adverse consequences by identifying irregularities including, for example: syndromes potentially related to medication therapy, emerging or existing adverse medication consequences, as well as the potential for adverse drug reactions and medication errors. The resident’s record may contain information regarding possible and/or actual medication irregularities. Possible sources to obtain this information include: the medication administration records (MAR); prescribers’ orders; progress, nursing and consultants’ notes; the Resident Assessment Instrument (RAI); laboratory and diagnostic test results, and other sources of information about behavior monitoring and/or changes in condition. The pharmacist may also obtain information from the Quality Measures/Quality Indicator reports, the attending physician, facility staff, and (as appropriate) from interviewing, assessing, and/or observing the resident.

The pharmacist’s review considers factors such as:

- Whether the physician and staff have documented objective findings, diagnoses and/or symptom(s) to support indications for use;
- Whether the physician and staff have identified and acted upon, or should be notified about, the resident’s allergies and/or potential side effects and significant medication interactions (such as medication-medication, medication-food, medication-disease, medication-herbal interactions);
- Whether the medication dose, frequency, route of administration, and duration are consistent with the resident’s condition, manufacturer’s recommendations, and applicable standards of practice;
- Whether the physician and staff have documented progress towards, or maintenance of, the goal(s) for the medication therapy;
- Whether the physician and staff have obtained and acted upon laboratory results, diagnostic studies, or other measurements (such as bowel function, intake and output) as applicable;
- Whether medication errors exist or circumstances exist that make them likely to occur; and
- Whether the physician and staff have noted and acted upon possible medication-related causes of recent or persistent changes in the resident’s condition such as worsening of an existing problem or the emergence of new signs or symptoms. The following are examples of changes potentially related to medication use that could occur at any age, however, some of the changes are more common in the geriatric population and may be unrelated to medications:
  - Anorexia and/or unplanned weight loss, or weight gain;
  - Behavioral changes, unusual behavior patterns (including increased distressed behavior);
  - Bowel function changes including constipation, ileus, impaction;
  - Confusion, cognitive decline, worsening of dementia (including delirium) of recent onset;
  - Dehydration, fluid/electrolyte imbalance;
  - Depression, mood disturbance;
  - Dysphagia, swallowing difficulty;
  - Excessive sedation, insomnia, or sleep disturbance;
  - Falls, dizziness, or evidence of impaired coordination;
  - Gastrointestinal bleeding;
  - Headaches, muscle pain, generalized aching or pain;
- Rash, pruritus;
- Seizure activity;
- Spontaneous or unexplained bleeding, bruising;
- Unexplained decline in functional status (e.g., ADLs, vision); and
- Urinary retention or incontinence.

Upon conducting the MRR, the pharmacist may identify and report concerns in one or more of the following categories: (See F329 for additional discussion of irregularities relating to dose, duration, indications for use, monitoring, and adverse consequences.)

- The use of a medication without identifiable evidence of adequate indications for use;
- The use of a medication to treat a clinical condition without identifiable evidence that safer alternatives or more clinically appropriate medications have been considered;
- The use of an appropriate medication that is not helping attain the intended treatment goals because of timing of administration, dosing intervals, sufficiency of dose, techniques of administration, or other reasons;
- The use of a medication in an excessive dose (including duplicate therapy) or for excessive duration, thereby placing the resident at greater risk for adverse consequences or causing existing adverse consequences;
- The presence of an adverse consequence associated with the resident’s current medication regimen;
- The use of a medication without evidence of adequate monitoring; i.e., either inadequate monitoring of the response to a medication or an inadequate response to the findings;
- Presence of medication errors or the risk for such errors;
- Presence of a clinical condition that might warrant initiation of medication therapy; and

**NOTE:** The presence of a diagnosis or symptom does not necessarily warrant medication, but often depends on the consideration of many factors simultaneously.
- A medication interaction associated with the current medication regimen.

The following table provides examples of some problematic medication interactions in the long-term care population. These examples represent common interactions but are not meant to be all inclusive.

**Common Medication-Medication Interactions in Long Term Care**

<table>
<thead>
<tr>
<th>Medication 1</th>
<th>Medication 2</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>warfarin</td>
<td>NSAIDs such as ibuprofen, naproxen, COX-2 inhibitors</td>
<td>Potential for serious gastrointestinal bleeding</td>
</tr>
<tr>
<td>warfarin</td>
<td>sulfonamides such as trimethoprim/sulfamethoxazole</td>
<td>Increased effects of warfarin, with potential for bleeding</td>
</tr>
<tr>
<td>macrolides such as clarithromycin, erythromycin</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Increased effects of warfarin, with potential for bleeding
warfarin
fluoroquinolones such as ciprofloxacin, levofloxacin, ofloxacin
Increased effects of warfarin, with potential for bleeding
warfarin
phenytoin
Increased effects of warfarin and/or phenytoin
ACE Inhibitors such as benazepril, captopril, enalapril, and lisinopril
potassium supplements
Elevated serum potassium levels
ACE Inhibitors such as benazepril, captopril, enalapril, and lisinopril
spironolactone
Elevated serum potassium levels
digoxin
amiodarone
digoxin toxicity
digoxin
verapamil
digoxin toxicity
theophylline
fluoroquinolones such as ciprofloxacin, levofloxacin, ofloxacin
theophylline toxicity

Location and Notification of Medication Regimen Review Findings

The pharmacist is expected to document either that no irregularity was identified or the nature of any identified irregularities. The pharmacist is responsible for reporting any identified irregularities to the attending physician and director of nursing. The timeliness of notification of irregularities depends on factors including the potential for or presence of serious adverse consequences; for example, immediate notification is indicated in cases of bleeding in a resident who is receiving anticoagulants or in cases of possible allergic reactions to antibiotic therapy. If no irregularities were identified during the review, the pharmacist includes a signed and dated statement to that effect. The facility and the pharmacist may collaborate to identify the most effective means for assuring appropriate notification. This notification may be done electronically.

The pharmacist does not need to document a continuing irregularity in the report each month if the pharmacist has deemed the irregularity to be clinically insignificant or evidence of a valid clinical reason for rejecting the pharmacist’s recommendation was provided. In this situation, the pharmacist need only reconsider annually whether to report the irregularity again or make a new recommendation.

The pharmacist’s findings are considered part of each resident’s clinical record. If documentation of the findings is not in the active record, it is maintained within the facility and is readily available for review. The interdisciplinary team is encouraged to review the reports and to get the pharmacist’s input on resident problems and issues. Establishing a consistent location for the pharmacist’s findings and recommendations can facilitate communication with the attending physician, the director of nursing, the remainder of the interdisciplinary team, the medical director, the resident and his or her legal representative (in accord with 42 CFR
Response to Irregularities Identified in the MRR
Throughout this guidance, a response from a physician regarding a medication problem implies appropriate communication, review, and resident management, but does not imply that the physician must necessarily order tests or treatments recommended or requested by the staff, unless the physician determines that those are medically valid and indicated. For those issues that require physician intervention, the physician either accepts and acts upon the report and potential recommendations or rejects all or some of the report and provides a brief explanation of why the recommendation is rejected, such as in a dated progress note. It is not acceptable for a physician to document only that he/she disagrees with the report, without providing some basis for disagreeing.
If there is the potential for serious harm and the attending physician does not concur with or take action on the report, the facility and the pharmacist should contact the facility’s medical director for guidance and possible intervention to resolve the issue. The facility should have a procedure to resolve the situation when the attending physician is also the medical director. For those recommendations that do not require a physician intervention, such as one to monitor vital signs or weights, the director of nursing or designated licensed nurse addresses and documents action(s) taken.

INVESTIGATIVE PROTOCOL
Refer to the Investigative Protocol at F329 for evaluation of medication regimen review.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)
Synopsis of regulation (F428)
This requirement has four aspects relating to the safety of the resident’s medication regimen, including:
• A review by the pharmacist of each resident’s medication regimen at least once a month or more frequently depending upon the resident’s condition and the risks or adverse consequences related to current medication(s);
• The identification of any irregularities;
• Reporting irregularities to the attending physician and the director of nursing; and
• Action in response to irregularities reported.

Criteria for compliance
Compliance with 42 CFR 483.60(c)(1) and (2), F428, Medication Regimen Review
The facility is in compliance with this requirement if:
• The pharmacist has performed a medication regimen review on each resident at least once a month or more frequently depending upon the resident’s condition and/or risks or adverse consequence associated with the medication regimen;
• The pharmacist has identified any existing irregularities;
• The pharmacist has reported any identified irregularities to the director of nursing and attending physician; and
• The report of any irregularities has been acted upon.
If not, cite F428.

Noncompliance for F428
After completing the Investigative Protocol, analyze the data in order to determine whether or not compliance with F428 exists. A determination of noncompliance with F428 does not require
a finding of harm to the resident. Noncompliance may include (but is not limited to) one or more of the following:

- The pharmacist failed to conduct an MRR at least monthly (or more frequently, as indicated).
- The pharmacist failed to identify or report the absence of or inadequate indications for use of a medication, or a medication or medication combination with significant potential for adverse consequences or medication interactions.
- The pharmacist failed to identify or report medications in a resident’s regimen that could (as of the review date) be causing or associated with new, worsening, or progressive signs and symptoms.
- The pharmacist failed to identify and report the absence of any explanation as to why or how the benefit of a medication(s) with potential for clinically significant adverse consequences outweighs the risk.
- The pharmacist failed to identify and report the lack of evidence or documentation regarding progress toward treatment goals.
- The facility failed to act upon a report of clinically significant risks or existing adverse consequences or other irregularities.

**Potential Tags for Additional Investigation**

If noncompliance with 483.60(c)(1) and (2) 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 should be considered when noncompliance has been identified include the following:

- **42 CFR 483.10(b)(11), F157, Notification of Changes**
  - Review whether the facility contacted the attending physician regarding a significant change in the resident’s condition in relation to a potential adverse consequence of a medication, or a need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a different form of treatment).
- **42 CFR 483.25(l), F329, Unnecessary Medications**
  - Review whether the resident is receiving any medications without an indication for use, in excessive dose or duration, with inadequate monitoring, or in the presence of any adverse consequences that indicate that the dose should be reduced or discontinued.
- **42 CFR 483.40(a), F385, Physician Supervision**
  - Review whether the attending physician supervised the resident’s medical treatment, including assessing the resident’s condition, identifying the need for and continuing use of medication to address the resident’s needs, and identifying and addressing adverse consequences related to medications.
- **42 CFR 483.40(b), F386, Physician Visits**
  - Review whether the attending physician or another designated practitioner reviewed the resident’s total program of care including the beneficial and adverse effects of medications and treatment, and provided a relevant progress note at each visit.
- **42 CFR 483.60(a)(b)(1), F425, Pharmacy Services**
  - Review whether the licensed pharmacist has provided consultation regarding all aspects of pharmaceutical services.
- **42 CFR 483.75(i), F501, Medical Director**
Review whether the medical director, when requested by the facility, interacted with the attending physician regarding an inadequate response to identified or reported potential medication irregularities and adverse consequences.

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant harm or potential for harm to the resident. The survey team must identify whether noncompliance cited at other tags (e.g., F329, F332/333) was the direct result of or related to inadequate or absent MRR or response to notification regarding irregularities.

The key elements for severity determination for F428 are as follows:

1. Presence of potential or actual harm/negative outcome(s) due to a facility failure related to the MRR.

Identify actual or potential harm/negative outcomes which for F428 may include, but are not limited to:

- The resident experienced a clinically significant adverse consequence associated with a medication.
- Irregularities within the medication regimen or inaccuracy of medication-related documents created the potential for adverse consequences such as overdose, respiratory depression, rash, or anorexia.

2. Degree of potential or actual harm/negative outcome(s) due to a facility failure related to the MRR.

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

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

3. The immediacy of correction required.

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

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F428. First, the team must rule out whether Severity Level 4, Immediate Jeopardy, to a resident’s health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Guidelines for Determining Immediate Jeopardy.)

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

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

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

- Has allowed, caused, or resulted in, or is likely to allow, cause, or result in serious injury, harm, impairment, or death to a resident; and
• Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures. Examples may include, but are not limited to:
  • Despite identifying irregularities with the potential for serious harm or death, the pharmacist did not report the irregularities to the attending physician or no action was taken on the irregularities reported.
  • Findings of noncompliance at Severity Level 4 at Tag(s) F309, F329, F332, or F333 that show evidence of process failures for conducting the MRR.
  • Repeated or cumulative failures in multiple areas of the medication regimen review process (e.g., failure to identify, report, or act upon) that resulted in the resident(s) experiencing actual or potential harm.

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

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy
Level 3 indicates noncompliance that resulted in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident’s inability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:
  • The pharmacist’s MRR failed to identify the indication for continued use for opioid analgesics that had been prescribed for a resident’s acute pain which had resolved. As a result of prolonged duration of use, the resident became more lethargic, withdrawn, and anorectic.
  • The pharmacist’s MRR identified that the staff were crushing medications that should not be crushed, based on inappropriate standing orders to crush all medications. As a result of facility failure to act upon the notification, the resident experienced clinically significant adverse consequences such as hypoglycemia or hypotension that required medical intervention.
  • The pharmacist’s MRR identified that medications were not being given as ordered (such as antiparkinsons or pain medications not given prior to physical therapy), which may have contributed to impaired function. The facility failed to take any action to adhere to the orders.
  • The physician and/or director of nursing failed to act in response to the pharmacist’s MRR which identified the indefinite continuation of an antidepressant in a resident who had no history of depression, who had been placed on the antidepressant without an evaluation to confirm presence of depression, and whose function and mood were not monitored while getting the medication for months. The resident experienced clinically significant adverse consequences such as falls, constipation, or change in weight.
  • The pharmacist’s MRR failed to identify and report the medication regimen as a possible cause of recurrent falling in a resident who was given increasing doses of anticonvulsants to treat behavioral symptoms related to dementia, resulting in serious injury.
  • The pharmacist’s MRR failed to identify and report clinically significant medication interactions in a resident who was started on warfarin, and who had also been receiving one or more of the following: digoxin, phenytoin, antibiotics, amiodarone, or an oral antifungal, resulting in a marked elevation in the INR with significant gastrointestinal bleeding or hematuria.
  • Findings of noncompliance at Severity Level 3 at tag(s) F309, F329, F332, F333 that show evidence of process failures for conducting the MRR.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.
Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

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

- The facility failed to respond to the pharmacist’s notification that the resident was not receiving all the medications ordered; however, there was no change in the resident condition.
- The pharmacist’s MRR failed to identify and report a resident who is receiving multiple antihypertensive medications, but is not being monitored for postural hypotension, and who complains of lightheadedness especially while upright.
- The pharmacist’s MRR failed to identify and report risks of hyperkalemia in a resident who has impaired renal function and is receiving an ACE inhibitor and potassium supplements.
- The pharmacist’s MRR failed to evaluate and report on the potential adverse consequences of a medication known to cause anorexia for a resident with a recently decreased appetite, who had not yet experienced a significant unplanned weight loss.
- Findings of noncompliance at Severity Level 2 at tag(s) F309, F329, or F332, F333 that show evidence of process failures for conducting the MRR.

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

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

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

- The pharmacist conducted the medication review, identified an irregularity that has not resulted in a negative outcome and is of minimal consequence (such as a multi-vitamin not being given as ordered) and reported to the director of nursing and attending physician, but neither of them acted upon the report.

F431
(Rev. 22, Issued: 12-15-06, Effective/Implementation: 12-18-06)
§483.60(b) Service Consultation. The facility must employ or obtain the services of a licensed pharmacist who--
(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and
(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

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

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

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

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

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

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

**DEFINITIONS** (refer to F425 and F428 for additional definitions)

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

**OVERVIEW**

Due to the number and types of medications that may be used and the vulnerable populations being served, the regulations require a long term care facility to have formal mechanisms to safely handle and control medications, and to maintain accurate and timely medication records. These regulations also require the facility to use a pharmacist to help establish and evaluate these mechanisms or systems. This guidance addresses those portions of the facility’s pharmaceutical services related to medication access and storage, appropriate security and safeguarding of controlled medications, and labeling of medications to assure that they are stored safely and are provided to the residents accurately and in accordance with the prescriber’s instructions.

**MEDICATION ACCESS AND STORAGE**

A facility is required to secure all medications in a locked storage area and to limit access to authorized personnel (for example, pharmacy technicians or assistants who have been delegated access to medications by the facility’s pharmacist as a function of their jobs) consistent with state or federal requirements and professional standards of practice. Storage areas may include, but are not limited to, drawers, cabinets, medication rooms, refrigerators, and carts. Depending on how the facility locks and stores medications, access to a
medication room may not necessarily provide access to the medications (for example, medications stored in a locked cart, locked cabinets, a locked refrigerator, or locked drawers within the medication room). When medications are not stored in separately locked compartments within a storage area, only appropriately authorized staff may have access to the storage area.

Access to medications can be controlled by keys, security codes or cards, or other technology such as fingerprints. Schedule II medications must be maintained in separately locked, permanently affixed compartments. The access system (e.g. key, security codes) used to lock Schedule II medications and other medications subject to abuse, cannot be the same access system used to obtain the non-scheduled medications. The facility must have a system to limit who has security access and when access is used. Exception: Controlled medications and those subject to abuse may be stored with non-controlled medications as part of a single unit package medication distribution system, if the supply of the medication(s) is minimal and a shortage is readily detectable.

During a medication pass, medications must be under the direct observation of the person administering the medications or locked in the medication storage area/cart. In addition, the facility should have procedures for the control and safe storage of medications for those residents who can self-administer medications.

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

CONTROLLED MEDICATIONS

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

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

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

• Records of usage and disposition of all controlled medications with sufficient detail to allow reconciliation (e.g., the medication administration record [MAR], proof-of-use sheets, or declining inventory sheets), including destruction, wastage, return to the pharmacy/manufacturer, or disposal in accordance with applicable State requirements;

• Periodic reconciliation of records of receipt, disposition and inventory for all controlled medications (monthly or more frequently as defined by facility procedures or when loss is identified). The reconciliation identifies loss or diversion of controlled medications so as to minimize the time between the actual loss or diversion and the time of detection and follow-up to determine the extent of loss. Because diversion can occur at any time, the reconciliation should
be done often enough to identify problems. Some State or other federal requirements may specify the frequency of reconciliation.
- If discrepancies are identified during the reconciliation, the pharmacist and the facility develop and implement recommendations for resolving them.
- If the systems have not been effective in preventing or identifying diversion or loss, it is important that the pharmacist and the facility review and revise related controls and procedures, as necessary, such as increasing the frequency of monitoring or the amount of detail used to document controlled substances.

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

**LABELING OF MEDICATIONS AND BIOLOGICALS**
This section requires facility compliance with currently accepted labeling requirements, even though the pharmacies are responsible for the actual labeling. Labeling of medications and biologicals dispensed by the pharmacy must be consistent with applicable federal and State requirements and currently accepted pharmaceutical principles and practices. Although medication delivery systems may vary, the medication label at a minimum includes the medication name (generic and/or brand) and strength, the expiration date when applicable, and typically includes the resident’s name, route of administration, appropriate instructions and precautions (such as shake well, with meals, do not crush, special storage instructions). For medications designed for multiple administrations (e.g., inhalers, eye drops), the label is affixed in a manner to promote administration to the resident for whom it was prescribed.

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

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

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

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

**DETERMINATION OF COMPLIANCE (Task 6, Appendix P)**

**Synopsis of regulation (F431)**
This requirement has several aspects. The pharmaceutical services must:
- Provide for the safe and secure storage of medications, i.e., medications must be stored at proper temperatures and locked at all times (except when under direct staff observation);
- Limit access to medications only to authorized staff;
• Label medications in accordance with Federal and State labeling requirements and accepted standards of practice; and
• Have safeguards and systems in place to control, account for, and periodically reconcile controlled medications.

Criteria for Compliance
Compliance with 42 CFR 483.60(b)(2)(3)(d)(e), F431, Labeling, Storage, and Controlled Medications
The facility is in compliance if:
• The facility safeguards medications by locking the medications, limiting access, and disposing of medications appropriately;
• Medications are stored under proper temperature controls and in accordance with manufacturers’ specifications;
• Medication labeling identifies, at a minimum, the medication’s name, strength, expiration date when applicable, and lot number, and provides instructions as necessary for safe administration;
• Schedule II medications are stored in separately locked, permanently affixed compartments, except when the facility uses single unit medication distribution systems in which the quantity stored is minimal and a missing dose can be readily detected; and
• Controlled medications are reconciled accurately.
If not, cite F431.

Noncompliance for F431
After completing the investigation, determine whether compliance with the regulation exists. Noncompliance for F431 may include (but is not limited to) facility failure to:
• Store medications to preserve their integrity, for example allowing medications that should be stored between 40 and 86 degrees Fahrenheit to either reach temperatures below 32 degrees or above 100 degrees;
• Provide accurate labeling with appropriate accessory and cautionary instructions, thereby creating a potential for the wrong medication to be administered or for the correct medications to be given by the wrong route; and
• Accurately reconcile controlled medications.

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)
Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant harm or potential for harm to the resident.
The key elements for severity determination for F431 are as follows:

1. Presence of actual or potential harm/negative outcome(s) due to a facility failure related to storage, labeling, or reconciliation of controlled medications.
Identify actual or potential harm/negative outcomes for F431 which may include, but are not limited to:
• Accidental ingestion of medication(s) by a resident(s) as a result of failure to lock medications;
• One or more residents received (or had the potential to receive) the wrong medication or dose or the correct medication by the wrong route as a result of inaccurate or incomplete labeling; or
• Potential for a resident(s) to receive potentially ineffective medication(s) as a result of storing medications or vaccines at wrong temperatures, resulting in their potential inactivation.

2. Degree of actual or potential harm/negative outcome(s) due to a facility failure related to storage, labeling, or reconciliation of controlled medications.
Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:
• If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or
• If harm has not yet occurred, determine the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.

3. The immediacy of correction required.
Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.
The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F431. First, the team must rule out whether Severity Level 4, Immediate Jeopardy, to a resident’s health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Guidelines for Determining Immediate Jeopardy.)

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

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety
Immediate Jeopardy is a situation in which the facility’s noncompliance with one or more requirements of participation:
• Has caused/resulted in, or is likely to cause, serious injury, harm, impairment, or death to a resident; and
• Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.
Examples may include, but are not limited to:
• The facility failed to restrict access to medications resulting in serious injury or harm or death from ingestion of the medications (e.g., warfarin, digoxin, antibiotics, opioids, anticonvulsants, antipsychotics) or posed a significant risk to the health of the residents resulting in the potential for clinically significant adverse consequences such as kidney or liver failure, anaphylaxis, cardiac arrest, or death; or
• As a result of an incorrect label on the package, staff administered the wrong medication or wrong dose(s) of a medication (e.g., anticonvulsant, antihyperglycemic, benzodiazepine) with a potential for clinically significant adverse consequences, which resulted in or had the potential for serious harm or death (e.g., toxic levels of the medication, unresponsiveness, uncontrolled seizures).

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

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy
Level 3 indicates noncompliance that resulted in actual harm, and can include but may not be limited to compromise, decline, or interference with the resident’s ability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:
• Medication labeling was incomplete and lacked instructions that the medication was not to be given with specific foods (e.g., milk or milk-based products) resulting in altered effectiveness of the medication and worsening of the residents’ symptoms, requiring medical intervention; or
• The facility failed to implement a system to reconcile controlled medications. As a result, medications were unavailable for residents for whom the medications were prescribed. Residents experienced moderate pain that compromised their ability to perform ADLs.

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

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

Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or the potential to compromise the resident’s ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided. Examples may include, but are not limited to:
• The facility’s medication cart was not kept locked or under direct observation of authorized staff and a wandering resident with dementia ingested a medication that he/she had taken off the cart but did not suffer any adverse consequences; or
• As a result of inaccurate labeling, the resident received the wrong medication or dose or the correct medication by the wrong route and experienced discomfort but did not require any interventions.

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

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

Level 1 indicates noncompliance that resulted in no harm to the resident, and the potential for no more than minimal harm. Examples may include, but are not limited to:
• The facility failed to reconcile controlled medications but there was no negative resident outcome and no potential for more than minimal harm.