Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene?

Are resident's dentures intact? Proper fit?

F412

§483.55(b) Nursing Facilities

The facility--

(1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, the following dental services to meet the needs of each resident:

(i) Routine dental services (to the extent covered under the State plan); and

(ii) Emergency dental services;

(2) Must, if necessary, assist the resident--

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office; and

(3) Must promptly refer residents with lost or damaged dentures to a dentist.

Interpretive Guidelines: §483.55(b)(1)(i)

For Medicaid residents, the facility must provide the resident, without charge, all emergency dental services, as well as those routine dental services that are covered under the State plan.

F425

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

§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:*

    - *Provision of consultative services by a licensed pharmacist between the pharmacist's visits, as necessary; and*

    - *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:*

    - *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);*

    - *The provision of medication-related information to health care professionals and residents;*

    - *The process of identifying, evaluating and addressing medication-related issues including the prevention and reporting of medication errors; and*

- *The provision, monitoring and/or the use of medication-related devices.*

- *"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:*
    - *Maximize the effectiveness (optimal therapeutic effect) of the medication (for example, antibiotics, antihypertensives, insulins, pain medications);*
    - *Avoid potential significant medication interactions such as medication-food or medication-medication interactions; and*
    - *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:*

    - *IV pumps or other IV delivery systems including calculating dosage, infusion rates, and compatibility of medications to be added to the IV;*

    - *Blood glucose meters, including calibration and cleaning between individual residents; and*

    - *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*

- *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*

  - *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*

  - *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*

  - *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:

- *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:*

    - *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.*

    - *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:*

- *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.*

- *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:*

  - *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*

  - *There were no negative resident outcomes or potential for more than minimal negative outcomes related to pharmaceutical services; and*

  - *Pharmaceutical procedures were in place; and*

  - *The facility was actively seeking a new pharmacist.*

    NOTE: *If there is no pharmacist and there were negative outcomes, or procedures were not in place or if the facility was not looking for a replacement, cite at a Severity Level 2 or higher severity.*