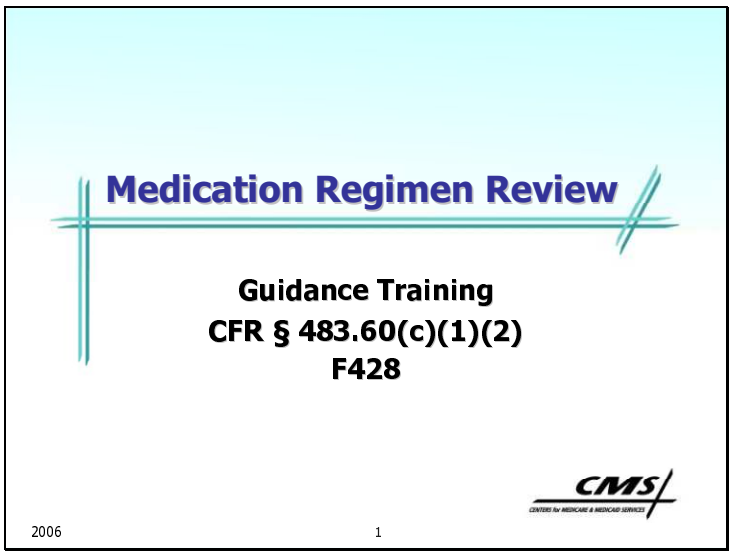
Centers for Medicare & Medicaid Services (CMS)

# Medication Regimen Review
# Instructor's Guide
## CFR § 483.60(c)(1)(2)
## F428

2006

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

Slide 1



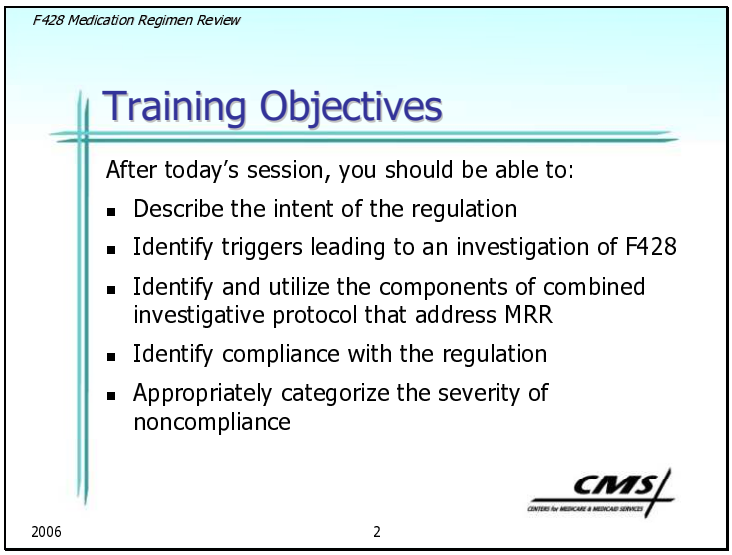

## Guidance Training

**Notes:**

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

**Message:** This guidance uses the term medications rather than drugs, except where the term drugs has become part of standard pharmaceutical nomenclature, such as adverse drug reaction.

Slide 2

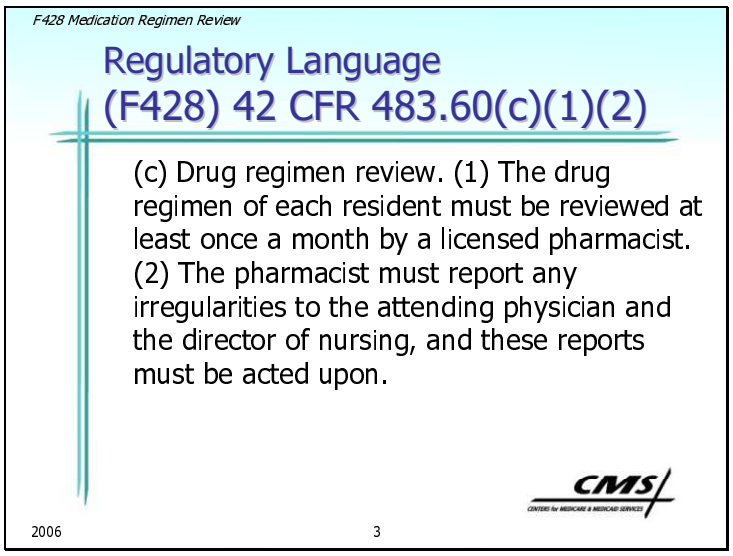



## Training Objectives

**Message:** 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 and well being. Many medications however also have the potential to cause clinically significant medication-related adverse consequences.

With that in mind, it is important to understand the regulation and its intent and to be able to investigate whether the facility is in compliance with the requirements of the regulation. If the facility is not in compliance, it will be important to assign an appropriate level of severity to the deficiency.

Slide 3



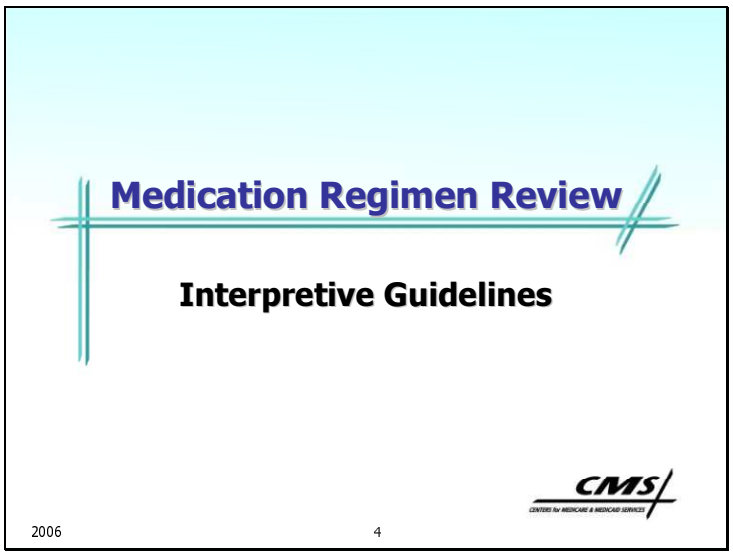

## Regulatory Language

**Message:** The 3 components of the requirement addressing medication regimen review have been merged into the single tag of F428. Although the regulatory language reflects mostly a process, that process has the potential for significant impact upon each resident.

For purposes of this training and in the guidance, references to "the pharmacist" mean the licensed pharmacist, whether employed directly by the facility or through arrangement.

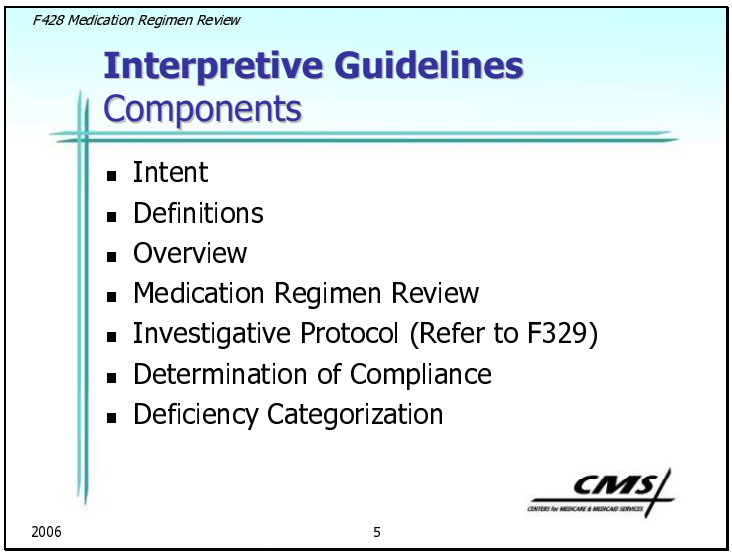
It is also important to note that the surveyor's review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.

Slide 4




## Interpretive Guidelines

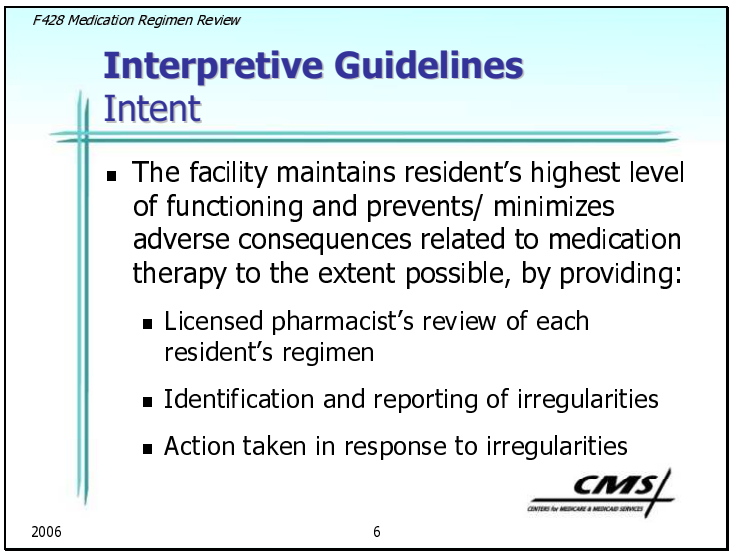
Slide 5




## Components

**Message:** We will discuss each of these components of the Guidance.

Slide 6



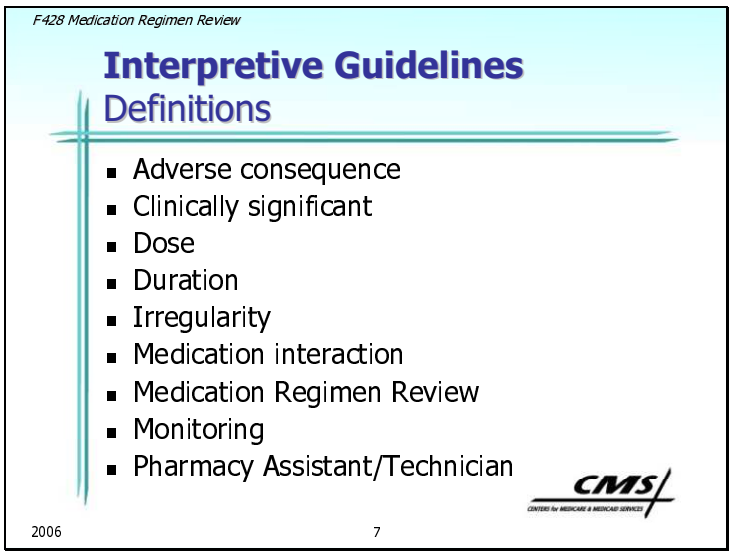

## Intent

**Message:** The intent of this regulation is that medications do no harm, but rather help the resident maintain or achieve his or her highest level of functioning, to the extent possible.

To help achieve this, there must be a medication regimen review by a licensed pharmacist at least monthly for each resident.

Depending upon the condition of the resident and the characteristics of the medications and risks for adverse consequences, a more frequent review may be necessary. If any irregularities are identified, they must be reported to the director of nursing and the attending physician and there must be action taken to address the irregularities.

Slide 7

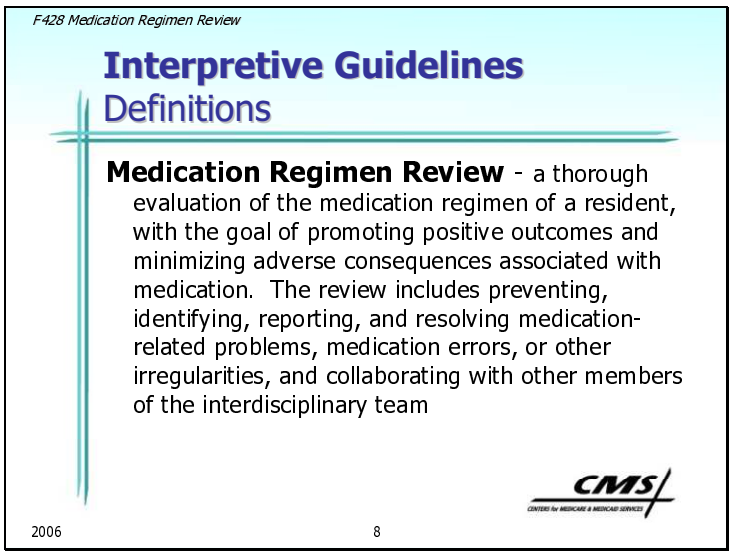



## Definitions

**Message:** Definitions are provided to clarify terminology related to pharmaceutical services and the management of each resident's medication regimen for effectiveness and safety. Although the guidelines include numerous definitions, we will only discuss Medication Regimen Review, Medication interaction, and Irregularity today.

Many of the other terms are discussed in the pharmacy tags at F425 or unnecessary medications at tag F329.

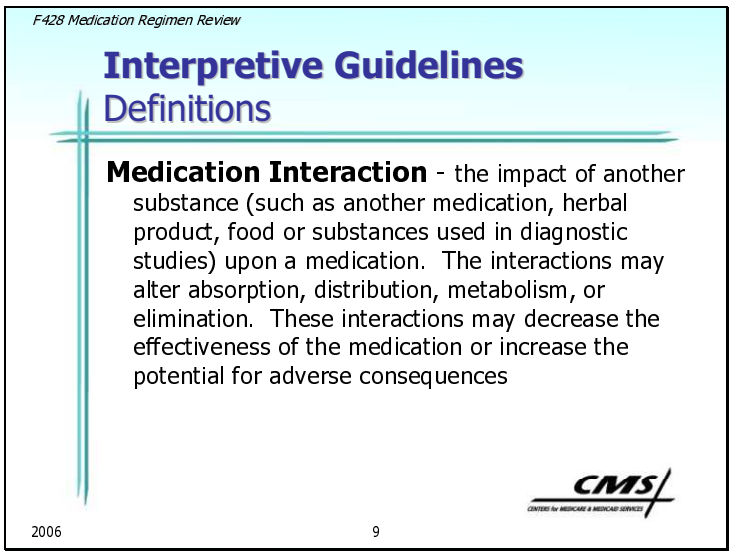
Slide 8




## Definitions

**Message:** As you can see by the definition, 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. We will discuss this process in more detail later in this training.

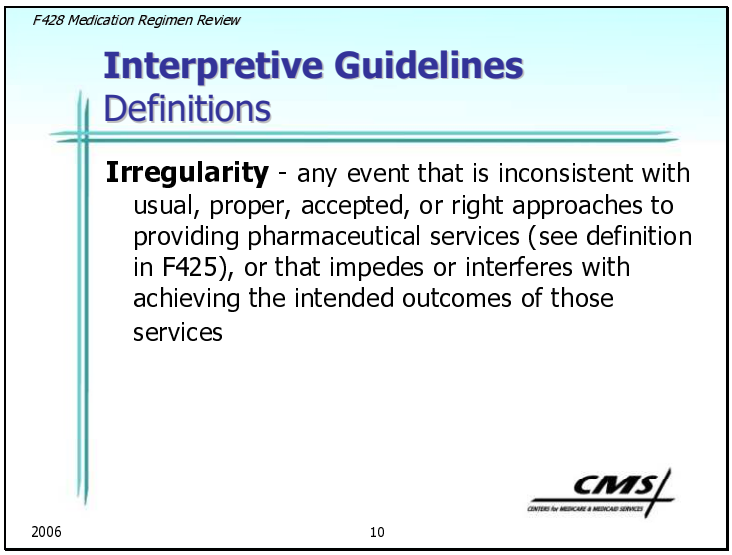
Slide 9




## Definitions

**Message:** It is important for prescribers, facility staff and the pharmacist to review for the possibility of a medication interaction associated with the current medication regimen. It may also be necessary to evaluate the regimen in relation to the times of meal service and the scheduled medication administration times in order to prevent and identify potential medication - food interaction.

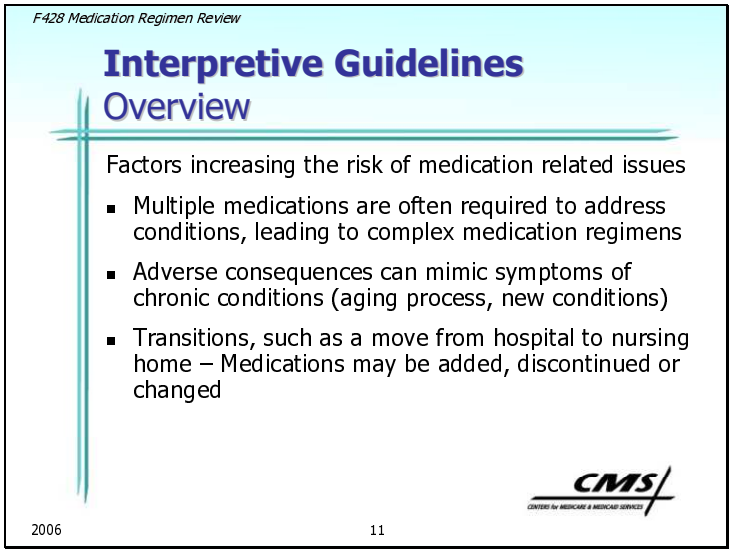
Slide 10




## Definitions

**Message:** The pharmacist should identify any irregularity that affects pharmaceutical services as it relates to resident or medical care or facility processes. This would include the processes for ordering, storing or disposing of medications, the scheduled times for administering a medication, transcribing medication orders, or documenting the administration of medications. The pharmacist may identify a problem with unnecessary medications such as the lack of indications for use. An example might include the pharmacist identification of the lack of information to support the use of an anticonvulsant or antidepressant medication for treating neuropathic pain.

Slide 11



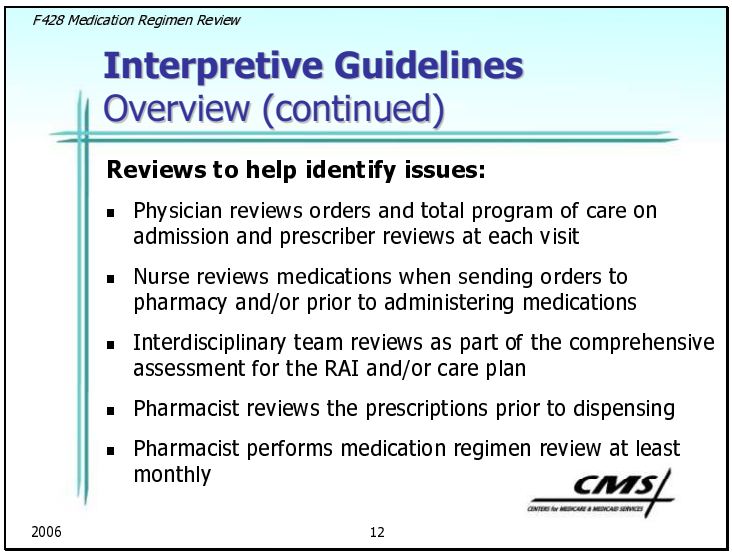

# Overview

**Message:** It is important to note that many nursing home residents require multiple medications to address their conditions, leading to complex medication regimens. The resident who is receiving a large number of medications or who has a more complex medication regimen is at greater the risk for an adverse medication-related consequence.

Some adverse consequences may appear to be end stages of a disease process or the emergence of a new disease. It may be the pharmacist who recognizes or suspects and reports that a resident's deterioration is potentially not the normal progression of a disease process, but is instead an adverse consequence.

The 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.

Slide 12

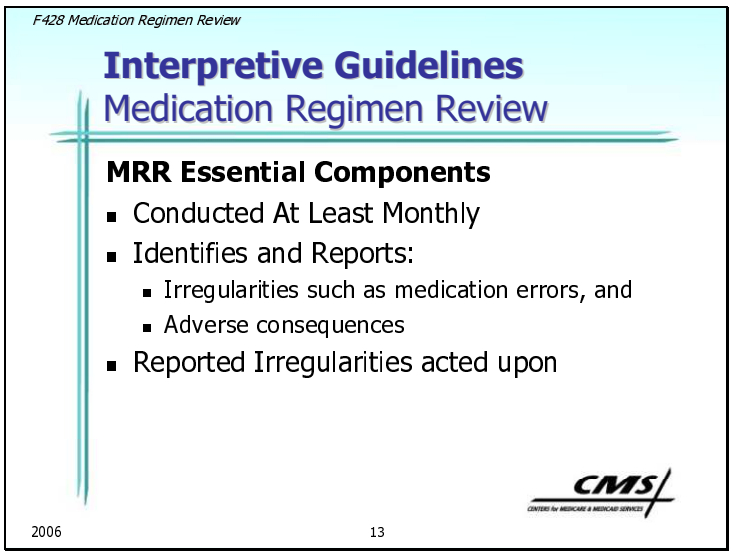



## Overview

**Message:** As you can see on the slide, there are a number of times during various phases of the care process, that issues or concerns regarding medication use may be identified and addressed.

The pharmacist role in this part of the care process includes providing consultation to the facility and the attending physician(s) or prescriber, regarding the medication regimen. During the performance of 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 is an important member of the interdisciplinary team and regulations prohibit the pharmacist from delegating the medication regimen reviews to ancillary staff.

Slide 13



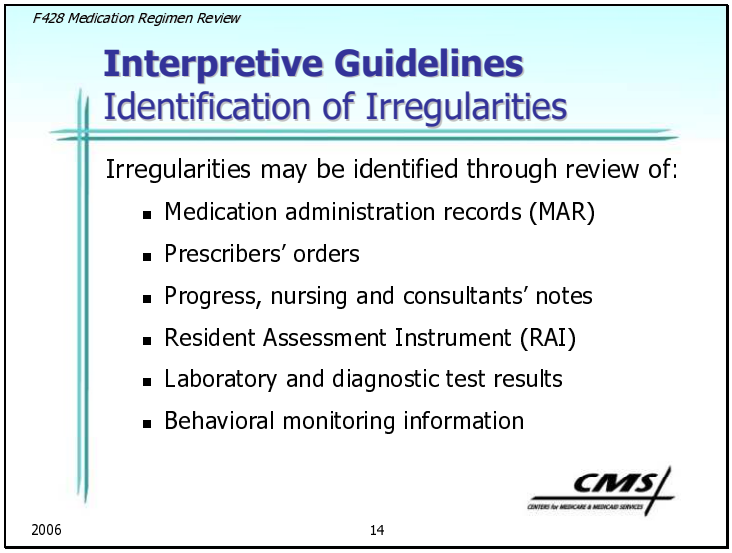

## Medication Regimen Review

**Message:** The MRR is an important component of the overall management and monitoring of a resident's medication regimen. 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.

Because the regulatory language requires that the MRR be conducted "at least once a month", it is understood that it may be necessary for the pharmacist to conduct the MRR more frequently, depending on the resident's condition and the risks for possible adverse consequences related to current medications. That is why communication between the facility, the physician or prescriber and the pharmacist is an important component of the care process.

MRR's are generally conducted in the facility so that the pharmacist may observe and speak with the resident, as appropriate, and obtain other important information about indications for use, potential medication irregularities or adverse consequences such as symptoms of dizziness, anorexia, or falls, which may only be attainable by talking with the staff , prescribers and reviewing the medical record. Electronic health and medication records and other available technology may permit the pharmacist to conduct some components of the review outside the facility.

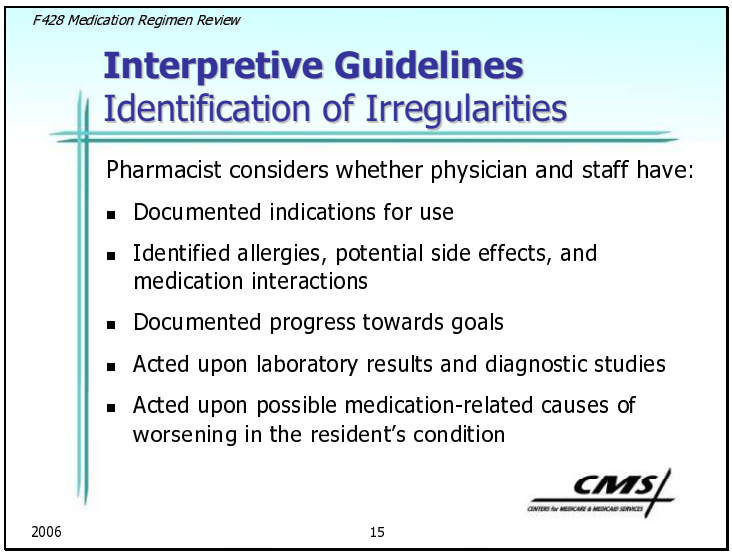
Slide 14




## Identification of Irregularities

**Message:** The pharmacist may identify irregularities from a variety of sources such as those listed but may also obtain information from interviews with the physician or prescriber, facility staff, and the resident as appropriate.

Slide 15

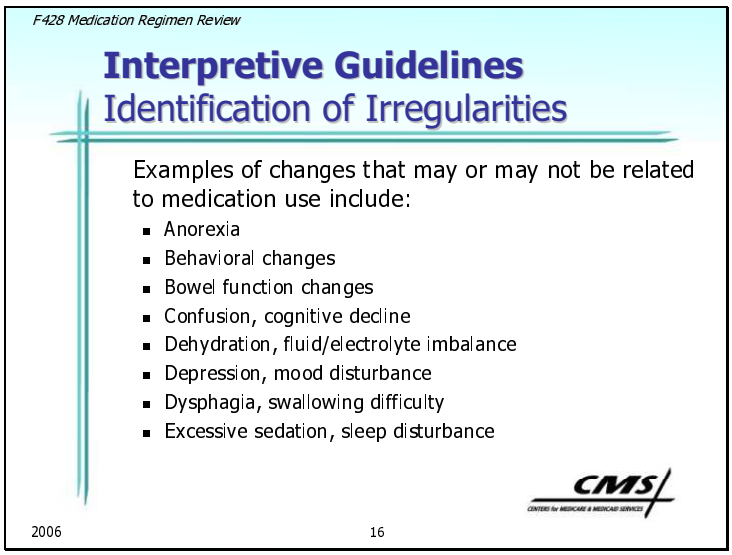



# Identification of Irregularities

**Message:** The pharmacist considers:

- Whether there are indications for use of the medication and the benefit outweighs the risk involved with the use of the specific medication
- Whether there are potential interactions within the regimen or the resident's diet
- Whether the resident's response to the medications is being monitored and action has been taken in response to evidence of medication toxicity or adverse drug reactions, or lack of progress toward the therapeutic goals for the medication
- 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 and
- Whether changes in the resident's condition may be the result of one or more of the medications the resident is receiving

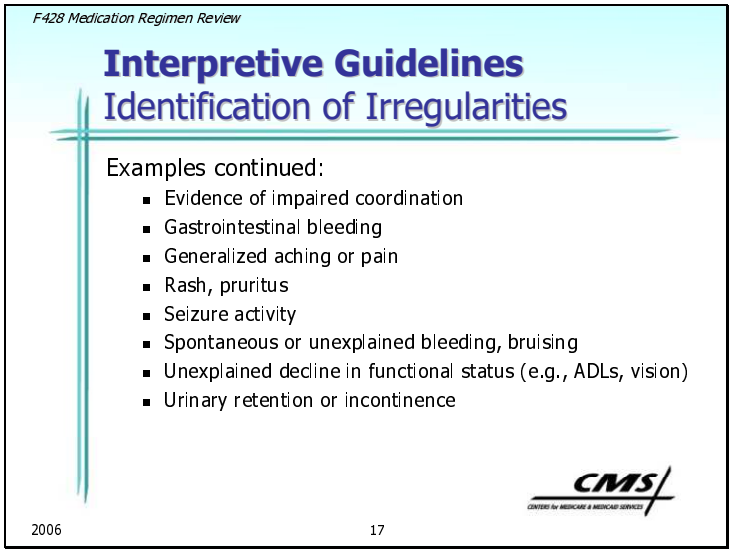
Slide 16




# Identification of Irregularities

**Message:** The examples of changes potentially related to medication use could occur at any age, however, some of the changes are more common in the older population and may be unrelated to medications.

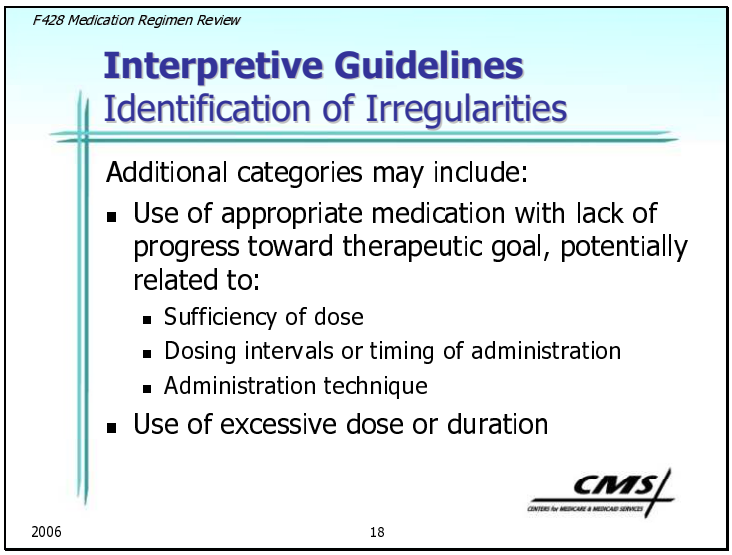
Slide 17




# Identification of Irregularities

**Message:** If the change is related to the use of the medications, the prescriber, and staff need to evaluate whether the benefit being achieved with the use of the medication outweighs the risk or presence of adverse consequence associated with the medications.

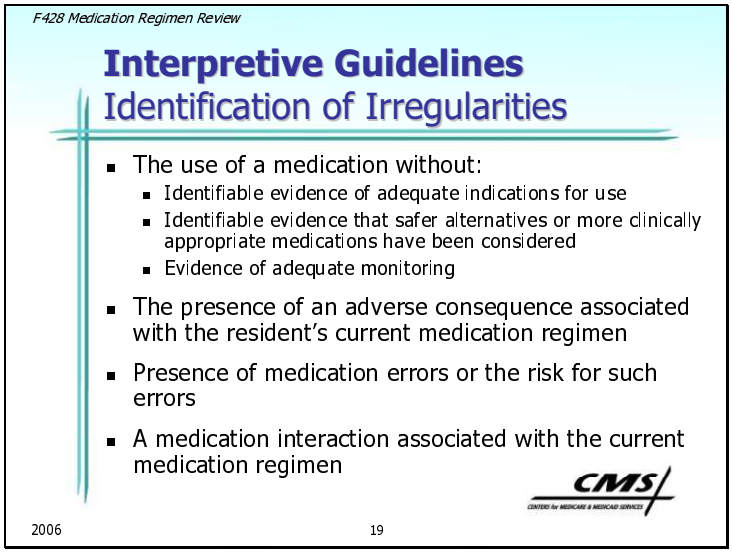
Slide 18




# Identification of Irregularities

**Message:** The pharmacist's review also considers factors such as concerns relating to dose, duration, indications for use, monitoring, gradual dose reduction for anti-psychotics, and adverse consequences. Specific information on these areas may be reviewed at tag F329, Unnecessary Medications.

Slide 19

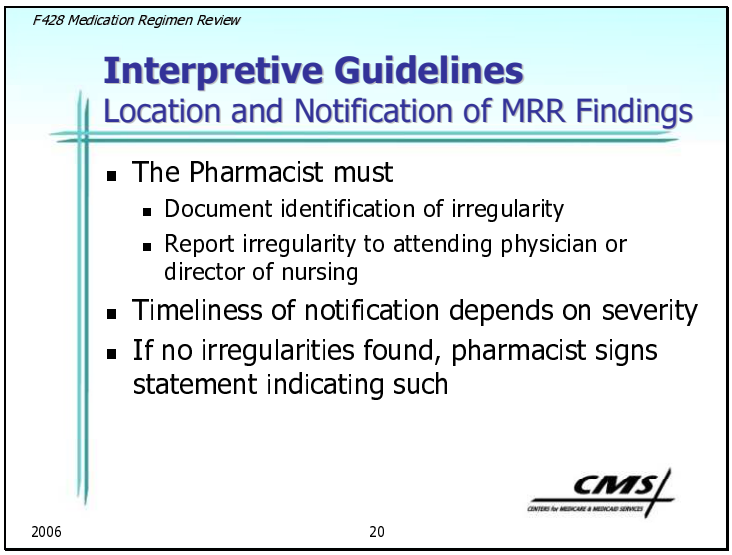



# Identification of Irregularities

**Message:** The guidance contains a table of examples of some problematic medication interactions in the long-term care population. Note that the medications frequently implicated were warfarin, digoxin, the ACE inhibitors and theophylline used in combination with some other medications. The examples represent common interactions but are not meant to be all inclusive.

It is also important to note that the use of the medication combinations in the table is not necessarily inappropriate and the examples are not intended to imply that the medications cannot be used simultaneously. Often, several medications with documented interactions can be given together safely. However, simultaneous use of such medications warrants careful consideration of potential alternatives, possible need to modify doses, and diligent monitoring.

Slide 20




# Location and Notification of MRR Findings

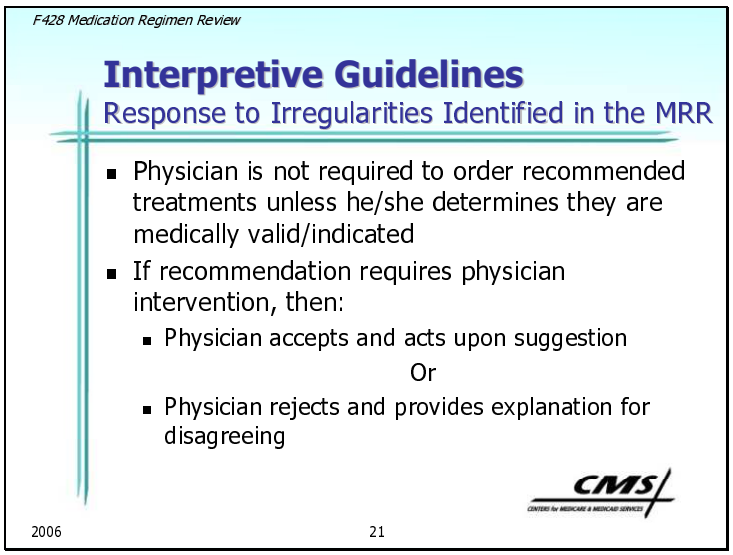
**Message:** The pharmacist's findings of any irregularities are reported to the attending physician and director of nursing. If the irregularity represents the potential for or presence of a serious adverse consequence, immediate notification is indicated, such as in cases of bleeding in a resident who is receiving anticoagulants or in cases of possible allergic reactions to antibiotic therapy.

The pharmacist's findings identifying irregularities or documenting that no irregularities were found are considered part of each resident's clinical record. If the reports of findings are not maintained in the active record, they must be maintained within the facility and be readily available for review. Establishing a consistent location for the pharmacist's findings and recommendations is recommended.

The pharmacist does not need to report a continuing irregularity monthly if the pharmacist considers the irregularity to be clinically insignificant or the physician has provided a clinically valid rationale for rejecting the pharmacist's recommendation. In these circumstances, the pharmacist needs to reconsider annually whether to report the irregularity or to make a new recommendation.

The interdisciplinary care team is encouraged to review the reports and to get the pharmacist's input on resident problems and issues.

Slide 21



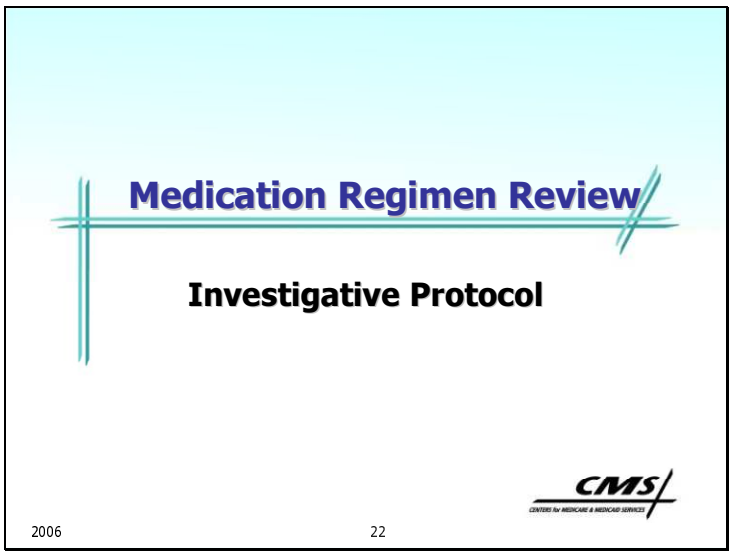

# Response to Irregularities Identified in the MRR

**Message:** Throughout the 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.

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.

Slide 22




## Investigative Protocol

**Note:** Refer to the Investigative Protocol at F329 for evaluation of compliance with medication regimen review at F428.

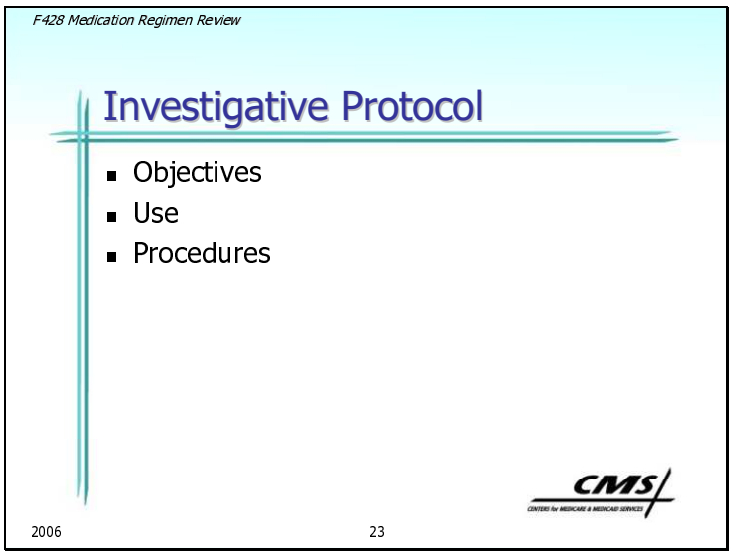
Because the processes for investigating compliance with the requirements for unnecessary medications and for Medication Regimen Review are closely related, the investigations of these requirements have been merged.

**Message:** Record each medication prescribed on the resident review.

In order to determine whether the facility is in compliance with the requirement for MRR, it is essential to have an understanding of, or have information about, the basic characteristic, of each medication prescribed for each resident in the sample.

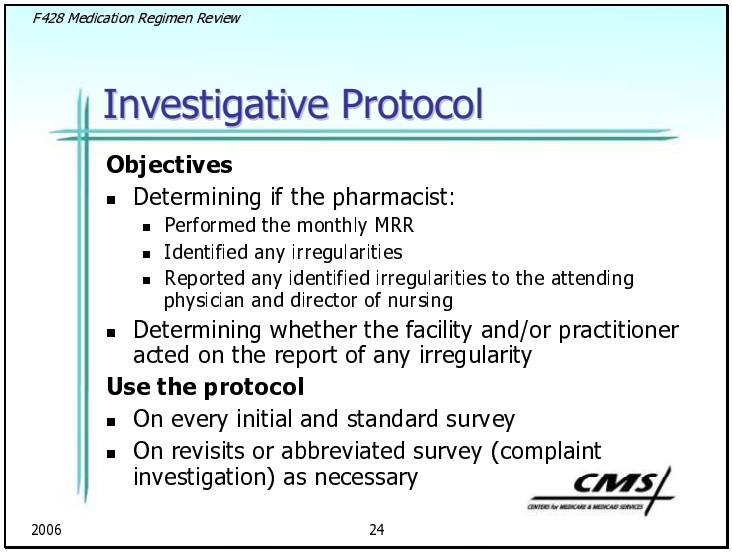
Additionally, if noncompliance at other tags, such as F309 with regard to maintaining highest practicable level of well-being, F329 with regard to unnecessary medications, or F332 or F333 with regard to medication errors has been identified, a determination needs to be made about whether these deficiencies were related to an absent or inadequate MRR or response to notification regarding irregularities.

Slide 23




# Investigative Protocol

Slide 24




# Investigative Protocol

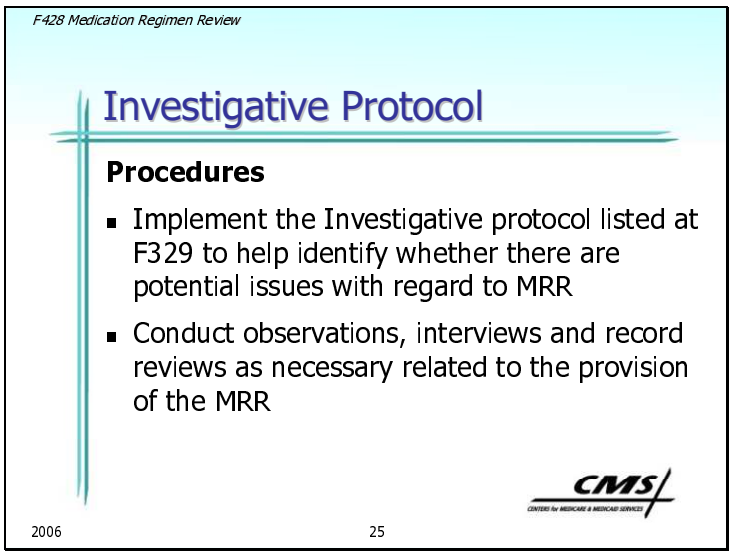
**Message:** As noted earlier, the review of medications by a surveyor is not intended to direct medication therapy. However, surveyors are expected to review factors related to the implementation, use, and monitoring of medications.

The surveyor is not expected to prove that an adverse consequence was directly caused by a medication or combination of medications, but rather that there was a failure in the care process related to considering and acting upon such possibilities.

If during the course of the review, you need to contact the attending physician regarding questions related to the medication regimen, it is recommended that the facility's staff have the opportunity to provide the necessary information about the resident and the concerns to the physician for review prior to your interview.

You may also need to contact the pharmacist to discuss issues or concerns related to the provision of the MRR.

Slide 25



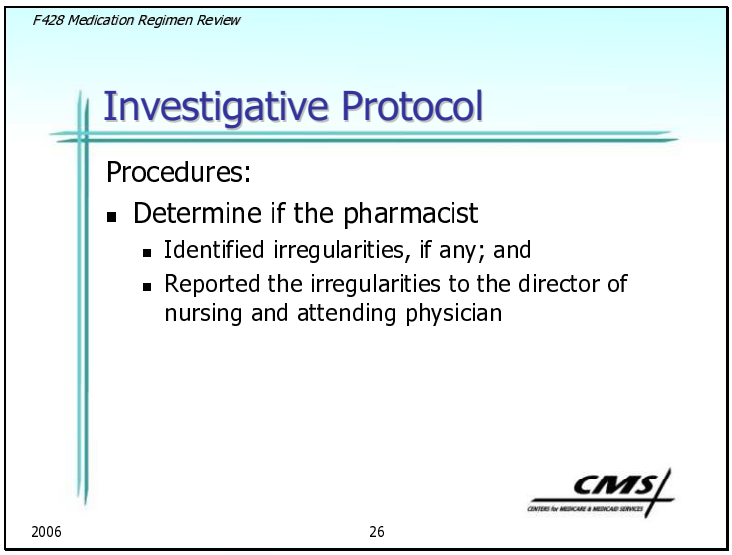

# Investigative Protocol

**Message:** Conduct a brief review of the resident's record to obtain background information which will help to guide your observations and interviews.

The investigative protocol, which is located at F329 - Unnecessary Drugs, has procedures including a table to use during the investigation which guides observations and record review. Interviews with staff, prescribers and the pharmacist may be indicated for follow-up to any concerns identified.

As you see on the table in the F329 protocol, during observation or record review, you may identify symptoms, signs, and conditions that may be associated with medications. For the purpose of this requirement, you would review to identify how the pharmacist identified and reported any potential irregularities in the resident's medication regimen.

Slide 26




# Investigative Protocol

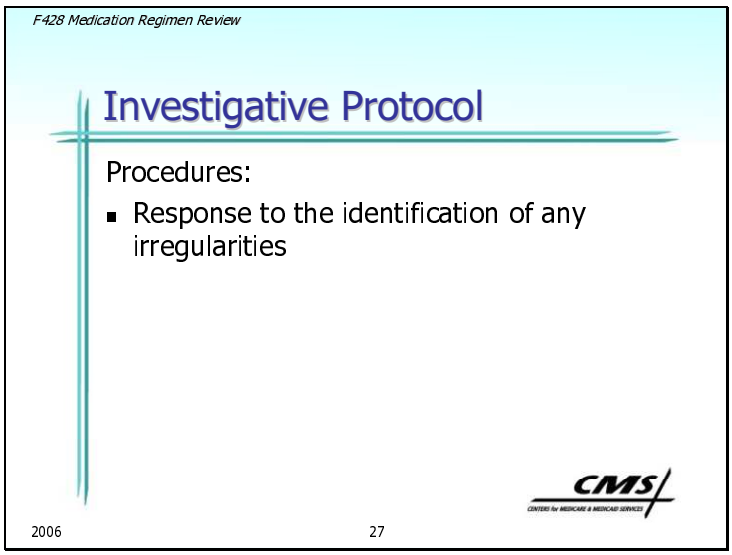
**Message:** If observations or record review indicate symptoms or changes in condition (refer to F329 Tables I and II, supplemented with current medication references), determine whether the facility considered medications as a potential cause of the change or symptom.

You may review the pharmacist monthly medication regimen to identify whether the report indicated the emergence or existence of clinically significant adverse consequences; or other possible irregularities such as excessive dose or duration, lack of monitoring, lack of indication for use, lack of GDR (as indicated) or behavioral interventions for residents receiving antipsychotics, medication interactions potentially affecting the medication's effectiveness.

If problems are identified with the MRR, you may need to interview the pharmacist to determine:

- How he/she conducts the MRR, including the frequency and extent of the medication review and under what circumstances a review might be conducted more often than monthly;
- How the facility communicates with him/her regarding medication-related issues in specific residents; and
- How he/she approaches the MRR process for short stay residents.

Slide 27




## Investigative Protocol

**Message:** If the pharmacist identified any irregularities, review to see how the attending physician and the director of nursing acted on any irregularities identified in the report.

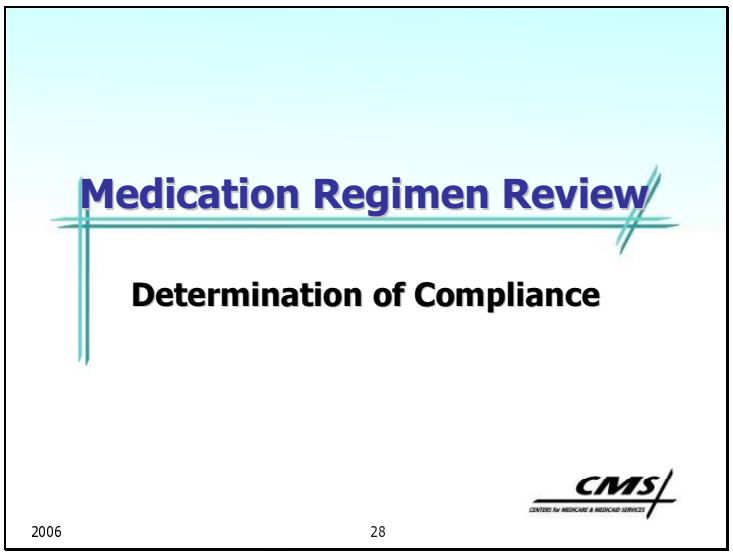
Examples of responses from the attending physician could include:

- Changing the medication regimen in response to the concern raised in the report (or after additional review of the situation);
- Providing a clinically pertinent rationale that is relevant to that specific resident's signs and symptoms, prognosis, test results, etc., documenting or indicating why the benefit of the medication(s) or dose(s) outweighed the risks of the adverse consequence;
- Providing a clinically pertinent rationale for why any gradual dose reduction (for antipsychotic medications) and/or tapering (for other medications) is contraindicated, even for a trial period.

If the pharmacist identified a suspected adverse consequence, and the attending physician did not respond, determine if staff followed up with the attending physician.

If the staff and pharmacist identify a medication that they believe may be causing a serious adverse consequence or a risk of clinically significant adverse consequences for the resident, and the attending physician did not address the risks or harm to the resident, determine what steps staff took; such as contacting the medical director to review the situation and address the issue with the attending physician, as necessary. You may wish to review additional guidance at tag F501 Medical Director.

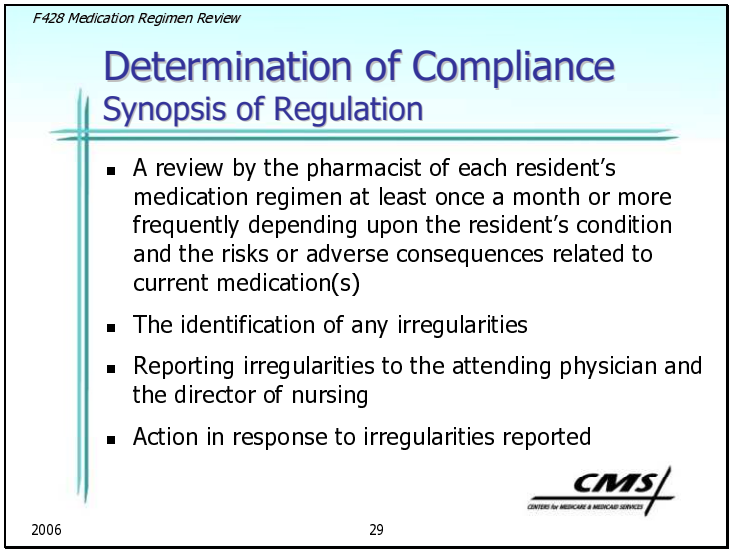
Slide 28




## Determination of Compliance

**Message:** This requirement contains both facility processes and resident specific requirements.

Slide 29

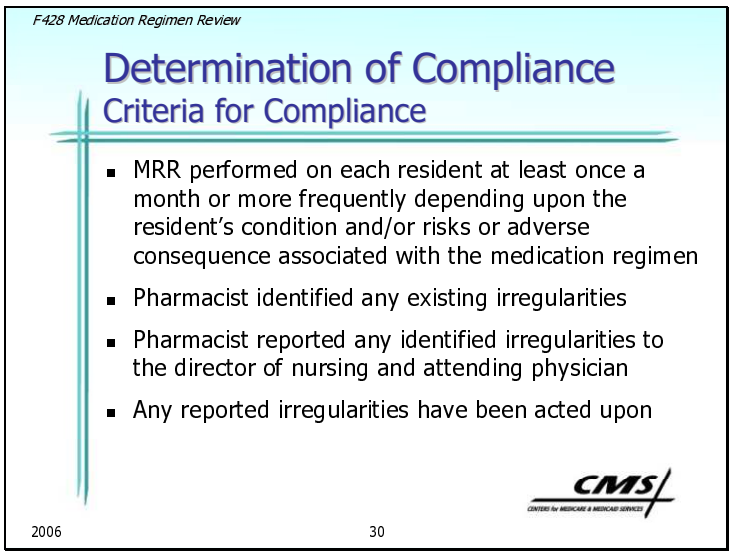



## Synopsis of Regulation

**Note:** *Permit time for participants to review the slide.*

**Message:** We have covered all 4 of these aspects of the regulation addressing MRR.

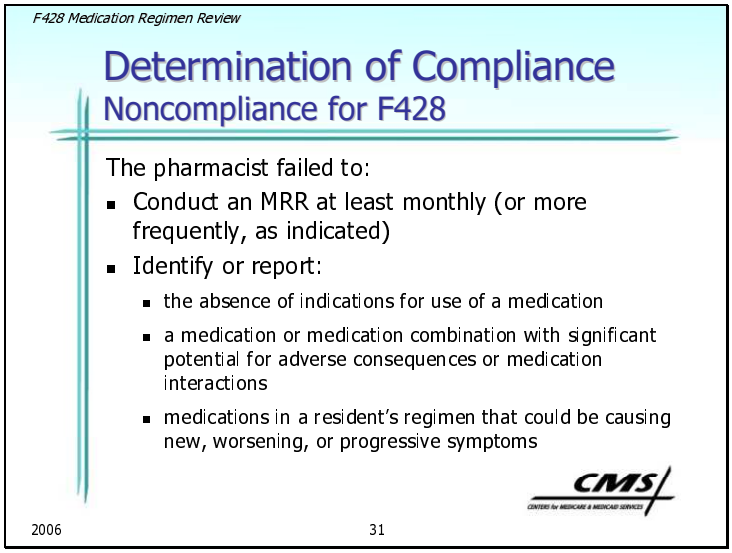
Slide 30




## Criteria for Compliance

**Message:** In your review of the requirements, you will have determined if the MRR was performed on your sampled residents and whether any irregularities were identified and reported, and whether any action was taken in response to the report of irregularities. If the facility did not meet any aspect of the requirement, cite F428.

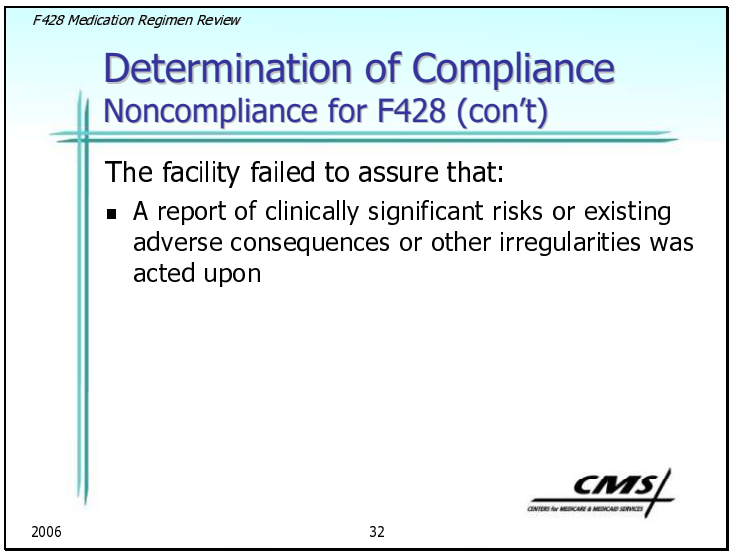
Slide 31




# Noncompliance for F428

**Message:** These are some examples of noncompliance with the MRR requirements. They include examples of pharmacist failure to identify and/or report irregularities as well as facility and/or physician failure to follow through or act upon the notice of an irregularity.

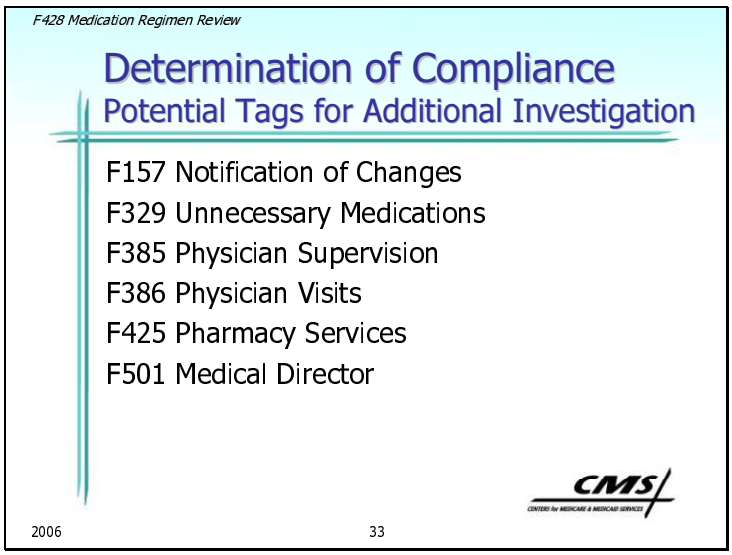
Slide 32




## Noncompliance for F428

**Message:** It is important that the entire process of the MRR is evaluated to assure that the system in place provides for not only the identification and reporting, but also the acting upon the report of any irregularities.

Slide 33




## Potential Tags for Additional Investigation

**Message:** If noncompliance with F428 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. You may have identified concerns such as:

For F157, 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 (for example, a need to discontinue an existing form of treatment due to adverse consequences, or to commence a different form of treatment); or

For F329, 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; or

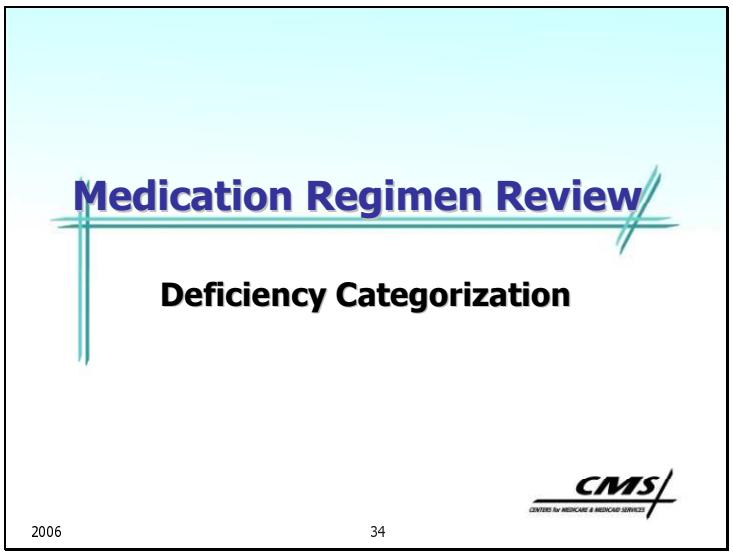
For F385, whether the attending physician supervised the resident's medical treatment, assessing the resident's condition, identifying the need for and continuing use of medication to address the resident's needs, and identifying and addressing adverse consequences related to medications; or

For F386, whether the attending physician or another designated practitioner reviewed the resident's total program of care including medications and treatment; or

For F425, whether the facility has a licensed pharmacist and whether the pharmacist has provided consultation regarding all aspects of pharmaceutical services; or

For F501, 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.

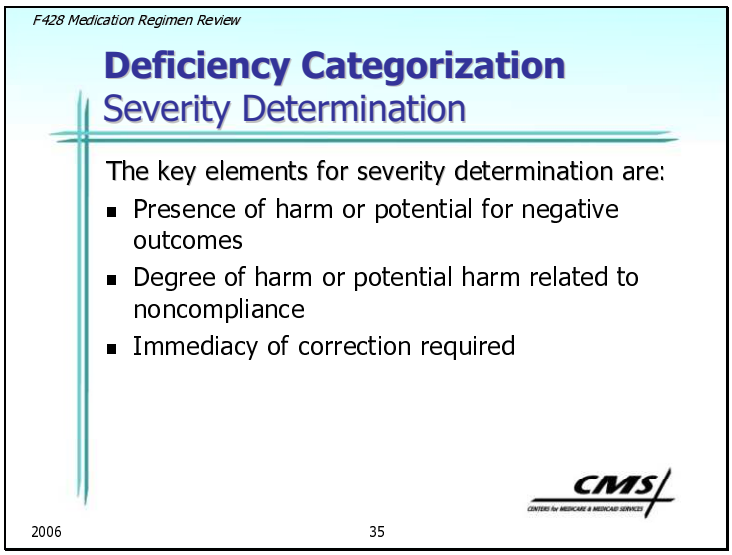
Slide 34




## Deficiency Categorization

**Message:** Once the survey team has completed its investigation, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant harm or potential for harm to the resident.

Slide 35




## Severity Determination

**Message:** **The three elements for severity determination include the following:**

**The presence of potential or actual harm or negative outcome(s) due to a facility failure related to the MRR.** Actual or potential harm or negative outcomes for F428 may include:

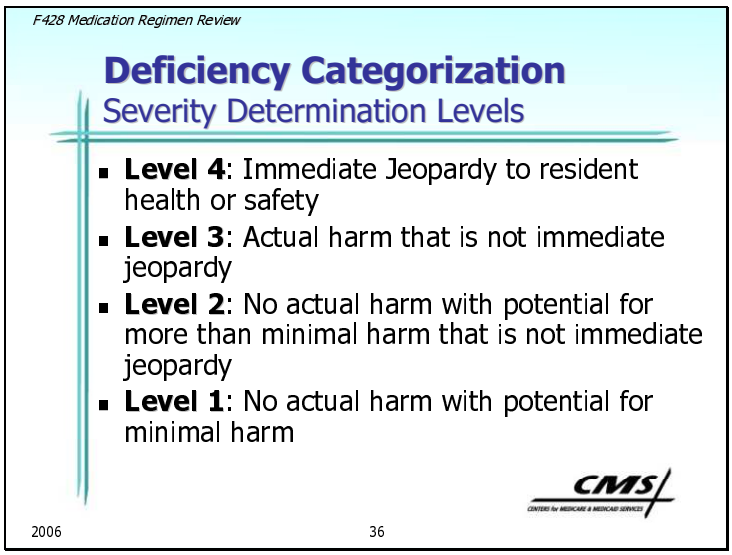
- The resident experienced a clinically significant adverse consequence associated with a medication as a result of the lack of response to an MRR identified irregularity.
- Significant irregularities within the medication regimen were not identified and reported and created the potential for adverse consequences such as overdose, respiratory depression, rash, or anorexia.

**The second element is the Degree of potential or actual harm/negative outcome(s) due to a facility failure related to the MRR and 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.

**And the third key element is the immediacy of correction required.**
The survey team needs to determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

Slide 36

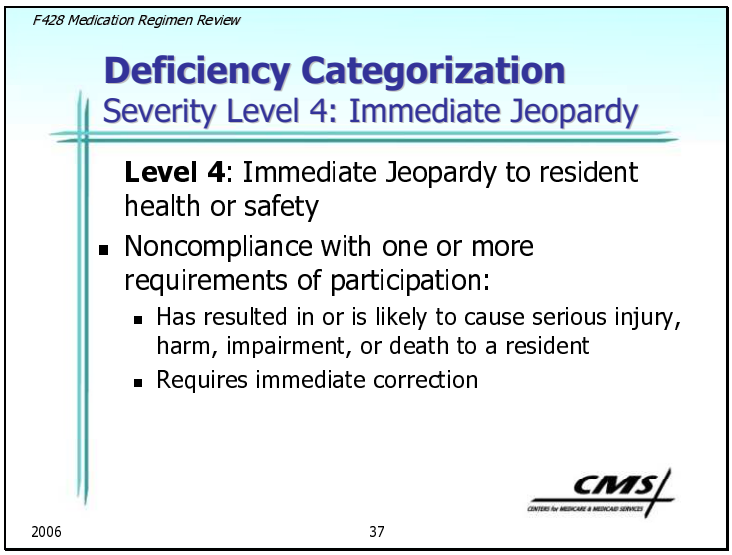



## Severity Determination Levels

**Message:** The survey team must evaluate the harm or potential for harm for tag F428 based upon the four levels of severity. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the non compliance in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

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

Slide 37




## Severity Level 4: Immediate Jeopardy

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

- You may have severity level 4 at this tag, if you have identified non compliance at severity Level 4 (Immediate Jeopardy) at another tag such as F309 Quality of Care, F329 Unnecessary Medications, F332 and F333 Medication Errors, and the noncompliance is related to evidence of process failures for conducting the MRR;

or

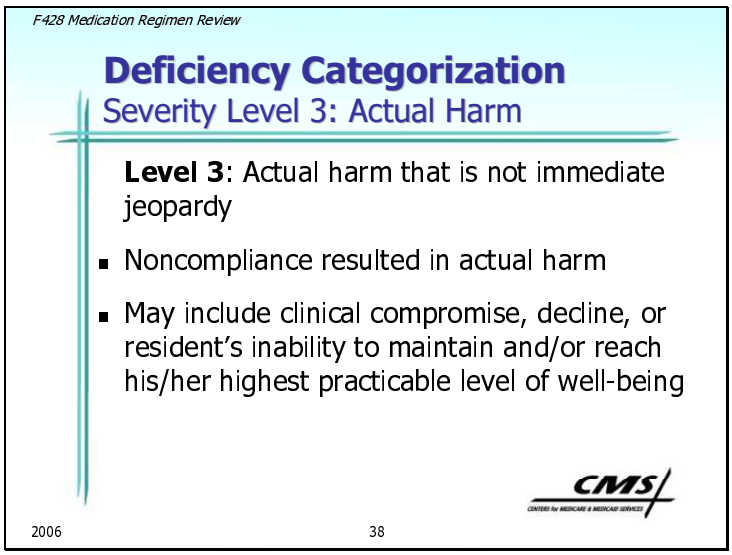
- You may have severity level 4 at this tag if despite identifying irregularities with the potential for serious harm or death, the pharmacist did not report the irregularities to the attending physician or no action was taken on the irregularities reported.

or

- You may have severity level 4 at this tag if you have identified repeated or cumulative failures in multiple areas of the medication regimen review process such as the failure to identify, report, or act upon irregularities that resulted in the resident(s) experiencing serious harm or the potential for serious harm.

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.

Slide 38




## Severity Level 3: Actual Harm

**Message:** Let's discuss some examples of non compliance which would come under Level 3 Severity.

- You may have severity level 3 at this tag if you have identified non compliance at severity Level 3 (actual harm) at another tag such as F309 Quality of Care, F329 Unnecessary Medications, F332 and F333 Medication Errors, and the noncompliance is related to evidence of process failures for conducting the MRR;

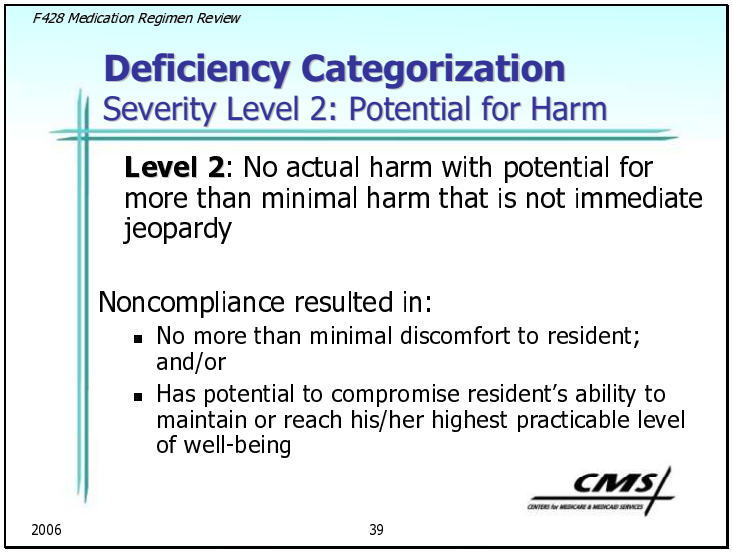
or

- You may have severity level 3 at this tag if the pharmacist's MRR failed to identify the lack of indication for continued use of 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.

or

- You may have severity level 3 at this tag if 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.

Slide 39




## Severity Level 2: Potential for Harm

**Message:** Non compliance which would come under level 2 Severity may include examples such as:

- You may have severity level 2 at this tag if you have identified findings of noncompliance at Severity Level 2 at tag(s) F309, F329, or F333 that show evidence of process failures for conducting the MRR.

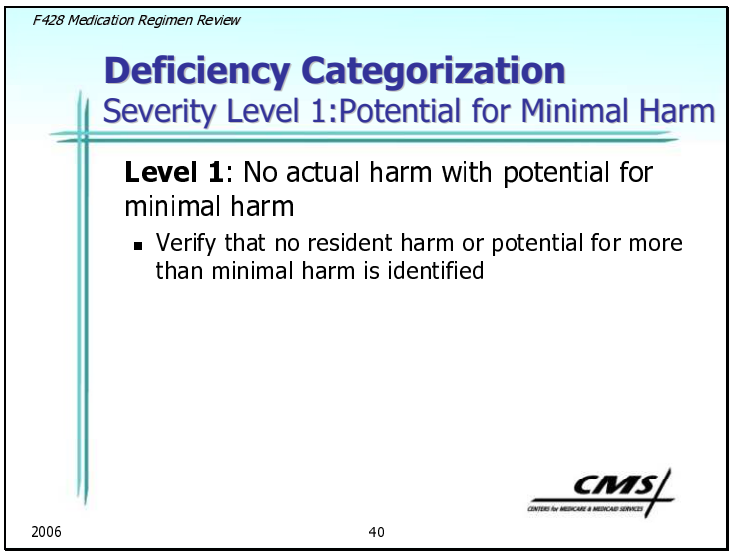
or

- You may have severity level 2 at this tag, if the facility failed to respond to the pharmacist's notification that the resident was not receiving one medication that was ordered; however, there was no change in the resident condition.

or

- The pharmacist's MRR failed to evaluate and report on the potential for an adverse consequence of a medication known to cause anorexia, in a resident with a recently decreased appetite and who had not experienced an unplanned weight loss.

Slide 40




## Severity Level 1: Potential for Minimal Harm

**Message:** An example of noncompliance with severity level 1 includes:

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.