

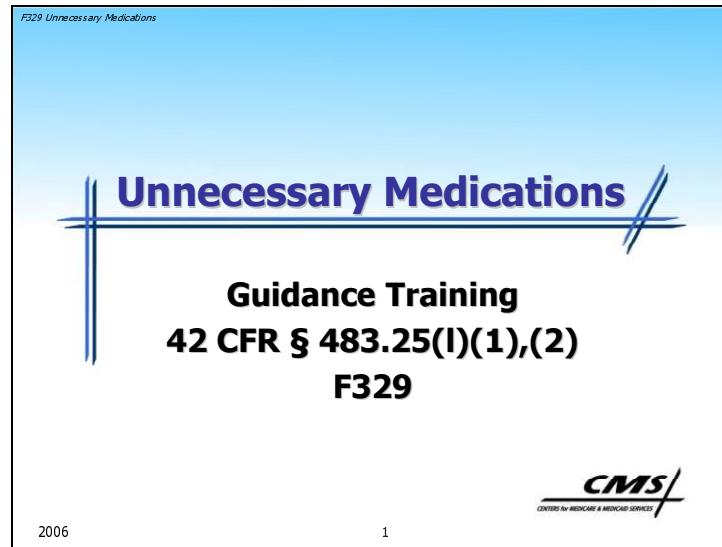


Centers for Medicare & Medicaid Services (CMS)

**Unnecessary Medications Guidance Training  
Instructor's Guide  
42 CFR § 483.25(l)(1),(2)  
F329**

2006

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



## Unnecessary Medications

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**Notes:**

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

**Message:**

Today, as we discuss Unnecessary Medications, you will note that we have used the term medications rather than drugs throughout this Guidance. The term “medications” is consistent with the regulatory provisions and has a more positive connotation. There are, however, instances where the term drug has been retained because it has become part of standard nomenclature, such as Adverse Drug Reaction.

F329 Unnecessary Medications

## Training Objectives

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

- Describe the intent of the regulation
- Explain the various medication management considerations required by the regulations
- Utilize the components of the investigative protocol
- Identify compliance with the regulation
- Appropriately categorize the severity of noncompliance

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## Training Objectives

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**Message:** As we know many residents take multiple medications. Each medication and combination of medications has the potential to affect the resident's longevity, quality of life and physical, mental and psychosocial function.

Therefore, it is important to remember, as we discuss Unnecessary Medications, the importance of the role each of us plays with regard to:

- Understanding the Regulatory requirements and Guidance,
- Applying the Investigative Protocol,
- Determining Compliance, and
- Assigning Levels of Severity to Noncompliance.

The Guidance to Surveyors contains a lot of information, but the information can be broken down into different segments which essentially apply the care process considerations to the management of medications.

**Quote of the Day:** The secret to getting ahead is getting started. The secret to getting started is breaking your complex overwhelming tasks into small manageable tasks, and then starting on the first one. ~ Mark Twain

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## Discussion Question

***What elements are included in the care process?***

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## Discussion Question

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**Message:** Talking about getting started, we mentioned that medications are an integral part of resident care and that the management of medications is based on the care process... The care process, problem solving process and the medical model are all similar processes.

**Discussion Question**

Answer to Discussion Question:

- Recognition/Identification of problem
- Assessment and definition of causative factors and diagnosis
- Management/Treatment or Development and Implementation of approaches
- Monitoring
- Reevaluation, assessment, and modification of approaches as necessary

Throughout today's session we will be discussing the role that the care process plays in managing medications.

F329 Unnecessary Medications

## Regulatory Language

### CFR § 483.25(l)(1) Unnecessary Medications

(1) *General.* Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

- (i) In excessive dose (including duplicate drug therapy); or
- (ii) For excessive duration; or
- (iii) Without adequate monitoring; or

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## Regulatory Language

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**Message:** Like many of the other long term care requirements, this Unnecessary Medications regulation focuses attention on the individual resident and not on the facility's population as a whole. Although much of the discussion in the Guidance centers on the older individual, the requirements of this regulation are applicable to the use of medication by each resident, regardless of age.

The regulatory text addressing Unnecessary Medications is divided into 2 major components: General and Antipsychotics.

F329 Unnecessary Medications

## Regulatory Language

### CFR § 483.25(l)(1) Unnecessary Medications

**(Cont'd)**

- (iv) Without adequate indications for its use; or
- (v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
- (vi) Any combinations of the reasons above.

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## Regulatory Language Continued

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**Message:** The General requirements dealing with dose, duration, indications for use, monitoring, and adverse consequences are applicable to all classes of medications, including the antipsychotics, but there are a couple of additional requirements governing the use of antipsychotics.

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## Regulatory Language

CFR § 483.25(l)(2) Unnecessary Medications

(2) *Antipsychotic Drugs.* Based on a comprehensive assessment of a resident, the facility must ensure that—

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and

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## Regulatory Language Continued

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**Message:** The 2 requirements specific to the use of antipsychotic medications used to have separate tag numbers (F330 and F331), but all the requirements regarding Unnecessary medications have now been folded into the F329 tag.

The requirement regarding not initiating an antipsychotic agent unless the antipsychotic is necessary to treat a specific condition mirrors the considerations used for identifying indications for use of any other medication. Therefore, we have not repeated that guidance specifically for the use of antipsychotic medications but have incorporated antipsychotic medications in the general guidance regarding indications for use.

F329 Unnecessary Medications

## Regulatory Language

CFR § 483.25(l)(2) Unnecessary Medications

(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

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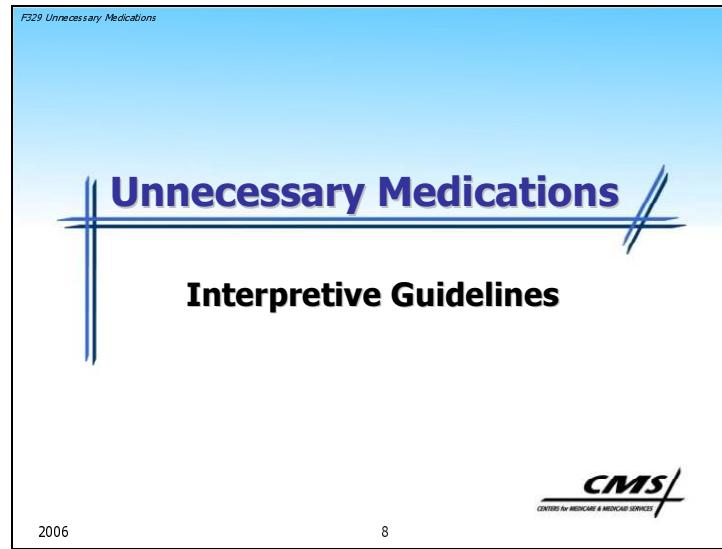
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## Regulatory Language Continued

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**Message:** While the principle of using the lowest effective dose for only the necessary duration is explicitly required in the language addressing Gradual Dose Reduction (GDR) for antipsychotics, that principle underlies the requirements addressing excessive dose and duration for all classes of medications.

We will discuss tapering, GDR, and behavioral interventions over the course of this presentation.



## Interpretive Guidelines

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**Message:** These interpretive guidelines provide CMS' authoritative interpretation of what the regulatory language means and will replace the current guidelines in Appendix PP for F329, F330, and F331.

The Investigative Protocol replaces the Investigative Protocol for Adverse Drug Reactions (ADR) currently in Appendix P.

F329 Unnecessary Medications

## Unnecessary Medications

### Components of the Interpretive Guidelines

- Intent
- Definitions
- Overview
- Medication Management
- Medication Tables
- Investigative Protocol
- Determination of Compliance
- Deficiency Categorization

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## Components of the Interpretive Guidelines

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**Message:** We will not discuss all of these components in great depth today, but we would like to cover the intent, some definitions, medication management and the regulatory considerations, the investigative protocol, determination of compliance and severity guidance in a little more detail.

It is important to note that the medications listed in the tables are presented to highlight examples of some common concerns regarding medication use. The lists are not all-inclusive and should not be the sole source of information used by the survey team to review medications prescribed for a resident. The lists should not be interpreted to be a new version of the Beers' list of medications. The lists of medications from previous versions of this guidance have been incorporated as appropriate into the tables of this revised guidance.

F329 Unnecessary Medications

## Interpretive Guidelines

### Intent

Medication Regimen is managed to:

- Promote/maintain highest practicable well-being
- Limit medications, doses and duration to clinically indicated
- Consider non-pharmacological interventions
- Minimize adverse consequences
- Recognize condition change/decline, evaluate role of medications and modify regimen if needed.

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## Intent

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**Message:** The intent of this requirement is that each resident's entire drug/medication regimen be managed and monitored to achieve the following goals:

- The medication regimen helps promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being, as identified by the resident and/or representative(s) in collaboration with the attending physician and facility staff;
- Each resident receives only those medications, in doses and for the duration clinically indicated to treat the resident's assessed condition(s);
- Non-pharmacological interventions (such as behavioral interventions) are considered and used when indicated, instead of, or in addition to, medication;
- Clinically significant adverse consequences are minimized; and
- The potential contribution of the medication regimen to an unanticipated decline or newly emerging or worsening symptom is recognized and evaluated, and the regimen is modified when appropriate.

The facility and attending physicians are responsible for managing and monitoring the medication regimen. The surveyor's role is to investigate the basis for decisions regarding the use of medications and identify when there has been a breakdown in the care process.

Because we recognize that the facility generally does not initiate or discontinue medications, we have acknowledged that the facility and the physician or prescriber have collaborative roles to maximize the benefit to the resident.

F329 Unnecessary Medications

## Interpretive Guidelines

### Definitions

- Adverse Consequences
- Behavioral Interventions
- Clinically Significant
- Distressed Behavior
- Indications for Use
- Monitoring
- Psychopharmacological Medication

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## Definitions

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**Message:** Although the guidelines include numerous definitions we will only discuss these seven terms. The rest of the definitions are defined in the Interpretive Guidelines. The definitions in the guidelines are provided to clarify terminology related to medications and to the evaluation and treatment of residents.

F329 Unnecessary Medications

## Interpretive Guidelines

### Definitions

**Adverse consequence** - is 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).

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## Definitions

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**Message:** “Adverse Consequences” is the term used in the regulatory text. Adverse drug reaction and side effect were the terms most frequently used in some of the previous Guidance. While Adverse Consequence incorporates the concept of Adverse Drug Reaction (ADR), it is a broader concept than ADR. An adverse consequence may include, for example, a fracture that occurred as a result of a fall that was likely associated with the use of medications, such as medications that cause clinically significant orthostatic hypotension, dizziness, muscular incoordination and so forth.

Although a side effect may be a type of ADR, it does not necessarily rise to the level of an adverse consequence. In fact, some prescribers will order certain medications specifically for their known side effects, for example, antidepressants with sedative properties. Unless the medication has a negative impact upon the resident, the side effect would not meet the definition of an adverse consequence.

F329 Unnecessary Medications

## Interpretive Guidelines

### Definitions

**Behavioral Interventions** – individualized non-pharmacological approaches (including direct care and activities) that are provided as part of a supportive physical and psychosocial environment and are directed toward preventing, relieving, and/or accommodating a resident's distressed behavior.

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## Definitions

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**Message:** One of the requirements addressing the use of antipsychotics is that the resident receives behavioral interventions in an effort to reduce or discontinue the antipsychotic medication. There may be several levels of behavioral interventions. The types of interventions need to be based upon an accurate assessment. The facility staff is responsible for the provision and integration of the interventions into the daily activity of the resident. If a resident receives antipsychotics and requires specialized services for the mentally ill, the facility is obligated to work with the state to assure that these services are provided.

F329 Unnecessary Medications

## Interpretive Guidelines

### Definitions

**Clinically significant** – refers to 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.

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## Definitions

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**Message:** “Clinically significant” is a new definition and is intended to separate out positive and negative issues or items of importance from those that are insignificant or a minor consequence or nuisance.

F329 Unnecessary Medications

## Interpretive Guidelines

### Definitions

**Distressed behavior** - is behavior that reflects individual discomfort or emotional strain. It may present as crying, apathetic or withdrawn behavior, or as verbal or physical actions such as: pacing, cursing, hitting, kicking, pushing, scratching, tearing things, or grabbing others.

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## Definitions

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**Message:** Distressed behavior captures the concept that the resident's behavior is the result of personal, physical, mental, or psychosocial distress. The term "distressed behavior" is less pejorative than previous terms and suggests that there is something causing or contributing to the behavior.

When medications are used to address distressed behavior, the nature of the behavior needs to be described, and the effect of the medication on the frequency and characteristics of the target behavior needs to be evaluated and documented, and to the extent possible, the underlying causes eliminated or reduced.

F329 Unnecessary Medications

## Interpretive Guidelines

### Definitions

**Indications for use** – is the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident's condition and therapeutic goals and is consistent with manufacturer's recommendations and/or clinical practice guidelines, clinical standards of practice, medication references, clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.

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## Definitions

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**Message:** A diagnosis alone without substantiating information in the record is not necessarily justification for the use of a medication. For example, adding a diagnosis of schizophrenia next to an order for an antipsychotic, or GERD next to an order for a protein pump inhibitor (PPI) when there is no supporting documentation that substantiates the diagnosis, does not meet the regulatory requirement regarding Indications for Use.

Another example could be a resident who is receiving a medication for which the resident has a known allergy. In this case, there should be documentation of an evaluation that indicates that the benefit of the resident receiving the medication exceeds the risk. This would indicate the appropriate consideration of the medication.

On some occasions, medications may be considered as meeting the requirements for Indications for Use based on clinical standards of practice. For example, prophylactic use of low-dose aspirin, pneumonia vaccine, or annual flu vaccines, when there are no contraindications, would meet the requirement.

F329 Unnecessary Medications

## Interpretive Guidelines

### Definitions

**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.

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## Definitions

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**Message:** Monitoring involves a two pronged approach to evaluating how the resident is responding to the treatment. One approach involves staff such as nursing assistants, dietary staff, physical therapist, or activities staff, who have an awareness of the resident and his or her usual patterns and level of functioning and who could detect and report any changes either positive or negative.

The second approach involves a periodic objective reassessment of the resident and his or her response to the medication.

F329 Unnecessary Medications

## Interpretive Guidelines

### Definitions

**Psychopharmacologic medications** – any medication used for managing behavior, stabilizing mood, or treating psychiatric disorders.

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## Definitions

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**Message:** Medications within any number of pharmacological classes potentially may be considered psychopharmacological medication. Generally, the therapeutic goal for use of the medication will determine if it meets the definition of a psychopharmacologic medication.

For example, if a resident is receiving an anticonvulsant medication and there is or has been no substantiated seizure disorder, it would be appropriate to inquire about the clinical rationale, therapeutic goals, and monitoring for use of the medication, because it could be being used to manage behavior.

Some other classes of medications that are, or have the potential to be psychopharmacologic agents include: the cognitive enhancers, antidepressants, antimanic medications, antipsychotics and anti-anxiety agents (anxiolytics).

F329 Unnecessary Medications

## Interpretive Guidelines Overview

### Goals for Medication Use:

- Maintain or improve function and wellbeing

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## Overview

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**Message:** When one or more medications are being used, the medications are an important aspect of resident care. They are administered for a variety of reasons, such as:

- Preventing a disease or a symptom;
- Diagnosing a condition or disease;
- Curing an illness;
- Slowing or arresting a disease process; or
- Reducing or eliminating symptoms.

The goal for the use of any medication is to achieve a positive physical, mental, and psychosocial outcome. As with all resident care, determining the appropriate use of medication involves:

- An accurate and complete assessment of the resident's condition and goals for treatment;
- Monitoring for the response to the medication;
- Consideration of clinical standards of practice and manufacturer's guidelines regarding dose and duration;
- Consideration of the type or characteristics of the medication.

In some cases, the use of non-pharmacological interventions may eliminate the need for a medication or may permit use of the lowest possible dose for a shorter duration.

F329 Unnecessary Medications

## Interpretive Guidelines

### Overview

- Non-pharmacological approaches require assessing and understanding causes for need of medication
- Approaches involve reduction/elimination of impediments, triggers and causes

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## Overview

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**Message:**

As a surveyor, you would expect some evidence that the interdisciplinary team, including the physician, other prescribers, and potentially the pharmacist, has determined, to the extent possible, the root cause of the condition, symptom, or disease which has lead to considering the use of a medication.

As part of that analysis, contributing factors and triggers are identified and in some situations, non pharmacological interventions may have been used instead of pharmacological interventions to address the issues.

**Examples:**

For example, if a resident has insomnia, have underlying contributing factors been considered, such as a caffeine intake in the late afternoon or evening, procedures that interrupt sleep, or the presence of excessive noise, variations in temperatures, such as too hot or too cold, and so forth.

Or if a resident has joint or muscle pain, has the level of activity, or positioning, or presence of swelling been considered?

What about the resident who may have episodic verbal or physical outbursts, was there an evaluation for the triggers to that behavior?

F329 Unnecessary Medications

## Interpretive Guidelines

### Overview

Examples of Non-Pharmacological Interventions:

- Modification of environment
- Modification/elimination of psychological stressors
  - Accommodation of previous lifelong activities or roles
  - Modification of staff/resident interactions
  - Behavioral Interventions

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## Overview

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**Notes:** Non Pharmacologic Interventions continued

**Message:** These are a few of the categories of non-pharmacological approaches that could be considered. Environmental considerations may include eliminating overcrowding; adjusting temperatures or lighting; or not using intercoms at night; or providing accessible equipment for toileting.

Perhaps it may be necessary to adjust the timing of care routines or to support the resident who has historically arisen early or gone to bed later, to modify the way staff approach the resident such as, addressing the resident by name before initiating any contact, approaching from the front so the resident may recognize his/her presence.

F329 Unnecessary Medications

## Interpretive Guidelines

### Medication Management

- Resident Choice & Advance Directives
- Indications for Use
- Monitoring
- Dose
- Duration
- Tapering/ Gradual Dose Reduction
- Adverse Consequences

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## Medication Management

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**Message:** The Medication Management discussion is the heart of the document and provides guidance for understanding the various regulatory considerations regarding unnecessary medications.

There are numerous places in the clinical record where information about aspects of the care process related to medications may be found. We don't require information to be in any particular location within the record. If there is difficulty locating information during a survey, the surveyor should ask the facility for assistance in locating the information.

The attending physician has a key leadership role in developing, monitoring and modifying the medication regimen and non-pharmacological interventions. The physician works with the resident and/or the resident's representative, other professionals and direct care staff who advocate on behalf of the resident and who identify, assess, monitor, and communicate the resident's needs, goals, and changes in condition.

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## Medication Management

### Resident Choice

- Right to make informed choices about care
- Physician and staff facilitate resident's decisions
- Safety of residents is considered

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## Resident Choice

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**Message:** A resident, or the resident's representative on behalf of the resident, has the right to be informed about the resident's condition; treatment options; risks/benefits and expected outcomes of treatment, and for the purpose of this discussion, to subsequently make informed choices about the use of medications including the right to refuse care and treatment.

The resident has the right to refuse treatment and if he or she does, the facility staff and physician should counsel the resident on the risks related to the refusal, and may offer appropriate alternatives such as offering the medication at another time or in another dosage form, as appropriate, or offer an alternative medication or non-pharmacological approaches, if available.

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## Medication Management

### Advance Directives

- Care provided consistent with the resident's condition and care instructions
- Do Not Resuscitate (DNR) refers only to CPR

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## Advance Directives

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**Message:** A resident may have written or verbal directions related to treatment choices (or a decision has been made by the resident's surrogate or representative) in accordance with state law. An advance directive is a means for the resident to communicate his or her wishes, which may include withdrawing or withholding medications.

Whether or not the resident has an advance directive, the facility is responsible for providing treatment, support, and other care consistent with the resident's condition and resident care instructions.

A Do Not Resuscitate (DNR) order does not indicate that the resident is declining other appropriate treatment and services.

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## Medication Management

### Indications for Use of Medication

Indications require evaluation of information such as:

- Comorbid conditions, signs, and symptoms
- Goals and preferences
- Allergies, potential interactions
- Past and current medications and interventions
- Recognition of need for end-of-life or palliative care
- Refusal of care and treatment
- Assessment instruments and diagnostic tools

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## Indications for Use of Medication

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**Message:** Indications for:

- Initiating;
- Continuing;
- Withdrawing a medication; or
- Withholding or modifying dosages;

are determined by assessing the resident's underlying condition, symptoms, and preferences.

An evaluation may include a variety of diagnostic tools and tests which establish a baseline and help determine diagnoses and prognoses. The extent of the evaluation may vary with the situation, such as whether the medications are being re-ordered or are the result of a condition change or decline.

F329 Unnecessary Medications

## Medication Management

### Indications for Use of Medication

Analysis is used to:

- Rule out other causes of symptoms
- Identify whether signs/symptoms are significant/persistent to warrant medication
- Determine if the medication addresses symptom/condition
- Identify whether the benefits outweigh risks

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## Indications for Use of Medication

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**Message:** Analyzing the data collected is an integral aspect of assessment. Analysis helps determine, to the extent possible, causes of symptoms that may or may not be disease related or that are caused by a disease not originally suspected. It helps clarify the clinical rationale or necessity for a medication (and potentially for non-pharmacological interventions). It also helps determine which medication and what dose offers the most benefit with the least risk.

The regulation does not prohibit “off-label use” or the use of medications for indications other than those indications originally approved by the FDA. For example, some anticonvulsants and some antidepressants have been prescribed to treat chronic pain. The facility should be able to refer to or provide clinical practice guidelines or published, peer-reviewed clinical studies supporting the off-label use.

Table 1 provides additional discussion regarding indications for use and documentation recommendations for a number of medications. The newly revised guidance addresses indications for use of antipsychotics both for approved and off-label uses.

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## Medication Management

### Indications for Use of Medication

#### Indications for Use of PRN

- Circumstances for use are evaluated and defined
- Frequency of administration defined

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## Indications for Use of Medication

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**Message:** The decision to use an as needed or PRN medication relies upon the same type of evaluation of the resident's condition, signs and symptoms, goals, and other considerations as required for other medications.

There is the additional consideration, however, of defining what specific circumstances warrant the episodic use of a medication and how frequently the medication may be used. As with other medications, the effectiveness of the PRN medications needs to be evaluated and monitored.

In some cases such as control of pain, the evaluation of the effectiveness will help determine whether the medication should be administered on a routine rather than PRN basis. If a medication is being ordered on a PRN basis to modify or alleviate distressed behavior, the indications for use should be clearly defined in objective terms such as defining what specific symptom is being addressed.

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## Medication Management

### Indications for Use of Medication

What do these 5 circumstances have in common?

- A clinically significant change in condition/status
- A new or recurrent clinically significant symptom
- A worsening of an existing problem or condition
- An unexplained decline in function or cognition
- Psychiatric disorders or distressed behavior

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## Indications for Use of Medication

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**Discussion** What do these 5 circumstances have in common?

**Question:**

**Answer:** There are a couple of common elements we'd like to focus on. First, each of these circumstances may be directly related to the use of one or more medications. The interdisciplinary team, including the prescriber, should evaluate the role of the medication regimen as a contributing factor before another medication is added to address a condition, problem or symptom.

A second common element underlying at least the first four of these conditions is that each of the conditions has involved some *degree* of change from a baseline condition. It is important, therefore, that the resident's condition be monitored in order to identify these changes and allow a reevaluation of the resident's condition, as soon as possible. Some of the long-term psychiatric diagnoses may not have involved a change, but other psychiatric conditions may represent a change, such as delirium or exacerbation of an enduring psychiatric disorder.

**Message:** There may be other circumstances when the resident's condition and proposed medications are evaluated including admission or readmission, a new medication order or renewal of orders, medications ordered by multiple prescribers, or an irregularity identified by the pharmacist during the medication regimen review (MRR).

F329 Unnecessary Medications

## Medication Management

### Monitoring for Efficacy & Adverse Consequences

**Effective Monitoring:**

- Understand indications and goals for use
- Identify baseline information/resident condition
- Understand characteristics of medication
- Ongoing vigilance
- Periodic re-evaluation

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## Monitoring for Efficacy & Adverse Consequences

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**Message:** Effective monitoring relies upon understanding the indications and goals for using the medication, identifying relevant baseline information, understanding the resident's condition and identifying the criteria for evaluating the benefit(s) of the medication.

Monitoring the resident's response to medication is needed to evaluate the ongoing benefits and risks and to provide a basis for deciding whether to continue or modify the use of a medication.

Monitoring involves:

- Evaluating resident's progress towards achieving therapeutic goals;
- Recognizing when adverse consequences may be emerging or have already occurred;
- Evaluating whether the medication is implicated in an adverse consequence; and
- Modifying the medication regimen, if indicated.

A study reported in 2005 by Gurwitz et all, reported that 42% of 815 adverse drug events In nursing homes were judged preventable, and that common omissions included inadequate monitoring and either lack of response or a delayed response to signs, symptoms, or laboratory evidence of medication toxicity.

Monitoring requires being vigilant and recognizing changes in condition both improvement and decline, and reporting and responding to the findings. Facilities can use both quantitative and qualitative monitoring parameters to facilitate a consistent and objective way to collect information. Monitoring may involve an objective evaluation such as assessing vital signs or using more formal assessment tools.

The guidance within the document provides a table that identifies examples of some tools that may be used for an initial assessment and/or monitoring, including behavioral monitoring.

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## Medication Management

### Monitoring for Efficacy & Adverse Consequences

Steps in Monitoring

- Identify information and how it will be obtained and reported
- Determine frequency
- Define method to communicate, analyze and act
- Re-evaluate and updating approaches

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## Monitoring for Efficacy & Adverse Consequences

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**Message:** Processes the facility may utilize when developing the criteria for monitoring medications include:

- Identifying what information is to be collected, who will be responsible for collecting the information, and how and where it will be recorded;
- Determining the frequency for the periodic planned evaluation of progress toward the therapeutic goals or screening for emergence of adverse consequence, which depends largely on factors we've discussed previously such as the resident's condition and the pharmacologic properties of the medication including special considerations for psychopharmacological medications;
- Defining who will communicate with the prescriber, what information should be conveyed, and when to ask the prescriber to reevaluate the medication regimen and consider modifying the regimen; and
- Re-evaluating and updating monitoring approaches when indicated, such as when the resident experiences changes, the medication regimen or care and services has changed or there are changes in the product specifications or FDA warnings.

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## Medication Management

### Monitoring for Efficacy & Adverse Consequences

Sources may help to define monitoring criteria:

- Manufacturers' package inserts, black-box warnings
- Facility policies and procedures
- Pharmacists
- Clinical guidelines or standards of practice
- Medication references
- Published clinical studies or articles

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## Monitoring for Efficacy & Adverse Consequences

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**Message:** There are many resources available for establishing the criteria for monitoring. Monitoring parameters need to be based on the resident's condition, the pharmacologic properties and associated risks of the medication being used, the individualized therapeutic goals, and the potential for clinically significant adverse consequences.

Some medications may be monitored using serum medication concentrations. The characteristics of some medications such as warfarin or vancomycin, which have limited ranges of safety, rely substantially on the serum medication concentrations reported. It is important to note that the levels of some other types of medications need to be reviewed in relation to the clinical presentation of the resident, such as the presence of seizure activity in a resident taking anticonvulsants.

Not all medications need to be, nor should they be, listed on the resident's care plan. Those that are relevant to include are those, for example, that have black box warnings, or which have the risk for clinically significant adverse consequences, such as warfarin, digoxin, antidepressants, amiodarone or antipsychotics.

If the facility has a written protocol or procedure addressing the monitoring specific to one of more of the medications the resident is receiving, the care plan may refer the care givers to that protocol, if the protocol is readily available within that unit, and in those cases, it is important to evaluate if those protocols are being implemented for the resident being reviewed.

F329 Unnecessary Medications

## Medication Management

### Monitoring for Efficacy & Adverse Consequences

- Review Psychopharmacological and Sedative/Hypnotic medications quarterly
- Documentation must include:
  - Resident's target symptoms and effect of medication
  - Changes in resident's function
  - Medication-related side effects or adverse consequences

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## Monitoring for Efficacy & Adverse Consequences

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**Message:** The interdisciplinary team should be reviewing medication use of the resident at least quarterly, including whether there is a need to continue the use of psychopharmacologic and sedative/hypnotic medications, and whether the dose continues to be appropriate.

Part of that review would include the effect of the medication on the severity, frequency, and other characteristics of the target symptoms; whether there have been any changes in the resident's function during the previous quarter; and whether the resident has experienced any medication-related adverse consequences during the previous quarter.

For example, the team would look at whether the resident's function has declined as a result of falls that may be associated with the prescribed medications or whether sleep hygiene techniques have been successfully implemented and the resident may be able to tolerate less frequent use or elimination of sedative hypnotics. Additionally, the review should evaluate whether the use of the medications is consistent with the current standards of practice, relevant clinical practice guidelines and/or manufacturer's specifications.

F329 Unnecessary Medications

## Medication Management

### Dose

- Dose influenced by:
  - Clinical response
  - Possible adverse consequences
  - Other resident- and medication-related variables
  - Route of administration

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## Dose

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**Message:** A prescriber's order for the dose of a medication is based on a variety of factors including the resident's diagnoses, signs and symptoms, current condition, age, lab and other test results, input from the interdisciplinary team about the resident, coexisting medication regimen and the type of medications, and therapeutic goals.

It is important to remember when reviewing the doses prescribed that many medications have not been tested on individuals with the advanced age or conditions of the nursing home populations and that adverse consequences can occur even if the dose received is within the manufacturer's specifications and relevant clinical practice guidelines.

Routes of administration affect the amount or dose of a medication received and require compliance with the manufacturer's guidelines for use. For example, the dose the resident receives from a fentanyl patch will be affected by the integrity of the patch and whether there is any additional heat or cold in the area of the patch. Doses may also be affected by the rate of an IV drip or crushing or chewing a sustained release oral capsule or tablet.

F329 Unnecessary Medications

## Medication Management

### Dose

- Duplicate therapy generally not indicated
- Examples of potentially problematic duplicate therapy:
  - ✓ Use of more than one product containing same medication
  - ✓ Concomitant use of multiple benzodiazepines
  - ✓ Use of medications from different therapeutic categories that have similar effects/properties

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## Dose

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**Message:** Unless current clinical standards of practice and documented clinical rationale confirm the benefit of using multiple medications from the same pharmaceutical class or with similar therapeutic effects, duplicate therapy is generally not indicated.

The documentation clarifies the rationale for and benefits of duplicate therapy and the approach to monitoring for benefits and adverse consequences.

Duplicate therapy may lead to a variety of outcomes, such as excessive doses and adverse consequences resulting from the additive effective of the compounds.

F329 Unnecessary Medications

## Medication Management

### Duration

Common considerations for appropriate duration:

- Enduring condition
- Time-limited condition
- Facility stop order or prescriber's order

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## Duration

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**Message:** Many conditions, such as hypertension or schizophrenia, require treatment for extended periods, while others, such as infections or GI upset, may resolve and no longer require medication therapy.

Periodic re-evaluation of the medication regimen is necessary to determine whether prolonged or indefinite use of a medication is indicated and is consistent with manufacturer's specifications or current standards of practice. Some medications have a manufacturer's cautionary note that the medication should not be used beyond a certain amount of time.

If medication initiated for a time-limited condition is continued after the initial indication for its use has resolved or medication is used beyond the time frame specified by the manufacturer, surveyors should expect to see documentation of the clinical rationale for the continued use of the medication.

Medication is discontinued in accordance with facility stop order or prescriber's order, unless justification for extended use is documented.

F329 Unnecessary Medications

## Medication Management

### Tapering and GDR

Goals of tapering or Gradual Dose Reduction (GDR):

- Use lowest effective dose
- Discontinue medication that no longer benefits the resident
- Minimize exposure to increased risk of adverse consequences

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## Tapering and GDR

**Message:** The guidance defines Gradual Dose Reduction as “the stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.”

Tapering may be indicated when the resident’s clinical condition has improved or stabilized or the underlying causes of symptoms have resolved and the type of medication requires gradual reduction of the dose in order to avoid adverse consequences that may occur, if the medication is stopped abruptly.

When a side effect is becoming troublesome or other medication-related adverse consequences may be emerging, the medication and dose should be evaluated to determine whether the dose can be reduced and still be effective or whether the medication should be discontinued.

The timing and duration of attempts to taper any medication depend on evaluation of multiple factors, such as the resident’s condition, characteristics of the medication, the medication regimen as a whole, etc.

F329 Unnecessary Medications

## Medication Management

### Tapering and GDR (Cont'd)

*When would the interdisciplinary team evaluate the resident's response to medications and consider reduction or discontinuation of medications?*

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## Tapering and GDR

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**Question:** In addition to the required comprehensive assessments, when would you expect evaluation of the resident's response to the medication(s) and consideration of whether reduction or discontinuation of medications is indicated?

**Answer:**

- During monthly medication regimen review
- During review of total care plan and renewing of orders
- During quarterly MDS review

We've already discussed monitoring of psychopharmacological and sedative-hypnotic medications and the expectation for a quarterly review of necessity and dose.

F329 Unnecessary Medications

## Medication Management

### Tapering and GDR (Cont'd)

- Antipsychotics & Psychopharmacological
  - Attempt GDR during two separate quarters initially; then attempt GDR annually
  - Contraindications to GDR:
    - Symptoms return or worsen
- Sedatives/Hypnotics
  - If used routinely, attempt GDR quarterly
  - Contraindications to GDR:
    - Physician documents rationale re: impaired function or exacerbation of disorder

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## Tapering and GDR

**Message:** The discussion in the Guidance regarding Gradual Dose Reduction (GDR) and the time frames has been significantly simplified. The Guidance is now more consistent between classes of medication such as anxiolytics and antipsychotics and speaks of quarterly time frames for review and attempts at GDR.

The expectation is that if tapering or GDR successfully lowered a dose once and the resident's condition remained stable, there should be continued attempts to lower the dose until the lowest effective dose has been achieved.

During the first year the resident is receiving an antipsychotic or other psychopharmacologic medication within the facility, there should be at least one attempt at GDR or tapering of the medication. That attempt should be, followed by a 2nd attempt in a subsequent quarter that same year, unless the first attempt within the facility demonstrated that GDR or tapering was clinically contraindicated. The attempts should be at least a month apart. After the 1st year, GDR or tapering should be attempted once a year.

GDR or tapering for the psychopharmacologic medications including antipsychotics may be considered clinically contraindicated if, during the dose reduction, the resident's target symptoms returned or worsened, and the physician documented the clinical rationale for why any additional attempts at GDR would be likely to impair the resident's function or increase distressed behavior or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

For as long as a resident is receiving a sedative hypnotic (or another class of medication intended to function as a sedative/hypnotic) routinely, there should be an attempt to taper the medication during each quarter. Before tapering the dose of a sedative hypnotic can be considered clinically contraindicated for the remainder of that year, tapering must have been

attempted during the previous 3 quarters and the physician have documented the clinical rationale for why any additional attempts at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

F329 Unnecessary Medications

## Medication Management

### Adverse Consequences

Increased Adverse Consequence Risk:

- Number of medications
- Certain pharmacological classes

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## Adverse Consequences

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**Message:** Any medication or combination of medications can cause adverse consequences. The higher the number of medications taken, the greater the risk of adverse consequences. Many classes of medications increase the risk, such as antipsychotics, anticoagulants, and NSAIDS.

When reviewing medications used by the resident, knowledge about the recognized safety profile, tolerability, dosing, and potential interactions is important. Adverse consequences range from those that occur quickly to those that develop insidiously. The adverse consequence may become evident at any time after the medication is initiated.

According to the literature, many, but not all, adverse consequences are preventable. Examples of ways to reduce the incidence of adverse consequences include:

- Following relevant clinical guidelines and manufacturer's specifications for use, dose, administration, duration;
- Defining appropriate indications for use;
- Monitoring for response to the medication; and
- Determining that the resident
  - Has no known allergies, sensitivities, or conditions that would preclude use of the medication and
  - Is not taking other medications, nutritional supplements or foods that would be incompatible with the prescribed medication.

F329 Unnecessary Medications

## Medication Management

### Adverse Consequences (Cont'd)

Delirium

- Common medication-related adverse consequence
- Individuals who have dementia may be at greater risk for delirium
- Delirium is associated with higher morbidity and mortality

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## Adverse Consequences

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**Message:** Delirium is one of the more frequent medication-related adverse consequences and significantly increases the risk for morbidity and mortality.

Some of the classic signs of delirium may be difficult to recognize and may be mistaken for the natural progression of dementia, particularly in the late stages of dementia. For example, these signs may include fluctuating level of consciousness, increasing disorientation, and difficulty paying attention.

Careful observation of the resident, review of the potential causes of the mental changes and distressed behavior, and appropriate and timely management of delirium are essential.

F329 Unnecessary Medications

## Interpretive Guidelines

### Table I: Medication Issues of Particular Relevance

Examples of categories of medications that:

- Have potential to cause clinically significant adverse consequences
- Have limited indications for use
- Require precautions in selection or use
- Require specific monitoring

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### Table I: Medication Issues of Particular Relevance

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**Message:** Surveyors should note that the table is based on primary and tertiary pharmaceutical references but is not all-inclusive. Since information continues to evolve and new medications are regularly becoming available, current sources on indications, precautions, doses, monitoring, and adverse consequences should be referenced.

Medications other than those listed in the table may present significant issues related to indications, dosage, duration, monitoring, or potential for clinically significant adverse consequences.

Surveyors should also note that “the listed doses for psychopharmacological medications are applicable to older individuals. The facility is encouraged to initiate therapy with lower doses and, when necessary, only gradually increase doses. The facility may exceed these doses if it provides evidence to show why higher doses were necessary to maintain or improve the resident’s function and quality of life.”

F329 Unnecessary Medications

## Interpretive Guidelines

### Table I: Medication Issues of Particular Relevance

Examples of Medications/groups of Medications provided in Table I

- Warfarin
- Antipsychotics
- Hypnotics

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## Table I: Medication Issues of Particular Relevance

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**Message:** In a joint report issued by the American Society for Clinical Pharmacists and American Medical Directors Association, warfarin was identified as frequently interacting with other medications ultimately increasing the potential for bleeding. The parameters for monitoring warfarin will frequently depend upon whether the protime/INR blood levels are stable, whether the prescribed dose has been consistent and whether new medications that may interact with the warfarin have been added to the regimen.

The guidance regarding antipsychotics has been revamped and simplified significantly. It now speaks to both enduring psychiatric conditions and acute psychiatric conditions and separates out the expectation regarding each situation. Tables for the daily dosage thresholds for antipsychotics used to manage behavioral symptoms related to dementing illnesses have been retained and where possible have been updated. The guidance also lists some of the more common adverse consequences associated with the use of antipsychotics.

The category of sedative hypnotics now includes an expectation that contributing causes be evaluated and addressed and that medications used to induce or improve the quality of sleep be evaluated, monitored, and subjected to tapering, even if the medication is not identified as being within the class of sedative hypnotics.

F329 Unnecessary Medications

**Interpretive Guidelines**

**Table II: Medications with Significant Anticholinergic Properties**

- Anticholinergic side effects are common
- Medications in many categories have anticholinergic properties
- Use of multiple medications with anticholinergic properties may be particularly problematic

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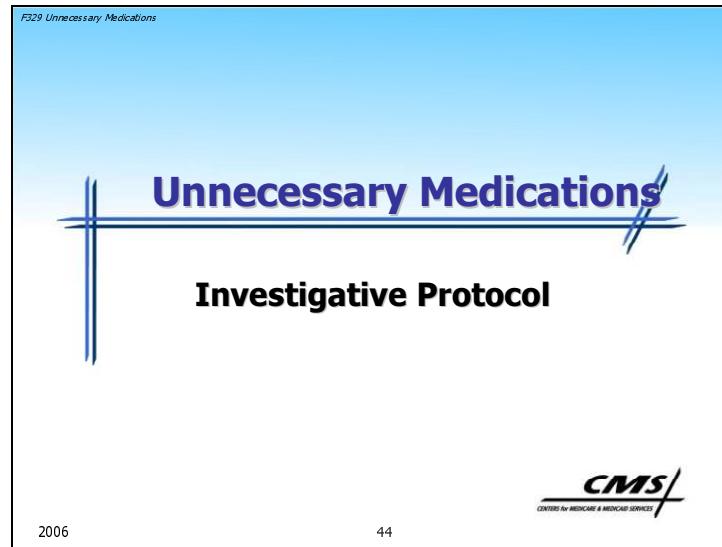
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## **Table II: Medications with Significant Anticholinergic Properties**

**Message:** Table II lists medications commonly associated with significant anticholinergic properties and potential adverse consequences, but the list is not all-inclusive.

Any of the signs and symptoms identified in the table may be caused by any of the medications listed, as well as by other medications that are not listed but have anticholinergic properties. The Table is provided to assist surveyors to quickly recognize a potential anticholinergic effect and potentially an associated medication.



## Investigative Protocol

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**Message:** The investigation for whether the facility is in compliance with the requirements for Unnecessary Medications has been merged with the investigation for whether the facility is in compliance with the requirements for Medication Regimen Review, because the requirements are closely related.

F329 Unnecessary Medications

## Investigative Protocol

Components

- Objectives
- Use
- Procedures

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## Investigative Protocol

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**Message:** The investigative protocol defines the objectives for the investigation and when the protocol will be used and describes procedures for surveyors to follow.

F329 Unnecessary Medications

## Investigative Protocol

### Objectives

To determine whether the resident receives:

- Only medications clinically indicated in the dose and duration to meet the resident's needs
- Non-pharmacological interventions when clinically indicated
- GDR attempts for antipsychotics unless clinically contraindicated and tapering for other medications

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## Objectives

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**Message:** The investigation will help determine whether the facility conforms to the regulation regarding indications for use, dose, duration, monitoring, adverse consequences of medications, as well as providing behavioral interventions and gradual dose reduction for antipsychotics, unless clinically contraindicated.

F329 Unnecessary Medications

## Investigative Protocol

### Objectives (Cont'd)

To determine if the facility and the prescriber:

- Monitor medication for effectiveness and emergence of adverse consequences
- Recognize, evaluate, followup on medication related adverse consequences

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## Objectives

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**Message:**

In addition, the investigation will evaluate some of the following components:

- Whether the resident is being monitored for his or her response to the medication, namely progress toward the therapeutic goal;
- Emergence of medication related adverse consequences; and
- Whether the medication regimen has been adjusted when clinically indicated.

F329 Unnecessary Medications

## Investigative Protocol

### Objectives (Cont'd)

- To determine if the pharmacist:
  - Performed MRR monthly and identified existing irregularities
  - Reported any identified irregularities to attending physician and DON
- To determine whether facility and/or practitioner acted upon report of irregularity

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## Objectives

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**Message:** The guidance for the medication regimen review located at F428 discusses in detail the expected pharmacist review including identifying and reporting irregularities.

Some aspects of the medication regimen review that are pertinent to this protocol include determining whether the pharmacist reviewed the medication regimen for irregularities, including any related to the requirements for F329 and any event related to receiving, interpreting, and implementing the prescribers' orders that could interfere with achieving the intended outcomes for a resident.

The guidance at F428 also describes circumstances requiring immediate notification of the physician and director of nursing in contrast to those that can be reported more routinely according to the facility established protocol.

The investigation also focuses upon whether the DON and/or physician acted upon the report of any existing irregularities.

F329 Unnecessary Medications

## Investigative Protocol

### Use

- Each sampled resident
- Standard survey
- Initial survey
- As necessary for:
  - Revisits
  - Abbreviated survey

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## Use

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**Message:** Note that the protocol is to be used for each resident in the sample during every initial and standard survey, as well as during revisits and abbreviated surveys, as necessary.

Remember:

Surveyors are not expected to prove that an adverse consequence was caused by medication or combination of medications but rather that there was a failure in the care process related to the administration of medications.

F329 Unnecessary Medications

## Investigative Protocol

### Procedures

Investigation involves:

- Observation and record review
- Interviews

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## Procedures

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**Message:** The investigation includes various approaches for gathering data including observation and record review; interviews; and review of the Medication Regimen Review.

Gather information regarding the resident's mental, physical, functional, and psychosocial status and the medication related goals identified in the care plan. Use this information as the basis for further review. Review the physician/prescribers orders, and if necessary, obtain a copy of the orders.

F329 Unnecessary Medications

## Investigative Protocol

### Procedures

#### Observation and Record Review

The table in the Protocol describes:

- Medication related signs and symptoms
- Expectations for review of all medications

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## Procedures

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**Message:** The Observation and Record Review components of the investigation involve two different approaches for reviewing for unnecessary medications. The important thing is that both approaches be used and the order of the tasks is less important.

The left column of the protocol table lists common signs and symptoms associated with the use of medications. This list, however, does not encompass all potential medication related signs and symptoms. If the surveyor learns that the resident has experienced any of the signs or symptoms that may be medication related, whether listed in the table or not, he or she:

- Should review the medications the resident is receiving or has recently received;
- Should follow up and question whether the medication may have contributed to the development of the signs and symptoms
- Should review whether the facility has evaluated for the potential association

Surveyors are expected to review and determine whether each prescribed medication meets the regulatory requirements for indications for use, dose, monitoring, and so forth.

Observations should be corroborated with additional information, such as record reviews and interviews.

Note deviations from the care plan and potential adverse consequences.

F329 Unnecessary Medications

## Investigative Protocol

### Procedures

Interview resident and responsible party to determine:

- Participation in care planning and decision making
- Consideration of non-pharmacological interventions
- Results/effectiveness of the medication therapy and non-pharmacological approaches

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## Procedures

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**Message:** The resident interview is intended to elicit information not only about the resident's participation in the care planning process and decision making, but

- What approaches were considered to address the particular symptom/sign or condition;
- Whether the interventions described in the care plan are consistent with the decisions made during care planning;
- Whether the approaches are being implemented
- Whether the resident can detect if the interventions are having a positive or negative effect, since he or she has been receiving the intervention/medication

The interview may provide information that is either not in the record or conflicts with the record. In which case, attempt to follow up on the information.

F329 Unnecessary Medications

## Investigative Protocol

### Procedures

Interview knowledgeable staff to determine:

- Impact of medication upon resident
- Clinical rationale for medication
- Awareness that signs and symptoms may be adverse consequences related to the medication regimen
- Communication with attending physician to discuss symptoms

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## Procedures

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**Message:** Interview knowledgeable staff, if during the review any of the following circumstances are identified:

- Concerns regarding resident function or well-being, medication dose or duration;
- Failure to implement the care plan interventions, including monitoring;
- The resident experienced a condition change or functional decline that may be related to the medication regimen.

During the interview, also determine what process is in place to assure care plan interventions for medication use are being implemented; whether and when the physician, and potentially the pharmacist, were notified of the onset of new symptoms, decline, or change of condition and whether staff requested an evaluation to determine if the symptoms may be related to the medication regimen.

F329 Unnecessary Medications

## Investigative Protocol

### Procedures

Interview knowledgeable staff to determine:

- Physician response to notification of suspected adverse medication consequences
- MRR identification of related signs and symptoms of suspected adverse medication consequences
- Staff notification of pharmacist

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## Procedures

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**Message:** During the interview, also inquire about:

- Whether the physician responded and the nature of the response to the notification of irregularities;
- Whether the pharmacist had identified and reported any of the changes as being a suspected adverse consequence related to the medication regimen; or
- Whether the staff had consulted with the pharmacist as indicated regarding suspected adverse consequences since the last pharmacist visit.

F329 Unnecessary Medications

## Investigative Protocol

### Procedures

Interview physician to determine:

- Staff notification regarding medication-related issues
- Assessment of the significance of medication-related issues and concerns
- Clinical rationale for management of resident's medications

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## Procedures

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**Message:** If you need to contact the physician, the facility staff should have an opportunity to provide to the physician the necessary information about the resident and the concerns to allow the physician to familiarize himself/herself with the circumstances prior to responding to your questions. If indicated, request the facility to provide you with copies of the same material provided to the physician, so that everyone is referring to the same information.

To the extent possible, attempt to address all concerns regarding that physician's residents during the same interview. If for example, the resident experienced a condition change and there was no input or a delay in response from the physician, inquire about staff notification and his or her assessment of the role of the medications and the significance of the medication related issues. Or, if the other hand, the issue deals with a medication exceeding the dose or duration recommended by current standards of practice, focus on his or her clinical rationale regarding managing the resident's medications.

F329 Unnecessary Medications

## Investigative Protocol

### Procedures

Medication Regimen Review – Determine:

- Whether the pharmacist reported any irregularities with the medication regimen
- Whether the attending physician or DON acted on identified irregularities
- Whether the pharmacist identified a suspected adverse consequence to which the attending physician did not respond, but the staff followed up

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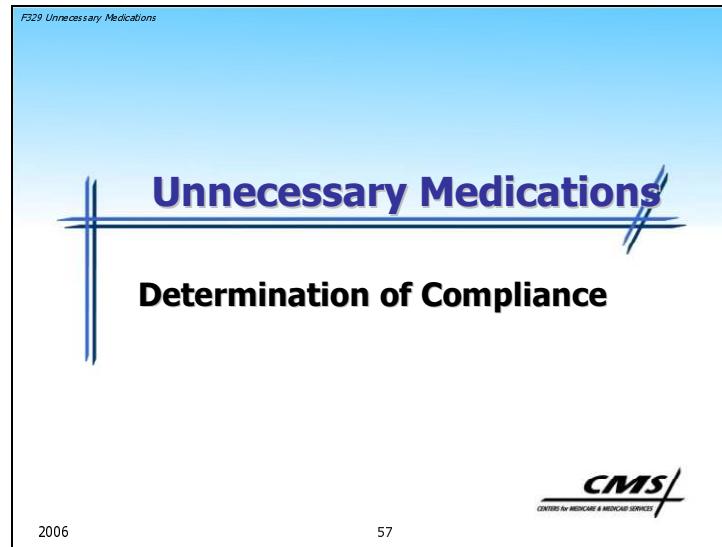
## Procedures

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**Message:** If you identify a potential irregularity with the medication orders, indications for use, dose, duration, medication interaction, the presence of or emergence of an adverse consequence that may be medication related, or a failure of the resident to progress toward the therapeutic goal, etc, review the MRR to determine if the pharmacist did identify the irregularity and reported it.

Determine if the physician and/or director of nursing acted upon the report. Also note whether the pharmacist would have had the opportunity to identify the irregularity, and if so and he/she did not identify and report the irregularity, interview the pharmacist to determine:

- How and when he/she conducts the MRR;
- How the facility communicates with the pharmacist regarding medication-related issues in specific residents; and
- How he/she approaches the MRR for short-stay residents.



## Determination of Compliance

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**Message:** Compliance with the requirements for MRR must be determined based upon the findings from the investigative protocol and the regulation and guidance provided at 42 CFR 483.60 (c) Pharmacy Services: Drug Regimen review (F428).

Compliance and severity of any non-compliance must be determined separately for each resident in the sample.

F329 Unnecessary Medications

## Determination of Compliance

**Synopsis of Regulation**

1. An adequate indication for use
2. Use of the appropriate dose
3. Provision of behavioral interventions and gradual dose reduction, unless clinically contraindicated, for those on antipsychotic medications
4. Use for the appropriate duration
5. Monitoring to determine progress towards goals and emergence of adverse consequences
6. Reduction of dose or discontinuation of medication in presence of adverse consequences

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## Determination of Compliance

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**Message:** The unnecessary medication requirement has six aspects in order to assure that medication therapy is appropriate for the individual resident. The facility must assure that medication therapy considers and meets each of these 6 aspects of the requirement.

F329 Unnecessary Medications

## Determination of Compliance

### Criteria for Compliance

The facility is in compliance if they, along with the prescriber:

- Assessed the resident
- Determined that medication therapy was indicated and identified the therapeutic goals
- Utilized appropriate doses and duration
- Implemented GDR and behavioral interventions, unless clinically contraindicated, for residents receiving antipsychotic medications

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## Criteria for Compliance

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**Message:** The facility works in collaboration with the physician and/or other prescribers to assure:

- The resident has been assessed:
  - To identify causes of the condition or symptoms, including determining whether the symptoms represent an adverse medication-related consequence; and
  - To confirm that medication therapy is indicated and that therapeutic goals have been identified
- Each medication and the dose and duration are clinically indicated to treat the resident's assessed conditions; and
- GDR and behavioral interventions have been implemented, unless clinically contraindicated, for each resident receiving an antipsychotic medication.

F329 Unnecessary Medications

## Determination of Compliance

### Criteria for Compliance

(Cont'd)

- Monitored for progress towards the therapeutic goal(s) and emergence of adverse consequences
- Adjusted/discontinued dose in response to adverse consequences

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## Criteria for Compliance

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**Note:** Continued

**Message:**

- The lowest effective dose possible is being used or discontinued as clinically indicated;
- The resident is being monitored for progress toward the therapeutic goal established for use of the medication and for the emergence of adverse medication-related consequences; and
- In response to the emergence or existence of an adverse consequence, the use of the medication is reviewed to assure the benefit outweighs the risks involved and the medication is potentially discontinued or the dose reduced as clinically indicated.

If not, cite F329

F329 Unnecessary Medications

## Determination of Compliance Noncompliance for F329

Aspects of the unnecessary medication requirement leading to noncompliance:

- Inadequate indications for use including antipsychotics
- Inadequate Monitoring
- Excessive Dose
- Excessive Duration
- Adverse Consequences
- Antipsychotic Medications without GDR and Behavioral Interventions unless clinically contraindicated

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## Noncompliance for F329

**Message:** Let's spend some time reviewing examples of each of the aspects of the unnecessary medication requirement that could lead to a citation of noncompliance at F329: These examples and others are identified within the Determination of Compliance section of the document.

**Examples:** **Examples of Inadequate Indications for Use include:**

- Prescribing or administering a medication despite a known allergy or clinically significant risks associated with that medication without determining that the benefit outweighed the risk or considering a safer medication.
- Failure to provide a clear clinical rationale for initiating or continuing a medication that ultimately resulted in an adverse consequence.
- Initiation of an antipsychotic medication or other psychopharmacological medication for a condition or distressed behavior resulting from a medical cause (e.g., UTI, congestive heart failure) without trying to address the underlying cause or stressor or indicating why it could not or should not be addressed.

**Examples of Inadequate Monitoring include:**

- Failure to monitor the response/effects of a medication and to respond when monitoring indicates a lack of progress toward the therapeutic goal (e.g., relief of pain or normalization of thyroid function) or the emergence of an adverse consequence
- Failure to carry out the monitoring that was ordered or the presence of inadequate monitoring for potential clinically significant adverse consequences.

**Examples of Excessive Dose (including duplicate therapy) include:**

- Giving a total amount of any medication at one time or over a period of time that exceeds the amount recommended by the manufacturer's label, clinical practice guidelines, or standards of practice for a resident's age and condition, without a documented clinically pertinent rationale.
- Failure to provide and/or document a clinical rationale for using multiple medications from the same pharmacological class.

**Examples of Excessive Duration include:**

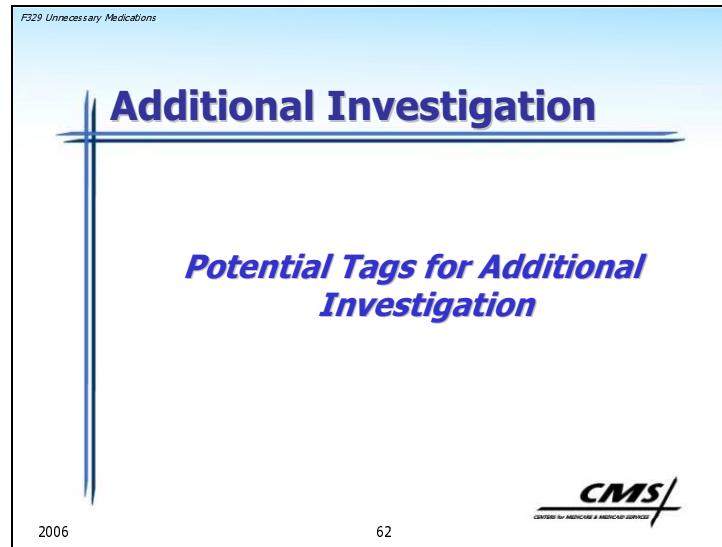
- Continuation beyond the manufacturer's recommended time frames, the stop date or duration indicated on the medication order, facility-established stop order policies, or clinical practice guidelines or standards of care without documented clinical justification.
- Continuation of a medication after the desired therapeutic goal has been achieved without evaluating whether the medication can offer any additional benefit

**Examples of Adverse Consequences which indicate the dose should be reduced or discontinued include:**

- Failure to discontinue a medication or reduce the dose or provide clinical justification for why the benefit outweighs the adverse consequences in the presence of a report of a clinically significant risk or probable adverse consequence.

**Examples of Antipsychotic Medication without Gradual Dose Reduction and Behavioral Interventions unless clinically contraindicated include:**

- Failure to attempt GDR without identification and documentation of clinical contraindications and
- Failure to identify a known clinical contraindication to GDR (such as previous exacerbation of the condition requiring an increased dose of medication) prior to attempting a GDR.

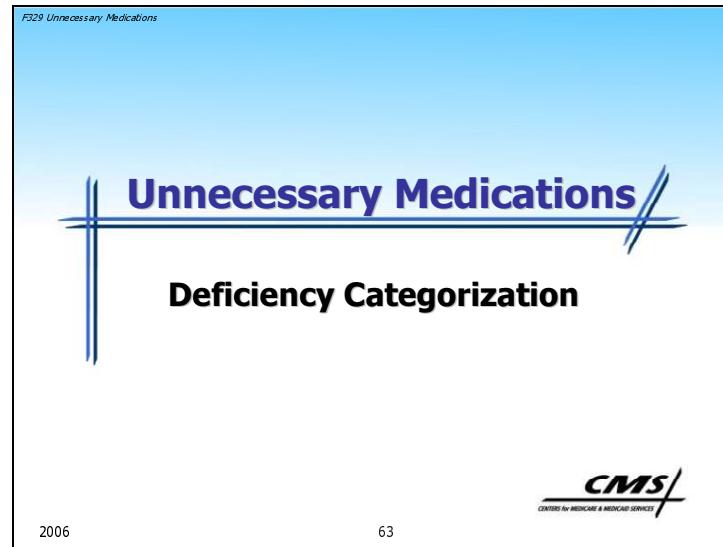


## Additional Investigation

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**Message:** During the course of the review for compliance with F329, questions or issues may have arisen with regard to whether the facility is in compliance with other requirements. It is important to investigate for compliance with those additional requirements before citing those tags as deficiencies.

The guidance provides a list of some of the tags where concerns may have arisen. The surveyor may investigate any other tag as deemed appropriate.



## Deficiency Categorization

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F329 Unnecessary Medications

## Deficiency Categorization

Components

- Severity determination
- Deficiency categorizations
  - Levels 4 through 1

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## Deficiency Categorization

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**Message:** We will briefly review the bases for determining the severity of a deficiency and provide examples of the severity levels.

F329 Unnecessary Medications

## Unnecessary Medications

### Severity Determination

The key elements for severity determination are:

- Presence of harm or potential for negative outcomes
- Degree of harm or potential harm related to noncompliance
- Immediacy of correction required

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## Severity Determination

**Message:** The bases for determining which level of Severity applies are:

1. Presence of potential or actual harm/negative outcome(s) related to unnecessary medications.

Examples of actual or potential harm/negative outcomes for F329 may include, but are not limited to:

- Potential for or actual presence of life-threatening toxicity from excessive dose or from lack of monitoring use of digoxin.
- Life threatening complications from use of an antibiotic when no clear indication for use has been established or response to the use has not been monitored.
- Injury resulting from the continuing use of a medication in the presence of predisposing risks or adverse consequences without intervening or reevaluating the need for and dose of the medication.

2. Degree of potential or actual harm/negative outcome(s) related to unnecessary 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 how likely is the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.
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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.

F329 Unnecessary Medications

## Deficiency Categorization

### Severity Determination Levels

- **Level 4:** Immediate Jeopardy to resident health or safety
- **Level 3:** Actual harm that is not immediate jeopardy
- **Level 2:** No actual harm with potential for more than minimal harm that is not immediate jeopardy
- **Level 1:** No actual harm with potential for minimal harm

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## Severity Determination Levels

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**Message:** The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F329.

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. Appendix Q provides additional guidance for determining Immediate Jeopardy.

The facility's failure to provide appropriate care and services to manage the resident's medication regimen to avoid unnecessary medications and minimize negative outcome places residents at risk for more than minimal harm. Because of this, Severity Level 1 does not apply for F329.

F329 Unnecessary Medications

## Deficiency Categorization

### Severity Level 4: Immediate Jeopardy

**Level 4:** Immediate Jeopardy to resident health or safety

- Noncompliance with one or more requirements of participation:
  - Has resulted in or is likely to result in serious injury, harm, impairment, or death to a resident; and
  - Requires immediate correction

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## Severity Level 4

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**Message:** Some examples of Severity Level 4 include:

- Failure to monitor PT/INR for a resident on anticoagulant therapy in accordance with current standards of practice **and** to recognize and/or respond to a life threatening adverse consequence related to anticoagulation.
- Failure to recognize developing serotonin syndrome (e.g., confusion, hallucinations, rapid heart beat or elevated temperature) in a resident receiving SSRI leading to the addition of medications with additive serotonin effect or medication to suppress the symptoms.
- Failure to recognize medication therapies (such as NSAIDs or COX-2 inhibitors, bisphosphonates) as potentially causing or contributing to the resident's gastrointestinal bleeding resulting in the continued administration of the medication, until the resident required hospitalization for severe bleeding.

F329 Unnecessary Medications

## Deficiency Categorization

### Severity Level 3: Actual Harm

**Level 3:** Actual harm that is not immediate jeopardy

- Noncompliance resulted in actual harm
- May include clinical compromise, decline, or resident's inability to maintain and/or reach his/her highest practicable level of well-being

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## Severity Level 3

**Message:** Some examples of Severity Level 3 include:

- Failure to suspend the administration of warfarin in response to an INR greater than 4 when spontaneous bruising or frank bleeding occurs, resulting in the need to transfuse or hospitalize the resident.
- Failure to evaluate the medication regimen as a potential cause of the resident's recent-onset seizure activity resulting in the addition of anticonvulsants to treat a potentially medication-related adverse consequence.
- Facility failure to implement a GDR that was not contraindicated in a resident receiving prolonged, continuous antipsychotic therapy resulting in functional decline, somnolence, lethargy, tremors, increased falling, or impaired ambulation.

F329 Unnecessary Medications

## Deficiency Categorization

### Severity Level 2: Potential for Harm

- **Level 2:** No actual harm with potential for more than minimal harm that is not immediate jeopardy

Noncompliance resulted in:

- No more than minimal discomfort to resident; and/or
- Has potential to compromise resident's ability to maintain or reach his/her highest practicable level of well-being

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## Severity Level 2

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**Message:** Some examples of Severity Level 2 include:

- Failure to change or suspend administration of the warfarin dose for a resident who has an INR greater than 4 and less than 9 but who has no bleeding or other symptoms related to the anticoagulation.
- Failure to identify and act upon minor symptoms of allergic response to medications, such as a rash which has not impacted the resident's function or physical well being.
- Failure to monitor a resident receiving psychopharmacological medications for response to therapy or for the emergence or presence of adverse consequences before the resident has experienced an adverse consequence or decline in function.

F329 Unnecessary Medications

## Deficiency Categorization

### Severity Level 1: Potential for Minimal Harm

**Level 1:** No actual harm with potential for minimal harm

- Noncompliance with F329 places resident at risk for more than minimal harm
- Severity Level 1 does not apply for F329

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## Severity Level 1

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**Message:** The facility's failure to provide appropriate care and services to manage the resident's medication regimen to avoid unnecessary medications and minimize negative outcome places residents at risk for more than minimal harm.

**Because of this, Severity Level 1 does not apply for F329.**