SELF SURVEY MODULE

F329 (Rev. 22, Issued: 12-15-06, Effective/Implementation: 12-18-06) §483.25(l) Unnecessary Drugs

F329

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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 therapy); or**
- **(ii) For excessive duration; or**
- **(iii) Without adequate monitoring; or**
- **(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.**

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

INTENT: §483.25(l) Unnecessary drugs

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.

NOTE: This guidance applies to all categories of medications including antipsychotic medications.

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

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

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.

DEFINITIONS

Definitions are provided to clarify terminology related to medications and to the evaluation and treatment of residents.

- **"**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., medicationmedication, medication-food, and medication-disease).

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

- "Anticholinergic side effect" is an effect of a medication that opposes or inhibits the activity of the parasympathetic (cholinergic) nervous system to the point of causing symptoms such as dry mouth, blurred vision, tachycardia, urinary retention, constipation, confusion, delirium, or hallucinations.
- "Behavioral interventions" are 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.
- "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.
- "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.
- "Dose" is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose. o "Excessive dose" means the total amount of any medication (including duplicate therapy)

given at one time or over a period of time that is greater than the amount recommended by the manufacturer's label, package insert, current standards of practice for a resident's age and condition, or clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals and that lacks evidence of:

– A review for the continued necessity of the dose;

– Attempts at, or consideration of the possibility of, tapering a medication; and

– A documented clinical rationale for the benefit of, or necessity for, the dose or for the use of multiple medications from the same pharmacological class.

• "Duplicate therapy" refers to multiple medications of the same pharmacological class/category or any medication therapy that substantially duplicates a particular effect of another medication that the individual is taking.

• "Duration" is the total length of time the medication is being received.

- "Excessive Duration" means the medication is administered beyond the manufacturer's recommended time frames or facility-established stop order policies, beyond the length of time advised by current standards of practice, clinical practice guidelines, clinical studies or evidence-based review articles, and/or without either evidence of additional therapeutic benefit for the resident or clinical evidence that would warrant the continued use of the medication.

• "Extrapyramidal symptoms (EPS)" are neurological side effects that can occur at any time from the first few days of treatment to years later. EPS includes various syndromes such as:

- Akathisia, which refers to a distressing feeling of internal restlessness that may appear as constant motion, the inability to sit still, fidgeting, pacing, or rocking.
- Medication-induced Parkinsonism, which refers to a syndrome of Parkinson-like symptoms including tremors, shuffling gait, slowness of movement, expressionless face, drooling, postural unsteadiness and rigidity of muscles in the limbs, neck and trunk.
- Dystonia, which refers to an acute, painful, spastic contraction of muscle groups (commonly the neck, eyes and trunk) that often occurs soon after initiating treatment and is more common in younger individuals.

• "Gradual Dose Reduction (GDR)" is 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.

• "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.

• "Insomnia" is the inability to sleep characterized by difficulty falling asleep, difficulty staying asleep, early waking, or non-restorative sleep, which may result in impaired physical, social, or cognitive function.

• "Medication Interaction" is the impact of another substance (such as another medication, nutritional supplement including herbal products, food, or substances

used in diagnostic studies) upon a medication. The interactions may alter absorption, distribution, metabolism, or elimination. These interactions may decrease the effectiveness of the medication or increase the potential for adverse consequences.

• "Medication Regimen Review" (MRR) is a thorough evaluation of the medication regimen by a pharmacist, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication. The review includes preventing, identifying, reporting, and resolving medication-related problems, medication errors, or other irregularities in collaboration with other members of the interdisciplinary team.[51]

• "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.

• "Neuroleptic Malignant Syndrome" (NMS) is a syndrome related to the use of medications, mainly antipsychotics, that typically presents with a sudden onset of diffuse muscle rigidity, high fever, labile blood pressure, tremor, and notable cognitive dysfunction. It is potentially fatal if not treated immediately, including stopping the offending medications.

• "Non-pharmacological interventions" refers to approaches to care that do not involve medications, generally directed towards stabilizing or improving a resident's mental, physical or psychosocial well-being.

• "Psychopharmacological medication" is any medication used for managing behavior, stabilizing mood, or treating psychiatric disorders.

• "Serotonin Syndrome" is a potentially serious clinical condition resulting from over stimulation of serotonin receptors. It is commonly related to the use of multiple serotonin-stimulating medications (e.g., SSRIs, SNRIs, triptans, certain antibiotics). Symptoms may include restlessness, hallucinations, confusion, loss of coordination, fast heart beat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting and diarrhea.

• "Tardive dyskinesia" refers to abnormal, recurrent, involuntary movements that may be irreversible and typically present as lateral movements of the tongue or jaw, tongue thrusting, chewing, frequent blinking, brow arching, grimacing, and lip smacking, although the trunk or other parts of the body may also be affected.

INVESTIGATIVE PROTOCOL
UNNECESSARY MEDICATIONS - MEDICATION REGIMEN REVIEW

Because they are closely related, the investigations of the requirements for medication regimen review and the review for unnecessary medications have been merged.

Objectives

- To determine whether each resident receives or is provided:
  - Only those medications that are clinically indicated in the dose and for the duration to meet his or her assessed needs;

- Non-pharmacological approaches when clinically indicated, in an effort to reduce the need for or the dose of a medication; and
- Gradual dose reduction attempts for antipsychotics (unless clinically contraindicated) and tapering of other medications, when clinically indicated, in an effort to discontinue the use or reduce the dose of the medication.

• To determine if the facility in collaboration with the prescriber:

- Identifies the parameters for monitoring medication(s) or medication combinations (including antipsychotics) that pose a risk for adverse consequences; and for monitoring the effectiveness of medications (including a comparison with therapeutic goals); and
- Recognizes and evaluates the onset or worsening of signs or symptoms, or a change in condition to determine whether these potentially may be related to the medication regimen; and follows-up as necessary upon identifying adverse consequences.

• To determine if the pharmacist:

- Performed the monthly medication regimen review, and identified any existing irregularities regarding indications for use, dose, duration, and the potential for, or the existence of adverse consequences or other irregularities; and
- Reported any identified irregularities to the attending physician and director of nursing.

• To determine whether the facility and/or practitioner acted on the report of any irregularity.

Use

Use this protocol during every initial and standard survey. In addition, this protocol may be used on revisits or abbreviated survey (complaint investigation) as necessary.

NOTE: This review 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 this review, the surveyor needs 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 his/her review prior to responding to the surveyor's inquiries.

Procedures Review the medications (prescription, over-the-counter medications, and nutritional supplements such as herbal products) currently ordered and/or discontinued by the prescriber at least back to the most recent signed recapitulation/reorder of all medications. Obtain a copy of the current orders if necessary. Gather information regarding the resident's mental, physical,

functional, and psychosocial status and the medication-related therapeutic goals identified in the care plan as the basis for further review.

1. Observation and Record Review

Use the table below to guide observations, record review, and interviews with the resident or representative and relevant staff. Observe whether the medication-related interventions are consistently implemented over time and across various shifts. Note deviations from the care plan as well as potential medication-related adverse consequences. Verify observations by gathering additional information; for example, additional record reviews and/or interviews with the resident or representative, relevant staff, and practitioners.

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS

REVIEW FOR HOW FACILITY MANAGED MEDICATIONS FOR THE RESIDENT

DETERMINE IF THE RESIDENT HAS BEEN TRANSFERRED TO REVIEW THE RECORD (INCLUDING THE CARE SYMPTOMS, SIGNS, AND CONDITIONS
THAT MAY BE ASSOCIATED WITH MEDICATIONS

REVIEW FOR HOW FACILITY MANAGED MEDICATIONS FOR THE RESIDENT

acute care since the last survey and/or has recently (e.g., the previous 3 months) experienced a change in condition or currently has signs and symptoms, such as:

- Anorexia and/or unplanned weight loss, or weight gain
- Behavioral changes, unusual behavior patterns (including increased distressed behavior)
- Bleeding or bruising, spontaneous or unexplained
- Bowel dysfunction including diarrhea, constipation and impaction
- Dehydration, fluid/electrolyte imbalance
- Depression, mood disturbance
- Dysphagia, swallowing difficulty
- Falls, dizziness, or evidence of impaired coordination
- Gastrointestinal bleeding
- Headaches, muscle pain, generalized or nonspecific aching or pain
- Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia(including delirium))
- Rash, pruritus
- Respiratory difficulty or changes
- Sedation (excessive), insomnia, or sleep disturbance
- Seizure activity
- Urinary retention or incontinence

If observations or record review indicate symptoms or changes in condition that may be related to medications (refer to Tables I and II, supplemented with current medication references), determine whether the facility considered medications as a potential cause of the change or

symptom. plan, comprehensive assessment, and other parts of the record as appropriate) to determine whether it reflects the following elements related to medication management for the resident:

- Clinical indications for use of the medication
- Consideration of nonpharmacological interventions
- Dose, including excessive dose and duplicate therapy
- Duration, including excessive duration
- Consideration of potential for tapering/GDR or rationale for clinical contraindication
- Monitoring for and reporting of:
    - Response to medications and progress toward therapeutic goals
    - Emergence of medication-related adverse consequences
- Adverse consequences, if present and potentially medication-related, note if there was:
    - Recognition, evaluation, reporting, and management by the facility
    - Physician action regarding potential medication-related adverse consequences

2. Interview

Interview the resident and or family/responsible party, to the extent possible, to determine:

- His/her participation in care planning and decision making, including discussions of the goals related to the use of medications;
- Whether approaches other than medications (as indicated) were discussed; and
- His/her evaluation of the results of the medication therapy and other approaches (such as decreasing symptoms of pain, improving functional ability).

If during the review, you identify concerns about the lack of indication for use; the dose or duration of a medication; lack of monitoring; failure to implement the care plan; or condition changes or functional decline that may be related to the medication regimen, interview knowledgeable staff to determine:

- Whether the resident has experienced any changes in the functioning or amount of activity that he/she is able to do;
- The clinical rationale for the use of the medication, dose or duration and how the interdisciplinary team is monitoring the resident's response to the medication;
- What process is in place to assure the care plan interventions for medication use are being implemented;
- Whether they were aware that the signs and symptoms may be adverse consequences related to the medication regimen;
- Whether the staff had contacted the attending physician to discuss the signs and symptoms and the current medication regimen;
- Whether and how the physician responded when informed of suspected adverse medication consequences; and
- Whether the pharmacist performed a medication regimen review and identified related signs and symptoms, or the staff informed the pharmacist of them if they occurred after the last pharmacist visit. Interview the physician, as appropriate, to determine:

• Whether staff notified him/her of potential medication-related issues and concerns; • His/her assessment of the significance of medication-related issues and concerns; and
• Rationale for his/her management of the resident's medications and/or medication-related issues or concerns.

3. Medication Regimen Review (MRR)

Review for compliance with the MRR requirements at F428. Determine:
• If the pharmacist had identified and reported to the director of nursing and attending physician any irregularities with the medication regimen such as:
  - The emergence or existence of clinically significant adverse consequences;
  - Excess 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; and

• Whether the attending physician and the director of nursing acted on any irregularities identified in the report. The responses from the attending physician could include the following:
  - Changed the medication regimen in response to the concern raised in the report (or after additional review of the situation);
  - Provided 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;
  - Provided 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; or
  - Provided a clinically pertinent rationale for why a particular medication, dose, or duration is appropriate for a resident despite its risks (for example, the resident has had recurrent seizures unless he/she receives anticonvulsant dosing that exceeds the usual recommended serum medication concentration level or therapeutic range, and the attending physician and facility have been monitoring for and addressing adverse consequences).

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

NOTE: 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; e.g., contacting the medical director to review the situation and address the issue with the attending physician, as necessary. See guidance at 42 CFR 483.75(i) Medical Director (F501) for additional guidance. If problems are identified with the MRR, interview the pharmacist, as indicated, 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.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation (F329)

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 (including antipsychotic agents) is based upon:
• An adequate indication for use;
• Use of the appropriate dose;
• Provision of behavioral interventions and gradual dose reduction for individuals receiving antipsychotics (unless clinically contraindicated) in an effort to reduce or discontinue the medication;
• Use for the appropriate duration;
• Adequate monitoring to determine whether therapeutic goals are being met and to detect the emergence or presence of adverse consequences; and
• Reduction of dose or discontinuation of the medication in the presence of adverse consequences, as indicated.

Criteria for Compliance

Compliance with 42 CFR 483.25(l), F329, Unnecessary Medications
For a resident who has been, or is, receiving medication(s), the facility is in compliance if they, in collaboration with the prescriber:
• Assessed the resident to ascertain, to the extent possible, the causes of the condition or symptoms requiring treatment, including recognizing, evaluating, and determining whether the condition or symptoms may have reflected an adverse medication consequence;
• Based on the assessment, determined that medication therapy was indicated and identified the therapeutic goals for the medication;
• Utilized only those medications in appropriate doses for the appropriate duration, which are clinically necessary to treat the resident's assessed condition(s);
• Implemented a gradual dose reduction and behavioral interventions for each resident receiving antipsychotic medications unless clinically contraindicated;
• Monitored the resident for progress towards the therapeutic goal(s) and for the emergence or presence of adverse consequences, as indicated by the resident's condition and the medication(s); and
• Adjusted or discontinued the dose of a medication in response to adverse consequences, unless clinically contraindicated.

If not, cite F329.

Noncompliance for F329

After completing the investigation, determine whether or not compliance with the regulation exists. Noncompliance for F329 may include:

• **Inadequate Indications for Use** – Examples of noncompliance related to a medication being used without adequate indications include, but are not limited to:

- Failure to document a clinical reason or demonstrate a clinically pertinent rationale, verbally or in writing, for using medication(s) for a specific resident.
- Prescribing or administering a medication despite an allergy to that medication, or without clarifying whether a true allergy existed as opposed to other reactions (e.g., idiosyncratic reaction or other side effect).
- Failure to provide a clear clinical rationale for continuing a medication that may be causing an adverse consequence.
- Initiation of an antipsychotic medication to manage distressed behavior without considering a possible underlying medical cause (e.g., UTI, congestive heart failure)or environmental or psychosocial stressor.
- Initiation of a medication presenting clinically significant risks without considering relative risks and benefits or potentially lower risk medications.
- Concomitant use of two or more medications in the same pharmacological class without a clinically pertinent explanation.

• **Inadequate Monitoring** – Examples of noncompliance related to inadequate monitoring include, but are not limited to:

- Failure to monitor the responses to or effects of a medication and failure 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 monitor a medication consistent with the current standard of practice or manufacturer's guidelines.
- Failure to carry out the monitoring that was ordered or failure to monitor for potential clinically significant adverse consequences. For example, use of warfarin in conjunction with:
  - Inadequate or absent monitoring of PT/INR during treatment; and/or
  - Failure to recognize and monitor the increased risk of adverse consequences when the resident is receiving other medications that are known to increase the risk of bleeding or to interact with warfarin and increase PT/INR.

Excessive Dose (including duplicate therapy) – Examples of noncompliance related to excessive dose include, but are not limited to:

- 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 recommendations, clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or standards of practice for a resident's age and condition, without a documented clinically pertinent rationale.
- Failure to consider periodically the continued necessity of the dose or the possibility of tapering a medication.
- Failure to provide and/or document a clinical rationale for using multiple medications from the same pharmacological class.

• **Excessive Duration** – Examples of noncompliance related to excessive duration include, but are not limited to:

- Continuation beyond the manufacturer's recommended time frames, the stop date or duration indicated on the medication order, facilityestablished stop order policies, or clinical practice guidelines, evidencebased studies from

medical/pharmacy journals, or current standards of practice, 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, for example:
  - – Use of an antibiotic beyond the recommended clinical guidelines or the facility policy without adequate reassessment of the resident and determination of continuing need.
  - – Failure to re-evaluate the rationale for continuing antipsychotic medication initiated in an emergency after the acute phase has stabilized.

• **Adverse Consequences** – Examples of noncompliance related to adverse consequences include, but are not limited to:

- Failure to act upon (i.e., discontinue a medication or reduce the dose or provide clinical justification for why the benefit outweighs the adverse consequences) a report of the risk for or presence of clinically significant adverse consequence(s);
- Failure to respond to actual or potentially clinically significant adverse consequences related to the use of warfarin when the PT/INR exceeds the target goal.

• **Antipsychotic Medications without Gradual Dose Reduction and Behavioral Interventions unless Clinically Contraindicated** – Examples of noncompliance related to this requirement include, but are not limited to:

- Failure to attempt GDR in the absence of identified and documented clinical contraindications.
- Prolonged or indefinite antipsychotic use without attempting gradual dose reductions.
- Failure to implement behavioral interventions to enable attempts to reduce or discontinue an antipsychotic medication.

Potential Tags for Additional Investigation

If noncompliance with 483.25(l) has been identified, then concerns with additional requirements may also have been identified. The surveyor is cautioned to investigate these related additional requirements before determining whether noncompliance with the additional requirements may be present. Examples of some of the related requirements that may be considered when noncompliance has been identified include the following:

• 42 CFR 483.10(b)(11), F157, Notification of Changes

- Review whether the facility contacted the attending physician regarding a significant change in the resident's condition in relation to a potential adverse consequence of a medication, or if the resident has not responded to medication therapy as anticipated and/or indicated.

• 42 CFR 483.10 (b)(3) and (4), F154, F155, Notice of Rights and Services and (d)(2) Free Choice

- Determine whether the resident was advised of her/his medical condition and therapy and was informed about her/his treatment including medications and the right to refuse treatments.

• 42 CFR 483.20(b), F272, Comprehensive Assessments

- Review whether the facility's initial and periodic comprehensive assessments include an assessment of the resident's medication regimen.

• 42 CFR 483.20(k)(1) and (2), F279, F280, Comprehensive Care Plans

- Review whether the resident's comprehensive care plan:

a) was based on the assessment of the resident's conditions, risks, needs, and behavior;
b) was consistent with the resident's therapeutic goals;
(c) considered the need to monitor for effectiveness based on those therapeutic goals and for the emergence or presence of adverse consequences; and (d) was revised as needed to address medication-related issues.

- 42 CFR 483.25(a)(1), F310, Decline in ADL
  - Review whether the facility had identified, evaluated, and responded to a new or rapidly progressive decline in function, development or worsening of movement disorders, increased fatigue and activity intolerance that affected the resident's ADL ability in relation to potential medication adverse consequences.
- 42 CFR 483.25(d), F315, Urinary Incontinence
  - Review whether the facility had identified, evaluated, and responded to a change in urinary function or continence status in relation to potential medication adverse consequences.
- 42 CFR 483.25(f)(1)&(2), F319, F320, Mental and Psychosocial Functioning
  - Review whether the facility had identified, evaluated, and responded to a change in behavior and/or psychosocial changes, including depression or other mood disturbance, distress, restlessness, increasing confusion, or delirium in relation to potential medication adverse consequences.
- 42 CFR 483.25(i)(1), F325, Nutritional Parameters
  - Review if the facility had identified, evaluated, and responded to a change in nutritional parameters, anorexia or unplanned weight loss, dysphagia, and/or swallowing disorders in relation to potential medication adverse consequences.
- 42 CFR 483.25(j), F327, Hydration
  - Review if the facility had identified, evaluated, and responded to a change in hydration or fluid or electrolyte balance (for example, high or low sodium or potassium) in relation to potential medication adverse consequences.
- 42 CFR 483.40(a), F385, Physician Supervision
  - Review if the attending physician supervised the resident's medical treatment, including assessing the resident's condition and medications, identifying the clinical rationale, and monitoring for and addressing adverse consequences.
- 42 CFR 483.40(b), F386, Physician Visits
  - Review if the attending physician or designee reviewed the resident's total program of care and wrote, signed, and dated progress notes covering pertinent aspects of the medication regimen and related issues.
- 42 CFR 483.60(c), F428, Medication Regimen Review
  - Review whether the licensed pharmacist has provided consultation regarding the integrity of medication-related records (e.g., MAR, physician order sheets, telephone orders), and potential or actual medication irregularities.
- 42 CFR 483.75(i), F501, Medical Director
  - Review whether the medical director, when requested by the facility, interacted with the attending physician regarding a failure to respond or an inadequate response to identified or reported potential medication irregularities and adverse consequences; and whether the medical director collaborated with the facility to help develop, implement, and evaluate policies and procedures for the safe and effective use of medications in the care of residents.

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F329 exists, the team must determine the severity of each deficiency, based on the resultant harm or potential for harm to the resident. The key elements for severity determination for F329 are as follows:

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

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

• Potential for life-threatening toxicity from excessive dose or lack of indication for the use of digoxin.

• Complications (such as diarrhea with life threatening fluid loss, nephrotoxicity, hearing loss, or anaphylactic shock) from use of an antibiotic when no clear indication for use has been established or response to the use has not been monitored.

• Fractures or falls with injury resulting from the continuing use of medications (e.g., hypnotics/sedatives, antipsychotics, antidepressants, antihypertensives) in the presence of predisposing risks or adverse consequences such as persistent dizziness or recurrent falling without intervening or reevaluating the need for and dose of the medication believed to be the cause of the gait instability.

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

3. The immediacy of correction required.

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

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag 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. (Follow the guidance in Appendix Q.)

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

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

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

• Has allowed, caused, or resulted in, or is likely to allow, cause, or result in serious injury, harm, impairment, or death to a resident; and

• Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures. Examples may include, but are not limited to:
• Failure to assess or respond appropriately for a resident taking warfarin who had an elevated INR of 9 or greater with or without bleeding, or the elevated INR persisted without assessment/follow-up.
• 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, motor restlessness, tremor) in a resident receiving a SSRI, leading to the addition of medications with additive serotonin effect or medication to suppress the symptoms.
• Failure to recognize and respond to signs and symptoms of neuroleptic malignant syndrome (NMS).
• In the presence of gastrointestinal bleeding, the failure to recognize medication therapies (such as NSAIDs or COX-2 inhibitors, bisphosphonates) as potentially causing or contributing to the gastrointestinal bleed, resulting in the continued administration of the medication, until the resident required hospitalization for severe bleeding.

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

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

Level 3 indicates noncompliance that resulted in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:
• Facility failure to take appropriate action (e.g., suspending administration of the anticoagulant) in response to an INR greater than 4 and less than 9 for a resident who is receiving warfarin until spontaneous bruising or frank bleeding occurs, resulting in the need to transfuse or hospitalize the resident.
• Facility failure to evaluate the medication regimen as a potential cause of seizure activity resulting in the addition of anticonvulsants to treat recent-onset seizures that can be adverse consequences of medications.
• 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.

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

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

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

• Facility failure to take appropriate action (e.g., change or suspend administration of the warfarin dose) for a resident who has an INR greater than 4 and less than 9 without any bleeding.
• Failure to monitor INR for a resident who has been stabilized on warfarin, but who has not had bleeding.
• Facility failure to identify and act upon minor symptoms of allergic response to medications, such as a rash.
• Facility failure to monitor 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 (e.g., monitoring periodically for symptoms of behavioral distress in someone receiving psychopharmacological medication; monitoring thyroid function at least annually in an individual receiving thyroid hormone replacement; and monitoring hydration status and basic metabolic profile for a resident receiving diuretics or ACE inhibitors, who had a change in mental status after the onset of diarrhea).

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

The failure of the facility 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. Therefore, Severity Level 1 does not apply for this regulatory requirement.