F-Tag Review Series
Comprehensive Review of Regulations & Interpretive Guidance for Top F-Tags
Unnecessary Drugs
F757-F758

Objectives
1. Identify the regulatory requirements related to Unnecessary Drugs
2. Identify survey procedures that describe how Unnecessary Drugs requirements are reviewed for compliance during the annual survey process
3. Identify examples of how F-Tags related to Unnecessary Drugs are commonly cited in the new LTCSP
4. Identify tools for the leadership team to use for monitoring compliance with Unnecessary Drugs requirements
5. Explain strategies for incorporating survey preparedness related to Unnecessary Drugs into facility QAPI processes

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Unnecessary Drugs
Overview of F-Tag Regulations & Interpretive Guidance

Pharmacy Services Regulations

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F757 - Regulatory Language

- §483.45(d) Unnecessary Drugs—General.
- Each resident’s drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—
  - §483.45(d)(1) In excessive dose (including duplicate drug therapy); or
  - §483.45(d)(2) For excessive duration; or
  - §483.45(d)(3) Without adequate monitoring; or
  - §483.45(d)(4) Without adequate indications for its use; or
  - §483.45(d)(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
  - §483.45(d)(6) Any combinations of the reasons stated in paragraphs (d)(1) through (f) of this section.
§483.45(c)(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:

- (i) Anti-psychotic;
- (ii) Anti-depressant;
- (iii) Anti-anxiety; and
- (iv) Hypnotic

§483.45(e) Psychotropic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that:

- §483.45(e)(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record; and
- §483.45(e)(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;

§483.45(e)(3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and
- §483.45(e)(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in §483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident’s medical record and indicate the duration for the PRN order.
- §483.45(e)(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

**Definitions**

- **Adverse Consequence**
  - A broad term referring to unwanted, uncomfortable, or dangerous effects that a drug may have, such as impairment or decline in an individual’s mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medications, medication-food, and medication-disease).

- **Anticholinergic side effect**
  - 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, hallucinations, flushing, and increased blood pressure. Types of medications that may produce anticholinergic side effects include:
  - Antihistamines
  - Antidepressants
  - Antipsychotics
  - Antiepileptics
  - Muscle relaxants
  - Certain medications used to treat cardiovascular conditions, Parkinson’s disease, urinary incontinence, gastrointestinal issues and vertigo.
Definitions

- Behavioral Interventions
  - Individualized, non-pharmacological approaches to care that are provided as part of a supportive physical and psychological environment, directed toward understanding, preventing, releasing, and/or accommodating a resident’s distress or loss of abilities, as well as maintaining or improving a resident’s mental, physical or psychosocial well-being.

- 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.

- Expressions or indications of distress
  - Refers to a person’s attempt to communicate unmet needs, discomfort, or thoughts that he or she may not be able to articulate. The expressions may present as crying, apathy, or withdraw, or as verbal or physical actions such as: pacing, cursing, hitting, kicking, pushing, scratching, tearing things, or grabbing others.

Definitions

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

- Excessive dose
  - 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, and accepted standards of practice for a resident’s age and condition.

- Duplicate therapy
  - 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.

Definitions

- Extrapyramidal symptoms (EPS)
  - Neurological side effects that can occur at any time from the first few days of treatment with antipsychotic medication to years later. EPS includes various syndromes such as:
    - Akathisia - a distressing feeling of internal restlessness that may appear as constant motion, the inability to sit still, fidgeting, pacing, or rocking.
    - Medication-induced Parkinsonism - 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 - 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)
  - 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.
Definitions

- **Indications for use**
  - 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.

- **Neuroleptic Malignant Syndrome (NMS)**
  - 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.

- **Serotonin Syndrome**
  - A potentially serious clinical condition resulting from overstimulation 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 heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting and diarrhea.

- **Tardive dyskinesia**
  - 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.

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F757 & F758 Interpretive Guidance

- Beers Criteria for Potentially Inappropriate Medication Use in Older Adults provides information on safely prescribing medications for older adults
  - [http://www.healthinaging.org/medications-older-adults/](http://www.healthinaging.org/medications-older-adults/)

- Nursing facility population at higher risk for adverse consequences

- Reducing need for & maximizing effectiveness of medications are important considerations
  - IDT should implement non-pharmacological approaches to care as part of medication management
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• Indications for initiating, withdrawing, or withholding medications, & use of non-pharmacological approaches determined by assessment of:
  – Underlying conditions
  – Current signs, symptoms, & expressions
  – Preferences & goals for treatment
  – Underlying causes
• Orders from multiple prescribers can increase chances of receiving unnecessary medications

F757 & F758 Interpretive Guidance

• Resources to help promote safe administration & monitoring of medications
  – Access to current medication references
  – Access to pertinent clinical protocols
  – Medication label warnings
  – Boxed warnings
  – Pharmacist

F757 & F758 Interpretive Guidance

Medication Management
• Recognition or identification of problem/need
• Assessment
• Diagnosis/cause identification
• Management/Treatment
• Monitoring
• Revising interventions
• Documenting medication management steps
F757 & F758 Interpretive Guidance
Medication Management

• Medication management should support & promote:
  – Involvement of resident and/or resident representative/family
  – Selection of medications(s) based on assessing relative benefits and risks to the individual resident;
  – Evaluation of physical, behavioral, mental, & psychosocial signs and symptoms, in order to identify the underlying cause(s), including adverse consequences of medications;
  – Selection and use of medications in doses and for the duration appropriate
  – Use of non-pharmacological approaches
  – Monitoring for efficacy & adverse consequences
  – Resident choice
  – Advance Directives

F757 & F758 Interpretive Guidance
Medication Management

• The regulations associated with medication management include consideration of:
  – Indication and clinical need for medication;
  – Dose (including duplicate therapy);
  – Duration;
  – Adequate monitoring for efficacy and adverse consequences; and
  – Preventing, identifying, and responding to adverse consequences.

F757 & F758 Interpretive Guidance
Medication Management

• With regard to psychotropic medications, the regulations additionally require:
  – Giving psychotropic medications only when necessary to treat a specific diagnosed and documented condition;
  – Implementing GDR and other non-pharmacologic interventions for residents who receive psychotropic medications, unless contraindicated; and
  – Limiting the timeframe for PRN psychotropic medications, which are not antipsychotic medications, to 14 days, unless a longer timeframe is deemed appropriate by the attending physician or the prescribing practitioner.
  – Limiting PRN psychotropic medications, which are antipsychotic medications, to 14 days and not entering a new order without first evaluating the resident.
F757 & F758 Interpretive Guidance

Indications for Use

• Medical record must show:
  – Documentation of adequate indications for medication’s use
  – The diagnosed condition for which medication is prescribed.
• To determine factors affecting signs, symptoms, & test results, evaluation of the resident by the IDT helps to identify resident’s:
  – Needs
  – Goals
  – Comorbid conditions
  – Prognosis
• Important when selecting initial medications and/or non-pharmacological approaches and when deciding whether to modify or discontinue a current medication.

F757 & F758 Interpretive Guidance

Indications for Use

• IDT evaluation should clarify:
  – If other causes for symptoms have been ruled out
  – Whether symptoms or related causes are persistent or clinically significant enough to warrant initiating or continuing medication
  – What non-pharmacological approaches implemented
  – If a specific medication is clinically indicated to manage the symptoms or condition
  – If intended or actual benefit is understood by resident/representative & is sufficient to justify potential risks associated with medication, dose, & duration

F757 & F758 Interpretive Guidance

Indications for Use

• Information to be considered & evaluated by IDT:
  – An appropriately detailed evaluation of mental, physical, psychosocial, and functional status, including comorbid conditions and pertinent psychiatric symptoms and diagnoses and a description of resident complaints, symptoms, and signs.
  – Each resident’s goals and preferences.
  – Allergies to medications and foods and potential for medication interactions.
  – History of prior and current medications and non-pharmacological interventions.
  – Recognition of the need for end-of-life or palliative care.
  – The basis for declining care, medication, and treatment and the identification of pertinent alternatives.
  – Documentation of indications of distress, delirium, or other changes in functional status.
**F757 & F758 Interpretive Guidance**

**Indications for Use**

- Circumstances that warrant evaluation of the resident and medication(s) include:
  - Admission or re-admission;
  - Clinically significant change in condition/status;
  - New, persistent, or recurrent clinically significant symptom or problem;
  - Worsening of an existing problem or condition;
  - Unexplained decline in function or cognition;
  - New medication order or renewal of orders;
  - Irregularity identified in the pharmacist’s medication regimen review;
  - Orders for PRN psychotropic and/or antipsychotic medications which are not prescribed to treat a diagnosed specific condition or do not meet the PRN requirements for psychotropic and antipsychotic medications.

**Dose**

- Prescribed based on factors such as:
  - Diagnosis
  - Signs & symptoms
  - Current condition
  - Age
  - Coexisting medication regimen
  - Review of lab & tests
  - Input from IDT
  - Type of medication
  - Therapeutic goals
- Route of administration influences absorption & dose received
- Duplicate therapy generally not indicated

**Duration**

- Periodic re-evaluation of medication regimen required to determine if continued use of medication is indicated
  - Has a time-limited condition resolved?
  - Is there documentation indicating why continued use is still relevant?
  - Is medication administered beyond prescriber established stop date?
  - Is PRN medication being administered on a regular basis?
- PRN medications need medical record documentation of:
  - Attending physician or prescribers evaluation of resident, indications or specific circumstances for use, & desired frequency of administration
F757 & F758 Interpretive Guidance
Monitoring for Efficacy & Adverse Consequences

- Gather information to:
  - Verify or differentiate underlying diagnoses or underlying causes of signs & symptoms
  - Incorporate into comprehensive care plan
  - Reflect person-centered medication related goals
  - Parameters for monitoring resident’s condition
  - Likely medication effects
  - Potential for adverse consequences
  - Facility protocols related to monitoring specific medications
  - Optimize the therapeutic benefit of medication therapy and minimize or prevent potential adverse consequences
  - Establish parameters for evaluating the ongoing need for the medication
  - Track progress and/or decline towards the therapeutic goal

- Sources of information to facilitate defining the monitoring criteria or parameters may include cautions, warnings, and identified adverse consequences from:
  - Manufacturers’ package inserts and boxed warnings;
  - Facility policies and procedures;
  - Pharmacists;
  - Clinical practice guidelines or clinical standards of practice;
  - Medication references; and
  - Clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals

- Monitoring steps:
  1. Identify essential information & how it will be obtained & reported
  2. Determine frequency of monitoring
     - Periodic planned evaluation of progress toward therapeutic goals
     - Continued vigilance for adverse consequences
  3. Define methods for communicating, analyzing, & acting upon relevant information
  4. Consider if changes in medication are warranted if goals are not met or experiencing adverse consequences
  5. Re-evaluate & update monitoring approaches
Monitoring for Efficacy & Adverse Consequences

• One in five residents experience at least one adverse event during SNF stay
  – 37% of these events related to medications & often preventable
  – Monitoring for Efficacy & Adverse Consequences: National Incidence among Medicare Beneficiaries at
  – The risk for adverse consequences increases with the number of medications being taken regularly & with medications from specific pharmacological classes

• CMS Adverse Drug Event Trigger Tool
  – Assists in identifying resident risk factors & triggers for adverse drug events
  – Use to determine whether systems & processes in place to minimize risk factors and mitigate harm to residents.
  – The tool is available on the CMS Nursing Home Quality Assurance and Performance Improvement website:

• Delirium
  – Presents as an alteration in attention & awareness associated with change in cognition not explained by current or emerging neurocognitive disorder
  – May result from medications or other factors
  – Identifying & addressing risk factors may reduce occurrence
  – Individuals with dementia may be more sensitive to medication effects & at greater risk for delirium
  – Often goes undiagnosed or is misinterpreted as dementia or psychiatric disorder
  – Develops rapidly over short period of time & usually follows a fluctuating course throughout the day
  – Common post-hospitalization
  – Signs & symptoms may be subtle & often missed
  – Failing to act quickly to identify & treat underlying causes may result in poor health outcomes or death
F757 & F758 Interpretive Guidance
Monitoring for Efficacy & Adverse Consequences

- Other adverse consequences:
  - Suicidal ideation
  - Recurrent debilitating anxiety
  - Extreme aggression or agitation
  - Significant decline in former social patterns
  - Social withdrawal
  - Psychomotor agitation or retardation
  - Inability to think or concentrate
  - Apathy

F758 Interpretive Guidance
Psychotropic Medications & Antipsychotic Medications

- Medications must be clinically indicated to treat a specific condition
  - Medical record must show documentation of diagnosed condition for which medication is prescribed

- Psychotropic medication
  - Anti-psychotics
  - Anti-depressants
  - Anti-anxiety
  - Hypnotics

- All may affect brain activities associated with mental processes & behavior

- Residents who take psychotropics must be monitored for any adverse consequences, specifically increased confusion or over-sedation

F758 Interpretive Guidance
Use of Psychotropic Medications in Specific Circumstances

- Acute or Emergency Situations (related to documented condition or diagnosis)
  - Clinician in conjunction with IDT must evaluate & document situation to identify & address any contributing & underlying causes of the acute condition & verify need for psychotropic
  - Use must be consistent with PRN requirements
  - Any continued use must be consistent with GDR requirements
F758 Interpretive Guidance
Use of Psychotropic Medications in Specific Circumstances

• Enduring Conditions (non-acute, chronic, or prolonged)
  – Before initiating or increasing psychotropic, symptoms & therapeutic goals must be clearly & specifically identified & documented
  – Must ensure that resident’s expressions or indications of distress are:
    • Not due to medical condition or problem that can be expected to improve or resolve as underlying condition is treated
    • Not due to environmental stressors alone that can be addressed
    • Not due to psychological stressors alone that can be addressed
    • Persistent
  – Must have clear documentation that distress persists & quality of life is negatively affected & that multiple non-pharmacological approaches have been attempted

F758 Interpretive Guidance
Use of Psychotropic Medications in Specific Circumstances

• New Admissions
  – Attending physician in collaboration with consultant pharmacist must re-evaluate use of psychotropic medication & consider whether or not it can be reduced or discontinued upon admission or soon after admission

F758 Interpretive Guidance
Monitoring of Psychotropic Medications

• Must evaluate effectiveness of medication & look for potential adverse consequences
• After initiating or increasing dose, behavioral symptoms must be reevaluated periodically to determine potential for discontinuing or reducing dose based on therapeutic goals & any adverse effect or functional impairment
F758 Interpretive Guidance
Potential Adverse Consequences

Must adequately monitor for adverse consequences such as:

- Anticholinergic effects
- Signs & symptoms of cardiac arrhythmias
- Increase in total cholesterol & triglycerides
- Unstable or poorly controlled blood sugar
- Weight gain
- Agitation
- Distress
- EPS
- Neuroleptic malignant syndrome
- Parkinsonism
- Tardive dyskinesia
- Cerebrovascular event

F758 Interpretive Guidance
Antipsychotic Medications

• Indication for use of antipsychotic must be thoroughly documented in medical record
• IDT must first identify & address any medical, physical, psychological causes, and/or social environmental triggers
• Must be administered at lowest possible dosage for shortest period of time
• Subject to GDR requirements

F758 Interpretive Guidance
Antipsychotic Medications

• Diagnoses alone do not necessarily warrant use of antipsychotic medication.
  - Antipsychotic medications may be indicated if:
    - Behavioral symptoms present a danger to the resident or others
    - Expressions or indications of distress cause significant distress to the resident;
      - If not clinically contraindicated, multiple non-pharmacological approaches have been attempted, but did not relieve the symptoms which are presenting a danger or significant distress
    - GDR was attempted, but clinical symptoms returned
• Documentation must clearly show:
  - Indication for antipsychotic
  - The multiple attempts to implement care-planned, non-pharmacological approaches
  - Ongoing evaluation of effectiveness of these interventions
Gradual Dose Reduction for Psychotropic Medications

• Purpose of tapering is to find optimal dose or determine whether continued use is benefiting resident
• Tapering may be indicated when:
  – Clinical condition has improved or stabilized
  – Underlying causes of original target symptoms have resolved
  – Non-pharmacological approaches have been effective in reducing symptoms

• Opportunities during care process to review medications & consider GDR:
  – During monthly medication regimen review
  – During routine physician/practitioner visits
  – During quarterly MDS review

• Timeframes & duration of GDR attempts depend on factors including:
  – Coexisting medication regimen
  – Underlying causes of symptoms
  – Individual risk factors
  – Pharmacologic characteristics of medication

• GDR required for psychotropic medications unless clinically contraindicated:
  – Within first year in which admitted, or after psychotropic initiated, must attempt in two separate quarters (with at least one month between attempts), unless clinically contraindicated
  – After first year, must attempt GDR annually, unless clinically contraindicated

• May be considered clinically contraindicated for reasons such as:
  – Target symptoms returned or worsened after most recent GDR attempt within the facility; and
  – Physician has documented clinical rationale for why any additional GDR attempt would be likely to impair resident’s function or increase distressed behavior
F758 Interpretive Guidance
Gradual Dose Reduction for Psychotropic Medication
• For those receiving psychotropics to treat a disorder other than expressions or indications of distress r/t dementia, the GDR may be considered clinically contraindicated for reasons such as:
  – Continued use is in accordance with relevant standards of practice & physician has documented clinical rationale for why any attempted reduction would likely impair residents function or exacerbate an underlying medical or psychiatric disorder
  – Target symptoms returned or worsened after most recent GDR attempt within facility & physician has documented clinical rationale for why any additional attempted dose reduction would likely impair or exacerbate underlying medical or psychiatric disorder

F758 Interpretive Guidance
PRN Orders for Psychotropic & Antipsychotic Medications
• In certain situations psychotropics may be prescribed on PRN basis, such as while dose is adjusted, to address acute or intermittent symptoms, or in an emergency
• Must not have PRN psychotropic order unless medication is necessary to treat a diagnosed specific condition
  – Prescriber must document diagnosed specific condition & indication for the PRN in medical record

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<th>Type of PRN order</th>
<th>Time Limitation</th>
<th>Exception</th>
<th>Required Action</th>
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<tr>
<td>PRN psychotropic, excluding antipsychotics</td>
<td>14 days</td>
<td>Order may be extended beyond 14 days if attending or prescriber believes it is appropriate to extend the order</td>
<td>Attending physician or prescriber should document rationale for extended time period in medical record &amp; indicate a specific duration</td>
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<tr>
<td>PRN antipsychotics</td>
<td>14 days</td>
<td>None</td>
<td>If attending physician or prescriber wishes to write a new order for PRN antipsychotic, must first evaluate resident to determine if new order for PRN antipsychotic is appropriate</td>
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F758 Interpretive Guidance
PRN Orders for Antipsychotic Medications

• Required evaluation before writing a new PRN antipsychotic order entails physician or prescriber to directly examine resident & assess current condition & progress to determine if the PRN antipsychotic is still needed
  – Report of resident’s condition from facility staff to prescriber does not constitute an evaluation
• As part of evaluation physician or prescriber must determine & document the following in medical record:
  – Is the antipsychotic still needed on a PRN basis
  – What is the benefit of the medication to the resident
  – Have the resident’s expressions or indications of distress improved as a result of the PRN medication?

F757 & F758
Key Elements of Non-Compliance

• Inadequate indications for use
  – Failure to document a clinical reason or a clinically pertinent rationale, for using medication(s) for a specific resident or for continuing medication(s) that may be causing an adverse consequence
  – Prescribing or administering a medication despite an allergy to that medication, or without clarifying whether a true allergy existed
  – Failure to consider relative risks and benefits or potentially lower risk medications before initiating medication(s) that present clinically significant risks
  – Failure to provide a clinically pertinent explanation for concomitant use of two or more medications in the same pharmacological class
  – Failure to consider other factors that may be causing expressions or indications of distress before initiating a psychotropic medication, such as an underlying medical condition (e.g., urinary tract infection, dehydration, delirium), environmental (lighting, noise) or psychosocial stressors
  – Administering a psychotropic medication(s), which the resident has not previously received, when it is not necessary to treat a specific condition that has been diagnosed and documented in the clinical record
  – Failure to attempt non-pharmacological approaches, unless clinically contraindicated, in efforts to discontinue psychotropic medications

• Inadequate Monitoring
  – Failure to monitor the responses to or effects of a medication
  – 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 for changes in psychosocial engagement resulting from adverse consequences of medications, (e.g., resident no longer participates in activities because medication causes confusion or lethargy)
  – 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 adverse consequences
  – Failure to consider whether the onset or worsening of symptoms, or a change of condition, may be related to a medication
  – Failure to monitor effectiveness of non-pharmacological approaches, unless clinically contraindicated, before prescribing and administering medications.
F757 & F758
Key Elements of Non-Compliance

- **Excessive duration**
  - 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, evidence-based 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 there is a continued need for the medication, for example, use of an antibiotic beyond the recommended clinical guidelines or the facility policy without adequate reassessment and evaluation of the resident

- **Adverse Consequences**
  - 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) or report the presence of adverse consequence(s)
  - Failure to monitor for the presence of adverse consequences related to the use of medications (particularly high-risk medications, such as warfarin, insulin, opioids, or medications requiring monitoring of blood work)
  - Failure to respond to the presence of adverse consequences related to the use of medications

F757 & F758
Key Elements of Non-Compliance

- **Psychotropic Medications**
  - Failure to present to the attending physician or prescribing practitioner the need to attempt GDR in the absence of identified and documented clinical contraindications
  - Use of psychotropic medication(s) without documentation of the need for the medication(s) to treat a specific diagnosed condition
  - PRN psychotropic medication ordered for longer than 14 days, without a documented rationale for continued use
  - Failure to implement person-centered, non-pharmacological approaches in the attempt to reduce or discontinue a psychotropic medication
  - Administering a new PRN antipsychotic medication for which the resident had a previous PRN order (for 14 days) but the medical record does not show that the attending physician or prescribing practitioner evaluated the resident for the appropriateness of the new order for the medication

Unnecessary Drugs LTC Survey Procedures
Survey procedures for assessing compliance with the F-Tag and citation examples
Initial Pool Process
Resident Interview Care Areas

• Insulin or Blood Thinner
  – Only ask for residents receiving insulin or an anticoagulant:
    • Do you get insulin or a blood thinner like Coumadin?
    • Have you had any problems with your blood sugars such as feeling dizzy or light headed? If so, when did they occur and how did staff respond?
    • Have you had any bleeding or bruising?
    • Have you talked to staff about this?
    • Any other issues?

Initial Pool Process
Resident Observation

• Psych Med Side Effects
  – Are any of the following observed?
    • Tongue thrusting or rolling?
    • Lip puckering or lip smacking
    • Rapid eye blinking/eyebrow raising
    • Pill rolling
    • Tremors

• Psych/Opioid Med Side Effects
  – Are any of the following observed?
    • Excessive sedation (e.g. difficult to rouse, always sleeping)
    • Dizziness

• AC Med Side Effects
  – Are any of the following observed?
    • Bruising
    • Bleeding

Initial Pool Process
Limited Record Review

• For all residents who are observed during the initial pool process, the record is reviewed for high risk meds and PASSAR only if the resident has the indicator present:
  – Is the resident receiving Insulin?
  – Is the resident receiving anticoagulant?
  – Is the resident currently receiving an antipsychotic and has a diagnosis of Alzheimer’s or dementia?

• For new admissions added to the Resident Listing who are observed during the initial pool process (i.e., they don’t have an MDS), the record is reviewed for high risk meds:
  – Is the resident currently receiving any of the following medications at least one time in the last 30 days? (Mark all that apply):
    • Antipsychotic:
      • Antianxiety
      • Antidepressant
      • Hypnotic
      • Anticoagulant
      • Antibiotic
      • Diuretic
      • Insulin
      • Opioids
    • None of the above
Unnecessary Medication Review

• System selects five residents for full medication review
  – Residents may or may not be in sample
• Use for a resident who has potentially unnecessary medications, is
  prescribed psychotropic medications or has the potential for an adverse
  outcome to determine whether facility practices are in place to identify,
  evaluate, and intervene for potential or actual unnecessary medications.
  – Use also to evaluate the medication regimen review (MRR) process.
• Residents selected will include (if available):
  – Insulin
  – Anticoagulant
  – Antipsychotic with Alzheimer’s or dementia
• Unnecessary Medications, Psychotropic Medications, and Medication
  Regimen Review Critical Element Pathway (Form CMS 20082)
  – Based on observation, interview, record review, and MDS

Investigation Process

- Observations
- Staff Interviews
- Pharmacist Interview
- Attending Practitioner, Medical Director, & DON interview
- Record Review

Critical Element Focus

1. Medication Regimen Review process
2. Free from Unnecessary Medications
3. Psychotropic Drug Use
4. Antibiotic Stewardship
5. Baseline/Comprehensive Care Plan
6. Comprehensive Assessment

Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review CE Pathway
(CMS-20082)
F757 Free From Unnecessary Drugs
Survey Trends

- MD most frequently cited F-tag in STD surveys
- 617 citations
  - Complaint Surveys = 92
  - Standard Surveys = 525
- Scope & Severity
  - D level = 440
  - E level = 158
  - G level = 9
  - H level = 3
  - J level = 3
  - K level = 4

This data is for the subset of providers for which there are survey records in CASPER as of 6/25/18.
Source: S&C QCOR (07/03/2018)

F757 IJ Citation Example - TX

- Facility failed to ensure residents drug regimen were free from unnecessary drugs for 1 of 14 residents reviewed for medications
  - Resident received diabetic medication, based on an erroneous transcription, without a diabetes diagnosis. This failure led to Resident being hospitalized for hypoglycemia.
  - A hospital discharge medication list dated 11/26/17 did not include orders for the oral hypoglycemic
  - LPN stated that when Resident was admitted, he had both computerized and hand-written orders from the hospital which she put into the system. She said the orders for glipizide and insulin were both on the hand-written orders, along with 2 other which she noted from Resident's medications list. She noted she is not sure why the medication lists were not put into the computer system, but felt she had processed them in time to get them into the system. She said the transcription error was not caught because she did not verify the medications because Resident's medications were not going right. She said it did not make sense to her why no medication list would include no medications he was allergic to. She said the wrong glucose level on the order was also noted, but not for the reason stated above.
  - On 11/29/17 resident had lab result showing critical glucose level, so MD ordered to check blood sugar, which was found to be in 40s, MD ordered to hold hypoglycemic agents. When wife was notified of this new order, she informed staff that he has never had diabetes or taken these medications. Nurse then reviewed chart & could not find orders for these medications. She notified MD who DCd orders & stated to monitor closely. Next morning was sent out with change in condition.

Corrective Action

- An Immediate Jeopardy was identified that existed from 11/26/17 to 12/1/17. This was determined to be past non-compliance. The facility implemented actions that corrected the non-compliance prior to the beginning of the survey.
  - On 12/1/17, all charts for patients on oral hypoglycemic medications were audited to ensure an appropriate diagnosis for use.
  - Starting 12/1/17, all new admissions medications since 11/30/17 were reviewed by nursing management for hospital orders received, whether there were hand-written orders, and whether the orders were entered into the computer system correctly.
  - The following in-services were performed:
    - 11/30/17 - LVN A was in-serviced on transcribing orders and best practice in regards to handwritten admission orders.
    - 11/30/17 - Charge nurses were in-serviced on transcription of new admission orders. Charge nurses were instructed that all admission orders were to be verified with discharging hospital as well as with facility admitting/transfer department.

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F757 IJ Citation Example - TX

- Facility failed to ensure each resident's drug regimen was free from unnecessary drugs for 2 of 6 residents reviewed for medications.
  - a) The facility did not adequately monitor 2 resident's PT/INR levels properly with the Coagucheck SX Machine and continued to administer anticoagulant medication to the resident after orders indicated the medication had been discontinued/reduced. Resident #1's INR was 23.64 & the resident had rectal bleeding, and expired.
  - b) The facility failed to ensure Resident #3's hospital discharge medication orders were followed and resumed a previous order.

F757 IJ Citation Example - CA

- Facility failed to ensure unnecessary medications were not given, in the presence of adverse consequences for one resident who was receiving large amounts of narcotics and alcohol without indications for its usage in the presence of a potential adverse consequences of consuming alcohol while out on pass for over five months (crossed referenced to F689).
  - These failures resulted in Resident falling three times, twice in one day, at the facility, sustaining an injury to the left index finger, left pinky finger, a periorbital hematoma and laceration to the right eyebrow, which required a transfer to the hospital and placement of six stitches. The failures also had the potential for the resident to become addicted to the narcotics, in addition, result in more injuries and possibly death.
  - Several episodes documented regarding resident being "drunk" and finding empty vodka bottles in room. Had history of multiple falls while "drunk". Staff scared of resident because he becomes mean & threatens them. Surveyors observed him throwing meal tray. Independent & appropriate for lower level of care. Stated he would move to apartment if facility paid for it. MD discussed resident's manipulative behaviors & his fear if dc narcotics he would not be addressing residents very real problems r/t pain & anxiety.

F757 IJ Citation Example – CA

Corrective Action

1. An order was written on 2/1/18 to discontinue the out on pass order for Resident. In addition, the physician gave a new medication order to use for 24 hours for any suspicion of intoxication or drug use.
2. An order was obtained for Resident to be discharged to a lower level of care and sober living options were to be researched and presented to Resident.
3. On 2/1/18, an interdisciplinary (IDT) meeting was conducted, including the attending physician, with Resident. The physician's new orders were discussed, as well as the resident's behavior toward the staff. Resident agreed with the orders and to treat the staff with respect.
4. The Director of Nursing (DON) initiated in-services on 1/31/18 to the Licensed Nurses on evaluation regarding residents returning from out on pass for signs of intoxication.
F757 IJ Citation Example - OR

- Facility failed to provide appropriate monitoring and dosing of medications for 8 residents reviewed for medications, pressure ulcers, hospitalization and behavior. One resident received a sub therapeutic dose of antibiotics used to treat an acute infection resulting in a worsening in her/his infection and a partial immobilization to her/his infected area. 3 Residents experienced delayed treatment
  - The pharmacy was under the impression someone else was managing the antibiotic dosing. The resident went to the emergency room and his PICC line was not replaced and antibiotic was stopped 11/15/17. MG was under the impression the antibiotic was to continue until 11/15/17 MD stated the continued low trough results indicating a less then therapeutic dose of antibiotic with no dosage adjustments and the discontinuation of the antibiotic before it was ordered to end caused Resident to have a worsening in her/his infection creating a partial immobilization to her/his infected area.
- INR was drawn on 10/11/17, with a result of 1.45 (significantly below the resident's goal therapeutic range). According to her MAR, she received the same dose on 10/12/17, although her INR was low. There was no evidence the provider was notified of this low result on 10/12/17, or if the same ordered medication for any new orders for antibiotics or any IV medication which required labs to assure orders were written appropriately and to follow pharmacy recommendations.
- DNS was responsible to ensure compliance

F757 IJ Citation Example – OR Corrective Action

- The immediate plan of correction included:
  - The facility verified to follow pharmacy recommendations for obtaining antibiotic throughs with the contracted facility medical director.
  - The facility in serviced licensed nurses on obtaining appropriate orders for antibiotics, to include trough orders per pharmacy recommendations.
  - A staff training roster was created to ensure training of staff currently working and staff scheduled on subsequent shifts. Agency nursing staff were added to the staff training roster as they were scheduled in order to ensure they received training prior to working. Training was provided by the DNS, nurse consultant or trained designee.
  - The DNS or a trained designee would, using a monitoring tool, monitor daily for any new orders for antibiotics or any IV medication which required labs to assure orders were written appropriately and to follow pharmacy recommendations.
  - DNS was responsible to ensure compliance

F757 IJ Citation Example- WA

- Facility failed to provide appropriate monitoring and dosing of medications for 8 residents reviewed for medications, pressure ulcers, hospitalization and behavior. One resident received a sub therapeutic dose of antibiotics used to treat an acute infection resulting in a worsening in her/his infection and a partial immobilization to her/his infected area. 3 Residents experienced delayed treatment.
  - The pharmacy was under the impression someone else was managing the antibiotic dosing. The resident went to the emergency room and his PICC line was not replaced and antibiotic was stopped 11/15/17. MG was under the impression the antibiotic was to continue until 11/15/17 MD stated the continued low trough results indicating a less then therapeutic dose of antibiotic with no dosage adjustments and the discontinuation of the antibiotic before it was ordered to end caused Resident to have a worsening in her/his infection creating a partial immobilization to her/his infected area.
- INR was drawn on 10/11/17, with a result of 1.45 (significantly below the resident's goal therapeutic range). According to her MAR, she received the same dose on 10/12/17, although her INR was low. There was no evidence the provider was notified of this low result on 10/12/17, or if the same ordered medication for any new orders for antibiotics or any IV medication which required labs to assure orders were written appropriately and to follow pharmacy recommendations.
- DNS was responsible to ensure compliance
F758 Free From Unnecessary Psychotropic Drugs
Survey Trends

- #6 most frequently cited F-tag in STD surveys
- 1,115 citations
  - Complaint Surveys = 80
  - Standard Surveys = 1,035
- Scope & Severity
  - D level = 806
  - E level = 302
  - F level = 1
  - G level = 4
  - J level = 2

This is valid for the subset of providers for which there are survey records in CASPER as of 6/25/18
Source: S&C QCOR (07/03/2018)

F758 IJ Citation Example - FL

- Facility failed to meet professional nursing standards of practice for 1 resident who was administered an excessive dose of an antipsychotic. The facility allowed an unauthorized psychiatric consultation that resulted in an unnecessary antipsychotic medication administered in an excessive dose in the absence of any documented behaviors or symptoms, and without the involvement of the attending physician, the interdisciplinary team, or the family. The resident suffered from adverse consequences from a significant medication error and unnecessary antipsychotic medication when she became lethargic and exhibited symptoms from an adverse drug event.

F758 IJ Citation Example - FL

- Immediate Jeopardy began when a resident’s psychiatrist ordered the resident an antipsychotic medication based on incorrect information that the resident was delusional thinking he was marrying a staff person. Actual Harm occurred when there was no monitoring of the resident for adverse effects from the drug sustaining a decrease in nutritional intake with weight loss, a reduction in physical abilities, increased sleepiness and lethargy, and a decline in quality of life as evidenced by decreased participation in smoking which was his activity of choice.
Unnecessary Medications QAPI
Strategies for monitoring compliance and incorporating survey preparedness into facility QAPI processes

Medication Monitoring

- Opioids
  - Assess pain, implement bowel program.
  - Bleeding/heaving
  - Protime/international normalized ratio (PT/INR)
  - Interaction with other medications
  - Must have policies around monitoring, lab work, and communication of lab values. Implementation of new orders in response to lab values and/or symptoms.

- Anticoagulant
  - Bleeding/bruising
  - Protime/international normalized ratio (PT/INR)
  - Interaction with other medications
  - Must have policies around monitoring, lab work, and communication of lab values. Implementation of new orders in response to lab values and/or symptoms.

- Diuretics
  - Edema
  - Potassium level
  - Signs of electrolyte imbalance

- Psychotropics
  - Monitor behavioral expressions or indications of distress

- Insulin
  - Blood glucose levels
  - Hemoglobin A1C
  - Symptoms of hyper/hypoglycemia

- Antibiotics
  - Interactions with other medications
  - Adverse events
  - Prescriptions must include documentation of:
    - Indication
    - Dose
    - Route
    - Duration
  - Must be reviewed 2-3 days after antibiotic initiation to assess response and labs.
  - Prescriber should reassess antibiotic selection as appropriate

Routine Review of High Risk Medications

- Acceptable clinical indication for use
- Use of written protocols or resources to guide antibiotic use
- Appropriate monitoring for each medication
- Appropriate dosing & duration for each medication
- Clinical rationale for continued use of medication
- System to monitor & address presence of or potential for adverse consequences
- System for & documentation for GDR for psychotropics
- Adherence to PRN requirements for PRN psychotropic & antipsychotic medications
- Medication care planned with individualized approaches to care & non-pharmacological interventions
Resources & Tools

- U.S. Department of Health and Human Services, National Institute of Mental Health Web site, which includes publications and clinical research information – www.nimh.nih.gov
- National Library of Medicine Drug Information Portal (medication class information)
- The Food and Drug Administration (FDA) webpage, Medwatch: The FDA Safety Information and Adverse Event Reporting Program
- The University of Maryland Medical Center Drug Interaction Tool
- American Medical Directors Association
  – www.amda.com
- American Society of Consultant Pharmacists
  – www.ASCP.com

References


Questions?

Type your questions using tool bar on right of your screen.

Please register to join us in August for the next session in the F-tag series: ADL Care for Dependent Residents

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