Psychotropic Medication Use in LTC
F-Tag Updates and GDR
Requirements

Presented by:
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Goals

1. Define the clinical implications of misuse of Psychotropics in LTC
2. Review the updated F-Tags on Psychotropic medication use in the State Operations Manual and recent Federal Surveyor activities
3. Outline our responsibilities and practical compliance strategies

State Operations Manual (SOM)
Appendix PP Updates

Better known as the F-Tags
• AKA the “Guidance to Surveyors”
• Full re-write of ALL F-Tags released June 30th, 2017; went into effect November 28, 2017
• Contained within: 28 Total Pages of Regulations and Guidance focused mainly on Psychotropics
• This is a significant re-write and expansion of the former F329 “Unnecessary Drugs” Tag
State Operations Manual
Appendix PP Update

F757: Unnecessary Medications
F758: Psychotropic Medications

“Antipsychotics” expanded to “Psychotropics”

For all the changes and additional new language, it’s (mostly) still all about (preventing mis)use in DEMENTIA.

Psychotropic Medication Use in LTC

Why are these drugs targeted?

• History of Misuse
  – Sedative effect, “Chemical restraint”

• Side Effect Profile
  – Anticholinergic Effects
  – Black Box Warning

• CMS Concerns about “Class Shifting”

State Operations Manual (SOM)
Psychotropics and GDR

Expanded Definition of Psychotropics includes:

• Antipsychotics (Haldol, Risperdal, Seroquel, Zyprexa, Abilify)

• Anxiolytics and Sedative/Hypnotics (Ativan, Xanax, Valium; Ambien)

• Antidepressants (Prozac, Paxil, Zoloft, Celexa, Lexapro, Trazodone)

• Other meds when used as Psychoactives
  (Depakote, Neurontin, Tegretol, Topamax, etc.)

Gradual Dose Reduction Rules Apply to ALL
Approved Uses of Psychotropics in LTC Facilities

Antipsychotics for Chronic Enduring Conditions:
- Schizophrenia (and related conditions)
- Bipolar Disorder (and related conditions)
- Major Depressive Disorder
- Huntington’s Disease
- Tourette’s Syndrome

Gradual Dose Reduction is NOT required unless:
- The resident is not responding adequately; OR
- is not tolerating the medication reasonably

FDA Approved Uses: Generally not subject to GDR

Use of Psychotropics in LTC Facilities

Other uses:
- Acute Delirium/Psychosis/Delusions
- Other “chronic” conditions that result in psychosis, delusions, and dangerous behaviors (e.g., Traumatic Brain Injury)
- Behavioral and Psychological Symptoms of Dementia

For the above uses of Antipsychotics and ALL Psychotropics, Gradual Dose Reduction IS required, unless:
- Prior GDR has failed; OR
- There is consistent, ongoing documentation as to why GDR is “clinically contraindicated”.

F757: Unnecessary Medications

F757
483.45.1 Unnecessary Drugs—General.
Each resident’s drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—

483.45(1) In excessive dose (including duplicate drug therapy); or
483.45(2) For excessive duration; or
483.45(3) Without adequate monitoring; or
483.45(4) Without adequate indications for its use; or
483.45(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
483.45(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.
### F758: Psychotropic Medications

<table>
<thead>
<tr>
<th>Paragraph</th>
<th>Description</th>
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<tbody>
<tr>
<td>§403.15(e)(3)</td>
<td>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.</td>
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<td>§403.45(e)</td>
<td>Psychotropic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that—</td>
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<tr>
<td>§403.45(e)(1)</td>
<td>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;</td>
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<tr>
<td>§403.45(e)(2)</td>
<td>Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;</td>
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### F758: Psychotropic Medications, continued...

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<tbody>
<tr>
<td>§403.45(e)(3)</td>
<td>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</td>
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<td>§403.45(e)(4)</td>
<td>PRN orders for psychotropic drugs are limited to 14 days. Except as provided in §403.45(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.</td>
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<tr>
<td>§403.45(e)(5)</td>
<td>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.</td>
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### F758: Psychotropic Medications

**Key requirements, restated: Specific Conditions; GDR; Time Limits on PRN’s**

- Giving psychotropic medication only when necessary to treat a specific diagnosed and documented condition; |
- Implementing GDR and other non-pharmacologic interventions for residents who receive psychotropic medication, unless contraindicated, and |
- Limiting the timeframe for PRN psychotropic medication, 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.
F758: Psychotropic Medications

Definition of a psychotropic drug:

"Psychotropic drug" is defined in the regulations at §433.45(c)(3), as "any drug that affects brain activities associated with mental processes and behavior." Psychotropic drugs include, but are not limited to the following categories: anti-psychotics, anti-depressants, anti-anxiety, and hypnotics.

Gradual Dose Reduction Requirements:

Within the first year in which a resident is admitted on a psychotropic medication or after the prescribing practitioner has initiated a psychotropic medication, the facility must attempt a GDR in two separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a GDR must be attempted annually, unless clinically contraindicated.

Determining when GDR is "Clinically Contraindicated":

For any individual who is receiving a psychotropic medication to treat a disorder other than expressions or indications of distress related to dementia (for example, schizophrenia, bipolar mania, depression with psychotic features, or another medical condition, other than dementia, which may cause psychosis), the GDR may be considered clinically contraindicated for reasons that include, but that are not limited to:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident’s function or exacerbate an underlying medical or psychiatric disorder; or
- The resident’s target symptoms returned or worsened after the most recent attempt at a GDR within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident’s function or exacerbate an underlying medical or psychiatric disorder.

Documenting "Clinically Contraindicated":

Scenario 1: Chronic Enduring Condition such as Schizophrenia, Bipolar Disorder, Major Depression:

"Continue Seroquel for chronic enduring condition of Bipolar disorder. Gradual dose reduction clinically contraindicated, resident highly likely to deteriorate and become a danger to self and others."

Scenario 2: Other chronic conditions OTHER THAN DEMENTIA that result in psychosis:

"Continue Risperdal for chronic psychosis related to Traumatic Brain Injury. Gradual dose reduction clinically contraindicated, resident highly likely to deteriorate and become a danger to self and others."

** In ALL OTHER SCENARIOS: Gradual Dose Reduction (GDR) in an effort to D/C MUST be attempted and fail in 2 consecutive quarters before GDR can be considered "Clinically Contraindicated."
F758: Psychotropic Medications

When Gradual Dose Reduction SHOULD be considered:

When use was initiated for dangerous, unresponsive behaviors in DEMENTIA or other acute conditions, and

• The targeted behavior has been absent for a period of 30 days or more
• The targeted behavior has not shown any improvement

In all uses (including Chronic Enduring Conditions), when the resident is experiencing possible side effects:

• Daytime Sedation/Oversedation
• Urinary retention, constipation, blurred vision, dry mouth
• Loss of glycemic control, changes in lipid profile, other lab abnormalities
• Unsteady gait, dizziness (including orthostatic hypotension), FALLS

When should you stop and contact a practitioner IMMEDIATELY?

• Significant fever with muscle rigidity (Neuroleptic Malignant Syndrome)
• ANY signs/symptoms of a Transient Ischemic Attack or Stroke

Recent Survey Activity and Recommendations:

1. REMEMBER: The focus remains on DEMENTIA
   a) Make sure you are identifying residents on psychotropics that have the word “Dementia” in the diagnosis. These WILL be the easy targets.

2. Be prepared to defend appropriate, long term use without GDR use in Major Depression and other Chronic Enduring Conditions

3. Beware of “Class Shifting”
   a) Anxiolytics (ex: Ativan, Xanax), Anticonvulsants for behaviors, and Antidepressants (for uses other than depression) are becoming just as big a focus!

4. Don’t fall into the trap of “Diagnosis Drift”
   a) Don’t write Schizophrenia (or Bipolar Disorder) unless the diagnosis is REAL.
   b) Key: Understanding the difference between the Survey Process and the CMS Five Star Quality Measures on Antipsychotics

Be Prepared for a Federal “Schizophrenia Focus” Survey!

• Specifically looking for “diagnosis drift” (or worse!)
  — “Incentives” to list Schizophrenia
  — Cause of drift more likely simply a misunderstanding of the regulations/requirements

• Process
  — 2 surveyors, 3 days (plus or minus)
  — Focus on MDS Submissions
    • Residents admitted without a psych Dx where Schizophrenia was subsequently added
    • “Late life” onset of Schizophrenia??
  — Justifications
    • PASRR Policy and PASRR Level 2 screens
    • Schizophrenia Care Plan
    • Psychiatry documentation

• What should we be doing?
F758: Psychotropic Medications

Monthly Psychoactive Tracking Report:

Guardian Consulting Services, Inc.
Consultant Pharmacists for Healthcare Facilities

F758: Psychotropic Medications

Consultant Pharmacists for Healthcare Organizations, Industry and the Community
Metro Area Healthcare Facility (Therapy)
Quality Assurance: Psychoactive Medication Use Monthly Summary
November, 2016

UNIT 4

The following residents had active orders for Psychotropics on the date(s) during which Medication Regimen review was performed for this unit in the month listed above.

<table>
<thead>
<tr>
<th>Resident ID</th>
<th>Medication</th>
<th>Do Dr Physicians Order</th>
<th>Date/Typical Duration</th>
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PRN Psychotropics (Other than Antipsychotics):
• 14 days, may be extended beyond 14 days provided rationale is documented by the practitioner and the time duration is specified.
  – This INCLUDES sleep induction meds such as Zolpidem (Ambien).

PRN Antipsychotics:
• Max 14 days, no exceptions. If the practitioner wishes to write a new PRN order, may only do so after “evaluating the resident”.
  – Hospice is NOT excluded from this guidance.

Guidance on PRN Antipsychotics and Psychotropics

Definition of “Evaluating” = “directly examining the resident”

The required evaluation of a resident before writing a new PRN order for an antipsychotic entails the attending physician or prescribing practitioner directly examining the resident and assessing the resident’s current condition and progress to determine if the PRN antipsychotic medication is still needed. As part of the evaluation, the attending physician or prescribing practitioner should, at a minimum, determine and document the following in the resident’s medical record:
• Is the antipsychotic medication 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?

Compliance Strategy: Continue to avoid PRN antipsychotics and psychotropics to the absolute greatest extent possible.
F758: Psychotropic Medications

Examples of Key Elements of Noncompliance

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; or
- Use of psychotropic medication(s) without documentation of the need for the medication(s) to treat a specific diagnosed condition; or
- FRS psychotropic medication ordered for longer than 14 days, without a documented rationale for continued use; or
- Failure to implement patient-centered, non-pharmacological approaches in the attempt to reduce or discontinue a psychotropic medication; or
- Administering a new FRS antipsychotic medication for which the resident had a previous FRS 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.

Psychotropic Medication Use in LTC

Final Thoughts:
- Gradual Dose Reduction WILL sometimes fail!
  - Expect and prepare for it;
  - Learn from it;
  - Don’t allow it to deter GDR for others
- GDR will often cause the resident to IMPROVE
- Identifying residents who could benefit from GDR is everyone’s responsibility!

State Operations Manual
Appendix PP Update

Useful P&P and info on GDR Available at: http://guardianconsulting.com/public-documents/
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