# Understanding F-758; Practical Approach with a Purpose

## Welcome!

- All lines are muted, so please ask your questions in Q&A
- For technical issues, chat to the 'Technical Support' Panelist
- Please actively participate in polling questions that will pop up on the lower righthand side of your screen

We will get started shortly!

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# William G. Day, DPh, PD, RPh, FASCP

## DOCTOR OF PHARMACY/GERIATRIC PHARMACOLOGIST

William Day, President and Chief Executive Officer for Pharmaceutical Consulting Services of America, which is one of the largest independent pharmaceutical consulting firms in the country founded in 1989 and currently servicing over 450 facilities in Louisiana, Arkansas, Oklahoma, Texas and Mississippi as well as numerous Psychiatric Hospitals, Group Homes and Hospice services. He has served on Boards for National and State pharmaceutical association and is a Past-President of the Louisiana Pharmacists Association. He also received a Fellowship in the American Society for Consulting Pharmacist and currently serves as President of the Louisiana Chapter. He is a member of LNHA, Mississippi Health Care Association and is an interdisciplinary team member of American Medical Directors Association. William Day was also recently appointed to serve as a Board Member for the Louisiana Geriatric Society (LGS)

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# Objectives

- Learn Today:
  - To provide NHs with tools that will enable them to perform effective GDRs
  - To provide NHs with GDR knowledge and tools contributing to enhanced positive resident outcome
- Use Tomorrow:
  - …
  - …

# Understanding F-758; Practical Approach with a Purpose

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President and Chief Executive Office
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# Ready for Take-Off?

# F-758

- §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;
- §483.45(e)(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in order to discontinue these

- §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.

# Intent

- §483.45(d) Unnecessary drugs and 483.45(c)(3) and (e) Psychotropic Drugs
- The intent of this requirement is that:
  - each resident's entire drug/medication regimen is managed and monitored to promote or maintain the resident's highest practicable mental, physical, and psychosocial wellbeing;
  - the facility implements gradual dose reductions(GDR) and non-pharmacological interventions, unless contraindicated, prior to initiating or instead of continuing psychotropic medication; and
  - PRN orders for psychotropic medications are only used when the medication is necessary and PRN use is limited.

- 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.

# Indication for Use

- The resident's medical record must show documentation of adequate indications for a medication's use and the diagnosed condition for which a medication is prescribed.
- An evaluation of the resident by the IDT helps to identify his/her needs, goals, comorbid conditions, and prognosis to determine factors (including medications and new or worsening medical conditions) that are affecting signs, symptoms, and test results

# Psychiatric Disorders

- Psychiatric disorders or expressions and/or indications of distress – As with all symptoms, it is important to seek the underlying cause of the distress.
- Some examples of potential causes include delirium, pain, psychiatric or neurological illness, environmental or psychological stressors, dementia, or substance intoxication or withdrawal.
- Non-pharmacologic approaches, unless clinically contraindicated, must be implemented to address expressions or indications of distress.
- However, medications may be effective when the underlying cause of a resident's distress has been determined, non-pharmacologic approaches to care have been ineffective, or expressions of distress have worsened.
- Medications may be unnecessary and are likely to cause harm when given without a clinical indication, at too high of a dose, for too long after the resident's distress has been resolved, or if the medications are not monitored.
- All approaches to care, including medications, need to be monitored for efficacy, risks, benefits, and harm and revised as necessary

- Regarding PRN medications, it is important that the medical record include documentation related to the attending physician's or other prescriber's evaluation of the resident and of indication(s), specific circumstance(s) for use, and the desired frequency of administration for each medication. As part of the evaluation, gathering and analyzing information helps define clinical indications and provide baseline data for subsequent monitoring

- A medication, which is prescribed on a PRN basis, is requested by the resident and/ or/administered by staff on a regular basis, indicating a more regular schedule may be needed.

# Psychotropic Medications

- Psychotropic Medications and Antipsychotic Medications (F758 Only Guidance) As clarified in the section on Indication for Use, residents must not receive any medications which are not clinically indicated to treat a specific condition. The medical record must show documentation of the diagnosed condition for which a medication is prescribed. This requirement is especially important when prescribing psychotropic medications which, as defined in this guidance, include, but are not limited to, the categories of anti-psychotic, anti-depressant, anti-anxiety, and hypnotic medications.

- All medications included in the psychotropic medication definition may affect brain activities associated with mental processes and behavior.
- Use of psychotropic medications, other than antipsychotics, should not increase when efforts to decrease antipsychotic medications are being implemented, unless the other types of psychotropic medications are clinically indicated

- Use of Psychotropic Medications in Specific Circumstances Acute or Emergency Situations:
  - When a psychotropic medication is being initiated or used to treat an emergency situation (i.e., acute onset or exacerbation of symptoms or immediate threat to health or safety of resident or others) related to a documented condition or diagnosis, a clinician in conjunction with the IDT must evaluate and document the situation to identify and address any contributing and underlying causes of the acute condition and verify the need for a psychotropic medication.
  - Use of psychotropic medication to treat an emergency situation must be consistent with the requirements regarding PRN orders for psychotropic and antipsychotic medications and any continued use must be consistent with the requirements for gradual dose reduction (GDR).

- New Admissions: Many residents are admitted to a SNF/NF already on a psychotropic medication. The medication may have been started in the hospital or the community, which can make it challenging for the IDT to identify the indication for use.
- However, the attending physician in collaboration with the consultant pharmacist must re-evaluate the use of the psychotropic medication and consider whether the medication can be reduced or discontinued upon admission or soon after admission.

# Monitoring Psychotropic Medications

- If the record shows evidence of adding other psychotropic medications or switching from one type of psychotropic medication to another category of psychotropic medication, surveyors must review the medical record to determine whether the prescribing practitioner provided a rationale.

- If the psychotropic medication is identified as possibly causing or contributing to adverse consequences as identified above, the facility and prescriber must determine whether the medication should be continued and document the rationale for the decision.
- Additionally, the medical record should show evidence that the resident, family member or representative is aware of and involved in the decision.
- In some cases, the benefits of treatment may outweigh the risks or burdens of treatment, so the medication may be continued.

# Antipsychotic Medications

- As with all medications, the indication for any prescribed first generation (also referred to as typical or conventional antipsychotic medication) or second generation (also referred to as atypical antipsychotic medication) antipsychotic medication must be thoroughly documented in the medical record.
- While antipsychotic medication may be prescribed for expressions or indications of distress, the IDT must first identify and address any medical, physical, psychological causes, and/or social/environmental triggers.
- Any prescribed antipsychotic medication must be administered at the lowest possible dosage for the shortest period of time and is subject to the GDR requirements for psychotropic medications.

# FOR REAL!!!!!!!!!!

- Antipsychotic medications (both first and second generation) have serious side effects and can be especially dangerous for elderly residents.
- When antipsychotic medications are used without an adequate rationale, or for the sole purpose of limiting or controlling expressions or indications of distress without first identifying the cause, there is little chance that they will be effective, and they commonly cause complications such as movement disorders, falls with injury, cerebrovascular adverse events (cerebrovascular accidents (CVA, commonly referred to as stroke), and transient ischemic events) and increased risk of death.

The FDA Boxed Warning which accompanies second generation anti-psychotics states,

*"Elderly patients with dementia related psychosis treated with atypical anti-psychotic drugs are at an increased risk of death."*

- Diagnoses alone do not necessarily warrant the use of an antipsychotic medication. Antipsychotic medications may be indicated if:
  - behavioral symptoms present a danger to the resident or others;
  - expressions or indications of distress that are 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; and/or
  - GDR was attempted, but clinical symptoms returned.

- If antipsychotic medications are prescribed, documentation must clearly show the indication for the antipsychotic medication, the multiple attempts to implement care-planned, nonpharmacological approaches, and ongoing evaluation of the effectiveness of these interventions.

- NOTE: If the resident's condition has not responded to treatment or has declined despite treatment, it is important to evaluate both the medication and the dose to determine whether the medication should be discontinued or the dosing should be altered, whether or not the facility has implemented GDR as required, or tapering.

- PRN Orders for Psychotropic and Antipsychotic Medications In certain situations, psychotropic medications may be prescribed on a PRN basis, such as while the dose is adjusted, to address acute or intermittent symptoms, or in an emergency.
- However, residents must not have PRN orders for psychotropic medications unless the medication is necessary to treat a diagnosed specific condition.
- The attending physician or prescribing practitioner must document the diagnosed specific condition and indication for the PRN medication in the medical record.

- 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?

- NOTE: Report of the resident's condition from facility staff to the attending physician or prescribing practitioner does not constitute an evaluation.

# Nursing Home Continuum of Care

1. My stomach hurts, kind of gassy may have some reflux: Reglan
2. I am hurting a little:  Norco/Ultram
3. My feet tingle: Elavil
4. I am sad:  Lexapro

# My First Visit to a Nursing Home:

- Mr. Reed, the man in the wheelchair that kept staring at me. There was something in his eyes that drew me to him. So, I reviewed his medications:
- 1. Diphenhydramine 25mg QHS PRN insomnia
- 2. Metoclopropamide 10mg AC and HS for GERD
- 3. Haldoperidol 1mg BID for decreased cognition and behaviors
- 4. Amitritiptyline 10mg QHS for Neuropathy
- 5. Methocarbamol 750mg BID for muscle spasms
- 6. Antihypertensive, Anticholesterol, Stool softeners, laxatives, etc.

# Questions?

# Objectives Check In!

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- Use Tomorrow:
  - …
  - …

**How will this change what you do?**
**Please tell us in the poll…**

# Closing Survey

## *Help Us Help You!*

- Please turn your attention to the poll that has popped up in your lower right-hand side of your screen
- Completion of this survey will help us steer our topics to better cater to your needs

# CMS 12th SOW Goals

## Behavioral Health Outcomes & Opioid Misuse

- ✓ Promote opioid best practices
- ✓ Decrease high dose opioid prescribing and opioid adverse events in all settings
- ✓ Increase access to behavioral health services

## Patient Safety

- ✓ Reduce risky medication combinations
- ✓ Reduce adverse drug events
- ✓ Reduce C. diff in all settings

## Chronic Disease Self-Management

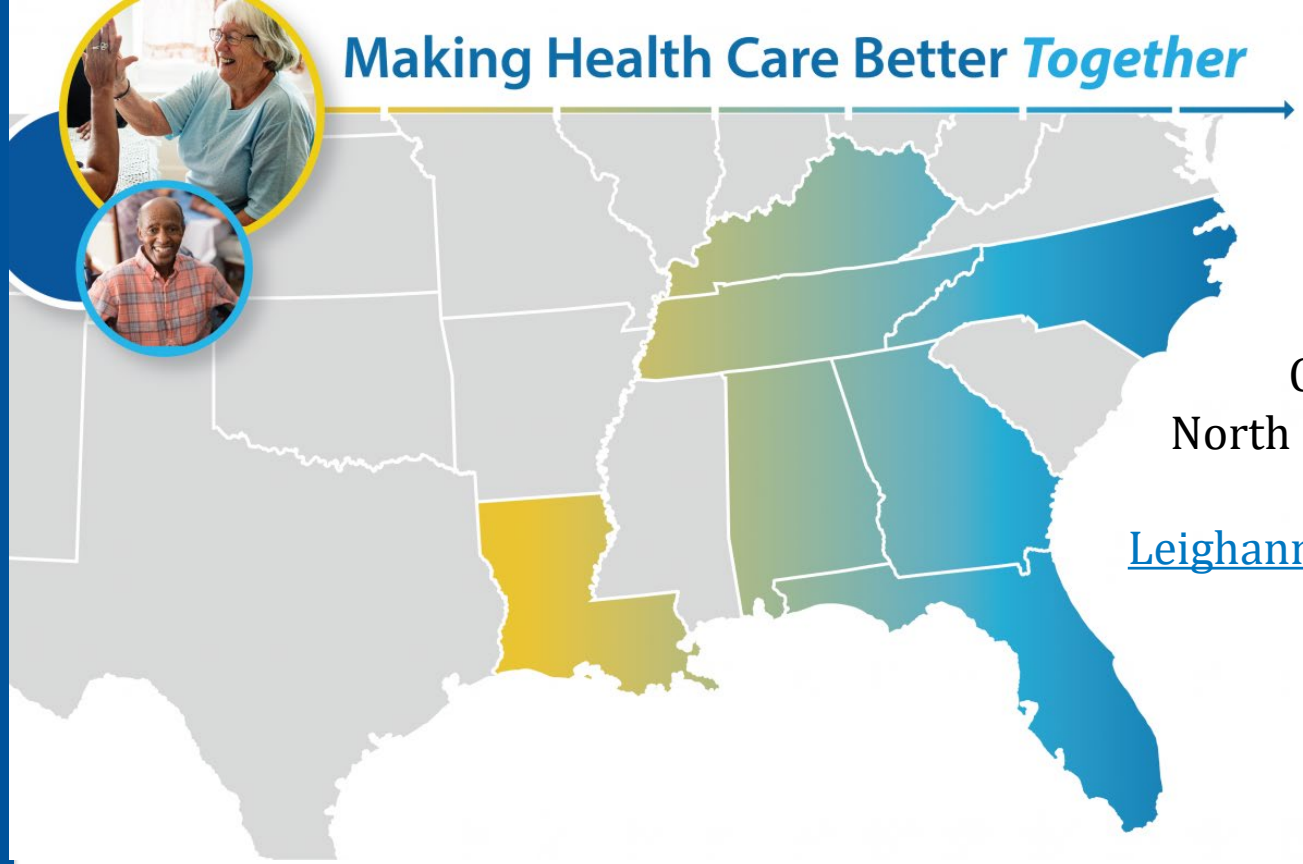
- ✓ Increase performance on ABCS clinical quality measures (i.e., aspirin use, blood pressure control, cholesterol management, cardiac rehab)
- ✓ Identify patients at high-risk for developing kidney disease & improve outcomes
- ✓ Identify patients at high risk for diabetes-related complications & improve outcomes

## Quality of Care Transitions

- ✓ Convene community coalitions
- ✓ Identify and promote optical care for super utilizers
- ✓ Reduce community-based adverse drug events

## Nursing Home Quality

- ✓ Improve the mean total quality score
- ✓ Develop national baselines for healthcare related infections in nursing homes
- ✓ Reduce emergency department visits and readmissions of short stay residents

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# Upcoming Events

## Learning and Action Webinars

| | |
|---|---|
| Nursing Homes<br>Tuesdays, 2pm ET/1pm CT | Community Coalitions<br>Thursdays, 12:30 pm ET/11:30am CT |
| August 17, 2021: Immunizations Let's Get Back to Basic Immunization Practices:<br>Assessment \| Recommendation \| Administration \| Documentation | July 22, 2021: Optimizing Transitional Care for Older Adults with Diabetes |
| September 21, 2021: Diagnostic Stewardship for C. Difficile Prevention | August 26, 2021: TBD |

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