Your Facility Needs Your Help- Regulatory Requirements for Reducing Anti-Psychotics

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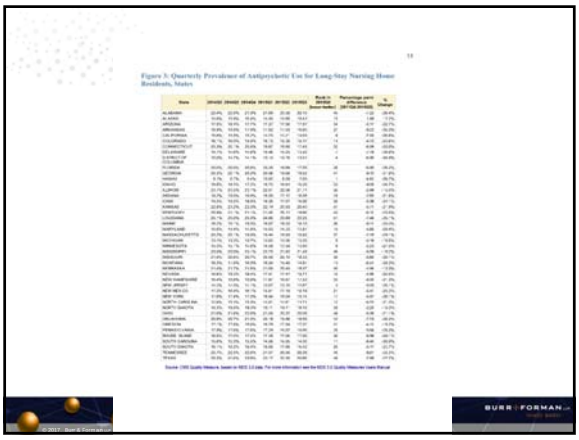
results matter

Reducing Anti-Psychotics

- Background
- Regulatory requirements
- Specific Issues

Background

- 2017 regulations updated to include unnecessary medications
- 2019 OIG Unnecessary Meds was the sixth-most frequently cited deficiency type for CY 2013- CY 2017
- Office of Inspector General (OIG) added to work plan in 2020



State	2014Q2	2014Q3	2014Q4	2015Q1	2015Q2	2015Q3	Rank in 2015Q3 (lower=better)	Percentage point difference (2011Q4-2015Q3)	% Change
ALABAMA	22.4%	22.0%	21.9%	21.69	20.58	20.10	45	-7.22	-26.4%

More recent data for 2018 and 2019 has Alabama at average of 19.3%

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Regulations – F757

- 42 CFR 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 –
    - In excessive does (including duplicative drug therapy); or
    - For excessive duration; or
    - Without adequate monitoring; or
    - Without adequate indications for its use; or
    - In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
    - Any combination of the above.

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42 CFR 483.45(c) - F758

- 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:
    - Anti-psychotic;
    - Anti-depressant;
    - Anti-anxiety; and
    - Hypnotic.

42 CFR 483.45(e) – F758

- Psychotropic drugs: Based on comprehensive assessment of a resident, the facility must ensure that:
  - Residents who have not used psychotropic drugs are not given unless necessary to treat a specific condition as diagnosed and documented in the clinical record;
  - Resident who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;
  - PRN – limited to 14 days unless attending physician or prescribing practitioner documents rationale in medical record;
  - PRN – cannot be renewed unless attending or prescribing evaluates the resident for appropriateness for the medication.

Intent

- Maintain highest practicable mental, physical and psychosocial well-being
- Gradual dose reductions (GDR) and non-pharmacological interventions, unless contraindicated
  - GDR is defined as “stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower does or if the dose or medication can be discontinued
- PRN orders are only used when medication necessary and PRN use is limited.

Unnecessary medications

- Psychotropics - F758
- Other medications – F757

Surveyors

- Not physicians
- Not pharmacists
- How do they determine if inappropriate?
  - "Surveyors are expected to investigate the basis for decisions and interventions affecting residents"
  - "Regulations and guidance…are not intended to supplant the judgment of a physician or prescribing practitioner…and in accordance with appropriate standards of practice."

Surveyor Guidance

- "Proper medication selection and prescribing (including dose, duration and type of medications) may help stabilize or improve a resident's outcome, quality of life and functional capacity. Any medication or combination of medications – or use of medication without adequate indications, in excessive dose, for an excessive duration or without adequate monitoring – may increase the risk of a broad range of adverse consequences such as medication interactions, depression, confusion, immobility, falls, hip fractures and death."

Surveyor Guidance- Issue Spotting

- Medication Management
  - Indication for Use
  - Dose
  - Duration
  - Monitoring

Medication Management

- As part of all medication management (especially psychotropic medications) it is important for the IDT to implement non-pharmacological approaches designed to meet the individual needs of each resident.
- Non-pharmacological approaches:

Medication Management

- The attending physician plays a key leadership role in medication management by developing, monitoring, and modifying the medication regimen in conjunction with residents, their families, and/or representatives and other professionals and direct care staff (the IDT).
- Medication management includes 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.

Medication Management

- Psychotropic medication management includes additional requirements
  - Only when necessary to treat a specific diagnosis and documented condition;
  - Implementing GDR and non-pharmacological interventions, unless contraindicated;
  - Limiting PRN psychotropic which ARE NOT antipsychotic to 14 days unless a longer timeframe is deemed appropriate by the physician or prescribing practitioner;
  - Limiting PRN psychotropic which ARE antipsychotic medications to 14 days and not entering a new order without first evaluating the resident.

Medication Management

- Isolated situations where pharmacological intervention is required first
- Even in those instances, a facility must develop and implement non-pharmacological interventions

Indications for Use

- Medical record must show documentation of adequate indications for a medication's use and the diagnosed condition for which a medication is prescribed.
- Evaluation process important to selecting initial medications and/or non-pharmacological approaches and when deciding whether to modify or discontinue a current medication.

Indications for Use

- Evaluation of resident should include
  - What other causes for the symptoms have been ruled out;
  - Whether the physical, mental, behavioral and/or psychosocial signs, symptoms or related causes are persistent or clinically significant enough to warrant initiation or continuation of medication therapy;
  - Whether non-pharmacological approaches are implemented;
  - Whether a particular medication is clinically indicated to manage the symptoms or condition; and
  - Whether intended or actual benefit is understood by the resident and is sufficient to justify potential risks adverse consequences.

Indications for Use

- Information to be considered
  - Mental, physical, psychosocial and functional status;
  - Resident's goals and preferences;
  - Allergies;
  - History of prior and current medications;
  - Recognition of need for end-of-life or palliative care;
  - Basis for declining care, medication and treatment;
  - Documentation of indications of distress, delirium or other changes in functional status.

Indications for Use

- When an evaluation should occur:
  - Admission or re-admission;
  - Significant change in condition;
  - New, persistent or recurrent clinically significant symptom or problem;
  - Worsening of existing problem or condition;
  - Unexplained decline in function or cognition;
  - A new medication order or renewal of orders; and
  - An irregularity in the medication regimen review.
  - Orders for PRN psychotropic or antipsychotic which are not prescribed to treat a diagnosed condition or do not meet PRN requirements (14 days)

Dose

- Why prescribed – diagnoses, signs and symptoms, condition, coexisting medication regimen, labs, goals and preferences.
- Route of administration
- Duplicate therapy – multiple medications from the same class or with similar therapeutic effects.
  - › Duplication high during transitions of care

Duration

- Clinical rationale for continued use
- PRN medications – documentation from attending physician or prescriber of evaluation of resident and indications, specific circumstances for use and desired frequency
- Common considerations
  - › Time-limited condition – nausea, cough, infection
  - › Medication administered beyond stop date would be excessive duration
  - › PRN being requested or administered regularly – should it be scheduled rather than PRN

Monitoring

- Verify diagnosis or causes of signs or symptoms
- Care plan
- Optimize therapeutic benefit
- Establish parameters for evaluating ongoing need;
- Track progress and/or decline

Psychotropic and Antipsychotic

- Residents must not receive any medications not clinically indicated to treat a specific condition.
- Medical record must contain diagnosed condition for which medication is prescribed.
- Medication must be appropriate to treat resident's specific, diagnosed and documented condition and the medication is beneficial to the resident as demonstrated by monitoring and documentation of the resident's response to the medication.

Psychotropic Medications

- Acute or emergency
  - Must be consistent with PRN and GDR
- Enduring conditions
- New Admissions
  - Admitted on psychotropic
  - Presents challenges in identifying indication for use
  - Attending physician MUST re-evaluate the use upon admission or soon after admission.

Psychotropic medications

- Monitoring
  - After initiating or increasing, behavioral symptoms must be re-evaluated- at least quarterly – to determine potential for reducing or discontinuing
  - If adding or switching, there must be documented rationale from prescribing practitioner
- Potential Adverse Consequences
  - General –flushing, blurred vision, dry mouth, altered mental status, difficulty urinating, falls, excessive sedation, constipation.
  - Cardiovascular
  - Metabolic
  - Neurologic
- If medication is possible cause, facility and prescriber must determine whether medication should be continued and document rationale for the decision.

Antipsychotic medications

- Must thoroughly document rationale for prescribing
- IDT must identify and address any medical, physical or psychosocial causes and/or social/environmental triggers prior to prescribing antipsychotics
- Lowest possible dosage
- Shortest period of tie
- Subject to GDR

Antipsychotic medications

- Diagnoses alone does not necessarily warrant use
- May be indicated if:
  - Behavioral symptoms present a danger to resident or others
  - Expressions or indications of distress that cause significant distress to the resident
  - If not contraindicated, multiple non-pharmacological approaches have been attempted but did not relieve symptoms; and/or
  - GDR was attempted but clinical symptoms return.

Gradual Dose Reduction

- Purpose: tapering a medication to find an optimal dose or to determine whether continued use of medication is benefitting the resident.
- When:
  - Clinical condition has improved or stabilized
  - Underlying causes of original target symptoms have resolved; and/or
  - Non-pharmacological approaches have been effective in reducing symptoms.

GDR

- Who/When
  - Pharmacist - Monthly medication regimen review
  - Attending physician – reviewing plan of care, orders or evaluating resident's response;
  - MDS quarterly review
- If resident's condition has not responded or has declined, evaluate both the medication and the dose.

GDR

- Within 1 year of resident admitted on psychotropic medication or after the prescribing practitioner has initiated a psychotropic medication, the facility MUST attempt a GDR
  - 2 separate quarters
  - With at least one month in between the attempts.
- After 1st year, GDR must be attempted annually, unless clinically contraindicated.
- Contraindications include but not limited to:
  - Symptoms return or worsen after the most recent attempt at GDR; AND
  - Physician documents clinical rationale for why dose reduction would likely impair the resident's function or distressed behavior.

PRN

- Physician must document the diagnosed specific condition and indication for the PRN medication in the medical record.

Type of PRN order	Time limit	Exception	Required Action
PRN psychotropic excluding antipsychotics	14 days	Can extend beyond if physician believes appropriate to extend.	Document rationale in medical record and indicate specific duration
PRN antipsychotics	14 days	NONE	If ordered, physician must first evaluate resident

PRN

- Antipsychotic – the evaluation must include
  - Direct examination
  - Assessment of current condition
  - Must document at a minimum
    - Is antipsychotic still needed on PRN basis?
    - What is benefit of medication for resident?
    - Have resident's expressions or indications of distress improved as a result of the PRN medication?
  - Report of resident's condition from facility staff to the physician does not constitute an evaluation.

Issues

- Resident coming from psychiatric facility whose behaviors controlled so being readmitted to facility.
- Facility requesting medications to address behaviors because unable to address behaviors with non-pharmacological interventions.
  - Surveyors may suggest this is for convenience of staff
  - Chemical restraint (F605)
- Ambulatory resident prescribed antipsychotic for acute delirium and significant side effect caused resident to stay in bed, develops stage III pressure sore.
- Severity Level 1 not available for this deficiency – no actual harm with potential for minimal harm.

QUESTIONS?

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