CMS to Focus on Reducing Inappropriate Use of Antipsychotics in Nursing Homes

In an October 26th meeting with key stakeholders, CMS Administrator, Dr. Donald Berwick, and several quality leaders at CMS called for improvement in how antipsychotics are used in the treatment of nursing home residents with dementia. Citing the FDA black-box warning and the fact that these medications have been linked to adverse outcomes in nursing home populations, Dr. Berwick asked stakeholders, including LeadingAge, to provide to CMS their proposals for reducing the prevalence of these medications in the nursing home setting. LeadingAge's response to Dr. Berwick focused on three general areas:

First, LeadingAge called for adequate data to ensure not only current baseline measurement, but also clear definitions for "appropriate" and "inappropriate" use of antipsychotic medications.

Second, LeadingAge cautioned that CMS's efforts should not target solely one class of drugs, as that may trigger the unintended consequence of increasing the use of other medications which have an equal, if not greater, safety risk. Rather, LeadingAge proposed that efforts to reduce inappropriate use of antipsychotics be put in the context of the current CMS requirements at F-tag 329: Unnecessary Drugs, a summary of which is provided below.

Third, LeadingAge recognized that any sustained quality improvement in this area must truly involve a collaborative effort of all stakeholders—physicians, nurses, pharmacists, direct care staff, consumers and CMS—and is best framed in terms of how to improve the care of residents with dementia. LeadingAge asserted that Advancing Excellence is the best model for such a comprehensive and wide-ranging collaboration, and now with almost 50% of nursing homes signed up for Advancing Excellence, it also presents the best vehicle for reaching nursing homes across the country.

While LeadingAge awaits the final recommendations from CMS based on the responses it received from stakeholders, it is clear from Dr. Berwick's statements that this will be an area of focus for the survey process. Accordingly, as noted above, LeadingAge has compiled a summary of the key requirements with respect to unnecessary drugs that can be used by LeadingAge members to guide their compliance efforts. LeadingAge recommends that members review with their clinical staff the key principles of "avoiding unnecessary drugs": Does each medication have a clear indication? Is there documentation of a positive response? Are clinical staff monitoring for adverse effects? Is the drug being used at the lowest effective dose and is the need for continuing the medication being assessed at regular intervals? Additional areas of focus include whether non-pharmacological interventions are indicated or have been tried, and whether or not the family or designated decision-maker has been informed of the risks and benefits and concurs with treatment.

Optimum care for residents with dementia is really at the core of person-centered care. LeadingAge acknowledges that this cannot be driven by a "one-fix" solution, but rather a broad, evidence-based approach that includes the entire interdisciplinary team. Effective collaboration and thorough documentation are the lynchpins to success that ultimately will translate into higher quality of care for our nation's nursing home residents.

Summary of Requirements for Unnecessary Drugs - F329

State Operations Manual (SOM); Appendix PP; Pages 344 – 426:
https://cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf

§483.25(l) Unnecessary Drugs
1. General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

(i) In excessive dose (including duplicate therapy); or
(ii) For excessive duration; or
(iii) Without adequate monitoring; or
(iv) Without adequate indications for its use; or
(v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
(vi) Any combinations of the reasons above.

2. Antipsychotic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that:

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and
(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

- The intent of these requirements is that the facility's medication management program supports and promotes selection of medications(s) based on assessing relative benefits and risks to the resident;
    - Evaluation of the resident's signs and symptoms to identify the underlying cause(s), including adverse consequences of medications;
    - Selection and use of medications in doses and for the duration appropriate to each resident's clinical conditions, age, and underlying causes of symptoms;

- Use of non-pharmacological interventions, when applicable, to minimize the need for medications, permit use of the lowest possible dose, or allow medications to be discontinued;
- Monitoring of medications for efficacy and clinically significant adverse consequences; and
- Accurate and appropriate documentation, i.e., "the resident's clinical record documents and communicates to the entire interdisciplinary team the basic elements of the care process."

- The guidance at F329 applies to all categories of medications, including antipsychotic medications.

Medication Management

- Medication management includes consideration of:
  - Indications for use (including initiation or continued use of antipsychotic medication);
  - Monitoring for efficacy and adverse consequences;
  - Dose (including duplicate therapy);
  - Duration;
  - Tapering of a medication dose/gradual dose reduction for antipsychotic medications;
  - Prevention, identification, and response to adverse consequences.

Compliance with 42 CFR 483.25(l), F329, Unnecessary Medications

The facility is in compliance if it has, in collaboration with the prescriber:

- Assessed the resident to ascertain, to the extent possible, the causes of the condition or symptoms requiring treatment, including recognizing, evaluating, and determining whether the condition or symptoms may have reflected an adverse consequence;
  - Circumstances that warrant evaluation may include:
    - Admission or re-admission;
    - A clinically significant change in condition/status;
    - A new, persistent, or recurrent clinically significant symptom or problem;
    - A worsening of an existing problem or condition;
    - An unexplained decline in function or cognition;
    - A new medication order or renewal of orders;
    - An irregularity identified in the pharmacist's monthly medication regimen review.
- Based on the assessment, determined that medication therapy was indicated and identified the therapeutic goals for the medication;

- Indications for Use includes the identified, documented clinical rationale for administering a medication based upon assessment of the resident's condition and therapeutic goals, and consistent with manufacturer's recommendations and/or clinical practice guidelines, clinical standards of practice, medication references, clinical studies or evidence-based review articles published in medical and/or pharmacy journals.
    - Regarding "as needed" (PRN) medications, it is important to evaluate and document the indication(s), specific circumstance(s) for use, and the desired frequency of administration.

- Utilized only those medications in appropriate doses for the appropriate duration, which are clinically necessary to treat the resident's assessed condition(s);
    - "Dose" is the total amount/strength/concentration of a medication given at one time or over a period of time.
    - "Excessive dose" is the total amount of any medication (including duplicate therapy) given at one time or over a period of time that is greater than the amount recommended by the manufacturer's label, package insert, current standards of practice for a resident's age and condition, or clinical studies or evidence-based review articles published in medical and/or pharmacy journals and that lacks evidence of:
        – A review for the continued necessity of the dose;
        – Attempts at, or consideration of the possibility of, tapering a medication; and
        – A documented clinical rationale for the benefit of, or necessity for, the dose or for the use of multiple medications from the same pharmacological class.
    - "Duplicate therapy" refers to multiple medications of the same pharmacological class/category or any medication therapy that substantially duplicates a particular effect of another medication being taken.
        - Duplicate therapy is generally not indicated unless current clinical standards of practice and documented clinical rationale confirm the benefits of multiple medications from the same class or with similar therapeutic effects.
        - Documentation is necessary to clarify the rationale for and benefits of duplicate therapy and the approach to monitoring for benefits and adverse consequences.
    - "Duration" is the total length of time the medication is being received.
        - "Excessive Duration" means the medication is administered beyond the manufacturer's recommended timeframes or facility-established stop order policies; beyond the length of time advised by current standards of practice, clinical practice guidelines, clinical studies or evidence-based review articles; and/or without

evidence of additional therapeutic benefit or clinical evidence warranting continued use.
        - Periodic re-evaluation of the medication regimen is necessary to determine whether prolonged or indefinite use of a medication is indicated.
        - Common considerations for appropriate duration may include:
            - A medication initiated as a result of a time-limited condition is discontinued when the condition has resolved, or documentation indicates why continued use is still relevant.
            - A medication is discontinued when indicated by facility stop order policy or by the prescriber's order, unless there is documentation of clinical justification for extended use.
- Implemented a gradual dose reduction and behavioral interventions for residents receiving antipsychotic medications unless clinically contraindicated;
    - "Gradual Dose Reduction (GDR)" is the stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.
        - The purpose of tapering a medication, e.g., during the monthly medication regimen review or MDS quarterly review, is to find an optimal dose or determine whether continued use is benefiting the resident.
    - "Behavioral interventions" are individualized non-pharmacological approaches provided as part of a supportive physical and psychosocial environment, and directed toward preventing, relieving, and/or accommodating a resident's distressed behavior.

- **Considerations under F329 Specific to Antipsychotics.**
    - Within the first year of an admission on an antipsychotic medication or after the facility has initiated an antipsychotic 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.
    - For an individual receiving an antipsychotic medication to treat behavioral symptoms related to dementia, the GDR may be considered clinically contraindicated if:
        - 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 increase distressed behavior.
    - For an individual receiving an antipsychotic medication to treat a psychiatric disorder other than behavioral symptoms related to dementia

(e.g., schizophrenia, bipolar mania, or depression with psychotic features), the GDR may be considered contraindicated, if:

- 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 cause psychiatric instability by exacerbating an underlying 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 cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

- Monitored the resident for efficacy of the medication regimen and for the emergence or presence of adverse consequences;
  - Monitoring has three aspects: Periodic planned evaluation of progress toward therapeutic goals; continued vigilance for adverse consequences; and evaluation of identified adverse consequences.
  - Key objectives include use of quantitative and qualitative parameters to track progress toward therapeutic goal(s) and to detect emergence or presence of adverse consequences.
  - Monitoring parameters are based on the resident's condition; the pharmacologic properties of the medication and its associated risks; individualized therapeutic goals; the potential for clinically significant adverse consequences.
  - Monitoring includes identifying essential information; how it will be obtained and reported; who is responsible; how it will be documented.
  - The information collected depends on therapeutic goals; detection of potential or actual adverse consequences; consideration of risk factors, such as medication-medication, medication-food interactions; clinical condition; properties of the medication; black-box warnings; history of adverse consequences related to a similar medication.
  - The monitoring process identifies who communicates with the prescriber; information to be conveyed; when to ask the prescriber to evaluate and consider modifying the medication regimen.
  - Frequency and duration of monitoring depend on factors such as clinical standards of practice; facility policies and procedures; manufacturer's specifications; the resident's clinical condition.
    - Psychopharmacologicals and sedative/hypnotics should be reviewed at least quarterly, with documentation for continuing the medication to include evaluation of the resident's target symptoms; the effect of the medication on severity, frequency, and other characteristics of the symptoms; any changes in

function (e.g., as identified in the MDS); and whether any medication-related adverse consequences were experienced.

- Adjusted or discontinued the dose of a medication in response to adverse consequences, unless clinically contraindicated.
    - The risk for adverse consequences increases with the number of medications being taken and with medications from specific pharmacological classes, such as anticoagulants, diuretics, antipsychotics, anti-infectives, and anticonvulsants., permanent injury, and death. [See p. 371, SOM for Tables I & II: classes of medications associated with frequent or severe adverse consequences].
        - Delirium (i.e., acute confusional state) is a common medication-related adverse consequence.
            - Individuals who have dementia may be more sensitive to medication effects and may be at greater risk for delirium. Some of the classic signs of delirium may be difficult to recognize and mistaken for the natural progression of dementia, particularly in the late stages of dementia.

Black Box Warnings

- The Food and Drug Administration (FDA) requires that manufacturers include warnings within labeling about adverse reactions and potential safety hazards identified both before and after approval of a medication, and what to do if they occur (www.fda.gov/medwatch/safety.htm).
- Manufacturers are required to update labels regarding newly identified safety hazards—regardless of whether causation has been proven and whether the medication is prescribed for a disease or condition that is not included in the "Indications and Usage" section of the labeling ("off-label" or unapproved use).
- The FDA may require manufacturers to place statements about serious problems prominently, in boxed or "black box" warnings, indicating a need to closely evaluate and monitor the potential benefits and risks of that medication.

Resident Choice

The resident's wishes and preferences must be considered. A resident and/or representative(s) has the right to be informed about the resident's condition; treatment options; relative risks and benefits of treatment; required monitoring; expected outcomes; and the right to refuse care and treatment. If a resident refuses treatment, the staff and physician should inform the resident of the risks related to refusal, and discuss appropriate alternatives such as offering the medication at another time or in another dosage form; or an alternative medication, or non-pharmacological approach, if available.

Medication Regimen Review (MRR)

- §483.60(c) Drug Regimen Review [F428; SOM page 536] mandates: (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist; and (2) The pharmacist must report any irregularities to the attending physician, and the director of nursing, and these reports must be acted upon.
- "(MRR) is the thorough evaluation of the medication regimen by a pharmacist, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication. The review includes preventing, identifying, reporting, and resolving medication-related problems, medication errors, or other irregularities in collaboration with other members of the interdisciplinary team."