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DQA Memo 09-015

To: Nursing Homes

NH 04

From: Otis Woods, Administrator
Division of Quality Assurance

Antipsychotic Medication Use for Individuals with Dementia

The purpose of this memo is to address the current federal Food and Drug Administration (FDA) Public Health Advisories on antipsychotic medication use for the treatment of behavioral disorders in elderly individuals with Alzheimer's disease, dementia or other organic brain syndrome.

Background

The FDA issued Public Health Advisories for all antipsychotic medications. The advisories can be accessed at <http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm053171.htm> and <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01851.html> . These advisories are a response to various studies that indicated increased mortality when antipsychotics were used for the treatment of behavioral disorders in elderly individuals with Alzheimer's disease, dementia or other organic brain syndrome. The advisories highlight FDA requirements for manufacturers to include a Boxed Warning in medication product labeling that describes the mortality risk and notes that antipsychotics (e.g., aripiprazole, olanzapine, quetiapine, risperidone, clozapine, ziprasidone, haloperidol and thioridazine) are not approved for the treatment of behavioral disorders in elderly individuals with dementia.

Discussion

Federal and State regulations establish various requirements related to medication use, some of which are very specific to antipsychotic use. **These regulations have not changed.**

The Division of Quality Assurance (DQA), as part of the nursing home survey process, investigates the use of antipsychotic medications for behaviors in residents with Alzheimer's disease, dementia or other organic brain syndrome. Through the investigation, surveyors determine compliance with the various antipsychotic medication regulations. DQA surveyors apply standards of practice for behavior treatment. In applying those standards, the following questions are considered by surveyors when antipsychotic medications are used for behaviors related to Alzheimer's disease, dementia or other organic brain syndrome:

- 1) Was the behavior persistent?
- 2) Was the behavior harmful?

- 3) Were other environmental, psychosocial or medical causes of the behavior ruled out?
- 4) If a behavior was persistent and harmful; if other environmental, psychosocial and medical causes were ruled out; and, if an antipsychotic medication is used, does the antipsychotic improve the behavior and is the antipsychotic used for the shortest time possible?
- 5) When antipsychotic medication is used for behaviors, can the facility show that it is monitoring for benefits and risks? This includes training staff to identify and document the effects of the medication on the resident and the practice of follow-up communication within the facility.
- 6) Has the facility discussed the risks and benefits of the medication with the resident and/or the resident's power of attorney or guardian?

In addition to this focus area, DQA surveyors may also investigate other areas. For instance, the facility's Medical Director is responsible for care coordination and resident care policies within the nursing home. Pharmacy Consultants are responsible for assisting facilities in the identification of medication-related problems. When there are problems with the use of antipsychotic medications, DQA surveyors may look into whether facilities worked with their medical director and pharmacy consultant to develop and implement plans of care or policies related to antipsychotic medication use for behavioral disorders in residents with Alzheimer's disease, dementia or other organic brain syndrome.

It is important to remember that, for most behaviors, antipsychotic medications have, in some cases, not been shown to be any more effective than a placebo. If an antipsychotic medication is used for a single resident behavior without first conducting a complete assessment, it is likely that there was not an adequate indication for the use of the antipsychotic. When there are not adequate indications for medication use, the medication may be considered unnecessary and the nursing home is at risk of violating state or federal rules or regulations.

Existing regulations have not changed with the FDA advisories. When antipsychotic medication is used for dementia-related behaviors, facilities must discuss the use of antipsychotic medication with the residents' families, consultant pharmacists, medical directors and physicians before starting or making any changes with antipsychotic therapy. Similarly, before starting or making any changes with antipsychotic therapy, facilities should document their consideration of all the standards related to antipsychotic medication use for residents whose behaviors are the result of Alzheimer's disease, dementia or other organic brain syndrome. When antipsychotic medications are used for behavior treatment, a monitoring plan that evaluates the medication's effectiveness and side effects must be in place. Medication monitoring is essential for the determination of effectiveness and requires appropriately trained direct care staff to recognize the side effects that may result from the medication. Communication between nursing staff and the facility's medical director and pharmacy consultant is, therefore, critical to ongoing antipsychotic medication monitoring within the facility.

If you have specific information regarding the use of and the ongoing monitoring of medications that contain the FDA black box warning, please contact Douglas Englebert, RPh, Pharmacy Practice Consultant, at (608) 266-5388, or e-mail him at: douglas.engelebert@dhs.wisconsin.gov