

**Facilitation of Change in Antipsychotic Prescription/Practice Habits
by Long-term Care Administrators**

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Background

Antipsychotic drugs are commonly prescribed to manage psychological and behavioral symptoms of dementia. The behavioral problems (BPs) most often reported by interprofessional members of the healthcare team as symptoms of dementia are resisting care and disruptive verbal behaviors (Cohen-Mansfield, Jensen, Resnick, & Norris, 2012). In 2005, the Food and Drug Administration (FDA) alerted healthcare providers that atypical antipsychotics were associated with an increased risk of mortality in elderly patients treated for dementia-related psychosis, and subsequently, in 2008, the FDA expanded the notice of increased risk of mortality to include conventional antipsychotics. Furthermore, non-pharmacologic interventions that would limit potential harm and increase overall quality of life for patients existed as well, and their use was encouraged. When antipsychotic medications are used without an adequate rationale or for the purpose of limiting or controlling behavior with an unidentified cause, there is little chance they will be effective. Analysis of antipsychotic use by 693,000 Medicare nursing home residents revealed that 28.5% of the doses received were excessive and that 32.2% lacked appropriate indications for use (Briesacher et al., 2005).

Because evidence showed a connection between antipsychotic drugs and overall mortality in older adults, the Centers for Medicare & Medicaid Services (CMS) released revisions to State Operations Manuals (SOMs) in 2012 directed at the reduction of unnecessary antipsychotic medication use in long-term care (CMS, 2012a). This sweeping reform cited research demonstrating evidence of harm and death as potential complications of antipsychotic use in the elderly. Excessive medication use and the movement toward patient-centered care were catalysts for change. Although medications may provide respite for care providers, the overarching concern was to prevent harm to the health and well-being of patients. The CMS's reduction

efforts were aimed largely at patients with a diagnosis of dementia, because patients with dementia, who may have BPs, were most frequently administered antipsychotic medications (Briesacher et al., 2005; Levinson, 2011). Yet the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE-AD) study in 2006 revealed no difference in behaviors in placebo and intervention groups of dementia patients treated with antipsychotics for BP reduction (Schneider, Tariot, et al., 2006). In addition, antipsychotics were found to commonly cause complications such as movement disorders, falls, hip fractures, cerebrovascular adverse events, and increased risk of death (Ray, Chung, Murray, Hall, & Stein, 2009; Rouchon et al., 2008; Schneider, Dagerman, & Insel, 2006).

For the present study, no literature could be found that directly addressed the role of long-term care administrators in facilitating change in antipsychotic prescription/practice habits. However, the literature, as well as national and state regulations, does indicate what long-term care leaders must understand about the reduction of antipsychotic medications and the use of non-pharmacologic methods to manage BPs in dementia or dementia patients who have delirium. Therefore, the purpose of this paper is to summarize key aspects of the literature and of federal and state regulations in order to address how administrative leaders can facilitate change in antipsychotic prescription/practice habits in long-term care.

Regulations and Guidelines

Administrators, including Directors of Nursing (DONs), in long-term care settings are directly responsible for ensuring regulatory compliance and quality of care. They must be aware of national standards and guidelines as well as best practices for the care of nursing home patients. In order to facilitate change and reduce the high prevalence of antipsychotic prescribing habits in dementia care, it is imperative for long-term care administration professionals to

understand the current regulations and guidelines set by the CMS. At a minimum, leaders should understand the state and federal regulations, their scope and severity, potential fines and remediation, or potential for closure due to the inability to maintain federal regulation adherence. Administrators must use the State Operations Manual (SOM) and familiarize themselves with the sections specific to antipsychotic medication use. They must also have an in-depth understanding of the Nursing Home Quality Measures' (QMs') metrics for tracking antipsychotic use.

State Operations Manual

Nursing Facilities (NFs) and Skilled Nursing Facilities (SNFs) must adhere to regulations set by the CMS. In order to receive payments from the CMS, these facilities must gain certification through unannounced site visits. Each state is responsible for certifying NFs and SNFs, and certification indicates that the facility is compliant with federal regulations. The state personnel who conduct the site visits must follow the SOM's protocols. These protocols are found in the SOM appendices. Each individual appendix includes the following three items:

- 1) Regulations, including the regulatory citation from the Codified Federal Regulations (CFRs)
- 2) Tag numbers (the alpha-numeric indexing system used to denote specific sections in each SOM Appendix)
- 3) Interpretive guidelines, also known as *Guidance to Surveyors*

The SOM's Appendices P (survey protocol for long-term care facilities) and PP (interpretive guidelines for long-term care facilities) are specific to nursing homes. Appendix P describes the protocols that surveyors must follow when visiting a facility and delineates the tasks that surveyors must accomplish. For example, Task 1 explains offsite survey preparation, Task 2 specifies entrance conference/onsite preparation activities, Task 3 details the activities of the

initial tour, and so forth. On the other hand, Appendix PP contains the CFR and Tags associated with each regulation. For example, CFR483.10 (a)(1)(2) relates to the exercise of rights, and the accompanying Tag to this regulation is F151 (CMS, 2015a).

Antipsychotic Misuse, Related Tags: F309 and F329

In 2012, the CMS began a medication reduction initiative with the goal of reducing antipsychotic drug use among long-term care residents by 15%. This initiative generated new guidance by the CMS in 2013 for surveyors of nursing homes in the area of dementia care, focusing specifically on the use of unnecessary drugs. Updates were later made to the SOM Appendices P and PP. The update to Appendix P ensured that a representative sampling of patients with dementia in a nursing home who received antipsychotic medications would be evaluated, while the updates to Appendix PP related to quality of care and unnecessary drug use in sections F309 and F329, respectively (CMS, 2013). The changes in F309 contained a new section of interpretative guidance relative to the review of care and services that patients with dementia receive. Revisions to F329 included updates to the antipsychotic section and new severity examples (CMS, 2013).

Tag F309 Necessary Care for Highest Practicable Well Being 42 CFR 483.25

Tag F309, which applies to dementia patients as well as other types of patients, states that each facility must provide the necessary care and services for residents to attain or maintain the highest *practicable* physical, mental, and psychosocial well-being possible, based on a comprehensive assessment and plan of care. Highest practicable physical, mental, and psychosocial well-being are considered to be the highest possible levels of functioning and well-being, limited by the individual's recognized pathology and normal aging process. *Highest practicable* is determined through a comprehensive resident assessment and by recognizing and

competently and thoroughly addressing the physical, mental, or psychosocial needs of the individual.

Tag F329 Free from Unnecessary Drugs 42 CFR 483.25(l)(2)(i,ii)

Tag F329 specifically states that each resident's drug regimen must be free of unnecessary drugs. An unnecessary drug is any drug used:

- In excessive dose (including duplicate drug therapy); or
- For excessive duration; or
- Without adequate monitoring; or
- Without adequate indications for its use; or
- In the presence of adverse consequences that indicate the dose should be reduced or discontinued; or
- Any combination of the previous reasons

In addition, based on a comprehensive assessment of a resident, the facility must ensure that:

- Residents who have not used antipsychotic drugs are not given such drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and
- Residents who use antipsychotic drugs receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in an effort to discontinue those drugs (CMS, 2014; Mollot & Butler, 2013).

One of the main goals of Tag F329 is to ensure that antipsychotic drugs are not the first line of treatment used to manage behaviors in dementia patients.

Tag F329 emphasizes that *general use* of antipsychotic medications is for mental disorders such as schizophrenia, delusional disorder, mood disorder, psychosis, Tourette's

disorder, Huntington disorder, and so forth. Since 2008, antipsychotic drugs carry an FDA Black Box warning, reminding healthcare providers about the dangers of using antipsychotic drugs to treat dementia-related psychosis. However, the CMS does not prohibit the use of antipsychotics for dementia, even though use of other measures first is strongly encouraged. Prescribing antipsychotic medication to a dementia resident is reasonable, if, for example, the resident presents a danger to self or others AND one or both of the following exist: (1) there is a high prevalence of psychotic behaviors, such as hallucinations, paranoia, or delusions; (2) behavioral interventions have been attempted and are included in the plan of care (CMS, 2013). If this is the case, facility administrators must ensure that necessary steps are taken by the staff to gradually reduce the dosage of antipsychotic medication prescribed to the resident. Tag F329 calls for a gradual dose reduction to ensure that staff members do not rely solely on antipsychotic drugs to manage disruptive behaviors (Molloy & Butler, 2013).

The expectation is for nursing homes to use a systematic approach for establishing individual care plans to ensure the highest level of well-being for each resident. Administrators should ensure that facility staff collect holistic information about residents, so that they can understand specific resident behaviors and develop effective interventions to manage patients' care (CMS, 2012b). Goals should focus on first understanding the root causes of disruptive or harmful behaviors and then pursuing non-pharmacological approaches for managing those behaviors. These goals must be met before advancing to the use of antipsychotic medications. Understanding the underlying cause(s) of the behavior avoids wrongful diagnoses based on other possible causes for the behaviors, including boredom, unfamiliar events of caregivers, fatigue, changes in routines, environmental stimuli, and so forth.

Nursing Home Quality Measures

In addition to updating Appendices P and PP of the SOM, the implementation of two QMs for monitoring the use of antipsychotics in nursing homes was added by the CMS: (1) the Short-Stay Antipsychotic Measure, and (2) the Long-Stay Antipsychotic Measure. Both QMs can be extracted from the Minimum Data Set (MDS). The MDS consists of a comprehensive assessment that is a requirement for every Medicare/Medicaid-certified nursing home. The purpose of this assessment is to obtain a snapshot of the long-term care residents' clinical status and quality of life. Moreover, the MDS is completed periodically to serve as a guideline to create individual care plans for each resident. The frequency of this assessment depends on the type of resident (short-stay or long-stay); however, performance of the assessment is necessary upon each facility admission and at least once per quarter.

Short-stay patients in a nursing home are those whose reimbursement for care is provided by Medicare Part A for a limited time, following a 3-day hospital stay. These patients are admitted to the long-term care facility to receive skilled services, such as physical therapy, occupational therapy, and skilled nursing care (CMS, 2016a). On the other hand, long-stay patients are those who have chosen a nursing home as their home and whose services (clinical staff, room and board, etc.) are paid privately or by Medicaid, but not by Medicare (CMS, 2016b).

Section N0410 of the MDS assessment addresses antipsychotic use (CMS, 2015b): *Indicate the number of days the resident received the following medications during the last 7 days or since admission or reentry if less than 7 days. Enter "0" if medication was not received by the resident during the last 7 days.* The answer options are Antipsychotic, Antianxiety, Antidepressant, and Hypnotic. Both of the QMs for monitoring antipsychotics were introduced in 2012 as part of the CMS campaign to reduce antipsychotic use by 15%. According to the CMS

website, by late 2014 nursing homes in the United States had achieved a 19.4% reduction, and a more recent goal has been established to reach a 30% reduction by 2016 (CMS, 2015c). Nursing homes are evaluated using a 5-star rating, which can be found at Nursing Home Compare, part of the Medicare.gov website. The stars for the rating are determined by the QMs, the annual survey, and nursing care hours (staffing). Therefore, the training and interdisciplinary collaboration in nursing homes are pivotal for achieving the CMS 2016 goal.

Training & Assessment

Long-term care administrators are responsible for ensuring that appropriate and timely staff education and re-education occur for all disciplines caring for patients. Healthcare delivery teams must be educated at the time of hiring and at least annually thereafter per regulatory standards for limiting antipsychotic use. As previously stated, the CMS expects nursing homes to follow a process that ensures non-pharmacological interventions for residents with dementia before considering antipsychotic drug use. Therefore, the RN nursing staff must be able to meet the following requirements for patient care:

- Recognition and Assessment
- Cause Identification and Diagnosis
- Development of Care Plan
- Individualized Approaches and Treatment (Gitlin, Kales, & Lyketsos, 2012)
- Monitoring, Follow-up, and Oversight
- Quality Assessment and Assurance (CMS, 2014)

In addition to updating the SOM and QMs, the CMS also developed the *National Partnership* with state and federal agencies (CMS, 2016c) to improve quality of care for long-term care residents, with a major focus on person-centered dementia care. Although front-line workers

provide direct resident care and are responsible for implementing non-pharmacologic interventions for dementia patients with BPs, they are generally insufficiently prepared to provide such care. Geriatric nurse practitioners and physicians, as well as experienced geriatric registered nurses, should train direct care staff in order to increase their competencies with dementia patients, but often they do not see themselves as having a role in such training (Cohen-Mansfield et al., 2012). Therefore, facility leaders must ensure that the training takes place, using the appropriate members of the interprofessional healthcare team.

Facility leaders must also ensure training about the appropriate use of restraints. When antipsychotic medications are used inappropriately, they are considered a chemical restraint. The use of chemical restraints violates CFR§483.25 Quality of Care, and failure to comply with this regulation will result in a federal violation of Tag F329, *Unnecessary Drugs*, and Tag F222, *Restraints*. Failure to provide appropriate education or training violates CFR§483.75, resulting in a violation of Tag F495, *Competency*, and/or Tag F497, *Regular In-Service Education*. Per Tag F497, nurse aides should have no less than 12 hours of in-service education per year. Tag F497 also requires initial and annual dementia management and patient abuse prevention training for all nurse aides.

Facility staff must also be trained in how to document assessments and observations of patients. On admission, a resident must receive a thorough assessment, which includes the resident's pain, social, and psychological status. The pain assessment should include determination of how the resident communicates pain, discomfort, or hunger. Dementia-specific pain scales, such as the Pain Assessment in Advanced Dementia (PAINAD), should be considered when evaluating pain in cognitively impaired residents (Warden, Hurley, & Volicer, 2003). Communication of emotional needs such as boredom or frustration should also be

determined. Thorough assessments should continue throughout the resident's stay. Subjective terms such as *aggressive* or *agitated* should not be used. Staff members should receive ongoing training about objective and thorough documentation of specific observations to describe patients' behaviors. Potential triggers and the environment must also be described and monitored. Co-existing acute and chronic conditions should be considered, including pain, constipation, urinary tract infections, and hunger when evaluating new or worsening behaviors.

The staff should also receive training about the appropriate use of antipsychotic medication and alternatives to medication use. When evaluating medication use, thorough documentation is required in order to determine potential causative factors of troubling behaviors and to consider potential non-pharmacologic interventions. When a patient is admitted to a long-term care facility, each of the patient's medications should be evaluated to determine whether there were initial clinical indications for taking the drugs. Many trial dose reductions are often initiated on admission due to a lack of valid clinical indications for the medications. Medication dose reductions can potentially save patients from further harm and assist them with achieving better quality of life. However, if the medication must remain in place, the interdisciplinary team must be aware of potential drug side effects, and appropriate patient monitoring must be in place. In addition, a medication regimen review by a licensed pharmacist must be documented per Tag F329. Any new psychoactive medication prescription or change to the dosage, timing, or revision of an existing psychoactive medication must be reviewed, and consent must be provided by the dedicated holder of the patient's power of attorney. This review and consent must be documented in the patient's record.

The assessment and medication plan are essential components of the patient care plan. Per FTag279 and FTag280, all care plans must be monitored for adherence and updated no less than

quarterly for chronic management. Furthermore, a system must be in place regarding communication of the care plan to the nurse aides. The care plan, which relies on assessment and documentation of daily nursing activity, must inform the care that is administered. Nursing home leaders must ensure that staff members reassess the effectiveness of the care plan interventions and revise the plan where needed. Also, input from the resident or resident's representative should be obtained, if possible.

When a resident's assessment, documentation, or plan of care is determined to lack substantial information, long-term care facility leaders must coach the involved staff members to achieve success. Each and every instance of thorough objective documentation, positive behavioral intervention, or trial dose reduction offers an opportunity to celebrate excellent patient care or to coach for success. Repeated and consistent conversation regarding antipsychotic use or avoidance should be a focus of the leadership team.

Interprofessional Team Coordination

Physicians, nurse practitioners, psychologists, and social workers are among the healthcare professionals who assist in the evaluation and treatment planning for patients with dementia who display BPs in long-term care facilities. Because the education and backgrounds of these professionals vary, they may differ in their approaches for assessing and treating BPs. However, a study by Cohen-Mansfield et al. (2012) indicated that the assessments used most frequently by all providers were based on information from the nursing staff, on asking about antecedents and consequences of behavior, and on speaking with long-term care residents themselves. Meetings with nursing assistants or the immediate care team were less frequent, although they did occur. Nurse practitioners were more likely to meet with family members, but they were less likely to refer patients to a psychologist or social worker. Collaboration among the interprofessional team,

including direct care nursing staff members/nurses aids, would draw on the strengths of all team members to improve care for nursing home residents (Cohen-Mansfield et al., 2012).

Pharmacists too are key members of the interprofessional team who can assist with medication management of long-term care residents. Medication reconciliation upon admission of a resident is crucial, and ongoing evaluation of prescribed medications is recommended, especially when multiple care providers may prescribe them.

Working with Families

Placement of a loved one into a long-term care facility introduces new challenges for family members, whose roles will include visiting, monitoring care, and serving as advocates (Gaugler, 2005a). Several studies have indicated that families may require collaborative support from healthcare team members (Gaugler, 2005b; Haesler, Bauer, & Nay, 2006). However, family members may be neglected due to the patients' needs. Also, information on education for direct care staff members and providers about establishing and promoting relationships with families is limited (Haesler et al., 2006). Families that place a loved one in long-term care experience ongoing loss, sadness, and guilt. They may seek connection and meaning with the staff, especially by seeking information about their loved one. Family members also want to learn more about how to communicate and interact with the resident who has dementia and who may be exhibiting delirium or BPs (Bramble, Moyle, & McAllister, 2009; Day & Higgins, 2015).

Ultimately, family members evaluate the care provided (Bramble et al., 2009), but these evaluations may or may not be based on credible evidence. Toye, Mathews, Hill, and Maher (2014) found that family members felt reassured and emotionally supported when their relative's care was delivered in a calm, understanding, cheerful way. Family members also make judgements about facility staffing, especially if their relative is left alone for long periods of time

and/or does not receive adequate pain control. It is therefore critical that long-term care facility leaders, especially the DON, meet with family members and support the staff's communication with families. The DON may also recognize that family members require counseling or social work services and suggest appropriate referrals. Improving staff-family relationships may ultimately reduce conflict and decrease staff frustrations (Hertzberg, Ekman, & Axelson, 2001), leading the family to feel better about the facility.

Ongoing Efforts to Maintain Antipsychotic Medication Reduction

Once antipsychotic medication reduction is achieved, long-term care facility leaders must continuously work to maintain the reduction. This is particularly true for residents with dementia, acute illness such as a urinary tract infection, or pain related to a fall or other injury, because these problems can potentially lead to an antipsychotic medication order. Facility leaders must remain diligent in tracking ongoing metrics and follow up on all reports of new or changing resident behaviors. Thorough evaluation of new or worsening behaviors should be completed by the interdisciplinary team. Critical thinking related to antipsychotic drug use must be emphasized and continuously monitored for educational opportunities for the staff and the patient's family members. Successful antipsychotic reduction requires consistent training and evaluation of person-centered care. Failure to consider and employ non-pharmacologic interventions versus the ease of using a psychoactive medication should be addressed immediately. There must be a continuous emphasis on the consideration of the individual's history, traits, and consequent interventions. Once a plan is in place, the cycle of monitoring, evaluation, and modification continues. To ensure continuity of care for the individual, consistent staffing schedules should be maintained to allow stability for the residents, families, and direct care providers. Staffing changes impair the ability to learn and foster holistic care of

the individual, whereas consistent staffing allows for continual analysis of the plan of care in place. Therefore, the DON should periodically review staffing assignments to determine whether turnover or other organizational factors are preventing the employment of consistent staffing schedules.

Summary

For this study, no literature could be found that specifically addressed the role of long-term care facility administrators in reducing the use of antipsychotic medications among patients with dementia or dementia with delirium. It is clear that facility leaders must understand all state and federal regulations as well as national quality and safety guidelines for antipsychotic medication use in elderly patients. Furthermore, long-term care facility leaders must understand the training needs of the direct care staff as well as other members of the interprofessional team. Moreover, the feelings and needs of family members of dementia patients are critical to successfully caring for these individuals in nursing homes. Therefore, long-term care administrators must not only manage the physical structure and fiscal health of the facility, they must ensure dementia care that is compliant with regulations, focused on the quality and safety of patients, and supportive of staff and families.

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