



Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 13-35-NH

DATE: May 24, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advanced Copy: Dementia Care in Nursing Homes: Clarification to Appendix P State Operations Manual (SOM) and Appendix PP in the SOM for F309 – Quality of Care and F329 – Unnecessary Drugs

Memorandum Summary

- **Guidance** – This memo conveys clarification to Appendices P and PP related to nursing home residents with dementia and unnecessary drug use.
- **Training** - Mandatory surveyor trainings are available online at <http://surveyortraining.cms.hhs.gov>.

National Partnership

On March 29, 2012, the Centers for Medicare & Medicaid Services (CMS) launched the National Partnership to Improve Dementia Care and Reduce Unnecessary Antipsychotic Drug Use in Nursing Homes (this is now referred to as the Partnership to Improve Dementia Care in Nursing Homes). The goal of this Partnership is to optimize the quality of life and function of residents in America’s nursing homes by improving approaches to meeting the health, psychosocial and behavioral health needs of all residents, especially those with dementia.

The CMS has joined with various stakeholders to improve dementia care in nursing homes. We are doing several things to support this work, including producing surveyor training videos as well as updating Appendix P and Appendix PP of the State Operations Manual (SOM). Individualized, person-centered approaches may help reduce potentially distressing or harmful behaviors and promote improved functional abilities and quality of life for residents.

It has been a common practice to use various types of psychopharmacological medications in nursing homes to try to address behaviors without first determining whether there is a medical, physical, functional, psychological, emotional, psychiatric, social or environmental cause of the behaviors. Medications may be effective when they are used appropriately to address significant, specific underlying medical or psychiatric causes, or new or worsening behavioral symptoms. However, medications may be ineffective and are likely to cause harm -if given

without a clinical indication. All interventions, including medications, need to be monitored for efficacy, risks, benefits and harm.

The problematic use of medications, such as antipsychotics, is part of a larger, growing concern. This concern is that nursing homes and other settings (i.e. hospitals, ambulatory care) may use medications as a “quick fix” for behavioral symptoms or as a substitute for a holistic approach that involves a thorough assessment of underlying causes of behaviors and individualized, person-centered interventions.

Antipsychotic medications are frequently prescribed for residents with dementia who have behavioral or psychological symptoms of dementia (BPSD).^{1,2} The term BPSD is used to describe behavior or other symptoms in individuals with dementia that cannot be attributed to a specific medical or psychiatric cause.

When antipsychotic medications are used without an adequate rationale, or for the purpose of limiting or controlling behavior of an unidentified cause, there is little chance that they will be effective. In addition, they commonly cause complications such as movement disorders, falls, hip fractures, cerebrovascular adverse events (cerebrovascular accidents and transient ischemic events) and increased risk of death.^{3,4,5,6} The Food & Drug Administration (FDA) Black Box Warnings Regarding Atypical Antipsychotics in Dementia provides, “Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo.”⁷

Dementia Care Principles

Fundamental principles of care for a resident with dementia include an interdisciplinary approach that focuses on the needs of the resident as well as the needs of the other residents in the nursing home. Sections 1819 and 1919 of the Social Security Act (the Act) and current regulations already require a number of essential elements to be in place in order for facilities to be in compliance with federal requirements on quality of care and quality of life. This revised CMS guidance and surveyor training highlight and re-emphasize a number of those key principles, including:

- 1. Person–Centered Care.** CMS requires nursing homes to provide a supportive environment that promotes comfort and recognizes individual needs and preferences.
- 2. Quality and Quantity of Staff.** The nursing home must provide staff, both in terms of quantity (direct care as well as supervisory staff) and quality to meet the needs of the residents as determined by resident assessments and individual plans of care.
- 3. Thorough Evaluation of New or Worsening Behaviors.** Residents who exhibit new or worsening BPSD should have an evaluation by the interdisciplinary team, including the physician, in order to identify and address treatable medical, physical, emotional, psychiatric, psychological, functional, social, and environmental factors that may be contributing to behaviors.

4. Individualized Approaches to Care. Current guidelines from the United States, United Kingdom, Canada and other countries recommend use of individualized approaches as a first line intervention (except in documented emergency situations or if clinically contraindicated) for BPSD.⁸⁻¹⁰ Utilizing a consistent process that focuses on a resident's individual needs and tries to understand behavior as a form of communication may help to reduce behavioral expressions of distress in some residents.

5. Critical Thinking Related to Antipsychotic Drug Use. In certain cases, residents may benefit from the use of medications. The resident should only be given medication if clinically indicated and as necessary to treat a specific condition and target symptoms as diagnosed and documented in the record. Residents who use antipsychotic drugs must receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in an effort discontinue these drugs.

NOTE: If during a survey, the team identifies a concern that an antipsychotic medication may potentially be administered for discipline, convenience and not being used to treat a medical symptom, the survey team should review F222 - 483.13(a) Right to be Free From Chemical Restraints.

6. Interviews with Prescribers. None of the guidance to surveyors should be construed as evaluating the practice of medicine. Surveyors are instructed to evaluate the process of care. Surveyors interview the attending physician or other primary care provider (NP, PA), behavioral health specialist, pharmacist and other team members to better understand the reasons for using a psychopharmacological agent or any other interventions for a specific resident.

7. Engagement of Resident and/or Representative in Decision-Making. In order to ensure judicious use of psychopharmacological medications, residents (to the extent possible) and/or family or resident representatives must be involved in the discussion of potential approaches to address behavioral symptoms. These discussions with the resident and/or family or representative should be documented in the medical record.

Guidance Updates and Surveyor Training

1. Surveyor training videos

Through work with our partners, CMS has developed a series of interactive training sessions around behavioral health and dementia care. Materials currently available to surveyors may be accessed on the surveyor training website at: <http://surveyortraining.cms.hhs.gov/index.aspx>.

We have made available three mandatory surveyor trainings (see S&C memo 13-34-ALL). The first training provides an overview of dementia care and potential approaches to addressing behavioral distress. The second training walks surveyors through portions of an annual survey and focuses on the evaluation of one resident with dementia. These two trainings are currently available on the surveyor training website. A third training video is under development that will provide a review of the revised interpretive guidance at F309 and changes to Table 1 for antipsychotic medications at F329. This final training will present case studies and discuss how

to identify potential F Tags and determine severity for non-compliance related to care of a resident with dementia.

2. Updates to Appendix P (Attachment A) include:

- Changes to the resident sampling process for the traditional survey (changes to QIS were included in the recent 10.1.3 release).

The change is intended to ensure that the survey sample includes an adequate number of residents with dementia who are receiving an antipsychotic medication. See Attachment A.

3. Updates to Appendix PP (Attachment B) include:

- A new section of interpretive guidance at F309 related to the review of care and services for a resident with dementia;
- Revisions to the antipsychotic medication section of Table 1 at F329;
- New severity example at the end of the interpretive guidance at F329 (Unnecessary drugs);

A surveyor checklist that may be used in either the traditional or QIS process (modeled after the CE pathways) is also provided (Attachment C). This checklist is not part of the SOM.

References:

1. Briesacher BA, Limcangco MR, Simoni-Wastila L et al. The quality of antipsychotic drug prescribing in nursing homes. *Arch Intern Med* 2005;165(June):1280-1285.
2. Levinson DR. Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents. Department of Health and Human Services Office of Inspector General Report (OEI-07-08-00150)05-04-2011 accessed at <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf>
3. Schneider L, Tariot P, Dagerman K. Effectiveness of atypical antipsychotic drugs in residents with Alzheimer's disease. *N Engl J Med* 2006;355:1525-1538.
4. Ray WA, Chung CP, Murray KT, et al: Atypical antipsychotic drugs and the risk of sudden cardiac death. *N Engl J Med* 2009;360:225—235.
5. Schneider LS, Dagerman K, Insel PS: Efficacy and adverse effects of atypical antipsychotics for dementia: meta-analysis of randomized, placebo-controlled trials. *American Journal of Geriatric Psychiatry* 2006 14:191—210.
6. Rochon P, Normand S, Gomes T et al. Antipsychotic therapy and short-term serious events in older adults with dementia. *Arch Intern Med* 2008;168:1090-1096.
7. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/ucm053171.htm>

8. The American Geriatrics Society. (2012). American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. Journal of American Geriatrics Society. New York. The American Geriatrics Society.

9. 3rd Canadian Consensus Conference on Diagnosis & Treatment of Dementia. (2007). Approved Recommendations. Montreal.

10. Scottish Intercollegiate Guidelines Network. (2006). Management of Patients with Dementia: A National Clinical Guideline. Scott Intercollegiate Guidelines Network.

Attachments: 3

Attachment A – SOM – Appendix P – Revision to Sample Selection for the Traditional Survey

Attachment B – SOM – Appendix PP – F309 – Interpretive Guidance for Care and Services of a Resident with Dementia; F329 – Interpretive Guidance for Drug Regimen Free from Unnecessary Drugs (includes only revised sections of F329, including Table 1, section on antipsychotic medications and the new severity example)

Attachment C – Surveyor Checklist for Review of Care and Services for a Resident with Dementia (This document is not considered a SOM revision or addition.)

For questions on this memorandum, please contact Michele Laughman at dnh_behavioralhealth@cms.hhs.gov.

Effective Date: This policy is in effect immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

Training: This policy should be shared with all appropriate survey and certification staff, their managers and the State/Regional Office training coordinators.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal: Advanced Copy

Date:

CHANGE REQUEST:

**SUBJECT: National Partnership to Improve Dementia Care in Nursing Homes;
Interim Changes to Appendix P State Operations Manual (SOM)**

I. SUMMARY OF CHANGES: We are providing interim guidance related to surveyors' assessment for compliance with requirements related to nursing home residents with dementia and unnecessary drug use. These updates include sampling for the traditional survey process in Appendix P.

In Appendix P, we have made changes to the resident sampling process for the traditional survey (changes to QIS were included in the recent 10.1.3 release). The change is intended to ensure that the survey sample includes an adequate number of residents with dementia who are receiving an antipsychotic medication.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance

IMPLEMENTATION DATE: Upon Issuance

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	App P/Revision to Sample Selection for the Traditional Survey/Task1/Off Site Preparation
R	App P/Revision to Sample Selection for the Traditional Survey/Task2/Entrance Conference/Onsite Preparatory Activities/A/Entrance Conference/3/The team coordinator should
R	App P/Revision to Sample Selection for the Traditional Survey/Task4/Revision to Sample Selection for Traditional Survey/D/Protocol/1/Phase 1 – Sample Selection

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service**

Appendix P - Revision to Sample Selection for the Traditional Survey*

Task 1 – Off Site Preparation

Use the Facility QM Report to pre-select concerns for any QM that is flagged at the 75th (or greater) national percentile.

NOTE: If either of the QM's for residents on antipsychotic medications are flagged, include the questions related to dementia care and antipsychotic medication use during the entrance conference (see Task 2 below).

Use the instructions identified in Task 2 and Task 4 in order to include a resident with dementia who is receiving an antipsychotic medication in the sample.

Task 2 – Entrance Conference/Onsite Preparatory Activities:

A. Entrance Conference

3. The team coordinator should:

- *Request a list of the names of residents who have a diagnosis of dementia and who are receiving, have received, or presently have PRN orders for antipsychotic medications over the past 30 days.*
- *If the facility population includes residents with dementia, ask the administrator or director of nursing to describe how the facility provides individualized care and services for residents with dementia and to provide policies related to the use of antipsychotic medications in residents with dementia.*

Task 4 –Sample Selection for Traditional Survey

Phase 1 - Sample Selection

- *Use the list of names of residents, who over the past 30 days, received, are presently receiving or have PRN orders for antipsychotic medications and have a diagnosis of dementia:*
 - *Compare this list to the off-site Phase 1 resident sample and determine if a resident from this list is already included in the Phase 1 sample; and*
 - *Ensure that, at a minimum, at least one of the residents on the list who is receiving an antipsychotic medication is in the Phase 1 sample for a comprehensive or focused record review.*

- *If the Phase 1 sample does not identify at least one resident that is on the facility provided list, the team should consider either replacing one resident from the Phase 1 sample with one resident from the facility provided list or adding a resident from the list to the sample. Consider the following:*
 1. *If selecting a replacement resident, attempt to select a resident from the facility provided list that was noted to be included in the same QM conditions as the resident who was removed.*
 2. *When considering the addition of a resident from this list, attempt to select a resident who is representative of areas of concern, such as triggering QM's at or above the 75% percentile or other special factors.*
- *Reference the "Review of Care and Services for a Resident with Dementia Checklist" while conducting this review.*

Appendix P - Sample Selection for the Quality Indicator Survey (QIS)

For the QIS, surveyors will not have to make an adjustment to the sample selection as the software will automatically identify the required sample. NOTE: An electronic version of the CMS Review of Care and Services for a Resident with Dementia Checklist is available and may be used either electronically or the surveyor may print a copy of the checklist to guide the Phase 2 investigation of care provided to a resident with dementia.

*This is revised guidance for portions of Tasks 1, 2 and 4 – it does not replace existing guidance in Appendix P for other aspects of those tasks.

CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal: Advanced Copy

Date:

CHANGE REQUEST:

SUBJECT: National Partnership to Improve Dementia Care in Nursing Homes; Interim Changes to Appendix PP in the State Operations Manual (SOM) for F309 – Quality of Care and F329 – Unnecessary Drugs

I. SUMMARY OF CHANGES: We are providing interim guidance related to surveyors' assessment for compliance with requirements related to nursing home residents with dementia and unnecessary drug use. These updates include Appendix PP F329 Table 1 and severity examples, as well as F309.

In Appendix PP, a new section of interpretative guidance at F309 related to the review of care and services for a resident with dementia has been added. At F329, new severity examples have been added at the end of the interpretative guidance and revisions to the antipsychotic medication section have been made to Table 1.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance

IMPLEMENTATION DATE: Upon Issuance

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	App PP/§483.25/F309/Quality of Care
R	App PP/§483.25/F329/Table 1/Medication Issues of Particular Relevance/Antipsychotic Medications
R	App PP/§483.25/F329/Additional Example

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements

	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

| *Unless otherwise specified, the effective date is the date of service.

F309

F309 – §483.25 Quality of Care

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

Intent: §483.25

The facility must ensure that the resident obtains optimal improvement or does not deteriorate within the limits of a resident's right to refuse treatment, and within the limits of recognized pathology and the normal aging process.

NOTE: Use guidance at F309 for review of quality of care not specifically covered by 42 CFR 483.25 (a)-(m). Tag F309 includes, but is not limited to, care such as *care of a resident with dementia*, end-of-life, diabetes, renal disease, fractures, congestive heart failure, non-pressure related skin ulcers, pain, and fecal impaction.

Review of Care and Services for a Resident with Dementia

Use this guidance for a resident with dementia. If the resident is receiving one or more psychopharmacological agents, also review the guidance at F329, Unnecessary Drugs.

*There is no specific investigative protocol for care of a resident with dementia. For the traditional survey, the surveyor may use the surveyor checklist titled, “**Review of Care and Services for a Resident with Dementia**” to assist in investigating the care and services provided to a resident with a diagnosis of dementia. For the QIS survey, the surveyor will use the general CE pathway and may use the checklist as a guide to completing that pathway.*

Definitions Related to Recognition and Management of Dementia

- Behavioral interventions are individualized approaches (including direct care and activities) that are provided as part of a supportive physical and psychosocial environment, and are directed toward understanding, preventing, relieving, and/or accommodating a resident's distress or loss of abilities.*
- Person-Centered or Person-Appropriate Care is care that is individualized by being tailored to all relevant considerations for that individual, including physical, functional, and psychosocial aspects. For example, activities should be relevant to the specific needs, interests, culture, background, etc. of the individual for whom they are developed and medical treatment should be tailored to an individual's risk factors, current conditions, past history, and details of any present symptoms.*
- Behavioral or Psychological Symptoms of Dementia (BPSD) is a term used to describe behavior or other symptoms in individuals with dementia that cannot be attributed to a specific medical or psychiatric cause. The term “behaviors” is more*

general and may encompass BPSD or responses by individuals to a situation, the environment or efforts to communicate an unmet need.

Overview of Dementia and Behavioral Health

What is Behavior?

Human behavior is the response of an individual to a wide variety of factors. Behavior is generated through brain function, which is in turn influenced by input from the rest of the body. Specific behavioral responses depends on many factors, including personal experience and past learning, inborn tendencies and genetic traits, the environment and response to the actions and reactions of other people. A condition (such as dementia) that affects the brain and the body may affect behavior.

What is Dementia?

Dementia is not a specific disease. It is a descriptive term for a collection of symptoms that can be caused by a number of disorders that affect the brain. People with dementia have significantly impaired intellectual functioning that interferes with normal activities and relationships. They also lose their ability to solve problems and maintain emotional control, and they may experience personality changes and behavioral problems, such as agitation, delusions, and hallucinations. While memory loss is a common symptom of dementia, memory loss by itself does not mean that a person has dementia. Doctors diagnose dementia only if two or more brain functions - such as memory and language skills -- are significantly impaired without loss of consciousness.

Some of the diseases that can cause symptoms of dementia are Alzheimer's disease, vascular dementia, Lewy body dementia, fronto-temporal dementia, Huntington's disease, and Creutzfeldt-Jakob disease. Doctors have identified other conditions that can cause dementia or dementia-like symptoms including reactions to medications, metabolic problems and endocrine abnormalities, nutritional deficiencies, infections, poisoning, brain tumors, anoxia or hypoxia (conditions in which the brain's oxygen supply is either reduced or cut off entirely), and heart and lung problems. Although it is common in very elderly individuals, dementia is not a normal part of the aging process.¹

Some individuals with dementia may have coexisting symptoms or psychiatric conditions such as depression or bipolar affective disorder, paranoia, delusions or hallucinations. Progressive dementia may exacerbate these and other symptoms.

Behavioral or psychological symptoms are often related to the brain disease in dementia; however behavior and other symptoms may also be caused or exacerbated by environmental triggers. Behavior often represents a person's attempt to communicate an unmet need, discomfort or thoughts that they can no longer articulate. Knowing detailed cultural, medical and psychosocial information about a person can help caregivers identify potential environmental or other triggers in order to prevent or reduce, to the extent possible, behavior or

other expressions of distress.² Because behavioral symptoms may be caused by medical conditions such as delirium, medication side effects, and psychiatric symptoms such as delusions or hallucinations, these should be considered as possible causes in addition to environmental triggers.

What is Delirium?

A resident may have undiagnosed delirium, which is an acute confusional state that includes symptoms very similar to those of dementia and psychiatric disorders. The diagnostic criteria for delirium include a fluctuating course throughout the day, inattention as evidenced by being easily distracted, cognitive changes, and perceptual disturbances³.

Delirium develops rapidly over a short time period, such as hours or days, and is associated with an altered level of consciousness. Delirium has an underlying physiologic cause that can generally be identified through a diagnostic evaluation. Potential causes include, but are not limited to, infection, fluid/electrolyte imbalance, medication, or multiple factors. Specific diagnostic criteria are outlined in the DSM IV-TR or the Confusion Assessment Method^{3,4}.

Classic delirium is often characterized as hyperactive (e.g., extreme restlessness, climbing out of bed); but more commonly delirium is hypoactive often leading to the misdiagnosis of dementia or a psychiatric disorder. Delirium is particularly common post-hospitalization; signs and symptoms may be subtle and therefore are often missed. Although generally thought to be short lived, delirium can persist for months.

Delirium and dementia are now recognized as being related. Individuals with dementia are at higher risk for developing delirium and it now appears that delirium increases the risk of developing dementia over time⁵. Recognizing delirium is critical, as failure to act quickly to identify and treat the underlying causes may result in poor health outcomes, hospitalization or even death⁶.

Therapeutic Interventions or Approaches

The use of any approach must be based on a careful, detailed assessment of physical, psychological and behavioral symptoms and underlying causes as well as potential situational or environmental reasons for the behaviors. Caregivers and practitioners are expected to understand or explain the rationale for interventions/approaches, to monitor the effectiveness of those interventions/approaches, and to provide ongoing assessment as to whether they are improving or stabilizing the resident's status or causing adverse consequences. Describing the details and possible consequences of resident behaviors helps to distinguish expressions such as restlessness or continual verbalization from potentially harmful actions such as kicking, biting or striking out at others. This description alone does not suggest that a specific intervention is or is not indicated; however, it is important information that may assist the care team (including the resident and/or family or representative) in decision-making and in matching selected interventions to the individual needs of each resident.

Identifying the frequency, intensity, duration and impact of behaviors, as well as the location, surroundings or situation in which they occur may help staff and practitioners identify individualized interventions or approaches to prevent or address the behaviors. Individualized, person-centered interventions must be implemented to address behavioral expressions of distress in persons with dementia. In many situations, medications may not be necessary; staff/practitioners should not automatically assume that medications are an appropriate treatment without a systematic evaluation of the resident. Examples of techniques or environmental modifications that may prevent certain behavior related to dementia may include (but are not limited to):

- *Arranging staffing to optimize familiarity with the resident (e.g., consistent caregiver assignment);*
- *Identifying, to the extent possible, factors that may underlie the resident's expressions of distress, as well as applying knowledge of lifelong patterns, preferences, and interests for daily activities to enhance quality of life and individualize routine care.*
- *Understanding that the resident with dementia may be responding predictably given the situation or surroundings. For example, being awakened at night in his/her bedroom by staff and not recognizing the staff could elicit an aggressive response; and*
- *Matching activities for a resident with dementia to his/her individual cognitive and other abilities and the specific behaviors in that individual based on the assessment.*

Medication Use in Dementia (see also F329)

It has been a common practice to use various types of psychopharmacological medications in nursing homes to try to address behavioral or psychological symptoms of dementia (BPSD)^{7,8} without first determining whether there is an underlying medical, physical, functional, psychosocial, emotional, psychiatric, or environmental cause of the behaviors. Medications may be effective when they are used appropriately to address significant, specific underlying medical and psychiatric causes or new or worsening behavioral symptoms. However, medications may be ineffective and are likely to cause harm when given without a clinical indication, at too high a dose or for too long after symptoms have resolved and if the medications are not monitored. All interventions including medications need to be monitored for efficacy, risks, benefits and harm.

These agents must only be used if the steps in the care process below and as outlined in F329 have been followed.

When antipsychotic medications are used without an adequate rationale, or for the sole purpose of limiting or controlling behavior of an unidentified cause, there is little chance that they will be effective, and they commonly cause complications such as movement disorders, falls, hip fractures, cerebrovascular adverse events (cerebrovascular accidents and transient ischemic events) and increased risk of death.^{9,10,11,12} The FDA Black Box

Warning Regarding Atypical Antipsychotics in Dementia states, “Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo.” The FDA issued a similar Black Box Warning for conventional antipsychotic drugs. (Additional information on the FDA black box warning is available at <http://www.fda.gov/Drugs/default.htm>.)

Recent studies suggest that certain antipsychotic medications may have greater risks than others in that same class of medications^{13,14}. Other classes of psychopharmacological agents may carry significant risks as well.

NOTE: If a concern is identified during a survey that an antipsychotic medication may potentially be administered for discipline, convenience and/or is not being used to treat a medical symptom, consider reviewing F222 - 483.13(a) Restraints, for the right to be free from any chemical restraints.

Resident and/or Family/Representative Involvement:

CMS expects that the resident and family/representatives, to the extent possible, are involved in helping staff to understand the potential underlying causes of behavioral distress and to participate in the development and implementation of the resident’s care plan. Residents have the right to be informed about their medical condition, care and treatment; they have the right to refuse treatment and the right to participate in the care plan process (See F154, F155, F242, F279, F280).

Facilities should be able to identify how they have involved residents/families/representatives in discussions about potential approaches to address behaviors and about the potential risks and benefits of a psychopharmacological medication (e.g., FDA black box warnings), the proposed course of treatment, expected duration of use of the medication, use of individualized approaches, plans to evaluate the effects of the treatment, and pertinent alternatives. The discussion should be documented in the resident’s record (See F154).

NOTE: some states have specific laws/licensing rules regarding the provision of informed consent. The State Agency determines and directs the surveyors regarding the review for those provisions under their State licensing authority. If non-compliance with the State regulation is identified, the surveyors may only cite this non-compliance at F492 when the Federal, State or local authority having jurisdiction has both made a determination of non-compliance AND has taken a final adverse action.

The facility should document attempts to include the family/representative, to the extent possible, in the decision-making process. If the family/representative is unable to participate in person, were further attempts made to include the family/representative in the discussions/development of the care planning through alternative methods, such as by phone or electronic methods?

If the resident lacks decision-making capacity and lacks an effective family/representative support, contact the facility social worker to determine what type of social services or referrals have been attempted to assist the resident (See F250).

During interviews with the family/representative, surveyors should ask if families have observed staff implementing the individualized care plan interventions that were developed (See F282).

Care Process for a Resident with Dementia

Fundamental principles of care for persons with dementia include an interdisciplinary team approach that focuses holistically on the needs of the resident as well as the needs of the other residents in the nursing home. It is important for the facility to have systems and procedures in place to assure that assessments are timely and accurate; interventions are described, consistently implemented, monitored, and revised as appropriate in accordance with current standards of practice.

It is expected that a facility's approach to care for a resident with dementia follows a systematic care process in order to gather and analyze information necessary to provide appropriate care and services, and that the resident and/or family or representative is engaged throughout the process. It is expected that the resident's record reflects the implementation of the following care processes:

- A. Recognition and Assessment;***
- B. Cause Identification and Diagnosis;***
- C. Development of Care Plan;***
- D. Individualized Approaches and Treatment;***
- E. Monitoring, Follow-up and Oversight; and***
- F. Quality Assessment and Assurance (QAA).***

See Additional Resources section below for some suggested resources that facilities may consult in developing their dementia care policies.

The following guidance aggregates requirements in a number of other F-tags such as comprehensive assessment, activities, resident rights, unnecessary medications and others, bringing that guidance together into a framework for evaluating care of individuals with dementia.

- A. Recognition and Assessment:***

This step includes collecting detailed information about a resident. The resident's record should reflect comprehensive information about the person including, but not limited to: past life experiences, description of behaviors, preferences such as those for daily routines, food, music, exercise and others; oral health, presence of pain, medical conditions; cognitive status and related abilities and medications. When reviewing the comprehensive assessment (see F272), the Care Area Assessment (CAA) Resources, particularly those related to Activities and Behavioral Symptoms, found in the Long-Term Care Facility Resident Assessment Instrument User's Manual, Version 3.0 may be helpful.

It is important to determine whether the record reflects the evaluation of, but is not limited to:

- How the resident typically communicates physical needs such as pain, discomfort, hunger or thirst, as well as emotional and psychological needs such as frustration or boredom; or a desire to do or express something that he/she cannot articulate;*
- The resident's usual and current cognitive patterns, mood and behavior, and whether these present a risk to the resident or others;*
- How the resident typically displays personal distress such as anxiety or fatigue.*

This and other information enables an understanding of the individual and provides a basis for cause identification (based on knowing the whole person and how the situation and environment may trigger behaviors) and individualized interventions. If the resident expresses distress, staff should specifically describe the behavior (including potential underlying causes, onset, duration, intensity, precipitating events or environmental triggers, etc.) and related factors (such as appearance and alertness) in the medical record with enough detail of the actual situation to permit cause identification and individualized interventions (See F514). For example, noting that the resident is generally "violent," "agitated" or "aggressive" does not identify the specific behavior exhibited by the resident. Noting instead that the resident responds in crowded, busy group activities by yelling or throwing furniture reflects not only a potential safety issue but should result in the resident being provided alternative activities to meet his/her needs.

B. Cause Identification and Diagnosis:

This step uses the information collected about an individual to help identify the physical, functional, psychosocial, environmental, and other potential causes of behavior and related symptoms, including how they interact with each other. Staff, in collaboration with the practitioner, should identify possible risk and causal/contributing factors for behaviors, such as:

- Presence of co-existing medical or psychiatric conditions, including acute/chronic pain, constipation, delirium and others, or worsening of mental function; and/or*
- Adverse consequences related to the resident's current medications (See F329).*

Staff must make an ongoing effort to identify and document the new onset or worsening behavioral symptoms, including whether or not the behavior presents a significant risk for adverse consequences to the resident and/or others.

The attending physician is responsible for supervising each resident's medical care. In addition, the facility must immediately consult with the resident's physician when there is a significant change in the resident's physical, mental, or psychosocial status (See F157). If the behaviors observed represent a change or worsening from the baseline, the attending physician/practitioner and staff are expected to consider potential underlying medical, physical, psychosocial, or environmental causes of the behaviors (See F385). If the resident has experienced two or more areas of decline or improvement, including a change related to behavior, a Significant Change in Clinical Status Assessment (SCSA) should be considered (see F274).

If medical causes are ruled out, the facility should attempt to establish other root causes of behavior using individualized, holistic knowledge about the person and when possible, information from the resident, family or previous caregivers, and direct care staff. This includes conducting a systematic analysis and consideration of possible causes, including but not limited to:

- Boredom; lack of meaningful activity or stimulation during customary routines and activities;*
- Anxiety related to changes in routines such as shift changes, unfamiliar or different caregivers, change of (or relationship with) roommate, inability to communicate;*
- Care routines (such as bathing) that are inconsistent with a person's preferences;*
- Personal needs not being met appropriately or sufficiently, such as hunger, thirst, constipation;*
- Fatigue, lack of sleep or change in sleep patterns which may make the person more likely to misinterpret environmental cues resulting in anxiety, aggression or confusion.*
- Environmental factors, for example noise levels that could be causing or contributing to discomfort or misinterpretation of noises such as over-head pages, alarms, etc. causing delusions and/or hallucinations.*
- Mismatch between the activities or routines selected and the resident's cognitive and other abilities to participate in those activities/routines. For example, a resident who has progressed from mid to later stages of dementia may become frustrated and upset if he/she is trying but unable to do things that she previously enjoyed, or unable to perform tasks such as dressing or grooming.*

C. Development of Care Plan:

This step identifies the approaches, interventions, therapies, medications, etc. for a specific resident. The care plan should include a well-defined problem-statement and should outline the goals of care. It should include measurable objectives and timetables for individualized interventions. It should also identify the responsibilities of various staff to implement the approaches effectively. The care plan should reflect:

- *Baseline and ongoing details (e.g., frequency, intensity, and duration) of common behavioral expressions and expected response to interventions (See F279);*
- *Specific goals for and monitoring of all interventions for effectiveness in responding to target behaviors/expressions of distress (See F279); and*
- *For any medications, indication/rationale for use, specific target behaviors and expected outcomes, dosage, duration, monitoring for efficacy and/or adverse consequences and (when applicable) plans for gradual dose reduction (GDR) if an antipsychotic medication is used (See F329).*

In developing the plan of care, the interdisciplinary team, in collaboration with the resident or family/representative, reviews the results of the assessment and cause identification above in order to develop individualized, person-centered interventions. Staff should determine, in collaboration with the practitioner, resident, and family/resident representative if and why behaviors should be addressed (e.g., severely distressing to resident and unrelieved by other approaches or interventions). Individualized, person-centered approaches should be implemented to address expressions of distress. These may include:

- *Non-pharmacological approaches. Section 483.25 (l)(2)(ii) - F329, requires that “Residents who use antipsychotic drugs receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.”*

The guidance at F248, §483.15(f)(1), Activities, provides examples of non-pharmacological approaches for several types of distressed behavior such as constant walking, yelling, going through others’ belongings, etc. Certain behavior may be anticipated and sometimes may be preventable based on understanding the underlying causes and possible triggers for each individual.

Current published clinical guidelines^{15,16,17,18,19} recommend use of non-pharmacological interventions for BPSD.

Utilizing a consistent process to address behaviors that focuses on the resident’s individual needs and tries to understand their behaviors as a form of communication may help to reduce behavioral expressions of distress in those residents.

Several techniques are also outlined in the CMS DVD series for nursing assistant training, "Hand in Hand," distributed to all U.S. nursing homes in 2012, and other materials available on the Advancing Excellence website: www.nhqualitycampaign.org.

NOTE: References to non-CMS sources or sites on the internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

- *Pharmacological interventions: In certain cases, residents may benefit from the use of medications. For example, a person who has a persistent, frightening delusion that she has left her children unattended and that they are in danger is inconsolable most of the day or night despite a number of staff and family approaches to address this fear. If other potential causes are ruled out, the team may determine that a trial of a low dose antipsychotic medication is warranted.*

If a psychopharmacologic medication is initiated or continued, review the guidance at F329, and interview staff about:

- *What was the person trying to communicate through their behavior;*
- *What were the possible reasons for the person's behavior that led to the initiation of the medication;*
- *What other approaches and interventions were attempted prior to the use of the antipsychotic medication;*
- *Was the family or representative contacted prior to initiating the medication;*
- *Was the medication clinically indicated and/or necessary to treat a specific condition and target symptoms as diagnosed and documented in the record;*
- *Was the medication adjusted to the lowest possible dosage to achieve the desired therapeutic effects;*
- *Were gradual dose reductions planned and behavioral interventions, unless clinically contraindicated, provided in an effort to discontinue the medication;*
- *Was the interdisciplinary team, including the primary care practitioner, involved in the care planning process; and*
- *How does the staff monitor for the effectiveness and possible adverse consequences of the medication.*

If the resident experienced a decline in function, an increased or worsening behavior, or less than anticipated level of improvement in response to interventions, or refused or resisted the interventions, the care plan approaches should be reviewed and revised/updated as appropriate (See F280).

D. Individualized Approaches and Treatment:

This step implements the care plan interventions to address the needs of a resident with dementia. It includes addressing the causes and consequences of the resident's behavior and staff communication and interactions with residents and families to try to prevent potentially distressing behaviors or symptoms. It is important to conduct sufficient observations in order to determine if the care plan is being implemented as written. Observations should focus on whether staff:

- Identify and document specific target behaviors, expressions of distress and desired outcomes (See F279 and F514); and*
- Implement appropriate, individualized, person-centered interventions and document the results (See F240, F309, F329 and F514);*
- Communicate and consistently implement the care plan, over time and across various shifts (See F282 and F498).*

Staffing and Staff Training

During observations, determine whether there are sufficient numbers of staff to consistently implement the care plan (See F353). The nursing home must provide staff, both in terms of quantity (direct care as well as supervisory staff) and quality to meet the needs of the residents as determined by resident assessments and individual plans of care. The facility must strive to staff in a way that optimizes familiarity with residents. The principles for quality include, but are not limited to, the facility ensuring that nursing assistants are able to demonstrate competency in skills and techniques necessary to care for residents' needs as identified through resident assessments, and as described in the plan of care (See F498). Surveyors should focus on observations of staff interactions with residents who have dementia to determine whether staff consistently applies basic principles for quality in the provision of care.

Nursing assistants must receive a performance review at least once every 12 months and receive regular in-service education based on the outcome of the reviews (See F497). In addition, the facility must provide training in care of individuals with dementia and related behaviors to nursing assistants when initially hired and annually thereafter.

Research on caregivers of people with dementia suggests that caregiver stress can have a significant impact on outcomes and behavioral expressions of distress in the individual with dementia. This may be true for family, community or institutional caregivers. Some facilities may have systems in place to assist their staff in identifying, addressing and supporting staff who may exhibit "caregiver stress." See the Additional Resources section here for an example of tools to assess caregiver stress.

Involvement of the Medical Team

During observations and record review, if potential medical causes of behavior or other symptoms (such as those indicating possible delirium or infection) were identified, determine whether the attending physician was contacted promptly and a workup and/or treatment were initiated (See F157 and F385). Residents who exhibit new or worsening BPSD should have an evaluation by the interdisciplinary team, including the physician and knowledgeable staff, in order to identify and address, to the extent possible, treatable medical, physical, emotional, psychiatric, psychological, functional, social, and environmental factors that may be contributing to behaviors, in order to develop a comprehensive plan of care to address expressions of distress. If a medication(s) was ordered, determine if the staff and practitioner identified and the medical record reflected documentation of the appropriate indication(s) for use (See F329, Table 1 and F428). For a resident who is receiving any type of psychopharmacologic medication, staff must attempt non-pharmacological interventions, unless clinically contraindicated (See F329 and F428).

None of the guidance to surveyors should be construed as evaluating the practice of medicine. Surveyors are instructed to evaluate the process of care, including the communication among the prescriber/practitioner, pharmacist, interdisciplinary team, resident or family/representative, and the review of the nursing home practice to prevent unnecessary use of psychopharmacological medications and to closely monitor those medications when they are used. Interviews with the attending physician or other primary care provider (e.g., NP, PA, CNS), medical director, behavioral health specialist and other team members help clarify the reasons for using a psychopharmacological medication or any other interventions for a specific resident. In addition, interviewing the medical director with regard to policies and procedures for behavioral health and psychopharmacological medication use is strongly encouraged.

F. Monitoring and Follow-up:

It is important that surveyors evaluate whether or not a facility used the steps identified above to develop the plan of care. To meet requirements related to monitoring and follow-up of care plan implementation, surveyors evaluate whether or not the interdisciplinary team reviewed a resident's progress towards defined goals, adjusted interventions as needed, and identified when care objectives were met. Monitoring and follow-up of care plan implementation includes, but is not limited to, the following:

- Staff monitors and documents (See F514) the implementation of the care plan, identifies effectiveness of interventions relative to target behaviors and/or psychological symptoms and changes in a resident's level of distress or emergence of adverse consequences.*
- In collaboration with the practitioner, staff adjusts the interventions based on the effectiveness and/or adverse consequences related to treatment (See F280, F329 and F428).*

- *If concerns are identified related to the effectiveness or potential or actual adverse consequences of a resident's medication regimen, staff must notify the physician and the physician must respond and, as necessary, initiate a change to the resident's care (F157, F385, F428);*
- *If the physician does not provide a timely and appropriate response to the notification, staff must contact the medical director for further review, and if the medical director was contacted, he/she must respond and intervene as needed (See F501).*

G. Quality Assessment and Assurance (QAA):

NOTE: Refer to F520 Quality Assessment and Assurance for guidance regarding information that is obtainable from the QAA committee.

This guidance addresses the evaluation of a facility's systemic approaches to deliver care and services for a resident with dementia. The medical director and the quality assessment and assurance committee can help the facility evaluate existing strategies for coordinating the care of a resident with dementia and ensure that facility policies and procedures are consistent with current standards of practice.

During interviews with the staff responsible for the QAA functions, determine whether the QAA committee has identified and corrected, as indicated, any quality deficiencies related to the care of residents with dementia. In addition, determine whether the QAA committee has monitored and overseen the following areas related to dementia care:

- *Whether resident care policies reflect the facility's overall approach to the care of residents with dementia including a clearly outlined process for their care (see also F501);*
- *How the facility monitors whether staff follow related policies and procedures in choosing and implementing individualized interventions for the care of each resident with dementia;*
- *Whether the facility has trained staff (such as nursing, dietary, therapy or rehabilitation staff, social workers) in how to communicate with and address behaviors in residents with dementia and were the trainings evaluated for effectiveness, including initial and annual dementia care training for CNAs (See F495 and F497);*
- *Whether there is sufficient staff to implement the care plan for residents with dementia, so that medication is not used instead of pertinent non-pharmacological interventions, unless clinically contraindicated (See F353 and F222);*

- *Whether staff collect and analyze data to monitor the pharmacological and non-pharmacological interventions used to care for residents with dementia; and*
- *How the committee helps the facility monitor responses to the issues and concerns identified through the consultant pharmacist medication regimen review (See F329 and F428).*

Criteria for Compliance (F309)

Compliance at F309, care for persons with dementia, is based upon a set of key principles. For a resident with dementia, the facility is in compliance with F309, care for persons with dementia, if they:

1. *Obtained details about the person's behaviors (nature, frequency, severity, and duration) and risks of those behaviors, and discussed potential underlying causes with the care team and (to the extent possible) resident, family or representative;*
2. *Excluded potentially remediable (medical, medication-related, psychiatric, physical, functional, psychosocial, emotional, environmental) causes of behaviors and determined if symptoms were severe, distressing or risky enough to adversely affect the safety of residents;*
3. *Implemented environmental and other approaches in an attempt to understand and address behavior as a form of communication and modified the environment and daily routines to meet the person's needs;*
4. *Implemented the care plan consistently and communicated across shifts and among caregivers and with the resident or family/representative (to the extent possible); and*
5. *Assessed the effects of the approaches, identified benefits and complications in a timely fashion, involved the attending physician and medical director as appropriate, and adjusted treatment accordingly.*

If not, cite F309.

(For residents with dementia for whom antipsychotic or other medications were prescribed, surveyors must also assess for compliance using guidance at F329, Unnecessary Medications).

DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F309 exists, the team must determine the severity of each deficiency, based on the resultant harm or potential for harm to the resident. (Note: some of the examples here involving residents with dementia who receive an antipsychotic medication may also be cited at F329. Surveyors should evaluate compliance at each tag separately).

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed, caused, or resulted in, or is likely to allow, cause, or result in serious injury, harm, impairment, or death to a resident; and*
- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.*

NOTE: *If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.*

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Level 3 indicates noncompliance that resulted in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.

NOTE: *If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.*

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided.

The following examples illustrate the differences among compliance and non-compliance at levels 4, 3 and 2 for F309 Review of a Resident with Dementia. This is only one example; surveyors must investigate each case as the specific situation will vary and may lead to different conclusions based on the evidence.

F309 – Review of a Resident with Dementia – Compliance Example

A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. The social worker's note, the nurses' notes and the care plan all included information from the family: they had reported on admission that the resident was now very fearful of showers. The RAI indicated choosing the method she was bathed was

“very important” and the resident’s daughter stated she preferred sponge baths due to her fear of showers. The interventions in the care plan were implemented consistently across all shifts and levels of staff. The nurses and social workers documented ongoing discussions with family and reassessments to ensure the resident’s needs were being met and that no new issues had been identified. The criteria for compliance were met.

F309 – Review of a Resident with Dementia - Level 4 Severity Non-compliance Example

A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. The social worker’s note, the nurses’ notes and the care plan all included information from the family: they had reported on admission that the resident was now very fearful of showers. The RAI indicated choosing the method the resident was bathed was “very important” and her daughter stated she preferred sponge baths due to her fear of showers.

In addition to the basic facts noted above in the level 4 severity non-compliance example:

- The surveyor observed an occurrence of bathing for the resident described above during the survey. The resident displayed substantial distress and fearfulness, calling out “help me,” crying, striking out and grabbing at the staff, and made repeated attempts to get out of the shower chair.*
- The staff member present called for a second staff member to help her complete the shower. Despite the resident’s cries for help, no other staff members intervened or attempted to determine whether or not her distress warranted a different approach to the bathing routine/schedule.*
- Significant psychological distress was noted during the bathing and for the remainder of the day and was documented in the nurse’s notes.*
- The surveyor observed that no other staff members intervened to assess the resident’s situation or consult the care plan during or after the bathing.*
- The surveyor interviewed direct care staff and nurses on the unit. One licensed nurse stated, “That resident always yells out during her shower” and attributed this to her dementia. Neither CNA interviewed was aware that the resident had sustained a hip fracture during a shower prior to admission.*
- The resident’s fear of bathing was noted in the care plan; however during interviews/observations, direct care staff could not articulate this information about the resident.*
- The staff admitted they had not considered alternative routines/approaches for bathing this resident, despite the fact that the family had reported the resident’s fear of showers and despite repeated episodes of distress.*
- In addition to the staff being unaware of the resident’s fear of showers, they also failed to investigate for other causes of the behavior.*

- *Upon further investigation related to quality assurance, there was no evidence that a physician attends QA&A meetings regularly.*
- *In reviewing staff training records, it appears that nursing assistants have not received training on how to care for residents with dementia.*

What is the evidence for non-compliance?

- *Resident exhibits adverse reaction to showers with verbal distress, combative behavior, and continuous struggling to get out of the chair.*
- *Facility failed to consider and rule out possible causes such as pain related to hip fracture while sitting in a shower chair or possible discomfort with the approach being used to bathe. Facility also failed to recognize the risk of a fall or injury due to combative behavior that required two staff members.*
- *Facility failed to develop and attempt alternate interventions.*
- *No staff member intervened despite the staff member present calling for help and hearing resident's cries for help and her obvious distress.*
- *Facility failed to develop a care plan intervention related to trying to reduce or eliminate extreme reactions to showers;*
- *Staff had appropriate care plan but failed to communicate across shifts and caregivers; and/or*
- *Facility failed to assess the effects of the interventions and try to modify interventions based on those assessments.*

Why is this Immediate Jeopardy?

See Decision-Making Grid with Components of Immediate Jeopardy below. Based on the severity of the resident's reaction, there was evidence that the resident experienced actual psychological harm. In addition, there was immediacy since the repeated attempts at showering the resident resulted in resident-to-staff altercations and placed her at risk for serious physical harm.

Furthermore, there was no evidence of physician participation in the QA&A committee and no evidence that nurse aides received required training in caring for and communicating with residents with dementia. This suggests a lack of effective systems and processes for the assessment and treatment of a resident with dementia. If so, these systems failures place this and potentially other residents with dementia at risk for serious harm. The facility is culpable for a deficient practice that must be addressed immediately in order to prevent further harm to this and other residents (surveyors may wish to consider whether or not there is a need to expand the sample).

Components of Immediate Jeopardy

Harm	
a. Actual - Was there an outcome of harm? Does the harm meet the definition of Immediate Jeopardy, e.g., has the provider's noncompliance caused serious injury, harm, impairment, or death to an individual?	Yes. Repeated, extreme reaction to attempts to bathe with visible anguish, crying and yelling out reflects actual psychological harm with no attempts to alter the care plan.
b. Potential – Is there a likelihood of potential harm? Does the potential harm meet the definition of Immediate Jeopardy; e.g., is the provider's noncompliance likely to cause serious injury, harm, impairment, or death to an individual?	Yes. Repeated risk of a serious fall on an already injured or vulnerable area due to the struggle related to attempted showering.
Immediacy	
Is the harm or potential harm likely to occur in the very near future to this individual or others in the entity, if immediate action is not taken?	Yes. Potential for subsequent harm (a fall or other injury, psychological harm) exists as the facility did not attempt to identify causes or modify alternate interventions related to showers. Other residents with dementia may also be at risk, as staff had not received training in caring for individuals with dementia including how to understand the communication efforts of residents with dementia. There was no evidence of physician participation with the QA&A committee.
Culpability	
Did the facility know about the situation? If so when did the facility first become aware?	Yes, it had happened repeatedly and the social worker and nurses had been informed on admission of the resident's fear and preferences. While the information was in the care plan, the team had not passed the information along to the direct care staff and staff did not review the care plan. Staff did not intervene during these episodes despite the resident's cries for help. These behaviors were attributed to her dementia and were not considered remediable.
Should the facility have known about the situation?	Yes. There were recurrent episodes and the family had reported similar behavior at home related to showers.

F309 – Review of a Resident with Dementia - Level 3 Severity Non-compliance Example

A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. The social services note, the nurses' notes and the care plan all included information from the family: they had reported on admission that the resident was now very fearful of showers. The RAI indicated choosing the method she was bathed was "very important" and her daughter stated she preferred sponge baths due to her fear of showers.

In addition to the basic facts noted above in the level 3 severity non-compliance example:

- The information about the resident's fear of bathing was in the care plan; however during interviews/observations, direct care staff could not articulate this information.***
- The surveyor determined that the resident was taken to the shower room three times in the three weeks since admission. Staff interviews revealed that each time the staff attempted to provide her with a shower, the resident immediately started to call out, "help me, help me." With each of the three attempts, the shower was stopped, the staff member documented "shower was refused" and the resident was given a sponge bath instead. On those days, the resident was noted to be anxious and fretful, wringing her hands and crying on and off for the rest of the day. These behaviors are not noted on other days.***
- No further investigation occurred after each incident. Neither the physician nor the family was involved in discussions regarding the resident's response to the shower and no change in the plan of care was evident after the attempts to shower the resident.***

Why is this Level 3 Severity?

There is evidence of actual psychosocial harm to this resident, with no attempts by the facility to identify the underlying cause of her expressions of distress. However this case does not meet the criteria for immediacy, since the staff did not attempt to actually place the resident into the shower once she started to resist. While staff failed to rule out underlying causes of the resident's behavior, they did provide an alternative when the resident resisted.

F309 – Review of a Resident with Dementia - Level 2 Severity Non-compliance Example

A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. It was documented in the social service and nurses' notes that the family had reported on admission that the resident was now very fearful of showers and preferred sponge baths. However, this information was not communicated to other staff nor was it incorporated into the care plan. The care plan stated that the resident would receive weekly showers.

In addition to the basic facts noted above in the level 2 severity example:

- *The resident's daughter insisted on bathing her mother herself for a period of time after admission, and provided sponge baths to the resident several times a week. The staff did not attempt to provide showers to the resident for several weeks after admission.*
- *At the next care plan meeting, the daughter discovered that her mother's care plan included "provide weekly showers," and was upset that the information about her mother's fear of showers had not been identified and addressed in the care plan.*

Why is this Level 2 Severity?

There is potential for more than minimal harm since significant psychological distress was reported by the family to occur consistently with attempts to shower the resident. In addition, the potential for serious physical harm exists if showers are attempted and the resident resists by trying to get up out of the shower chair or becoming combative with staff. This is Level 2 because actual harm did not occur.

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Additional Resources

NOTE: References to non-CMS sources or sites on the internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

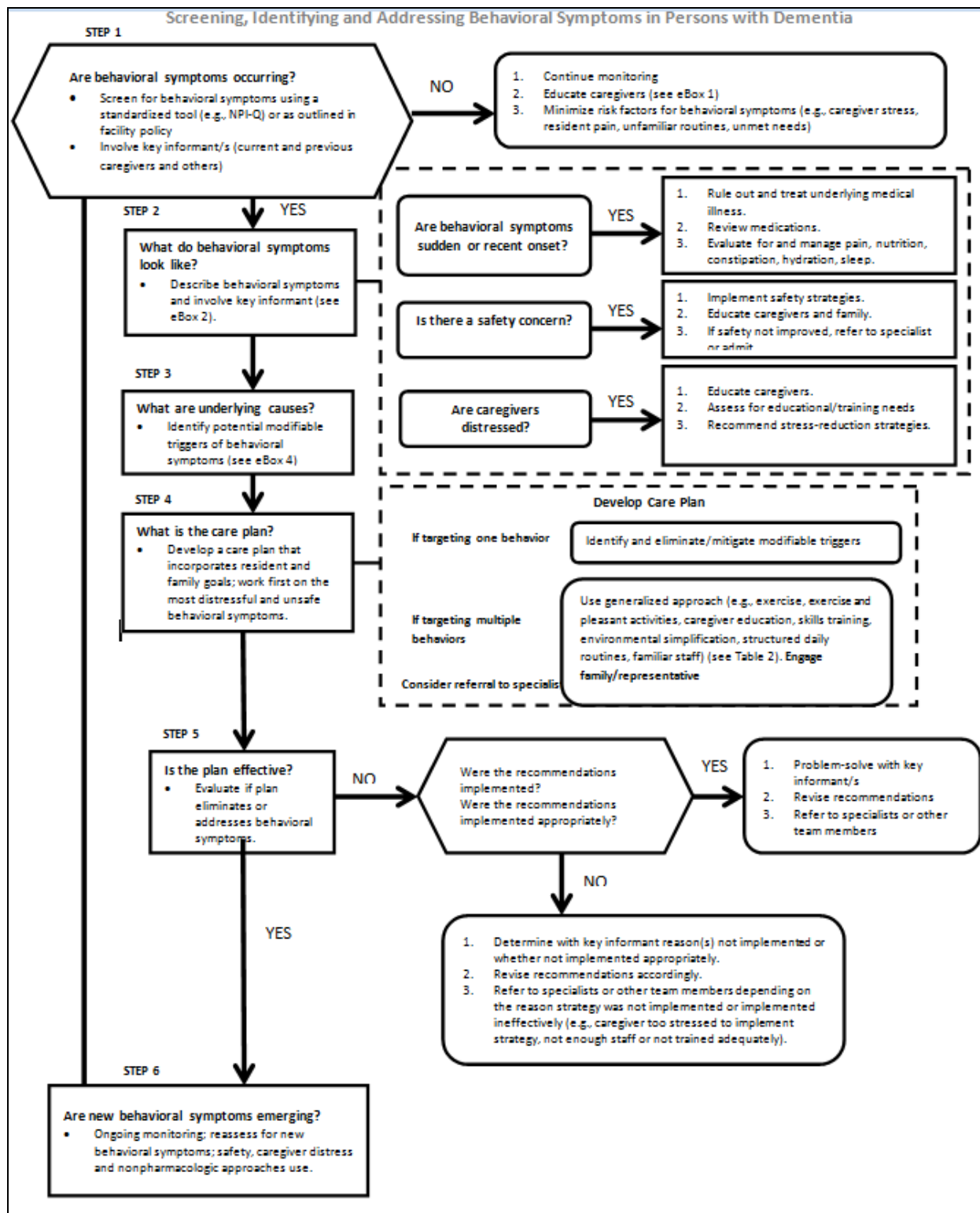
Some clinical resources that identify the challenges and basic principles of dementia care include, but are not limited to:

- *Advancing Excellence in America's Nursing Homes. www.nhqualitycampaign.org*

- *Diagnostic and Statistical Manual of Mental Disorders DSM IV-TR Fourth edition. 2000 American Psychiatric Association.*
- *Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA 2012; 308(19): 2020-2029.*
- *Hand in Hand. For information, to download the training modules or inquire about receiving a copy or replacement copies of the Hand in Hand Toolkit please visit <http://www.cms-handinhandtoolkit.info/Index.aspx>*
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Additional Resources

- *Excerpt adapted from: Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA, November 21, 2012; 308(19): 2020-2029. © 2012 American Medical Association. All rights reserved.*



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List of Boxes

Box 1 – Key Considerations Caregivers Need to Know to Help Prevent Behavioral Symptoms

Box 2 – Informal Assessment: Brief Questions to Guide Describing Behavioral Symptoms

Box 3 – Checklist of Factors to Consider to Identify Potential Causes of Behavioral Symptoms

Box 1 – Key Considerations Caregivers Need to Know to Help Prevent Behavioral Symptoms

Effectively communicate:

- *Use calm voice*
- *Offer no more than two choices*
- *Do not use open-ended questions*
- *Keep it simple – do not over explain or discuss events happening in the future*

Attend to resident’s nonverbal communications:

- *Grimacing may be a sign of pain*
- *Ringing hands may be a sign of anxiety, feelings of insecurity*

Relax the rules - there is no right or wrong way to perform an activity if resident is safe

Establish a structured daily routine for resident that is predictable

Keep resident engaged in activities of interest and that match capabilities

Use cueing strategies (e.g., touch, verbal directions) to help people with executive dysfunction initiate, sequence, and execute daily activities

Understand behaviors are not intentional or done “in spite” but are a consequence of erosion in person’s ability to initiate or comprehend steps of a task or its purpose

- Inform physician immediately of changes in behavior as they occur (e.g., sleep disruptions, withdrawal, increased confusion)*

- Take care of self as a caregiver/team member:*
 - *Exercise regularly*

 - *Involve other staff and family/representative in care responsibilities as appropriate*

 - *Discuss stressful situations with colleagues and supervisors and brainstorm about potential solutions*

 - *Use stress reduction techniques (see Hand in Hand, CMS video series available in nursing home, or other resources for suggestions)*

Box 2 - Informal Assessment: Brief Questions to Guide Describing Behavioral Symptoms

- What is the behavior? Can you describe the behavior?*
 - *What did he/she do?*
 - *What did he/she say?*
 - *What did you do and say?*

- Why is this behavior a problem? What about it really gets to you or makes you upset?*

- When does the behavior occur?*
 - *What time of day?*
 - *What day(s) of the week?*

- How often did the behavior happen in the past week? Past month?*

- Where does the behavior occur?*
 - *Is there a particular room/setting within the facility where the behavior occurs (e.g., during activities, in dining room, in person's own room with daily care routines)?*

Excerpt adapted from: Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA, November 21, 2012; 308(19): 2020-2029. © 2012 American Medical Association. All rights reserved.

- Can you recognize any patterns?*
 - Does the behavior happen at the same time every day?*
- What happens right before the behavior occurs?*
- Who is around when the behavior occurs and how do they react?*
- What is the environment like where the behavior occurs?*
 - Is there a lot of stimulation (television, noise, people)?*
- How would you like this behavior to change? When would you consider the problem “solved”?*

Note: Adapted from randomized trials and the NIH Resources for Enhancing Alzheimer’s Caregiver Health (REACH I and II).

Box 3 – Checklist of Factors to Consider to Identify Potential Causes of Behavioral Symptoms

1. Resident-based Factors

- Altered emotional status (feelings of insecurity, sadness, anxiety, or loneliness)*
- Lack of daily routines*
- Sensory deficits (hearing, sight)*
- Basic physical needs (hydration, constipation, body temperature)*
- Interests and preferences not being met*
- Level of stimulation (under or over) not appropriate*
- Health issues (underlying infection)*
- Impact of other illness or conditions*
- Pain*

- Medications (changes in, dosage, polypharmacy, failure to take, inappropriate medication administration)*
- Ambulation and/or difficulty finding one's way (getting lost)*
- Challenges performing daily activities of living (bathing, dressing, using the toilet, grooming, eating)*
- Sleep cycle disruptions*

2. Caregiver-based Factors

- Communications too complex*
- Emotional tone is harsh*
- High level of distress*
- Lack of availability (staffing issues)*
- Poor health status*
- Expectations are too high or too low*
- Cultural expectations and care values and beliefs that are not good fit with dementia care needs*
- Style of caregiving not good fit*
- Poor relationship with resident*
- Lack of education about disease and behaviors*
- Lack of supportive network or system within facility for dementia care*
- Limited opportunities for respite*
- Strained financial situation influencing work performance*

Excerpt adapted from: Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA, November 21, 2012; 308(19): 2020-2029. © 2012 American Medical Association. All rights reserved.

Employment and other family care responsibilities

3. Environmental-based factors

Level of physical and/or social stimulation (too much or too little)

Room arrangements

○ *Amount of clutter*

○ *Needed items are out-of-sight or not in where person can see them*

Lack of appropriate visual cues

Safety risk

Too hot or too cold

Lack of needed adaptive equipment (grab bars in bathroom)

Poor lighting

F329

Antipsychotic medications	
<p>All classes, e.g.,</p> <p>First generation (conventional) agents, e.g.</p> <ul style="list-style-type: none"> • chlorpromazine • fluphenazine • haloperidol • loxapine • mesoridazine • molindone • perphenazine • promazine • thioridazine • thiothixene • trifluoperazine • triflupromazine <p>Second generation (atypical) agents, e.g.</p> <ul style="list-style-type: none"> • <i>asenapine</i> • aripiprazole • clozapine • <i>iloperidone</i> • <i>lurasidone</i> • olanzapine • <i>paliperidone</i> • quetiapine • risperidone • ziprasidone 	<p>Indications <i>for Use</i>:</p> <p><i>A. Conditions Other than Dementia</i></p> <p>An antipsychotic medication should <i>generally</i> be used only for the following conditions/diagnoses as documented in the record and as meets the definition(s) in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Training Revision (DSM-IV TR) or subsequent editions):</p> <ul style="list-style-type: none"> ○ Schizophrenia ○ Schizo-affective disorder ○ <i>Schizophreniform disorder</i> ○ <i>Delusional disorder</i> ○ <i>Mood disorders (e.g. bipolar disorder, severe depression refractory to other therapies and/or with psychotic features)</i> ○ Psychosis <i>in the absence of dementia</i> ○ <i>Medical illnesses with psychotic symptoms (e.g., neoplastic disease or delirium) and/or treatment related psychosis or mania (e.g., high-dose steroids)</i> ○ <i>Tourette’s Disorder</i> ○ <i>Huntington disease</i> ○ <i>Hiccups (not induced by other medications)</i> ○ <i>Nausea and vomiting associated with cancer or chemotherapy</i> <p><i>B. Behavioral or Psychological Symptoms of Dementia (BPSD)</i></p> <p><i>(Use this guidance in conjunction with guidance at §483.25 F309 Quality of Care, Review of Care and Services for a Resident with Dementia. Also consider §483.10(d)(2) F154, Right to be informed in advance</i></p>

about care and treatment; F155, Right to refuse treatment; and §483.10(d)(3) F280, Right to participate in planning care and treatment.)

Antipsychotic medications are only appropriate for elderly residents in a small minority of circumstances (unless the antipsychotic is prescribed to treat previously diagnosed mental illness such as schizophrenia or possibly other conditions listed above). All antipsychotic medications carry a Food and Drug Administration (FDA) Black Box Warning. Since June 16, 2008, FDA warned healthcare professionals that both conventional and atypical antipsychotics are associated with an increased risk of death in elderly patients treated for dementia-related psychosis.

Addition information is available at:

<http://www.fda.gov/Drugs/default.htm>.

(A black box warning means that medical studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects. It is the strongest warning that the U.S. Food and Drug Administration can require a pharmaceutical company to place on the labeling of a prescription drug, or in the product literature describing it. The intent of 483.25(l) is that each resident's entire medication regimen be managed and monitored to promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being.)

Antipsychotic medications may be considered for elderly residents with dementia but only after medical, physical, functional, psychological, emotional psychiatric, social and environmental causes have been identified and addressed. Antipsychotic medications must be prescribed at the lowest possible dosage for the shortest period of time and are subject to gradual dose reduction and re-review.

Inadequate Indications:

Antipsychotic medications in persons with dementia should not be used if the only indication is one or more of the following:

- *wandering*

- *poor self-care*
- *restlessness*
- *impaired memory*
- *mild anxiety*
- *insomnia*
- *inattention or indifference to surroundings*
- *sadness or crying alone that is not related to depression or other psychiatric disorders*
- *fidgeting*
- *nervousness*
- *uncooperativeness (e.g. refusal of or difficulty receiving care).*

Criteria:

All of the above highlight conditions/diagnoses where antipsychotic medications may possibly be appropriate, but diagnoses alone do not warrant the use of an antipsychotic unless the following criteria are also met:

- *The behavioral symptoms present a danger to the resident or others*

AND one or both of the following:

- *The symptoms are identified as being due to mania or psychosis (such as: auditory, visual, or other hallucinations; delusions, paranoia or grandiosity);*

OR

- *Behavioral interventions have been attempted and included in the plan of care, except in an emergency.*

Additional Criteria:

Acute Situations/Emergency

When an antipsychotic 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 one or more of the aforementioned conditions/diagnoses, *the use must meet the above criteria* and all of the following additional requirements:

1. The acute treatment period is limited to seven days or less; AND
2. *A clinician in conjunction with the interdisciplinary team must evaluate and document the situation within 7 days to identify and address any contributing and underlying causes of the acute condition and verify the continuing need for an antipsychotic medication.*
3. *If the behaviors persist beyond the emergency situation, pertinent non-pharmacological interventions must be attempted, unless clinically contraindicated, and documented following the resolution of the acute psychiatric event.*

Additional Criteria:

Enduring Conditions

Antipsychotic medications may be used to treat an enduring (i.e., non-acute; chronic or prolonged) condition, if the clinical condition/diagnosis meets the criteria in Section B above.

In addition, before initiating or increasing an antipsychotic medication for enduring conditions, the target behavior/s must be clearly and specifically identified and documented. Monitoring must ensure that the behavioral symptoms are:

1. Not due to a medical condition or problem (*e.g., pain, fluid or electrolyte imbalance, infection, obstipation, medication side effect or polypharmacy*) that can be expected to improve or resolve as the underlying condition is treated *or the offending medication(s) are discontinued;*

AND

2. *Not due to environmental stressors alone (e.g., alteration in the resident's customary location or daily routine, unfamiliar care provider, hunger or thirst, excessive noise for that individual, inadequate or inappropriate staff response), that can be addressed to improve the symptoms or maintain safety;*

AND

3. *Not due to psychological stressors alone (e.g., loneliness, taunting, abuse), anxiety or fear stemming from misunderstanding related to his or her cognitive impairment (e.g., the mistaken belief that this is not where he/she lives or inability to find his or her clothes or glasses, unaddressed sensory deficits) that can be expected to improve or resolve as the situation is addressed;*

AND

4. *Persistent. In this case, there must be clear documented evidence in the medical record that the situation or condition continues or recurs over time (persists) and that other approaches that have been attempted have failed to adequately address the behavioral/psychological symptoms and that the resident's quality of life is negatively affected by the behaviors/symptoms as described above.*

New Admissions:

Many residents are admitted to a SNF/NF already on an antipsychotic medication. The medication may have been started in the hospital or the community, which can make it challenging for the facility and clinical team to identify the indication for use. However, the facility is responsible for:

- *Preadmission screening for mentally ill and intellectually disabled individuals, and;*

	<ul style="list-style-type: none">• <i>Obtaining physician's orders for the resident's immediate care.</i> <p><i>This PASRR screening (F285) should provide pertinent information including appropriate clinical indications for the use of an antipsychotic.</i></p> <p><i>For residents who do not require PASRR screening and are admitted on an antipsychotic medication, the facility must re-evaluate the use of the antipsychotic medication at the time of admission and/or within two weeks of admission (at the time of the initial MDS assessment) and consider whether or not the medication can be reduced (tapered) or discontinued).</i></p>
	<p><i>Dosage:</i></p> <p><i>When dosing an antipsychotic, the treatment should be at the lowest possible dose to improve the target symptoms being monitored. It is important to note that doses for acute indications (e.g. delirium or acute psychosis) may differ from those used for long-term treatment of various conditions.</i></p> <p><i>The table below is provided only as a general guide for residents with dementia who have met all of the criteria outlined above. Orders for doses greater than those that appear in the table warrant closer review for adverse effects and risk/benefit evaluation. However, also note that in some cases, residents may require lower doses than those listed on the table. This is an individual, clinical decision based on a number of complex factors. Surveyors are strongly advised to speak with the practitioner/prescriber and/or consultant pharmacist in cases where an antipsychotic medication is prescribed for an elderly resident with dementia.</i></p>

**Daily Dose Thresholds for Antipsychotic Medications
Used *to Treat Residents with BPSD***

Generic Name	Maximum Total Dosage (mg) per day
<i>First Generation or Typical Agents</i>	
chlorpromazine	75
fluphenazine	4
haloperidol	2
loxapine	10
molindone	10
perphenazine	8
thioridazine	75 *
thiothixene	7
trifluoperazine	8
<i>Second Generation or Atypical</i>	
aripiprazole	10
clozapine	50
olanzapine	5
quetiapine	150
risperidone	2
ziprasidone	**
<i>paliperidone</i>	**
<i>asenapine</i>	**
<i>iloperidone</i>	**
<i>lurasidone</i>	**

** Due to additional black box warnings of QTC prolongation, its use should be avoided.*

*** No studies have been conducted or have results available to assess the drug's safety or efficacy in older adults with dementia.*

Duration:

Refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance.

Monitoring:

When monitoring antipsychotics, it is important to not only evaluate ongoing effectiveness and potential adverse consequences, as discussed below, but also to evaluate the use of any other psychopharmacological medications (e.g. mood stabilizers, benzodiazepines) being given to the resident. Specifically, surveyors should review the record to determine whether the facility can explain the rationale for adding, or switching from an antipsychotic to another category (or categories) of psychopharmacological agents; otherwise, both may potentially be unnecessary medications. Surveyors should investigate further in cases where more than one antipsychotic agent has been prescribed. Surveyors should investigate further in cases where more than one antipsychotic agent has been prescribed, or where an antipsychotic has been discontinued and a medication such as a mood stabilizer has been added.

Effectiveness:

After initiating or increasing the dose of an antipsychotic medication, the behavioral symptoms must be reevaluated periodically (at least during quarterly care plan review, but often more frequently, depending on the resident's response to the medication) to determine the effectiveness of the antipsychotic and the potential for reducing or discontinuing the dose based on target symptoms and any adverse effects or functional impairment.

Potential Adverse Consequences:

The facility assures that residents are being adequately monitored for adverse consequences such as:

- **General:** anticholinergic effects (see Table II), falls, excessive sedation
- **Cardiovascular:** cardiac arrhythmias, orthostatic hypotension
- **Metabolic:** increase in total cholesterol and triglycerides, unstable or poorly controlled blood sugar, weight gain
- **Neurologic:** akathisia, neuroleptic malignant

syndrome (NMS), parkinsonism, tardive dyskinesia, cerebrovascular event (e.g., stroke, transient ischemic attack (TIA)) in individuals with dementia

If the antipsychotic medication is identified as probably causing or contributing to adverse consequences as identified above, the facility must act upon this. In some cases, the benefits of treatment will still be considered to outweigh the risks or burdens of treatment, so the medication may be continued; however, the facility and prescriber must document the rationale for the decision and also that the resident, family member or legal representative is aware of and involved in the decision to continue the medication.

F329

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F329 exists, the team must determine the severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The key elements for severity determination for F329 are as follows:

1. Presence of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications.

Examples of actual or potential harm/negative outcomes for F329 may include, but are not limited to:

- Potential for life-threatening toxicity from excessive dose or lack of indication for the use of digoxin.
- Complications (such as diarrhea with life threatening fluid loss, nephrotoxicity, hearing loss, or anaphylactic shock) from use of an antibiotic when no clear indication for use has been established or response to the use has not been monitored.
- Fractures or falls with injury resulting from the continuing use of medications (e.g., hypnotics/sedatives, antipsychotics, antidepressants, antihypertensives) in the presence of predisposing risks or adverse consequences such as persistent dizziness or recurrent falling without intervening or reevaluating the need for and dose of the medication believed to be the cause of the gait instability.

2. Degree of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications.

Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or
- If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.

3. The immediacy of correction required.

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F329. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance which allowed or caused the immediate jeopardy.

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed, caused, or resulted in, or is likely to allow, cause, or result in serious injury, harm, impairment, or death to a resident; and

- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures. Examples may include, but are not limited to:
 - Failure to assess or respond appropriately for a resident taking warfarin who had an elevated INR of 9 or greater with or without bleeding, or the elevated INR persisted without assessment/follow-up.
 - Failure to monitor PT/INR for a resident on anticoagulant therapy in accordance with current standards of practice and to recognize and/or respond to a life threatening adverse consequence related to anticoagulation.
 - Failure to recognize developing serotonin syndrome (e.g., confusion, motor restlessness, tremor) in a resident receiving a SSRI, leading to the addition of medications with additive serotonin effect or medication to suppress the symptoms.
 - Failure to recognize and respond to signs and symptoms of neuroleptic malignant syndrome (NMS).
 - In the presence of gastrointestinal bleeding, the failure to recognize medication therapies (such as NSAIDs or COX-2 inhibitors, bisphosphonates) as potentially causing or contributing to the gastrointestinal bleed, resulting in the continued administration of the medication, until the resident required hospitalization for severe bleeding.

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Level 3 indicates noncompliance that resulted in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:

- Facility failure to take appropriate action (e.g., suspending administration of the anticoagulant) in response to an INR greater than 4 and less than 9 for a resident who is receiving warfarin until spontaneous bruising or frank bleeding occurs, resulting in the need to transfuse or hospitalize the resident.
- Facility failure to evaluate the medication regimen as a potential cause of seizure activity resulting in the addition of anticonvulsants to treat recent-onset seizures that can be adverse consequences of medications.
- Facility failure to implement a GDR that was not contraindicated in a resident receiving prolonged, continuous antipsychotic therapy resulting in functional decline, somnolence, lethargy, tremors, increased falling, or impaired ambulation.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided. Examples may include, but are not limited to:

- Facility failure to take appropriate action (e.g., change or suspend administration of the warfarin dose) for a resident who has an INR greater than 4 and less than 9 without any bleeding.

- Failure to monitor INR for a resident who has been stabilized on warfarin, but who has not had bleeding.
- Facility failure to identify and act upon minor symptoms of allergic response to medications, such as a rash.
- Facility failure to monitor for response to therapy or for the emergence or presence of adverse consequences before the resident has experienced an adverse consequence or decline in function (e.g., monitoring periodically for symptoms of behavioral distress in someone receiving psychopharmacological medication; monitoring thyroid function at least annually in an individual receiving thyroid hormone replacement; and monitoring hydration status and basic metabolic profile for a resident receiving diuretics or ACE inhibitors, who had a change in mental status after the onset of diarrhea).

Severity Level 1: No Actual Harm with Potential for Minimal Harm

The failure of the facility to provide appropriate care and services to manage the resident's medication regimen to avoid unnecessary medications and minimize negative outcome places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F329 - Additional Example under Investigative Protocol

The following example illustrates the differences between compliance, and non-compliance at severity levels 4, 3 and 2 related to the use of antipsychotic medication when circumstances and outcomes change:

F329 – Compliance Example

An 89 year old male was re-admitted to the nursing home from the hospital. Upon readmission, diagnoses included pneumonia, CHF, and dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden development, one day after admission, of delirium with psychotic features. The resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Upon readmission to the nursing home, the nurse practitioner contacted the hospitalist by telephone to review the case. They agreed that if the resident did not exhibit signs/symptoms of acute delirium over the next week, it would be reasonable to taper and discontinue the antipsychotic medication. The nurse practitioner communicated this information to the nursing staff and consultant pharmacist – the nursing staff included this information in the plan of care. After a week, no target behaviors were observed. The medication was tapered and discontinued, with ongoing monitoring in place for the potential recurrence of symptoms. The facility has met the criteria for compliance.

F329 - Level 4 Severity Non-compliance Example

An 89 year old male was re-admitted to the nursing home from the hospital. Admitting diagnoses included pneumonia, CHF, and dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden

development, one day after admission, of delirium with psychotic features. The resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Approximately 4 months after nursing home readmission, the resident was still receiving the antipsychotic medication. Staff was monitoring for the identified target behaviors; however, documentation revealed that the resident had not exhibited any of the target behaviors for over 3 months. The facility failed to evaluate and/or consider gradual dose reductions, and had not attempted alternative approaches in an effort to discontinue the medication. The consultant pharmacist had recommended gradual dose reductions, but the physician had indicated that the medication was to be continued.

The record indicated that the resident was exhibiting orthostatic hypotension and was at high risk for falling. In addition, he was no longer attending group activities as he was sleeping off and on throughout the day. Staff had identified that the resident, who had been ambulatory with one staff person at admission, was no longer ambulating, was weaker and was in a recliner in his room during the day and evening. The resident had several areas on his hips and coccyx which were identified as Stage III pressure ulcers; he was losing weight due to decreased appetite and was drinking insufficient amounts of fluids.

When interviewed, staff stated that they believed the resident's decline was related to his dementia. They had not considered reducing or discontinuing the medication and failed to recognize that the medication had been initially ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely.

The facility failed to evaluate for the ongoing indication of use of the antipsychotic after symptoms were no longer present, had not monitored for the presence of adverse consequences, had not attempted gradual dose reductions nor implemented any behavioral interventions. The facility staff had not contacted the medical director to evaluate the resident's response and consider discussing the case with the attending physician. Following additional investigation, it was determined that the quality assessment and assurance (QAA) committee did not conduct any oversight or monitoring of residents who were receiving antipsychotics to assure that there were appropriate clinical indications for use and that behavioral interventions and gradual dose reductions were attempted.

Why is this Immediate Jeopardy?

This resident is now so compromised (he has developed pressure ulcers, has reduced food and fluid intake, is experiencing blood pressure fluctuations and is at risk for falls) that immediate action is required to prevent a serious illness or injury. While immediate jeopardy may exist when only one resident is affected, in this case the lack of systems and processes for review of psychopharmacological medications in residents with dementia indicates that other residents on these medications could potentially be at risk for serious harm as well.

F329 - Level 3 Severity Non-compliance Example

An 89 year old male was re-admitted to the nursing home from the hospital. Admitting diagnoses included pneumonia, heart failure, dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden development, one day after admission, of delirium with psychotic features. The resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Approximately 3 months after nursing home readmission, the resident was still receiving the antipsychotic medication. The record indicated that the resident was now having difficulty with mobility and was more dependent on staff for ADLs such as bed mobility and transfers. Staff had identified that the resident was in a recliner in his room during the day and evening and was drowsy more often throughout the day. Staff documented that the resident had a small stage II pressure ulcer.

Staff was monitoring the identified target behaviors and documentation revealed the resident had not exhibited the target behaviors for the past 3 months. However, the facility failed to evaluate and/or consider gradual dose reductions, and had not attempted behavioral interventions in an effort to discontinue the medication. Staff failed to recognize that the medication had initially been ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely.

Why is this level 3 Severity?

The staff had not identified/evaluated the causal factors for the ongoing use of the medication, nor the potential that the medication could have been contributing to the resident's decline in ADLs, alertness and skin condition. Staff failed to recognize that the medication had initially been ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely. The facility failed to consider a gradual dose reduction. The resident had actual harm (ADL decline, stage II pressure ulcer) that could have been related to the medication. However, this is not a level 4 severity because the requirement for immediacy is not met.

Level 2 Severity

An 89 year old male was re-admitted to the nursing home sub-acute unit from the hospital. Admitting diagnoses included pneumonia, heart failure, dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden development, one day after admission, of delirium with psychotic features. The

resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Approximately 3 months after admission, the resident was still receiving the antipsychotic medication and staff was monitoring for target behaviors and for the presence of adverse consequences. The record revealed that the resident had not had any adverse consequences and was no longer exhibiting the target behaviors. However, the facility failed to evaluate and/or consider gradual dose reductions, and had not attempted behavioral interventions in an effort to discontinue the medication. Staff failed to recognize that the medication had been initially ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely.

Why is this level 2 Severity?

While the resident is at risk for potential for more than minimal harm from ongoing use of an antipsychotic medication without a clear clinical indication, the staff did not document any actual harm.

This is only one example. Specific evidence may differ in actual situations and surveyors should evaluate each situation individually as no one example applies to every situation.

Checklist

Review of Care and Services for a Resident with Dementia (for use with the Interpretive Guidance at F309)

Assessment and Underlying Cause Identification

- ✓ Did staff describe behavior (onset, duration, intensity, possible precipitating events or environmental triggers, etc.) and related factors (appearance, alertness, etc.) in the medical record with enough specific detail of the actual situation to permit underlying cause identification to the extent possible?
- ✓ If the behaviors represent a sudden change or worsening from baseline, did staff contact the attending physician/practitioner immediately for a medical evaluation, as appropriate?
- ✓ If medical causes are ruled out, did staff attempt to establish other root causes of the behavior using individualized knowledge about the person and when possible, information from the resident, family, previous caregivers and/or direct care staff?
- ✓ As part of the comprehensive assessment did facility staff evaluate:
 - The resident's usual and current cognitive patterns, mood and behavior, and whether these present a risk to the resident or others?
 - How the resident typically communicates a need such as pain, discomfort, hunger, thirst or frustration?
 - Prior life patterns and preferences customary responses to triggers such as stress, anxiety or fatigue, as provided by family, caregivers, and others who are familiar with the resident before or after admission?
- ✓ Did staff, in collaboration with the practitioner, identify risk and causal/contributing factors for behaviors, such as:
 - Presence of co-existing medical or psychiatric conditions, or decline in cognitive function?
 - Adverse consequences related to the resident's current medications?

1. *If the condition or risks were present at the time of the required comprehensive assessment, did the facility comprehensively assess the physical, mental and psychosocial needs of the resident with dementia to identify the risks and/or to determine underlying causes (to the extent possible) of the resident's behavioral and/or mental psychosocial symptoms, and needed adaptations, and the impact upon the resident's function, mood and cognition?*

If No, cite F272

Care Planning

- ✓ Was the resident and/or family/representative involved (to the extent possible) in discussions about the potential use of any interventions, and was this documented in the medical record?
- ✓ Does the care plan reflect an individualized team approach with measureable goals, timetables and specific interventions for the management of behavioral and psychological symptoms?
- ✓ Does the care plan include:
 - Involvement of the resident/representative to the extent possible?
 - A description of and how to prevent targeted behaviors?
 - Why behaviors should be prevented or otherwise addressed (e.g., severely distressing to resident)?
 - Monitoring of the effectiveness of any/all interventions?
- ✓ If the resident or family/representative refused a recommended treatment or approach, was counseling on consequences and alternative approaches to address behavioral symptoms provided?

Note: If the resident lacks decisional capacity and lacks effective family/representative support, contact the facility social worker to determine what type of social services or referrals have been attempted to assist the resident.

2. *Did the facility develop a plan of care with measurable goals and interventions to address the care and treatment for a resident with dementia related to the behavioral and/or mental/psychosocial symptoms, in accordance with the assessment, resident's wishes and current standards of practice? If No, cite F279*

Implementation of the Care Plan

Did staff:

Identify, document and communicate specific targeted behaviors and expressions of distress as well as desired outcomes?

- ✓ Implement individualized, person-centered interventions by qualified persons and document the results?
- ✓ Communicate and consistently implement the care plan, over time and across various shifts?
- ✓ If there is a sudden change in the resident's condition and medical causes of behavior or other symptoms (e.g., delirium or infection) are suspected, is the physician contacted immediately and treatment initiated?
- ✓ Is there a sufficient number of staff to consistently implement the care plan? (*Surveyors should focus on observations of staff interactions with residents who have dementia to determine whether staff consistently applies basic dementia care principles in the care of those individuals*).

3. Did the facility provide or arrange services to be provided by qualified persons in accordance with the resident's written plan of care? If No, cite F282

Note: If during the survey a concern is identified that an antipsychotic medication is given by staff for purposes of discipline or convenience and not required to treat the resident's medical symptoms, review F222 – §483.13(a).

Care Plan Revision/Monitoring and Follow up

- ✓ Does staff, in collaboration with the practitioner, adjust the interventions based on the impact on behavior or other symptoms as well as any adverse consequences related to treatment?
- ✓ When concerns related to the effectiveness or adverse consequences of a resident's treatment regimen are identified:
 - Does staff modify the care plan and, if appropriate, notify the physician and does the physician respond and initiate a change to the resident's care as necessary?

4. Did the facility reassess the effectiveness of the interventions and review and revise the plan of care (with input from the resident or representative, to the extent possible), if necessary, to meet the needs of the resident with dementia? If No, cite F280

- If the physician does not respond to the notification, does staff contact the medical director for further review? If the medical director was contacted, does he/she respond and intervene as needed?

5. Did the facility provide the necessary care and services for a resident with dementia to support his or her highest practicable level of physical, mental and psychosocial well-being in accordance with the comprehensive assessment and plan of care? If No, cite F309

Quality Assessment and Assurance

Note: Please refer to F520 Quality Assessment and Assurance for guidance regarding the information that may be obtained from the QAA committee.

- ✓ Do resident care policies and procedures clearly outline a systematic process for the care of residents with dementia?
- ✓ Does the QAA Committee monitor for consistent implementation of the policies and procedures for the care of residents with dementia?
- ✓ Has the QAA committee corrected any identified quality deficiencies related to the care of residents with dementia?
- ✓ Has the QAA committee provided monitoring and oversight for the care and services for a resident with dementia?