



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 16-15-NH

DATE: March 25, 2016

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: State Operations Manual (SOM) Surveyor Guidance Revisions Related to
Psychosocial Harm in Nursing Homes

Memorandum Summary

- **F329 Draft Revision:** The Centers for Medicare & Medicaid Services (CMS) has revised guidance to surveyors in Appendix PP of the SOM under F329 to enhance ease of use for surveyors and to include language related to how unnecessary use of medications may cause psychosocial harm to residents.
- **Psychosocial Outcome Severity Guide:** CMS has revised language in the Psychosocial Outcome Severity Guide in Appendix P of the SOM.
- **Revisions to Selected F tags:** CMS has added language to selected F tags to emphasize the risk of psychosocial harm associated with noncompliance with specific regulations.
- The regulatory language remains unchanged.

Background

In 2006, CMS issued the Psychosocial Outcome Severity Guide in Appendix P of the SOM. The guide provided instructions, definitions, and criteria to help surveyors determine the correct levels of negative psychosocial outcomes that developed, continued, or worsened because of a facility's noncompliance. While surveyors currently cite instances of psychosocial harm, CMS believes these revisions will help guide surveyors to identify psychosocial harm or potential harm. The revisions also support activities or actions to improve resident safety and increase quality and reliability of care for better outcomes.

Psychosocial Harm Revisions

The CMS has revised guidance at F329 in Appendix PP. Revisions include:

- Removing medication tables to make F329 easier to use.
- Replacing medication tables with up-to-date medication resources.
- Revising Deficiency Categorization examples to show that noncompliance at F329 can cause significant psychosocial harm.

The CMS requested feedback from surveyors about the medication tables. While the tables contain useful information, they have not been routinely updated and CMS determined that providing up-to-date medication resources would be more helpful to surveyors. The new resources provide information on use, side effects, adverse consequences, drug classifications, and interactions. Additionally, some of the current deficiency categorization examples show a combination of psychosocial and physical harm. The revised examples show how surveyors may cite F329 when psychosocial harm alone occurs.

The CMS has also added language to other F tags listed below. While surveyors may find negative psychosocial outcomes related to any regulations, these areas may be more susceptible to a negative psychosocial outcome or contain a psychosocial element that may be greater in severity than the physical outcome:

- F221/222
- F223/224/225/226
- F241
- F242
- F246
- F248
- F250
- F310
- F320
- F353

The new language in each tag emphasizes the risk of psychosocial harm associated with noncompliance at specific regulations and refers surveyors to the Psychosocial Outcome Severity Guide.

Lastly, language has been added to the Psychosocial Outcome Severity Guide in Appendix P to reference F tags where residents may be more at risk for actual or potential psychosocial harm.

Contact: Please forward any questions regarding this memorandum or the guidance revisions to the CMS DNH triage team, DNH_TriageTeam@cms.hhs.gov.

Effective Date: 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. The contents of this letter supports activities or actions to improve resident safety and increase quality and reliability of care for better outcomes.

/s/

Thomas E. Hamilton

Attachment (s)-

Advanced Copy SOM Appendix PP Psychosocial Harm in Nursing Homes

Advanced Copy SOM F329PSRevision

Advanced Copy SOM PS harmtags

cc: Survey and Certification Regional Office Management

CMS Manual System

Department of Health &
Human Services (DHHS)

Pub. 100-07 State Operations Provider Certification

Centers for Medicare &
Medicaid Services (CMS)

Transmittal – Advance Copy

Date:

SUBJECT: Revisions to the State Operations Manual (SOM) - Appendix PP – Guidance to Surveyors for Long Term Care Facilities

I. SUMMARY OF CHANGES: This instruction revises interpretive guidance for F329 to provide additional information to surveyors about consideration of psychosocial harm when assessing compliance related to unnecessary medications.

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: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix PP Guidance to Surveyors for Long Term Care Facilities/F329 §483.25(l)

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.

F329
(Rev.)

§483.25(l) Unnecessary Drugs

1. General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

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

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

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

INTENT: §483.25(l) Unnecessary drugs

The intent of this requirement is that each resident's entire drug/medication regimen be managed and monitored to achieve the following goals:

- The medication regimen helps promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being, as identified by the resident and/or representative(s) in collaboration with the attending physician and facility staff;
- Each resident receives only those medications, in doses and for the duration clinically indicated to treat the resident's assessed condition(s);
- Non-pharmacological interventions (such as behavioral interventions) are considered and used when indicated, instead of, or in addition to, medication;
- Clinically significant adverse consequences are minimized; and
- The potential contribution of the medication regimen to an unanticipated decline or newly emerging or worsening symptom is recognized and evaluated, and the regimen is modified when appropriate.

NOTE: This guidance applies to all categories of medications including

antipsychotic medications.

Although the regulatory language refers to “drugs,” the guidance in this document generally will refer to “medications,” except in those situations where the term “drug” has become part of an established pharmaceutical term (e.g., adverse drug event, and adverse drug reaction or consequence).

For purposes of this guidance, references to “the pharmacist” mean the facility’s licensed pharmacist, whether employed directly by the facility or through arrangement.

The surveyor’s review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.

DEFINITIONS

Definitions are provided to clarify terminology related to medications and to the evaluation and treatment of residents.

- “Adverse consequence” is an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in an individual’s mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease).

NOTE: Adverse drug reaction (ADR) is a form of adverse consequences. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment. The term “side effect” is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.

- “Anticholinergic side effect” is an effect of a medication that opposes or inhibits the activity of the parasympathetic (cholinergic) nervous system to the point of causing symptoms such as dry mouth, blurred vision, tachycardia, urinary retention, constipation, confusion, delirium, hallucinations, *flushing, and increased blood pressure. Types of medications that may produce anticholinergic side effects include:*
 - *Antihistamines, antidepressants, antipsychotics, antiemetics, muscle relaxants; and*
 - *Certain medications used to treat cardiovascular conditions, Parkinson’s disease, urinary incontinence, gastrointestinal issues and vertigo.*

- “Behavioral interventions” are individualized non-pharmacological approaches (including direct care and activities) that are provided as part of a supportive physical and psychosocial environment, and are directed toward preventing, relieving, and/or accommodating a resident’s distressed behavior.
- “Clinically significant” refers to effects, results, or consequences that materially affect or are likely to affect an individual’s mental, physical, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.
- “Distressed behavior” is behavior that reflects individual discomfort or emotional strain. It may present as crying, apathetic or withdrawn behavior, or as verbal or physical actions such as: pacing, cursing, hitting, kicking, pushing, scratching, tearing things, or grabbing others. *Distressed behavior may be treated with medications but should also be addressed through nonpharmacological approaches. Certain medications may also cause or contribute to distressed behavior.*
- “Dose” is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.
 - “Excessive dose” means the total amount of any medication (including duplicate therapy) given at one time or over a period of time that is greater than the amount recommended by the manufacturer’s label, package insert, current standards of practice for a resident’s age and condition, or clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals and that lacks evidence of:
 - A review for the continued necessity of the dose;
 - Attempts at, or consideration of the possibility of, tapering a medication; and,
 - A documented clinical rationale for the benefit of, or necessity for, the dose or for the use of multiple medications from the same pharmacological class.
- “Duplicate therapy” refers to multiple medications of the same pharmacological class/category or any medication therapy that substantially duplicates a particular effect of another medication that the individual is taking.
- “Duration” is the total length of time the medication is being received.

- “Excessive Duration” means the medication is administered beyond the manufacturer’s recommended time frames or facility-established stop order policies, beyond the length of time advised by current standards of practice, clinical practice guidelines, clinical studies or evidence-based review articles, and/or without either evidence of additional therapeutic benefit for the resident or clinical evidence that would warrant the continued use of the medication.
- “Extrapyramidal symptoms (EPS)” are neurological side effects that can occur at any time from the first few days of treatment to years later. EPS includes various syndromes such as:
 - Akathisia, which refers to a distressing feeling of internal restlessness that may appear as constant motion, the inability to sit still, fidgeting, pacing, or rocking.
 - Medication-induced Parkinsonism, which refers to a syndrome of Parkinson-like symptoms including tremors, shuffling gait, slowness of movement, expressionless face, drooling, postural unsteadiness and rigidity of muscles in the limbs, neck and trunk.
 - Dystonia, which refers to an acute, painful, spastic contraction of muscle groups (commonly the neck, eyes and trunk) that often occurs soon after initiating treatment and is more common in younger individuals.
- “Gradual Dose Reduction (GDR)” is the stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.
- “Indications for use” is the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident’s condition and therapeutic goals and is consistent with manufacturer’s recommendations and/or clinical practice guidelines, clinical standards of practice, medication references, clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.
- “Insomnia” is the inability to sleep characterized by difficulty falling asleep, difficulty staying asleep, early waking, or non-restorative sleep, which may result in impaired physical, social, or cognitive function.
- “Medication Interaction” is the impact of another substance (such as another medication, nutritional supplement including herbal products, food, or substances used in diagnostic studies) upon a medication. The interactions may alter absorption, distribution, metabolism, or elimination. These interactions may decrease the effectiveness of the medication or increase the potential for adverse consequences.

- “Medication Regimen Review” (MRR) is a thorough evaluation of the medication regimen by a pharmacist, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication. The review includes preventing, identifying, reporting, and resolving medication-related problems, medication errors, or other irregularities in collaboration with other members of the interdisciplinary team.¹
- “Monitoring” is the ongoing collection and analysis of information (such as observations and diagnostic test results) and comparison to baseline data in order to:
 - Ascertain the individual’s response to treatment and care, including progress or lack of progress toward a therapeutic goal;
 - Detect any complications or adverse consequences of the condition or of the treatments; and
 - Support decisions about modifying, discontinuing, or continuing any interventions.
- “Neuroleptic Malignant Syndrome” (NMS) is a syndrome related to the use of medications, mainly antipsychotics, that typically presents with a sudden onset of diffuse muscle rigidity, high fever, labile blood pressure, tremor, and notable cognitive dysfunction. It is potentially fatal if not treated immediately, including stopping the offending medications.
- “Non-pharmacological interventions” refers to approaches to care that do not involve medications, generally directed towards stabilizing or improving a resident’s mental, physical or psychosocial well-being.
- “Psychopharmacological medication” is any medication used for managing behavior, stabilizing mood, or treating psychiatric disorders.
- “Serotonin Syndrome” is a potentially serious clinical condition resulting from overstimulation of serotonin receptors. It is commonly related to the use of multiple serotonin-stimulating medications (e.g., SSRIs, SNRIs, triptans, certain antibiotics). Symptoms may include restlessness, hallucinations, confusion, loss of coordination, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting and diarrhea.
- “Tardive dyskinesia” refers to abnormal, recurrent, involuntary movements that may be irreversible and typically present as lateral movements of the tongue or jaw, tongue thrusting, chewing, frequent blinking, brow arching, grimacing, and lip smacking, although the trunk or other parts of the body may also be affected.

OVERVIEW

Medications are an integral part of the care provided to residents of nursing facilities. They are administered to try to achieve various outcomes, such as curing an illness, diagnosing a disease or condition, arresting or slowing a disease process, reducing or eliminating symptoms, or preventing a disease or symptom.

A study of 33,301 nursing facility residents found that an average of 6.7 medications were ordered per resident, with 27 percent of residents taking nine or more medications.² Analysis of antipsychotic use by 693,000 Medicare nursing home residents revealed that 28.5 percent of the doses received were excessive and 32.2 percent lacked appropriate indications for use.³

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

Intrinsic factors including physiological changes accompanying the aging process, multiple comorbidities, and certain medical conditions may affect the absorption, distribution, metabolism or elimination of medications from the body and may also increase an individual's risk of adverse consequences.

While assuring that only those medications required to treat the resident's assessed condition are being used, reducing the need for and maximizing the effectiveness of medications are important considerations for all residents. Therefore, as part of all medication management (including antipsychotics), it is important for the interdisciplinary team to consider non-pharmacological approaches. Educating facility staff and providers in addition to implementing non-pharmacological approaches to resident conditions prior to, and/or in conjunction with, the use of medications may minimize the need for medications or reduce the dose and duration of those medications.⁴

Examples of non-pharmacological interventions may include:

- Increasing the amount of resident exercise, intake of liquids and dietary fiber in conjunction with an individualized bowel regimen to prevent or reduce constipation and the use of medications (e.g. laxatives and stool softeners);
- Identifying, addressing, and eliminating or reducing underlying causes of distressed behavior such as boredom and pain;
- Using sleep hygiene techniques and individualized sleep routines;
- Accommodating the resident's behavior and needs by supporting and encouraging activities reminiscent of lifelong work or activity patterns, such as providing early morning activity for a farmer used to awakening early;

- Individualizing toileting schedules to prevent incontinence and avoid the use of incontinence medications that may have significant adverse consequences (e.g., anticholinergic effects);
- Developing interventions that are specific to resident’s interests, abilities, strengths and needs, such as simplifying or segmenting tasks for a resident who has trouble following complex directions;
- Using massage, hot/warm or cold compresses to address a resident’s pain or discomfort; or
- Enhancing the taste and presentation of food, assisting the resident to eat, addressing food preferences, and increasing finger foods and snacks for an individual with dementia, to improve appetite and avoid the unnecessary use of medications intended to stimulate appetite.
- *Arranging staffing to optimize familiarity and consistency for a resident with symptoms of dementia.*

The indications for initiating, withdrawing, or withholding medication(s), as well as the use of non-pharmacological approaches, are determined by assessing the resident’s underlying condition, current signs and symptoms, and preferences and goals for treatment. This includes, where possible, the identification of the underlying cause(s), since a diagnosis alone may not warrant treatment with medication.

Orders from multiple prescribers can increase the resident’s chances of receiving unnecessary medications. Many residents receive orders for medications from several practitioners, for example, attending and on-call physicians, consultants, and nurse practitioner(s). It is important that the facility clearly identify who is responsible for prescribing and identifying the indications for use of medication(s), for providing and administering the medication(s), and for monitoring the resident for the effects and potential adverse consequence of the medication regimen. This is also important when care is delivered or ordered by diverse sources such as consultants, providers, or suppliers (e.g., hospice or dialysis programs).

Staff and practitioner access to current medication references and pertinent clinical protocols helps to promote safe administration and monitoring of medications. One of the existing mechanisms to warn prescribers about risks associated with medications is the Food and Drug Administration (FDA) requirement that manufacturers include within the medication labeling warnings about adverse reactions and potential safety hazards identified both before and after approval of a medication, and what to do if they occur (Visit: www.fda.gov/medwatch/safety.htm). Manufacturers are required to update labels to warn about newly identified safety hazards—regardless of whether causation has been proven and whether the medication is prescribed for a disease or condition that is not included in the “Indications and Usage” section of the labeling (so-called “off-label” or unapproved use). The FDA may require manufacturers to place statements about serious

problems in a prominently displayed box (so-called boxed or “black box” warnings), which indicates a need to closely evaluate and monitor the potential benefits and risks of that medication.

The facility’s pharmacist is a valuable source of information about medications. Listings or descriptions of most significant risks, recommended doses, medication interactions, cautions, etc. can be found in widely available, standard references, and computer software and systems that provide up-to-date information. It is important to note that some of the medication information found in many of these references is not specific to older adults or institutionalized individuals.

Clinical standards of practice and clinical guidelines established by professional groups are useful to guide clinicians. Some of the recognized clinical resources available for understanding the overall treatment and management of medical problems, symptoms and medication consequences and precautions include the:

- American Geriatrics Society <http://www.americangeriatrics.org>;
- American Medical Directors Association, <http://www.amda.com>;
- American Psychiatric Association, <http://www.psychiatry.org/>
- American Society of Consultant Pharmacists, <http://www.ASCP.com>;
- Agency for Healthcare Research and Quality (AHRQ) <http://www.ahrq.gov>;
- American Association for Geriatric Psychiatry, <http://www.aagponline.org/>;
- Association for Practitioners in Infection Control and Epidemiology, www.apic.org;
- National Guideline Clearinghouse, <http://www.guideline.gov/>;
- Quality Improvement Organizations, <http://qioprogram.org/>;
- U.S. Department of Health and Human Services, Food and Drug Administration Web site <http://www.fda.gov/medwatch/safety.htm>;
- U.S. Department of Health and Human Services, National Institute of Mental Health Web site, which includes publications and clinical research information <http://www.nimh.nih.gov>;

NOTE: References to non-CMS sources or sites on the Internet included above or later in this document 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.

Although these guidelines generally emphasize the older adult resident, adverse consequences can occur in anyone at any age; therefore, these requirements apply to residents of all ages.

MEDICATION MANAGEMENT

Medication management is based in the care process and includes recognition or identification of the problem/need, assessment, diagnosis/cause identification, management/treatment, monitoring, and revising interventions, as warranted. The attending physician plays a key leadership role in medication management by developing, monitoring, and modifying the medication regimen in conjunction with residents and/or representative(s) and other professionals and direct care staff (the interdisciplinary team). When selecting medications and non-pharmacological interventions, members of the interdisciplinary team participate in the care process to identify, assess, address, advocate for, monitor, and communicate the resident's needs and changes in condition.

This guidance is intended to help the surveyor determine whether the facility's medication management supports and promotes:

- Selection of medications(s) based on assessing relative benefits and risks to the individual resident;
- Evaluation of a resident's *physical, behavioral, and psychosocial* signs and symptoms, in order to identify the underlying cause(s), including adverse consequences of medications;
- Selection and use of medications in doses and for the duration appropriate to each resident's clinical conditions, age, and underlying causes of symptoms;
- The use of non-pharmacological interventions, when applicable, to minimize the need for medications, permit use of the lowest possible dose, or allow medications to be discontinued; and
- The monitoring of medications for efficacy and clinically significant adverse consequences.

The resident's clinical record documents and communicates to the entire team the basic elements of the care process. Information about aspects of the care process related to medications may be found in various locations within the record, such as: hospital discharge summaries and transfer notes, progress notes and interdisciplinary notes, history and physical examination, Resident Assessment Instrument (RAI), plan of care, laboratory reports, professional consults, medication orders, Medication Regimen Review

(MRR) reports, and Medication Administration Records (MAR).

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

Advance Directives – A resident may have written or verbal directions related to treatment choices (or a decision has been made by the resident’s surrogate or representative) in accordance with state law. An advance directive is a means for the resident to communicate his or her wishes, which may include withdrawing or withholding medications. Whether or not a resident has an advanced directive, the facility is responsible for giving treatment, support, and other care that is consistent with the resident’s condition and applicable care instructions.

NOTE: Choosing not to be resuscitated (reflected in a “Do Not Resuscitate” (DNR) order) indicates that the resident should not be resuscitated if respirations and/or cardiac function cease. A DNR order by itself does not indicate that the resident has declined other appropriate treatment and services.

The regulations associated with medication management include consideration of:

- I. Indications for use of medication (including initiation or continued use of antipsychotic medication);
- II. Monitoring for efficacy and adverse consequences;
- III. Dose (including duplicate therapy);
- IV. Duration;
- V. Tapering of a medication dose/gradual dose reduction for antipsychotic medications; and,
- VI. Prevention, identification, and response to adverse consequences.

I. Indications for Use of Medication (including Initiation or Continued Use of an Antipsychotic Medication)

An evaluation of the resident helps to identify his/her needs, comorbid conditions, and prognosis to determine factors (including medications and new or worsening medical conditions) that are affecting signs, symptoms, and test results. This evaluation process is important when making initial medication/intervention selections and when deciding whether to modify or discontinue a current medication intervention. Regarding “as needed” (PRN) medications, it is important to evaluate and document the indication(s), specific circumstance(s) for use, and the desired frequency of administration. As part of the evaluation, gathering and analyzing information helps define clinical indications and provide baseline data for subsequent monitoring. The evaluation also clarifies:

- Whether other causes for the symptoms (including behavioral distress that could mimic a psychiatric disorder) have been ruled out;
- Whether the *physical and/or psychosocial* signs, symptoms, or related causes are persistent or clinically significant enough (e.g., causing functional decline) to warrant the initiation or continuation of medication therapy;
- Whether non-pharmacological interventions are considered;
- Whether a particular medication is clinically indicated to manage the symptom or condition; and
- Whether the intended or actual benefit is sufficient to justify the potential risk(s) or adverse consequences associated with the selected medication, dose, and duration.

The content and extent of the evaluation may vary with the situation and may employ various assessment instruments and diagnostic tools. Examples of information to be considered and evaluated may include, but are not limited to, the following:

- An appropriately detailed evaluation of mental, physical, psychosocial, and functional status, including comorbid conditions and pertinent psychiatric symptoms and diagnoses and a description of resident complaints, symptoms, and signs (including the onset, scope, frequency, intensity, precipitating factors, and other important features);
- Each resident’s goals and preferences;
- Allergies to medications and foods and potential for medication interactions;
- A history of prior and current medications and non-pharmacological interventions (including therapeutic effectiveness and any adverse consequences);
- Recognition of the need for end-of-life or palliative care; and

- The refusal of care and treatment, including the basis for declining it, and the identification of pertinent alternatives.

NOTE: The CAAs, an integral part of the comprehensive resident assessment, help identify some possible categories of causes of various symptoms including: behavioral symptoms of distress, delirium, and changes in functional status. Refer to 42 CFR 483.20 and the MDS and CAAs.

Circumstances that warrant evaluation of the resident and medication(s) may include:

- Admission or re-admission;
- A clinically significant change in condition/status;
- A new, persistent, or recurrent clinically significant symptom or problem;
- A worsening of an existing problem or condition;
- An unexplained decline in function or cognition;
- A new medication order or renewal of orders; and,
- An irregularity identified in the pharmacist's monthly medication regimen review.

Specific considerations related to these circumstances may include the following:

- **Admission (or Readmission)** – Some residents may be admitted on medications for an undocumented chronic condition or without a clear indication as to why a medication was begun or should be continued. It is expected that the attending physician, pharmacist, and staff subsequently determine if continuing the medication is justified by evaluating the resident's clinical condition, risks, existing medication regimen, and related factors. If the indications for continuing the medication are unclear, or if the resident's symptoms could represent a clinically significant adverse consequence, additional consideration of the rationale for the medication(s) is warranted.
- **Multiple prescribers** – Regardless of who the prescribers are, the continuation of a medication needs to be evaluated to determine if the medication is still warranted in the context of the resident's other medications and comorbidities. Medications prescribed by a specialist or begun in another care setting, such as the hospital, need to have a clinically pertinent documented rationale.
- **New medication order as an emergency measure** – When a resident is experiencing an acute medical problem or psychiatric emergency (e.g., the resident's behavior poses an immediate risk to the resident or others), medications may be required. In these situations, it is important to identify and address the

underlying causes of the problem or symptoms. Once the acute phase has stabilized, the staff and prescriber consider whether medications are still relevant. Subsequently, the medication is reduced or discontinued as soon as possible or the clinical rationale for continuing the medication is documented.

When psychopharmacological medications are used as an emergency measure, adjunctive approaches, such as behavioral interventions and techniques should be considered and implemented as appropriate. Longer term management options should be discussed with the resident and/or representative(s).

- **Psychiatric disorders or distressed behavior** – As with all symptoms, it is important to seek the underlying cause of distressed behavior, either before or while treating the symptom. Examples of potential causes include:
 - Delirium;
 - Pain;
 - Chronic psychiatric illness such as schizophrenia or schizoaffective disorder;
 - Acute psychotic illness such as brief reactive psychosis;
 - Substance intoxication or withdrawal;
 - Environmental stressors (e.g., excessive heat, noise, overcrowding);
 - Psychological stressors (e.g., disruption of the resident’s customary daily routine, grief over nursing home admission or health status, abuse, taunting, intimidation);
 - Neurological illnesses such as Huntington’s disease or Tourette’s syndrome; or,
 - Medical illnesses such as Alzheimer’s disease, Lewy body disease, vascular dementia, or frontotemporal dementia.

II. Monitoring for Efficacy and Adverse Consequences

The information gathered during the initial and ongoing evaluations is essential to:

- Incorporate into a comprehensive care plan that reflects appropriate medication related goals and parameters for monitoring the resident’s condition, including the likely medication effects and potential for adverse consequences. Examples of this information may include the FDA boxed warnings or adverse consequences that may be rare, but have sudden onset or that may be irreversible. If the facility has established protocols for monitoring specific medications and the protocols are accessible for staff use, the care plan may refer staff to these protocols;

- Optimize the therapeutic benefit of medication therapy and minimize or prevent potential adverse consequences;
- Establish parameters for evaluating the ongoing need for the medication; and,
- Verify or differentiate the underlying diagnoses or other underlying causes of signs and symptoms.

The key objectives for monitoring the use of medications are to track progress towards the therapeutic goal(s) and to detect the emergence or presence of any adverse consequences. Effective monitoring relies upon understanding the indications and goals for using the medication, identifying relevant baseline information, identifying the criteria for evaluating the benefit(s) of the medication, and recognizing and evaluating adverse consequences. Monitoring parameters are based on the resident's condition, the pharmacologic properties of the medication being used and its associated risks, individualized therapeutic goals, and the potential for clinically significant adverse consequences.

Adverse consequences related to medications are common enough to warrant serious attention and close monitoring. *An Office of the Inspector General (OIG) report on adverse events in skilled nursing facilities (SNFs) found one in five SNF residents experienced at least one adverse event and 37 percent of these events were related to medications.⁵ The report found 66 percent of medication-related adverse events to be preventable because the events often occurred due to substandard treatment or insufficient monitoring. Additionally, the OIG found that the use of multiple medications often complicated the determination of the primary cause of events, particularly when the primary cause was related to another medication.*

Sources of information to facilitate defining the monitoring criteria or parameters may include cautions, warnings, and identified adverse consequences from:

- Manufacturers' package inserts and black-box warnings;
- Facility policies and procedures;
- Pharmacists;
- Clinical practice guidelines or clinical standards of practice;
- Medication references; and
- Clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.

Monitoring of the resident's response to any medication(s) is essential to evaluate the ongoing benefits as well as risks of various medications. It is important, for example, to

monitor the effectiveness of medications used to address behavioral symptoms (e.g., behavioral monitoring) or to treat hypertension (e.g., periodic pulse and blood pressure). Monitoring for adverse consequences involves ongoing vigilance and may periodically involve objective evaluation (e.g., assessing vital signs may be indicated if a medication is known to affect blood pressure, pulse rate and rhythm, or temperature). Using quantitative and qualitative monitoring parameters facilitates consistent and objective collection of information by the facility.

Monitoring involves several steps, including:

- **Identifying the essential information and how it will be obtained and reported.** It is important to consider who is responsible for obtaining the information, which information should be collected, and how the information will be documented. The information that is collected depends on therapeutic goals, detection of potential or actual adverse consequences, and consideration of risk factors, such as:
 - Medication-medication, medication-food interactions;
 - Clinical condition (for example renal disease);
 - Properties of the medication;
 - Black-box warnings; and,
 - History of adverse consequences related to a similar medication.
- **Determining the frequency of monitoring.** The frequency and duration of monitoring needed to identify therapeutic effectiveness and adverse consequences will depend on factors such as clinical standards of practice, facility policies and procedures, manufacturer's specifications, and the resident's clinical condition. Monitoring involves three aspects:
 - Periodic planned evaluation of progress toward the therapeutic goals;
 - Continued vigilance for adverse consequences; and,
 - Evaluation of identified adverse consequences.

For example, when monitoring all psychopharmacological medications and sedative/hypnotics, the facility should review the continued need for them, at least quarterly (i.e., a 3 month period), and document the rationale for continuing the medication, including evidence that the following had been evaluated:

- The resident's target symptoms and the effect of the medication on the severity, frequency, and other characteristics of the symptoms;

- Any changes in the resident's function during the previous quarter (e.g., as identified in the Minimum Data Set); and
- Whether the resident experienced any medication-related adverse consequences during the previous quarter.

An important aspect of the review would include whether the pharmacological management of the resident's medical and/or psychiatric disorder is consistent with recommendations from relevant clinical practice guidelines, current standards of practice, and/or manufacturer's specifications.

- **Defining the methods for communicating, analyzing, and acting upon relevant information.** The monitoring process needs to identify who is to communicate with the prescriber, what information is to be conveyed, and when to ask the prescriber to evaluate and consider modifying the medication regimen.

It is important to consider whether a resident's medications are promoting or maintaining a resident's highest practicable level of function. If the therapeutic goals are not being met or the resident is experiencing adverse consequences, it is essential for the prescriber in collaboration with facility staff and pharmacist to consider whether current medications and doses continue to be appropriate or should be reduced, changed, or discontinued.

- **Re-evaluating and updating monitoring approaches.** Modification of monitoring may be necessary when the resident experiences changes, such as:
 - Acute onset of signs or symptoms or worsening of chronic disease;
 - Decline in function or cognition;
 - Addition or discontinuation of medications and/or non-pharmacological interventions;
 - Addition or discontinuation of care and services such as enteral feedings; and,
 - Significant changes in diet that may affect medication absorption or effectiveness or increase adverse consequences.

Additional examples of circumstances that may indicate a need to modify the monitoring include: changes in manufacturer's specifications, FDA warnings, pertinent clinical practice guidelines, or other literature about how and what to monitor.

III. Dose (Including Duplicate Therapy)

A prescriber orders medication(s) based on a variety of factors including the resident's diagnoses, signs and symptoms, current condition, age, coexisting medication regimen,

review of lab and other test results, input from the interdisciplinary team about the resident, the type of medication(s), and therapeutic goals being considered or used.

Factors influencing the appropriateness of any dose include the resident's clinical response, possible adverse consequences, and other resident and medication-related variables. Often, lab test results such as serum medication concentrations are only a rough guide to dosing. Significant adverse consequences can occur even when the concentration is within the therapeutic range. Serum concentrations alone may not necessarily indicate a need for dose adjustments, but may warrant further evaluation of a dose or the medication regimen.

The route of administration influences a medication's absorption and ultimately the dose received. Examples of factors that can affect the absorption of medications delivered by transdermal patches include skin temperature and moisture, and the integrity of the patch. Similarly, the flow rate of intravenous solutions affects the amount received at a given time.

Duplicate therapy is generally not indicated, unless current clinical standards of practice and documented clinical rationale confirm the benefits of multiple medications from the same class or with similar therapeutic effects. Some examples of potentially problematic duplicate therapy include:

- Use of more than one product containing the same medication can lead to excessive doses of a medication, such as concomitant use of acetaminophen/hydrocodone and acetaminophen, which may increase the risk of acetaminophen toxicity;
- Use of multiple laxatives to improve or maintain bowel movements, which may lead to abdominal pain or diarrhea;
- Concomitant use of multiple benzodiazepines such as lorazepam for anxiety and temazepam for sleep, which may increase fall risk; or,
- Use of medications from different therapeutic categories that have similar effects or properties, such as multiple medications with anticholinergic effects (e.g., oxybutynin and diphenhydramine), which may increase the risk of delirium or excessive sedation.

Documentation is necessary to clarify the rationale for and benefits of duplicate therapy and the approach to monitoring for benefits and adverse consequences. This documentation may be found in various areas of the resident's clinical record.

IV. Duration

Many conditions require treatment for extended periods, while others may resolve and no longer require medication therapy. For example:

- Acute conditions such as cough and cold symptoms, upper respiratory condition, nausea and/or vomiting, acute pain, psychiatric or behavioral symptoms;
- Proton pump inhibitors (PPIs)/H2 blockers used for prophylaxis during the acute phase of a medical illness should be tapered and possibly discontinued after the acute phase of the illness has resolved, unless there is a valid clinical indication for prolonged use.

Periodic re-evaluation of the medication regimen is necessary to determine whether prolonged or indefinite use of a medication is indicated. The clinical rationale for continued use of a medication(s) may have been demonstrated in the clinical record, or the staff and prescriber may present pertinent clinical reasons for the duration of use. Common considerations for appropriate duration may include:

- A medication initiated as a result of a time-limited condition (for example, delirium, pain, infection, nausea and vomiting, cold and cough symptoms, or itching) is then discontinued when the condition has resolved, or there is documentation indicating why continued use is still relevant. Failure to review whether the underlying cause has resolved may lead to excessive duration.
- A medication is discontinued when indicated by facility stop order policy or by the prescriber's order, unless there is documentation of the clinical justification for its extended use. A medication administered beyond the stop date established in the prescriber's order or by facility policy, without evidence of clinical justification for continued use of the medication, may be considered excessive duration.

V. Tapering of a Medication Dose/Gradual Dose Reduction (GDR)

The requirements underlying this guidance emphasize the importance of seeking an appropriate dose and duration for each medication and minimizing the risk of adverse consequences. The purpose of tapering a medication is to find an optimal dose or to determine whether continued use of the medication is benefiting the resident. Tapering may be indicated when the resident's clinical condition has improved or stabilized, the underlying causes of the original target symptoms have resolved, and/or non-pharmacological interventions, including behavioral interventions, have been effective in reducing the symptoms.

There are various opportunities during the care process to evaluate the effects of medications on a resident's function and behavior, and to consider whether the medications should be continued, reduced, discontinued, or otherwise modified. Examples of these opportunities include:

- During the monthly medication regimen review, the pharmacist evaluates resident-related information for dose, duration, continued need, and the emergence of adverse consequences for all medications;

- When evaluating the resident’s progress, the practitioner reviews the total plan of care, orders, the resident’s response to medication(s), and determines whether to continue, modify, or stop a medication; and
- During the quarterly MDS review, the facility evaluates mood, function, behavior, and other domains that may be affected by medications.

Sometimes, the decision about whether to continue a medication is clear; for example, someone with a history of multiple episodes of depression or recurrent seizures may need an antidepressant or anticonvulsant medication indefinitely. Often, however, the only way to know whether a medication is needed indefinitely and whether the dose remains appropriate is to try reducing the dose and to monitor the resident closely for improvement, stabilization, or decline.

The time frames and duration of attempts to taper any medication depend on factors including the coexisting medication regimen, the underlying causes of symptoms, individual risk factors, and pharmacologic characteristics of the medications. Some medications (e.g., antidepressants, sedative/hypnotics, opioids) require more gradual tapering so as to minimize or prevent withdrawal symptoms or other adverse consequences.

NOTE: If the resident’s condition has not responded to treatment or has declined despite treatment, it is important to evaluate both the medication and the dose to determine whether the medication should be discontinued or the dosing should be altered, whether or not the facility has implemented GDR as required, or tapering.

Considerations Specific to Antipsychotics. The regulation addressing the use of antipsychotic medications identifies the process of tapering as a “gradual dose reduction (GDR)” and requires a GDR, unless clinically contraindicated.

Within the first year in which a resident is admitted on an antipsychotic medication or after the facility has initiated an antipsychotic medication, the facility must attempt a GDR in two separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a GDR must be attempted annually, unless clinically contraindicated.

For any individual who is receiving an antipsychotic medication to treat behavioral symptoms related to dementia, the GDR may be considered clinically contraindicated if:

- The resident’s target symptoms returned or worsened after the most recent attempt at a GDR within the facility; and
- The physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident’s function or increase distressed behavior.

For any individual who is receiving an antipsychotic medication to treat a psychiatric disorder other than behavioral symptoms related to dementia (for example, schizophrenia, bipolar mania, or depression with psychotic features), the GDR may be considered contraindicated, if:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying psychiatric disorder; or
- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

Attempted Tapering Relative to Continued Indication or Optimal Dose

As noted, attempted tapering is one way to determine whether a specific medication is still indicated, and whether target symptoms and risks can be managed with a lesser dose of a medication. As noted, many medications in various categories can be tapered safely. The following examples of tapering relate to two common categories of concern: sedatives / hypnotics and psychopharmacologic medications (other than antipsychotic and sedatives/hypnotics medications).

Tapering Considerations Specific to Sedatives/Hypnotics.

For as long as a resident remains on a sedative/hypnotic that is used routinely and beyond the manufacturer's recommendations for duration of use, the facility should attempt to taper the medication quarterly unless clinically contraindicated. Clinically contraindicated means:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder; or
- The resident's target symptoms returned or worsened after the most recent attempt at tapering the dose within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

Considerations Specific to Psychopharmacological Medications (Other Than Antipsychotics and Sedatives/Hypnotics).

During the first year in which a resident is admitted on a psychopharmacological medication (other than an antipsychotic or a sedative/hypnotic), or after the facility has

initiated such medication, the facility should attempt to taper the medication during at least two separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a tapering should be attempted annually, unless clinically contraindicated. The tapering may be considered clinically contraindicated, if:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder; or
- The resident's target symptoms returned or worsened after the most recent attempt at tapering the dose within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

VI. Adverse Consequences

Any medication or combination of medications (for example interactions between multiple medications with sedative or anticholinergic effects) can cause adverse consequences. Some adverse consequences occur quickly or abruptly, while others are more insidious and develop over time. Adverse consequences may become evident at any time after the medication is initiated, e.g., when there is a change in dose or after another medication has been added.

When reviewing medications used for a resident, it is important to be aware of the medication's recognized safety profile, tolerability, dosing, and potential medication interactions. Although a resident may have an unanticipated reaction to a medication that is not always preventable, many ADRs can be anticipated, minimized, or prevented. Some adverse consequences may be avoided by:

- Following relevant clinical guidelines and manufacturer's specifications for use, dose, administration, duration, and monitoring of the medication;
- Defining appropriate indications for use; and
- Determining that the resident:
 - Has no known allergies to the medication;
 - Is not taking other medications, nutritional supplements including herbal products, or foods that would be incompatible with the prescribed medication; and
 - Has no condition, history, or sensitivities that would preclude use of that medication.

Published studies have sought to identify the frequency, severity, and preventability of adverse consequences. Neuropsychiatric, hemorrhagic, gastrointestinal, renal/electrolyte abnormalities and metabolic/endocrine complications were the most common overall and preventable adverse consequences identified in two nursing home studies. Specifically, a study of 18 community-based nursing homes reported that approximately 50 percent (276/546) of all the adverse consequences—and 72 percent of those characterized as fatal, life-threatening, or serious—were considered preventable.⁶ A second study of two academic-based nursing homes reported that inadequate monitoring, failure to act on the monitoring, and errors in ordering, including wrong dose, wrong medication, and medication-medication interactions were the most frequent causes for the preventable adverse consequences.⁷

The risk for adverse consequences increases with both the number of medications being taken regularly and with medications from specific pharmacological classes, such as anticoagulants, diuretics, antipsychotics, anti-infectives, and anticonvulsants.^{8,9} Adverse consequences can range from minimal harm to functional decline, hospitalization, permanent injury, and death.

Delirium (i.e., acute confusional state) is a common adverse consequence *that may result from medications as well as other factors including electrolyte imbalances or infections.* In many facilities, a majority of the residents have dementia. Individuals who have dementia may be more sensitive to medication effects and may be at greater risk for delirium.¹⁰ *While delirium is not always preventable, identifying and addressing risk factors may reduce the occurrence.* The presence of delirium is associated with higher morbidity and mortality. Some of the classic signs of delirium may be difficult to recognize and may be mistaken for the natural progression of dementia, particularly in the late stages of dementia. *Delirium often presents with symptoms of restlessness and agitation but, in older residents, may present with increased lethargy and sedation. Use of medications to treat delirium may increase confusion and exacerbate other delirium symptoms and should only be used at the lowest dose for the shortest period of time possible.*¹¹ Careful observation of the resident (including mental status and level of consciousness), review of the potential causes (e.g., medications, fluid and electrolyte imbalance, infections) of the mental changes and distressed behavior, and appropriate and timely management of delirium are essential.

INVESTIGATIVE PROTOCOL

UNNECESSARY MEDICATIONS - MEDICATION REGIMEN REVIEW

Because they are closely related, the investigations of the requirements for medication regimen review and the review for unnecessary medications have been merged.

Objectives

- To determine whether each resident receives or is provided:
 - Only those medications that are clinically indicated in the dose and for the duration to meet his or her assessed needs;
 - Non-pharmacological approaches when clinically indicated, in an effort to reduce the need for or the dose of a medication; and
 - Gradual dose reduction attempts for antipsychotics (unless clinically contraindicated) and tapering of other medications, when clinically indicated, in an effort to discontinue the use or reduce the dose of the medication.
- To determine if the facility in collaboration with the prescriber:
 - Identifies the parameters for monitoring medication(s) or medication combinations (including antipsychotics) that pose a risk for adverse consequences; and for monitoring the effectiveness of medications (including a comparison with therapeutic goals); and
 - Recognizes and evaluates the onset or worsening of signs or symptoms, or a change in condition to determine whether these potentially may be related to the medication regimen; and follows-up as necessary upon identifying adverse consequences.
- To determine if the pharmacist:
 - Performed the monthly medication regimen review, and identified any existing irregularities regarding indications for use, dose, duration, and the potential for, or the existence of adverse consequences or other irregularities; and
 - Reported any identified irregularities to the attending physician and director of nursing.
- To determine whether the facility and/or practitioner acted on the report of any irregularity.

Use

Use this protocol during every initial and standard survey. In addition, this protocol may be used on revisits or abbreviated survey (complaint investigation) as necessary.

NOTE: This review is not intended to direct medication therapy. However, surveyors are expected to review factors related to the implementation, use, and monitoring of medications.

The surveyor is not expected to prove that an adverse consequence was directly caused by a medication or combination of medications, but rather that there was a failure in the care process related to considering and acting upon such possibilities.

If during the course of this review, the surveyor needs to contact the attending physician regarding questions related to the medication regimen, it is recommended that the facility's staff have the opportunity to provide the necessary information about the resident and the concerns to the physician for his/her review prior to responding to the surveyor's inquiries.

Procedures

Review the medications (prescription, over-the-counter medications, and nutritional supplements such as herbal products) currently ordered and/or discontinued by the prescriber at least back to the most recent signed recapitulation/reorder of all medications. Obtain a copy of the current orders if necessary. Gather information regarding the resident's mental, physical, functional, and psychosocial status and the medication-related therapeutic goals identified in the care plan as the basis for further review.

1. Observation and Record Review

Use the table below to guide observations, record review, and interviews with the resident or representative and relevant staff. Observe whether the medication-related interventions are consistently implemented over time and across various shifts. Note deviations from the care plan as well as potential medication-related adverse consequences. Verify observations by gathering additional information; for example, additional record reviews and/or interviews with the resident or representative, relevant staff, and practitioners.

<p align="center">SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS</p>	<p align="center">REVIEW FOR HOW FACILITY MANAGED MEDICATIONS FOR THE RESIDENT</p>
<p>Determine if the resident has been transferred to acute care since the last survey and/or has recently (e.g., the previous 3 months) experienced a change in condition or currently has signs and symptoms, such as:</p> <ul style="list-style-type: none"> • Anorexia and/or unplanned weight loss, or weight gain • <i>Apathy</i> 	<p>Review the record (including the care plan, comprehensive assessment, and other parts of the record as appropriate) to determine whether it reflects the following elements related to medication management for the resident:</p> <ul style="list-style-type: none"> • Clinical indications for use of the medication

<p align="center">SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS</p>	<p align="center">REVIEW FOR HOW FACILITY MANAGED MEDICATIONS FOR THE RESIDENT</p>
<ul style="list-style-type: none"> • Behavioral changes, unusual behavior patterns (including increased distressed behavior, <i>social isolation or withdrawal</i>) • Bleeding or bruising, spontaneous or unexplained • Bowel dysfunction including diarrhea, constipation and impaction • Dehydration, fluid/electrolyte imbalance • Depression, mood disturbance • Dysphagia, swallowing difficulty • Falls, dizziness, or evidence of impaired coordination • Gastrointestinal bleeding • Headaches, muscle pain, generalized or nonspecific aching or pain • <i>Lethargy</i> • Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia (including delirium), <i>inability to concentrate</i>) • <i>Psychomotor agitation (e.g., restlessness, inability to sit still, pacing, hand-wringing, or pulling or rubbing of the skin, clothing, or other objects).</i> • <i>Psychomotor retardation (e.g., slowed speech, thinking, and body movements)</i> • Rash, pruritus • Respiratory difficulty or changes • Sedation (excessive), insomnia, or sleep disturbance • Seizure activity • Urinary retention or incontinence <p>If observations or record review indicate symptoms or changes in condition that may be related to medications, determine whether the facility considered medications as a potential cause of the change or symptom.</p>	<ul style="list-style-type: none"> • Consideration of non-pharmacological interventions • Dose, including excessive dose and duplicate therapy • Duration, including excessive duration • Consideration of potential for tapering/GDR or rationale for clinical contraindication • Monitoring for and reporting of: <ul style="list-style-type: none"> ○ Response to medications and progress toward therapeutic goals ○ Emergence of medication-related adverse consequences • Adverse consequences, if present and potentially medication-related, note if there was: <ul style="list-style-type: none"> ○ Recognition, evaluation, reporting, and management by the facility ○ Physician action regarding potential medication-related adverse consequences

2. Interview

Interview the resident and or family/responsible party, to the extent possible, to determine:

- His/her participation in care planning and decision making, including discussions of the goals related to the use of medications;
- Whether approaches other than medications (as indicated) were discussed; and,
- His/her evaluation of the results of the medication therapy and other approaches (such as decreasing symptoms of pain, improving functional ability, decline in physical, mental, or psychosocial functioning since starting or increasing medication).

If during the review, you identify concerns about the lack of indication for use; the dose or duration of a medication; lack of monitoring; failure to implement the care plan; or condition changes or functional decline that may be related to the medication regimen, interview knowledgeable staff to determine:

- Whether the resident has experienced any changes in the functioning or amount of activity that he/she is able to do;
- The clinical rationale for the use of the medication, dose or duration and how the interdisciplinary team is monitoring the resident's response to the medication;
- What process is in place to assure the care plan interventions for medication use are being implemented;
- Whether they were aware that the signs and symptoms may be adverse consequences related to the medication regimen;
- Whether the staff had contacted the attending physician to discuss the signs and symptoms and the current medication regimen;
- Whether and how the physician responded when informed of suspected adverse medication consequences; and,
- Whether the pharmacist performed a medication regimen review and identified related signs and symptoms, or the staff informed the pharmacist of them if they occurred after the last pharmacist visit.

Interview the physician, as appropriate, to determine:

- Whether staff notified him/her of potential medication-related issues and concerns;
- His/her assessment of the significance of medication-related issues and concerns; and,
- Rationale for his/her management of the resident's medications and/or medication-related issues or concerns.

3. Medication Regimen Review (MRR)

Review for compliance with the MRR requirements at F428. Determine:

- If the pharmacist had identified and reported to the director of nursing and attending physician any irregularities with the medication regimen such as:
 - The emergence or existence of clinically significant adverse consequences;
 - Excess dose or duration, lack of monitoring, lack of indication for use, lack of GDR (as indicated) or behavioral interventions for residents receiving antipsychotics, medication interactions potentially affecting the medication's effectiveness; and,
- Whether the attending physician and the director of nursing acted on any irregularities identified in the report. The responses from the attending physician could include the following:
 - Changed the medication regimen in response to the concern raised in the report (or after additional review of the situation);
 - Provided a clinically pertinent rationale that is relevant to that specific resident's signs and symptoms, prognosis, test results, etc., documenting or indicating why the benefit of the medication(s) or dose(s) outweighed the risks of the adverse consequence;
 - Provided a clinically pertinent rationale for why any gradual dose reduction (for antipsychotic medications) and/or tapering (for other medications) is contraindicated, even for a trial period; or
 - Provided a clinically pertinent rationale for why a particular medication, dose, or duration is appropriate for a resident despite its risks (for example, the resident has had recurrent seizures unless he/she receives anticonvulsant dosing that exceeds the usual recommended serum medication concentration level or therapeutic range, and the attending physician and facility have been monitoring for and addressing adverse consequences).

- If the pharmacist identified a suspected adverse consequence, and the attending physician did not respond, determine if staff followed up with the attending physician.

NOTE: If the staff and pharmacist identify a medication that they believe may be causing a serious adverse consequence or a risk of clinically significant adverse consequences for the resident, and the attending physician did not address the risks or harm to the resident, determine what steps staff took; e.g., contacting the medical director to review the situation and address the issue with the attending physician, as necessary. See guidance at 42 CFR 483.75(i) Medical Director (F501) for additional guidance.

If problems are identified with the MRR, interview the pharmacist, as indicated, to determine:

- How he/she conducts the MRR, including the frequency and extent of the medication review and under what circumstances a review might be conducted more often than monthly;
- How the facility communicates with him/her regarding medication-related issues in specific residents; and
- How he/she approaches the MRR process for short stay residents.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation (F329)

The unnecessary medication requirement has six aspects in order to assure that medication therapy is appropriate for the individual resident. The facility must assure that medication therapy (including antipsychotic agents) is based upon:

- An adequate indication for use;
- Use of the appropriate dose;
- Provision of behavioral interventions and gradual dose reduction for individuals receiving antipsychotics (unless clinically contraindicated) in an effort to reduce or discontinue the medication;
- Use for the appropriate duration;
- Adequate monitoring to determine whether therapeutic goals are being met and to detect the emergence or presence of adverse consequences; and

- Reduction of dose or discontinuation of the medication in the presence of adverse consequences, as indicated.

If not, cite F329.

Noncompliance for F329

After completing the investigation, determine whether *noncompliance* with the regulation exists. Noncompliance for F329 may include:

- **Inadequate Indications for Use** – Examples of noncompliance related to a medication being used without adequate indications include, but are not limited to:
 - Failure to document a clinical reason or demonstrate a clinically pertinent rationale, verbally or in writing, for using medication(s) for a specific resident.
 - Prescribing or administering a medication despite an allergy to that medication, or without clarifying whether a true allergy existed as opposed to other reactions (e.g., idiosyncratic reaction or other side effect).
 - Failure to provide a clear clinical rationale for continuing a medication that may be causing an adverse consequence.
 - Initiation of an antipsychotic medication to manage distressed behavior without considering a possible underlying medical cause (e.g., UTI, congestive heart failure, *delirium*) or environmental or psychosocial stressor.
 - Initiation of a medication presenting clinically significant risks without considering relative risks and benefits or potentially lower risk medications.
 - Concomitant use of two or more medications in the same pharmacological class without a clinically pertinent explanation.
- **Inadequate Monitoring** – Examples of noncompliance related to inadequate monitoring include, but are not limited to:
 - Failure to monitor the responses to or effects of a medication and failure to respond when monitoring indicates a lack of progress toward the therapeutic goal (e.g., relief of pain or normalization of thyroid function) or the emergence of an adverse consequence.
 - *Failure to monitor for changes in psychosocial functioning resulting from adverse consequences of medications, e.g., resident no longer*

participates in activities because medication causes confusion or lethargy.

- Failure to monitor a medication consistent with the current standard of practice or manufacturer's guidelines.
- Failure to carry out the monitoring that was ordered or failure to monitor for potential clinically significant adverse consequences. For example, use of warfarin in conjunction with:
 - Inadequate or absent monitoring of PT/INR during treatment; and/or
 - Failure to recognize and monitor the increased risk of adverse consequences when the resident is receiving other medications that are known to increase the risk of bleeding or to interact with warfarin and increase PT/INR.

Excessive Dose (including duplicate therapy) – Examples of noncompliance related to excessive dose include, but are not limited to:

- Giving a total amount of any medication at one time or over a period of time that exceeds the amount recommended by the manufacturer's recommendations, clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or standards of practice for a resident's age and condition, without a documented clinically pertinent rationale.
 - Failure to consider periodically the continued necessity of the dose or the possibility of tapering a medication.
 - Failure to provide and/or document a clinical rationale for using multiple medications from the same pharmacological class.
- **Excessive Duration** – Examples of noncompliance related to excessive duration include, but are not limited to:
 - Continuation beyond the manufacturer's recommended time frames, the stop date or duration indicated on the medication order, facility-established stop order policies, or clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or current standards of practice, without documented clinical justification.
 - Continuation of a medication after the desired therapeutic goal has been achieved without evaluating whether the medication can offer any additional benefit, for example:

- Use of an antibiotic beyond the recommended clinical guidelines or the facility policy without adequate reassessment of the resident and determination of continuing need.
 - Failure to re-evaluate the rationale for continuing antipsychotic medication initiated in an emergency after the acute phase has stabilized.
- **Adverse Consequences** – Examples of noncompliance related to adverse consequences include, but are not limited to:
 - Failure to act upon (i.e., discontinue a medication or reduce the dose or provide clinical justification for why the benefit outweighs the adverse consequences) a report of the risk for or presence of clinically significant adverse consequence(s);
 - Failure to respond to actual or potentially clinically significant adverse consequences related to the use of warfarin when the PT/INR exceeds the target goal.
- **Antipsychotic Medications without Gradual Dose Reduction and Behavioral Interventions unless Clinically Contraindicated** – Examples of noncompliance related to this requirement include, but are not limited to:
 - Failure to attempt GDR in the absence of identified and documented clinical contraindications.
 - Prolonged or indefinite antipsychotic use without attempting gradual dose reductions.
 - Failure to implement behavioral interventions to enable attempts to reduce or discontinue an antipsychotic medication.
 - *Failure to discontinue an antipsychotic, prescribed for acute delirium, once delirium symptoms have subsided.*

Potential Tags for Additional Investigation

If noncompliance with §483.25(l) has been identified, then concerns with additional requirements may also have been identified. The surveyor is cautioned to investigate these related additional requirements before determining whether noncompliance with the additional requirements may be present. Examples of some of the related requirements that may be considered when noncompliance has been identified include the following:

- 42 CFR 483.10(b)(11), F157, Notification of Changes
 - Review whether the facility contacted the attending physician regarding a significant change in the resident's condition in relation to a potential

adverse consequence of a medication, or if the resident has not responded to medication therapy as anticipated and/or indicated.

- 42 CFR 483.10 (b)(3) and (4), F154, F155, Notice of Rights and Services and (d)(2) Free Choice
 - Determine whether the resident was advised of her/his medical condition and therapy and was informed about her/his treatment including medications and the right to refuse treatments.
- *42 CFR 483.13(a), F222, Restraints*
 - *Determine whether sedative, antipsychotic, or anti-anxiety medications are used for discipline, convenience, to subdue, or sedate rather than to treat medical symptoms. Using medications as chemical restraints may result in symptoms of withdrawal, depression, or reduced social contact.*
- *42 CFR 483.15(f), F248, Activities*
 - *Review whether the facility provides activities that address a resident's needs and may permit discontinuation or reduction of psychopharmacological medications. Review also whether adverse consequences of medications interfere with a resident's ability to participate in activities.*
- 42 CFR 483.20(b), F272, Comprehensive Assessments
 - Review whether the facility's initial and periodic comprehensive assessments include an assessment of the resident's medication regimen.
- 42 CFR 483.20(k)(1) and (2), F279, F280, Comprehensive Care Plans
 - Review whether the resident's comprehensive care plan: (a) was based on the assessment of the resident's conditions, risks, needs, and behavior; (b) was consistent with the resident's therapeutic goals; (c) considered the need to monitor for effectiveness based on those therapeutic goals and for the emergence or presence of adverse consequences; and (d) was revised as needed to address medication-related issues.
- 42 CFR 483.25(a)(1), F310, Decline in ADL
 - Review whether the facility had identified, evaluated, and responded to a new or rapidly progressive decline in function, development or worsening of movement disorders, increased fatigue and activity intolerance that affected the resident's ADL ability in relation to potential medication adverse consequences.

- 42 CFR 483.25(d), F315, Urinary Incontinence
 - Review whether the facility had identified, evaluated, and responded to a change in urinary function or continence status in relation to potential medication adverse consequences.
- 42 CFR 483.25(f)(1)&(2), F319, F320, Mental and Psychosocial Functioning
 - Review whether the facility had identified, evaluated, and responded to a change in behavior and/or psychosocial changes, including depression or other mood disturbance, distress, restlessness, increasing confusion, or delirium in relation to potential medication adverse consequences.
- 42 CFR 483.25(i)(1), F325, Nutritional Parameters
 - Review if the facility had identified, evaluated, and responded to a change in nutritional parameters, anorexia or unplanned weight loss, dysphagia, and/or swallowing disorders in relation to potential medication adverse consequences.
- 42 CFR 483.25(j), F327, Hydration
 - Review if the facility had identified, evaluated, and responded to a change in hydration or fluid or electrolyte balance (for example, high or low sodium or potassium) in relation to potential medication adverse consequences.
- 42 CFR 483.40(a), F385, Physician Supervision
 - Review if the attending physician supervised the resident's medical treatment, including assessing the resident's condition and medications, identifying the clinical rationale, and monitoring for and addressing adverse consequences.
- 42 CFR 483.40(b), F386, Physician Visits
 - Review if the attending physician or designee reviewed the resident's total program of care and wrote, signed, and dated progress notes covering pertinent aspects of the medication regimen and related issues.
- 42 CFR 483.60(c), F428, Medication Regimen Review
 - Review whether the licensed pharmacist has provided consultation regarding the integrity of medication-related records (e.g., MAR, physician order sheets, telephone orders), and potential or actual medication irregularities.

- 42 CFR 483.75(i), F501, Medical Director
 - Review whether the medical director, when requested by the facility, interacted with the attending physician regarding a failure to respond or an inadequate response to identified or reported potential medication irregularities and adverse consequences; and whether the medical director collaborated with the facility to help develop, implement, and evaluate policies and procedures for the safe and effective use of medications in the care of residents.

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 survey team may have identified actual or potential negative physical harm, actual or potential negative psychosocial harm or both resulting from unnecessary medications. Negative psychosocial outcomes related to unnecessary medications may include: suicidal ideation, recurrent debilitating anxiety, extreme aggression or agitation, significant decline in former social patterns, social withdrawal, psychomotor agitation or retardation, inability to think or concentrate, and apathy. See also the Psychosocial Outcome Severity Guide in Appendix P, Section E for additional information on evaluating the severity of psychosocial outcomes.

The key elements for severity determination for F329 are:

- *Presence of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications;*
- *Degree of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications; and,*
- *The immediacy of correction required.*

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 determine whether or not 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. 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. (Follow the guidance in Appendix Q.)

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 International Normalized Ratio (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 respond appropriately to an INR level that is below the target range for treatment of atrial fibrillation, prevention of deep vein thrombosis (DVT) or pulmonary embolus, or other documented indication.*
- 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).
- *Failure to recognize that symptoms of increased confusion and that newly developed inability to do activities of daily living resulting in hospitalization are the result of excessive doses of antipsychotic given without adequate clinical indication.*
- 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.
- *Failure to recognize that continuation of an antipsychotic, originally prescribed for acute delirium, has caused significant changes in the resident's behavior from the resident's baseline—the resident no longer participates in activities, has difficulty concentrating and carrying on conversations and spends most of the day in the room, sleeping in a recliner or in bed. Continuation of the antipsychotic without indication resulted in significant psychosocial harm.*

- *Failure to re-evaluate continuation of an antipsychotic originally prescribed for acute delirium which resulted in significant side effects from the medication-- the resident stayed in bed most of the day, developed a stage III pressure ulcer, and new onset of orthostatic hypotension putting the resident at risk for falls.*

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 *or failure to take appropriate action for an INR that is below the therapeutic level to prevent clot formation resulting in hospitalization for a DVT.*
- 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.
- *Failure to evaluate the medication regimen as a possible cause of resident's decline in functioning evidenced by withdrawal, crying, loss of interest in activities, and social isolation.*
- *Failure to evaluate a resident for a gradual dose reduction for medication originally prescribed to treat delirium. Delirium symptoms had subsided but resident was drowsy and inactive during the day as a result of the medication causing a decline in psychosocial functioning.*

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, *decline in social functioning, or oversedation* 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).
- *The facility failed to initiate a gradual dose reduction for or discontinue an antipsychotic medication originally ordered for delirium symptoms. The delirium symptoms have subsided but the resident continues to receive the antipsychotic medication at the original dose.*

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.

MEDICATION RESOURCES AND TOOLS

The following resources and tools provide information on medications including black box warnings, appropriate dosing, medication categories, drug interactions, and medication safety information. Some of these resources also assist in identifying the correct class of a medication (e.g., identifying whether a medication is an antipsychotic or psychotropic medication).

- *MedlinePlus, <https://www.nlm.nih.gov/medlineplus/druginformation.html>*
- *National Library of Medicine Drug Information Portal, <http://druginfo.nlm.nih.gov/drugportal/drug/categories>.*
- *The Food and Drug Administration (FDA) webpage, Medwatch: The FDA Safety Information and Adverse Event Reporting Program, <http://www.fda.gov/Safety/MedWatch/default.htm>*
- *GlobalRPh Drug Reference, <http://globalrph.com/drug-A.htm>*
- *The TakeRX website's generic drug prefix and suffix list, <http://www.takerx.com/class.html>*
- *The DrugLib.com Index of Drugs by Category, <http://www.druglib.com/drugindex/category/>*
- *The University of Maryland Medical Center Drug Interaction Tool, <http://umm.edu/health/medical/drug-interaction-tool>*

This list is not all-inclusive. CMS is not responsible for the content or accessibility of pages found at these sites. URL addresses were current as of the date of this publication.

ENDNOTES

- ¹ Adapted from American Society of Consultant Pharmacists (ASCP) Guidelines for Assessing the Quality of Drug Regimen Review in Long-Term Care Facilities.
- ² Tobias, DE & Sey, M. (2001). General and psychotherapeutic medication use in 328 nursing facilities: A year 2000 national survey. *The Consultant Pharmacist*, 15, pp. 34-42.
- ³ Briesacher, B.A., Limcangco, M.R., Simoni-Wastila, L., Doshi, J.A., Levens, S.R., Shea, D.G., & Stuart, B. (2005). The quality of antipsychotic drug prescribing in nursing homes. *Archives of Internal Medicine*, 165, pp. 1280-1285.
- ⁴ Ray, W.A., Taylor, J.A., Meador, K.G., Lichtenstein, M.J., Griffin, M.R., Fought, R., Adams, M.L., & Blazer, D.G. (1993). Reducing antipsychotic drug use in nursing homes. A controlled trial of provider education. *Archives of Internal Medicine*, 153(6), pp. 713-21.
- ⁵ *U.S. Department of Health and Human Services, Office of Inspector General. (2014, February). Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries. (Publication No. OEI-06-11-00370). Retrieved from <http://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf>.*
- ⁶ Gurwitz, J.H., Field, T.S., Avorn, J., McCormick, D., Jain, S., Eckler, M., Benser, M., Edmondson, A.C., & Bates, D.W. (2000). Incidence and preventability of adverse drug events in nursing homes. *American Journal of Medicine*, 109, pp. 87-94.
- ⁷ Gurwitz, J.H., Field, T.S., Avorn, J., McCormick, D., Jain, S., Eckler, M., Benser, M., Edmondson, A.C., & Bates, D.W. (2000). Incidence and preventability of adverse drug events in nursing homes. *American Journal of Medicine*, 109, pp. 87-94.
- ⁸ Field T.S., Gurwitz J.H., Avorn J., McCormick, D., Shailavi, J., Eckler, M., Benser, M., & Bates, D.W. (2001). Risk factors for adverse drug events among nursing home residents. *Archives of Internal Medicine*, 161, pp. 1629-34.
- ⁹ Denham, M.J. (1990). Adverse drug reactions. *British Medical Bulletin*, 46, pp. 53-62.
- ¹⁰ Rosen's Emergency Medicine: Concepts and Clinical Practice, 5th ed., (2002). Marx, J.A., Hockberger, R.S., Walls, R.M., Adams, J., Barkin, R.M., Danzl, D.F., Gausche-Hill, M., Hamilton, G.C., Ling, L.J., & Newton, E. (Eds.). St Louis: Mosby, Inc., p. 1469.

¹¹ Fong, T.G., Tulebaev, S.R., & Inouye, S.K. (2009). *Delirium in elderly adults: diagnosis, prevention and treatment. Nature Reviews Neurology, 5, pp. 210-220.*

CMS Manual System

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

Transmittal—Advance Copy

Date:

SUBJECT: Revisions to the State Operations Manual (SOM) - Appendix PP – Guidance to Surveyors for Long Term Care Facilities

I. SUMMARY OF CHANGES: This instruction revises interpretive guidance for the sections listed below to provide additional information to surveyors about consideration of psychosocial harm when assessing compliance with specific regulations.

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: (N/A if manual not updated.)

(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix PP Guidance to Surveyors for Long Term Care Facilities/F221/222 §483.13(a)
R	Appendix PP Guidance to Surveyors for Long Term Care Facilities/F241 §483.15(a)
R	Appendix PP Guidance to Surveyors for Long Term Care Facilities/F242 §483.15(b)
R	Appendix PP Guidance to Surveyors for Long Term Care Facilities/F246 §483.15(e)
R	Appendix PP Guidance to Surveyors for Long Term Care Facilities/F248 §483.15(f)
R	Appendix PP Guidance to Surveyors for Long Term Care Facilities/F250 §483.15(g)
R	Appendix PP Guidance to Surveyors for Long Term Care Facilities/F310 §483.25(a)(1)
R	Appendix PP Guidance to Surveyors for Long Term Care Facilities/F320 §483.25(f)(2)
R	Appendix PP Guidance to Surveyors for Long Term Care Facilities/F353 §483.30

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.**

F221

Use Tag F221 for deficiencies concerning **physical** restraints.

USE GUIDANCE UNDER TAG F222

F222

(Rev.)

Use Tag F222 for deficiencies concerning **chemical** restraints.

§483.13(a) Restraints

The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

Intent §483.13(a)

The intent of this requirement is for each person to attain and maintain his/her highest practicable well-being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints.

Definitions

“Chemical Restraints” is defined as any drug that is used for discipline or convenience and not required to treat medical symptoms.

“Convenience” is defined as any action taken by the facility to control a resident's behavior or manage a resident's behavior with a lesser amount of effort by the facility and not in the resident's best interest.

“Discipline” is defined as any action taken by the facility for the purpose of punishing or penalizing residents.

“Freedom of movement” means any change in place or position for the body or any part of the body that the person is physically able to control.

“Medical Symptom” is defined as an indication or characteristic of a physical or psychological condition.

“Physical Restraints” are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body (e.g. leg

restraints, arm restraints, hand mitts, soft ties or vests, lap cushions, and lap trays the resident cannot remove easily).

“Removes easily” means that the manual method, device, material, or equipment can be removed intentionally by the resident in the same manner as it was applied by the staff (e.g., side rails are put down, not climbed over; buckles are intentionally unbuckled; ties or knots are intentionally untied; etc.) considering the resident’s physical condition and ability to accomplish objective (e.g., transfer to a chair, get to the bathroom in time).

Overview

Restraints may not be used for staff convenience. However, if the resident needs emergency care, restraints may be used for brief periods to permit medical treatment to proceed unless the facility has a notice indicating that the resident has previously made a valid refusal of the treatment in question. If a resident’s unanticipated violent or aggressive behavior places him/her or others in imminent danger, the resident does not have the right to refuse the use of restraints. In this situation, the use of restraints is a measure of last resort to protect the safety of the resident or others and must not extend beyond the immediate episode. The facility may not use restraints in violation of the regulation solely based on a legal surrogate or representative’s request or approval.

Finally, residents who are restrained may face a loss of autonomy, dignity and self-respect, and may show symptoms of withdrawal, depression, or reduced social contact.

Facility practices that meet the definition of a restraint include, but are not limited to:

- Using side rails that keep a resident from voluntarily getting out of bed;
- Tucking in or using *Velcro* to hold a sheet, fabric, or clothing tightly so that a resident’s movement is restricted;
- Using devices in conjunction with a chair, such as trays, tables, bars or belts, that the resident cannot remove easily, that prevent the resident from rising;
- Placing a resident in a chair that prevents a resident from rising; and
- Placing a chair or bed so close to a wall that the wall prevents the resident from rising out of the chair or voluntarily getting out of bed.

NOTE: An enclosed framed wheeled walker, with or without a posterior seat, would not meet the definition of a restraint if the resident could easily open the front gate and exit the device. If the resident cannot open the front gate (due to cognitive or physical limitations that prevent him or her from exiting the device or because the device has been altered to prevent the resident from exiting the device), the enclosed framed wheeled walker would meet the definition of a restraint since the device would restrict the resident’s freedom of movement (e.g. transferring to another

chair, to the commode, or into the bed). The decision on whether framed wheeled walkers are a restraint must be made on an individual basis.

Side Rails

Side rails sometimes restrain residents. The use of side rails as restraints is prohibited unless they are necessary to treat a resident's medical symptoms or assist with physical functioning. Residents who attempt to exit a bed through, between, over or around side rails are at risk of injury or death. The potential for serious injury is more likely from a fall from a bed with raised side rails than from a fall from a bed where side rails are not used. They also potentially increase the likelihood that the resident will spend more time in bed and fall when attempting to transfer from the bed.

As with other restraints, for residents who are restrained by side rails, it is expected that the process facilities employ to reduce the use of side rails as restraints is systematic and gradual to ensure the resident's safety while treating the resident's medical symptom.

The same device may have the effect of restraining one individual but not another, depending on the individual resident's condition and circumstances. For example, partial rails may assist one resident to enter and exit the bed independently while acting as a restraint for another.

Medical Symptom and Restraint Use

Objective findings derived from clinical evaluation and the resident's subjective symptoms should be considered to determine the presence of a medical symptom. The resident's subjective symptoms may not be used as the sole basis for using a restraint. In addition, the resident's medical symptoms should not be viewed in isolation; rather, the symptoms should be viewed in the context of the resident's condition, circumstances, and environment. Before a resident is restrained, the facility must determine the presence of a specific medical symptom that would require the use of restraints, and how their use would treat the medical symptom, protect the resident's safety, and assist the resident in attaining or maintaining his or her highest practicable level of physical and psychosocial well-being. This includes the facility's discussion with the resident, (and/or if indicated) their legal surrogate or representative of potential risks and benefits of all options under consideration including using a restraint, not using a restraint, and alternatives to restraint use.

Medical symptoms that warrant the use of restraints must be documented in the resident's medical record, ongoing assessments, and care plans. Surveyors should be aware that physical restraints as an intervention do not treat the underlying causes of medical symptoms and that they should be used temporarily and not be used without also seeking to identify and address the physical or psychosocial condition causing the medical symptom. While there must be a physician's order reflecting the presence of a medical symptom, CMS will hold the facility ultimately accountable for the appropriateness of that determination. The physician's order alone is not sufficient to warrant the use of the restraint. It is further expected, for those residents whose care plans indicate the need for restraints, that the facility engages in a systematic and gradual process toward reducing restraints (e.g., gradually increasing the time for ambulation and

muscle strengthening activities). This systematic process would also apply to recently admitted residents for whom restraints were used in the previous setting.

NOTE: Falls do not constitute self-injurious behavior or a medical symptom that warrants the use of a physical restraint. Although restraints have been traditionally used as a falls prevention approach, they have major, serious drawbacks and can contribute to serious injuries. There is no evidence that the use of physical restraints, including but not limited to side rails, will prevent or reduce falls. Additionally, falls that occur while a person is physically restrained often result in more severe injuries (e.g., strangulation, entrapment).¹

Orthotic Body Devices

Orthotic body devices may be used solely for therapeutic purposes to improve the overall functional capacity of the resident.

Assessment and Care Planning for Restraint Use

There are instances where, after assessment and care planning, a least restrictive restraint may be deemed appropriate for an individual resident to attain or maintain his or her highest practicable physical and psychosocial well-being. This does not alter the facility's responsibility to assess and care plan restraint use on an ongoing basis.

Before using a device for mobility or transfer, assessment should include a review of the resident's:

- Bed mobility (e.g., would the use of a device assist the resident to turn from side to side? Is the resident totally immobile and unable to change position without assistance?); and,
- Ability to transfer between positions, to and from bed or chair, to stand and toilet (e.g., does the raised side rail add risk to the resident's ability to transfer?).

The facility must design its interventions not only to minimize or eliminate the medical symptom, but also to identify and address any underlying problems causing the medical symptom.

- Interventions that the facility might incorporate in care planning include:
 - Providing restorative care to enhance abilities to stand, transfer, and walk safely;
 - Providing a device such as a trapeze to increase a resident's mobility in bed;
 - Placing the bed lower to the floor and surrounding the bed with a soft mat;
 - Equipping the resident with a device that monitors his/her attempts to arise;

- o Providing frequent monitoring by staff with periodic assisted toileting for residents who attempt to arise to use the bathroom;
- o Furnishing visual and verbal reminders to use the call bell for residents who are able to comprehend this information and are able to use the call bell device; and/or,
- o Providing exercise and therapeutic interventions, based on individual assessment and care planning, that may assist the resident in achieving proper body position, balance and alignment, without the potential negative effects associated with restraint use.

Procedures: §483.13(a)

Determine if the facility follows a systematic process of evaluation and care planning prior to using restraints. Since continued restraint use is associated with a potential for a decline in functioning if the risk is not addressed, determine if the interdisciplinary team addressed the risk of decline at the time restraint use was initiated and that the care plan reflected measures to minimize a decline. Also determine if the plan of care was consistently implemented. Determine whether the decline can be attributed to a disease progression or inappropriate use of restraints.

For sampled residents observed as physically restrained during the survey or whose clinical records show the use of physical restraints within 30 days of the survey, determine whether the facility used the restraint for convenience or discipline, or a therapeutic intervention for specific periods to attain and maintain the resident's highest practicable physical, mental, or psychosocial well-being.

Probes: §483.13(a)

This systematic approach should answer these questions:

1. What are the medical symptoms that led to the consideration of the use of restraints?
2. Are these symptoms caused by failure to:
 - a. Meet individual needs in accordance with the resident assessments?
 - b. Use rehabilitative/restorative care?
 - c. Provide meaningful activities?
 - d. Manipulate the resident's environment, including seating?
3. Can the cause(s) of the medical symptoms be eliminated or reduced?

4. If the cause(s) cannot be eliminated or reduced, then has the facility attempted to use alternatives in order to avoid a decline in physical functioning associated with restraint use?
5. If alternatives have been tried and deemed unsuccessful, does the facility use the least restrictive restraint for the least amount of time? Does the facility monitor and adjust care to reduce the potential for negative outcomes while continually trying to find and use less restrictive alternatives?
6. Did the resident or legal surrogate make an informed choice about the use of restraints? Were risks, benefits, and alternatives explained?
7. Does the facility use the Care Area Assessments (CAAs) to evaluate the appropriateness of restraint use?
8. Has the facility re-evaluated the need for the restraint, made efforts to eliminate its use and maintained residents' strength and mobility?

DEFICIENCY CATEGORIZATION (See SOM Appendix P, Part IV)

Surveyors should be mindful of the elevated risk of psychosocial harm associated with the regulation at tags F221/222 that may lead to noncompliance, and consider this during their investigation.

Once the team has completed their investigation, analyzed the data, reviewed the regulatory requirements, and identified any deficient practice(s) that demonstrate that noncompliance with the regulations at F221/222 exists, the team must determine the scope and severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The survey team must consider the potential for both physical and psychosocial harm when determining the scope and severity of deficiencies related to chemical and physical restraints.

See also the Psychosocial Outcome Severity Guide and Investigative Protocol in Appendix P, Part IV, Section E for additional information on evaluating the severity of psychosocial outcomes.

¹ American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. Guideline for the prevention of falls in older persons. *Journal of the American Geriatrics Society*. 49(5):664-72, 2001 May.

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F241

(Rev.)

§483.15(a) - Dignity

The facility must promote care for residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality.

Interpretive Guidelines: §483.15(a)

“Dignity” means that in their interactions with residents, staff carries out activities that assist the resident to maintain and enhance his/her self-esteem and self-worth. Some examples include (but are not limited to):

- Grooming residents as they wish to be groomed (e.g., hair combed and styled, beards shaved/trimmed, nails clean and clipped);
- Encouraging and assisting residents to dress in their own clothes appropriate to the time of day and individual preferences rather than hospital-type gowns;
- Assisting residents to attend activities of their own choosing;
- Labeling each resident's clothing in a way that respects his or her dignity (e.g., placing labeling on the inside of shoes and clothing);
- Promoting resident independence and dignity in dining such as avoidance of:
 - Day-to-day use of plastic cutlery and paper/plastic dishware;
 - Bibs (also known as clothing protectors) instead of napkins (except by resident choice);
 - Staff standing over residents while assisting them to eat;
 - Staff interacting/conversing only with each other rather than with residents while assisting residents;
- Respecting residents' private space and property (e.g., not changing radio or television station without resident's permission, knocking on doors and requesting permission to enter, closing doors as requested by the resident, not moving or inspecting resident's personal possessions without permission);
- Respecting residents by speaking respectfully, addressing the resident with a name of the resident's choice, avoiding use of labels for residents such as “feeders,” not

- excluding residents from conversations or discussing residents in community settings in which others can overhear private information;
- Focusing on residents as individuals when they talk to them and addressing residents as individuals when providing care and services;
 - Maintaining an environment in which there are no signs posted in residents' rooms or in staff work areas able to be seen by other residents and/or visitors that include confidential clinical or personal information (such as information about incontinence, cognitive status). It is allowable to post signs with this type of information in more private locations such as the inside of a closet or in staff locations that are not viewable by the public. An exception can be made in an individual case if a resident or responsible family member insists on the posting of care information at the bedside (e.g., do not take blood pressure in right arm). This does not prohibit the display of resident names on their doors nor does it prohibit display of resident memorabilia and/or biographical information in or outside their rooms with their consent or the consent of the responsible party if the resident is unable to give consent. (This restriction does not include the CDC isolation precaution transmission-based signage for reasons of public health protection, as long as the sign does not reveal the type of infection);
 - Grooming residents as they wish to be groomed (e.g., removal of facial hair for women, maintaining the resident's personal preferences regarding hair length/style, facial hair for men, and clothing style).

NOTE: For issues of failure to keep dependent residents' faces, hands, fingernails, hair, and clothing clean, refer to Activities of Daily Living (ADLs), Tag F312;

- Maintaining resident privacy of body including keeping residents sufficiently covered, such as with a robe, while being taken to areas outside their room, such as the bathing area (one method of ensuring resident privacy and dignity is to transport residents while they are dressed and assist them to dress and undress in the bathing room).
- NOTE:** For issues of lack of visual privacy for a resident while that resident is receiving ADL care from staff in the bedroom, bathroom, or bathing room, refer to §483.10(e), Privacy and Confidentiality, Tag F164. Use Dignity F241 for issues of visual privacy while residents are being transported through common areas or are uncovered in their rooms and in view of others when not receiving care; and
- Refraining from practices demeaning to residents such as keeping urinary catheter bags uncovered, refusing to comply with a resident's request for toileting assistance during meal times, and restricting residents from use of common areas open to the general public such as lobbies and restrooms, unless they are on transmission-based

isolation precautions or are restricted according to their care planned needs. An exception can be made for certain restrooms that are not equipped with call cords for safety.

Procedures: §483.15(a)

For a sampled resident, use resident and family interviews as well as information from the Resident Assessment Instrument (RAI) to consider the resident's former life style and personal choices made while in the facility to obtain a picture of the resident's individual needs and preferences.

Throughout the survey, observe: Do staff show respect for residents? When staff interact with a resident, do staff pay attention to the resident as an individual? Do staff respond in a timely manner to the resident's requests for assistance? Do they explain to the resident what care they are doing or where they are taking the resident? Do staff groom residents as they wish to be groomed?

In group activities, do staff members focus attention on the group of residents? Or, do staff members appear distracted when they interact with residents? For example, do they continue to talk with each other while doing a "task" for a resident(s) as if the resident were not present?

Are residents restricted from using common areas open to the public such as the lobby or common area restrooms? If so, determine if the particular area is restricted to the resident for the resident's safety. For example, does the restroom lack a call cord for safety? If so, that restroom may be restricted from resident use. Are there signs regarding care information posted in view in residents' rooms? If these are observed, determine if such signs are there by resident or family direction. If so, these signs are allowable. If a particular resident has been restricted from common areas by the care team, confer with staff to determine the reason for the restriction.

Do staff members communicate personal information about residents in a way that protects the confidentiality of the information and the dignity of residents? This includes both verbal and written communications such as signage in resident rooms and lists of residents with certain conditions such as incontinence and pressure ulcers (or verbal staff reports of these confidential matters) at nursing stations in view or in hearing of residents and visitors. This does not include clinical information written in a resident's record.

Determine if staff members respond in a dignified manner to residents with cognitive impairments, such as not contradicting what residents are saying, and addressing what residents are trying to express (the agenda) behind their behavior. For example, a resident with dementia may be attempting to exit the building in the afternoon, but the actual intent is a desire to meet her children at the school bus, as she did when a young mother. Allowing the behavior under supervision such as walking with the resident without challenging or disputing the resident's intent and conversing with the resident about the desire (tell me about your children) may assist the behavior to dissipate, and the staff member can then invite the resident to come along to have a drink or snack or participate in a task or activity. For more information about "agenda" behavior, see Rader, J., Tornquist, E, Individualized Dementia Care: Creative, Compassionate

Approaches, 1995, New York: Springer Publishing Company, or Fazio, S. Seman, D., Stansell, J., Rethinking Alzheimer's Care. Baltimore: Health Professions Press, 1999.

If the survey team identifies potential compliance issues regarding the privacy of residents during treatment, refer to §483.10(e), Privacy and Confidentiality, Tag F164.

DEFICIENCY CATEGORIZATION (See SOM Appendix P, Part IV)

Surveyors should be mindful of the elevated risk of psychosocial harm associated with the regulation at tag F241 that may lead to noncompliance, and consider this during their investigation.

Once the team has completed their investigation, analyzed the data, reviewed the regulatory requirements, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F241 exists, the team must determine the scope and severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The survey team must consider the potential for both physical and psychosocial harm when determining the scope and severity of deficiencies related to dignity.

See also the Psychosocial Outcome Severity Guide and Investigative Protocol in Appendix P, Part IV, Section E for additional information on evaluating the severity of psychosocial outcomes.

F242

(Rev.)

§483.15(b) - Self-Determination and Participation

The resident has the right to--

- (1) Choose activities, schedules, and health care consistent with his or her interests, assessments, and plans of care;**
- (2) Interact with members of the community both inside and outside the facility; and**
- (3) Make choices about aspects of his or her life in the facility that are significant to the resident.**

Intent: §483.15(b)

The intent of this requirement is to specify that the facility must create an environment that is respectful of the right of each resident to exercise his or her autonomy regarding what the resident considers to be important facets of his or her life. This includes actively seeking information from the resident regarding significant interests and preferences in order to provide

necessary assistance to help residents fulfill their choices over aspects of their lives in the facility.

Interpretive Guidelines: §483.15(b)

Many types of choices are mentioned in this regulatory requirement. The first of these is choice over “activities.” It is an important right for a resident to have choices to participate in preferred activities, whether they are part of the formal activities program or self-directed. However, the regulation at §483.15(f) Activities, F248 covers both formal and self-directed activities. For issues concerning choices over activities, use Tag F248.

The second listed choice is “schedules.” Residents have the right to have a choice over their schedules, consistent with their interests, assessments and plans of care. Choice over “schedules” includes (but is not limited to) choices over the schedules that are important to the resident, such as daily waking, eating, bathing, and the time for going to bed at night. Residents have the right to choose health care schedules consistent with their interests and preferences, and the facility should gather this information in order to be proactive in assisting residents to fulfill their choices. For example, if a resident mentions that her therapy is scheduled at the time of her favorite television program, the facility should accommodate the resident to the extent that it can.

If the resident refuses a bath because he or she prefers a shower or a different bathing method such as in-bed bathing, prefers it at a different time of day or on a different day, does not feel well that day, is uneasy about the aide assigned to help or is worried about falling, the staff member should make the necessary adjustments realizing the resident is not refusing to be clean but refusing the bath under the circumstance provided. The facility staff should meet with the resident to make adjustments in the care plan to accommodate his or her preferences.

NOTE: For issues regarding choice over arrangement of furniture and adaptations to the resident’s bedroom and bathroom, see §483.15(e)(1), Accommodation of Needs, Tag F246.

According to this requirement at §483.15(b)(3), residents have the right to make choices about aspects of their lives that are significant to them. One example includes the right to choose to room with a person of the resident’s choice if both parties are residents of the facility, and both consent to the choice.

If a facility changes its policy to prohibit smoking, it must allow current residents who smoke to continue smoking in an area that maintains the quality of life for these residents. Weather permitting, this may be an outside area. Residents admitted after the facility changes its policy must be informed of this policy at admission. (See §483.10(b)(1)).

Procedures: §483.15(b)

During resident and family interviews, determine if the resident is able to exercise her/his choices regarding personal activities, including whether the facility provides assistance as needed to the resident to be able to engage in their preferred activities on a routine basis.

During resident and family interviews, determine what time the resident awakens and goes to sleep, and whether this is the resident's preferred time. Also determine whether the facility is honoring the resident's preferences regarding the timing (morning, afternoon, evening and how many times a week) for bathing and also the method (shower, bath, in-bed bathing). Obtain further information as necessary from observations and staff interviews. If the resident is unaware of the right to make such choices, determine whether the facility has actively sought information from the resident and/or family (for a resident unable to express choices) regarding preferences and whether these choices have been made known to caregivers.

DEFICIENCY CATEGORIZATION (See SOM Appendix P, Part IV)

Surveyors should be mindful of the elevated risk of psychosocial harm associated with the regulation at tag F242 that may lead to noncompliance, and consider this during their investigation.

Once the team has completed their investigation, analyzed the data, reviewed the regulatory requirements, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F242 exists, the team must determine the scope and severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The survey team must consider the potential for both physical and psychosocial harm when determining the scope and severity of deficiencies related to self-determination and participation.

See also the Psychosocial Outcome Severity Guide and Investigative Protocol in Appendix P, Part IV, Section E for additional information on evaluating the severity of psychosocial outcomes.

F246

(Rev.)

§483.15(e) - Accommodation of Needs

A resident has the right to --

§483.15(e)(1) - Reside and receive services in the facility with reasonable accommodation of individual needs and preferences, except when the health or safety of the individual or other residents would be endangered; and

Interpretive Guidelines: §483.15(e)(1)

“Reasonable accommodations of individual needs and preferences,” means the facility's efforts to individualize the resident's physical environment. This includes the physical environment of

the resident's bedroom and bathroom, as well as individualizing as much as feasible the facility's common living areas. The facility's physical environment and staff behaviors should be directed toward assisting the resident in maintaining and/or achieving independent functioning, dignity, and well-being to the extent possible in accordance with the resident's own needs and preferences.

NOTE: For issues regarding the psychosocial environment experienced by the resident, such as being ignored by staff, being made to feel unwelcome or that their care needs are burdensome to staff, refer to §483.15(a), Tag F241, Dignity.

The facility is responsible for evaluating each resident's unique needs and preferences and ensuring that the environment accommodates the resident to the extent reasonable and does not endanger the health or safety of individuals or other residents. This includes making adaptations of the resident's bedroom and bathroom furniture and fixtures, as necessary to ensure that the resident can (if able):

- Open and close drawers and turn faucets on and off;
- See her/himself in a mirror and have toiletry articles easily within reach while using the sink;
- Open and close bedroom and bathroom doors, easily access areas of their room and bath, and operate room lighting;
- Use bathroom facilities as independently as possible with access to assistive devices (such as grab bars within reach) if needed; and
- Perform other desired tasks such as turning a table light on and off, using the call bell; etc.

NOTE: If a resident cannot reach her/his clothing in the closet, if the resident does not have private closet space, or if the resident does not have needed furniture (such as a chair) refer to §483.15(h)(4) and §483.70(d)(2)(iv), Tag F461.

The facility should strive to provide reasonably sufficient electric outlets to accommodate the resident's need to safely use her/his electronic personal items, as long as caution is maintained to not overload circuits. The bedroom should include comfortable seating for the resident and task lighting that is sufficient and appropriate for the resident's chosen activities. The facility should accommodate the resident's preferences for arrangement of furniture to the extent space allows, including facilitating resident choice about where to place their bed in their room (as long as the roommate, if any, concurs). There may be some limitations on furniture arrangement, such as not placing a bed over a heat register, or not placing a bed far from the call cord so as to make it unreachable from the bedside.

The facility should also ensure that furniture and fixtures in common areas frequented by residents are accommodating of physical limitations of residents. Furnishings in common areas

should enhance residents' abilities to maintain their independence, such as being able to arise from living room furniture. The facility should provide seating with appropriate seat height, depth, firmness, and with arms that assist residents to arise to a standing position. One method of accommodating residents of different heights and differing types of needs in common areas is through the use of different sizes and types of furniture.

NOTE: If residents are prohibited from using common area restrooms, the lobby, or dining rooms outside of meal times, refer to §483.15(a), Tag F241, Dignity. For issues of sufficient lighting, refer to §483.15(h)(5), Tag F256, Adequate and Comfortable Lighting.

Staff should strive to reasonably accommodate the resident's needs and preferences as the resident makes use of the physical environment. This includes ensuring that items the resident needs to use are available and accessible to encourage confidence and independence (such as grooming supplies reachable near the bathroom sink), needed adaptive equipment (such as door handle grippers) are maintained in place, and functional furniture is arranged to accommodate the resident's needs and preferences, etc. This does not apply to residents who need extensive staff assistance and are incapable of using these room adaptations.

Staff should interact with the resident in a way that takes into account the physical limitations of the resident, assures communication, and maintains respect; for example, getting down to eye level with a resident who is sitting, speaking so a resident with limited hearing who reads lips can see their mouth when they speak, utilizing a hearing amplification device such as a pocket-talker if the resident has such a device, etc. Residents who use glasses, hearing aids, or similar devices should have them in use (except when the resident refuses), clean, and functional.

Procedures: §483.15(e)(1)

Observe the resident using her/his room and common areas and interview the resident if possible to determine if the environment has been adapted as necessary to accommodate the resident's needs and preferences, as described above. Observe staff/resident interactions to determine if staff members adapt their interactions so that a resident with limited sight or hearing can see and hear them. Are hearing aids and glasses in use, clean, and functional? Determine if staff keep needed items within the resident's reach and provide necessary assistance (set up) to help maintain the resident's independent use of their environment to the maximum extent possible for the resident. Determine if the resident has the call system within reach and is able to use it if desired. (This does not include a resident who is too severely impaired to comprehend or is comatose.) Some residents need adaptations for limited hand dexterity or other physical limitations, such as larger buttons that can be pushed by a fist or bright colors to accommodate visual limitations.

Review the extent to which the facility adapts the physical environment to enable residents to maintain unassisted functioning. These adaptations include, but are not limited to:

- Furniture and adaptive equipment that enable residents to stand independently, transfer without assistance (e.g., arm supports, correct chair height and depth, firm support),

maintain body symmetry, participate in resident-preferred activities, and promote mobility and independence for residents in going to the bathroom (e.g., grab bars, elevated toilet seats).

- Easily useable fixtures, drawer handles, faucets, etc.;
- Personal items kept within reach for independent use in the bathroom; and,
- Bedroom furniture arranged to the residents' preferences as much as possible.

Determine if staff use appropriate measures to facilitate communication with residents who have difficulty communicating. For example, do staff communicate at eye level, and do they remove a resident from noisy surroundings if that resident is having difficulty hearing what is said?

If the facility has outdoor smoking areas, how have they accommodated residents when the weather is inclement?

DEFICIENCY CATEGORIZATION (See SOM Appendix P, Part IV)

Surveyors should be mindful of the elevated risk of psychosocial harm associated with the regulation at tag F246 that may lead to noncompliance, and consider this during their investigation.

Once the team has completed their investigation, analyzed the data, reviewed the regulatory requirements, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F246 exists, the team must determine the scope and severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The survey team must consider the potential for both physical and psychosocial harm when determining the scope and severity of deficiencies related to accommodation of needs.

See also the Psychosocial Outcome Severity Guide and Investigative Protocol in Appendix P, Part IV, Section E for additional information on evaluating the severity of psychosocial outcomes.

F248

(Rev.)

§483.15(f) Activities

§483.15(f)(1) The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

INTENT: §483.15(f)(1) Activities

The intent of this requirement is that:

- The facility identifies each resident's interests and needs; and,
- The facility involves the resident in an ongoing program of activities that is designed to appeal to his or her interests and to enhance the resident's highest practicable level of physical, mental, and psychosocial well-being.

DEFINITIONS

Definitions are provided to clarify key terms used in this guidance.

- “Activities” refer to any endeavor, other than routine ADLs, in which a resident participates that is intended to enhance her/his sense of well-being and to promote or enhance physical, cognitive, and emotional health. These include, but are not limited to, activities that promote self-esteem, pleasure, comfort, education, creativity, success, and independence.

NOTE: ADL-related activities, such as manicures/pedicures, hair styling, and makeovers, may be considered part of the activities program.

- “One-to-One Programming” refers to programming provided to residents who will not, or cannot, effectively plan their own activity pursuits, or residents needing specialized or extended programs to enhance their overall daily routine and activity pursuit needs.
- “Person Appropriate” refers to the idea that each resident has a personal identity and history that involves more than just their medical illnesses or functional impairments. Activities should be relevant to the specific needs, interests, culture, background, etc. of the individual for whom they are developed.
- “Program of Activities” includes a combination of large and small group, one-to-one, and self-directed activities; and a system that supports the development, implementation, and evaluation of the activities provided to the residents in the facility.¹

OVERVIEW

In long term care, an ongoing program of activities refers to the provision of activities in accordance with and based upon an individual resident’s comprehensive assessment. The Institute of Medicine (IOM)’s 1986 report, “Improving the Quality of Care in Nursing Homes,” became the basis for the “Nursing Home Reform” part of OBRA ‘87 and the current OBRA long term care regulations. The IOM Report identified the need for residents in nursing homes to receive care and/or services to maximize their highest practicable quality of life. However, defining “quality of life” has been difficult, as it is subjective for each person. Thus, it is

important for the facility to conduct an individualized assessment of each resident to provide additional opportunities to help enhance a resident's self-esteem and dignity.

Research findings and the observations of positive resident outcomes confirm that activities are an integral component of residents' lives. Residents have indicated that daily life and involvement should be meaningful. Activities are meaningful when they reflect a person's interests and lifestyle, are enjoyable to the person, help the person to feel useful, and provide a sense of belonging.²

Residents' Views on Activities

Activities are relevant and valuable to residents' quality of life. In a large-scale study commissioned by CMS, 160 residents in 40 nursing homes were interviewed about what quality of life meant to them. The study found that residents "overwhelmingly assigned priority to dignity, although they labeled this concern in many ways." The researchers determined that the two main components of dignity, in the words of these residents, were "independence" and "positive self-image." Residents listed, under the categories of independence and positive self-image, the elements of "choice of activities" and "activities that amount to something," such as those that produce or teach something; activities using skills from residents' former work; religious activities; and activities that contribute to the nursing home.

The report stated that, "Residents not only discussed particular activities that gave them a sense of purpose but also indicated that a lack of appropriate activities contributes to having no sense of purpose." "Residents rarely mentioned participating in activities as a way to just 'keep busy' or just to socialize. The relevance of the activities to the residents' lives must be considered."

According to the study, residents wanted a variety of activities, including those that are not childish, require thinking (such as word games), are gender-specific, produce something useful, relate to previous work of residents, allow for socializing with visitors and participating in community events, and are physically active. The study found that the above concepts were relevant to both interviewable and non-interviewable residents. Researchers observed that non-interviewable residents appeared "happier" and "less agitated" in homes with many planned activities for them.

Non-traditional Approaches to Activities

Surveyors need to be aware that some facilities may take a non-traditional approach to activities. In neighborhoods/households, all staff may be trained as nurse aides and are responsible to provide activities, and activities may resemble those of a private home.³ Residents, staff, and families may interact in ways that reflect daily life, instead of in formal activities programs. Residents may be more involved in the ongoing activities in their living area, such as care-planned approaches including chores, preparing foods, meeting with other residents to choose spontaneous activities, and leading an activity. It has been reported that, "some culture changed homes might not have a traditional activities calendar, and instead focus on community life to include activities. Instead of an "activities director," some homes have a Community Life

Coordinator, a Community Developer, or other title for the individual directing the activities program.⁴

For more information on activities in homes changing to a resident-directed culture, the following websites are available as resources: www.pioneernetwork.net; www.culturechangenow.com; www.qualitypartnersri.org (click on nursing homes); and www.edenalt.com.

ASSESSMENT

The information gathered through the assessment process should be used to develop the activities component of the comprehensive care plan. The ongoing program of activities should match the skills, abilities, needs, and preferences of each resident with the demands of the activity and the characteristics of the physical, social and cultural environments.⁵

In order to develop individualized care planning goals and approaches, the facility should obtain sufficient, detailed information (even if the Activities RAP is not triggered) to determine what activities the resident prefers and what adaptations, if any, are needed.⁶

NOTE: RAPs have been replaced by CAAs. The above reference to the use of the RAP is interchangeable with the use of the CAA.

The facility may use, but need not duplicate, information from other sources, such as the RAI, including the CAAs, assessments by other disciplines, observation, and resident and family interviews. Other sources of relevant information include the resident's lifelong interests, spirituality, life roles, goals, strengths, needs and activity pursuit patterns and preferences.⁷ This assessment should be completed by or under the supervision of a qualified professional (see F249 for definition of qualified professional).

NOTE: Some residents may be independently capable of pursuing their own activities without intervention from the facility. This information should be noted in the assessment and identified in the plan of care.

CARE PLANNING

Care planning involves identification of the resident's interests, preferences, and abilities; and any issues, concerns, problems, or needs affecting the resident's involvement/engagement in activities.⁸ In addition to the activities component of the comprehensive care plan, information may also be found in a separate activity plan, on a CNA flow sheet, in a progress note, etc.

Activity goals related to the comprehensive care plan should be based on measurable objectives and focused on desired outcomes (e.g., engagement in an activity that matches the resident's ability, maintaining attention to the activity for a specified period of time, expressing satisfaction with the activity verbally or non-verbally), not merely on attendance at a certain number of activities per week.

NOTE: For residents with no discernable response, service provision is still expected and may include one-to-one activities such as talking to the resident, reading to the resident about prior interests, or applying lotion while stroking the resident's hands or feet.

Activities can occur at any time, are not limited to formal activities being provided only by activities staff, and can include activities provided by other facility staff, volunteers, visitors, residents, and family members. All relevant departments should collaborate to develop and implement an individualized activities program for each resident.

Some medications, such as diuretics, or conditions such as pain, incontinence, etc. may affect the resident's participation in activities. Therefore, additional steps may be needed to facilitate the resident's participation in activities, such as:

- If not contraindicated, timing the administration of medications, to the extent possible, to avoid interfering with the resident's ability to participate or to remain at a scheduled activity; or
- If not contraindicated, modifying the administration time of pain medication to allow the medication to take effect prior to an activity the resident enjoys.

The care plan should also identify the discipline(s) that will carry out the approaches. For example:

- Notifying residents of preferred activities;
- Transporting residents who need assistance to and from activities (including indoor, outdoor, and outings);
- Providing needed functional assistance (such as toileting and eating assistance); and
- Providing needed supplies or adaptations, such as obtaining and returning audio books, setting up adaptive equipment, etc.

Concepts the facility should have considered in the development of the activities component of the resident's comprehensive care plan include the following, as applicable to the resident:

- A continuation of life roles, consistent with resident preferences and functional capacity (e.g., to continue work or hobbies such as cooking, table setting, repairing small appliances)⁹;
- Encouraging and supporting the development of new interests, hobbies, and skills (e.g., training on using the Internet); and,
- Connecting with the community, such as places of worship, veterans' groups, volunteer groups, support groups, wellness groups, athletic or educational connections (via outings or invitations to outside groups to visit the facility).

The facility may need to consider accommodations in schedules, supplies and timing in order to optimize a resident's ability to participate in an activity of choice. Examples of accommodations may include, but are not limited to:

- Altering a therapy or a bath/shower schedule to make it possible for a resident to attend a desired activity that occurs at the same time as the therapy session or bath;
- Assisting residents, as needed, to get to and participate in desired activities (e.g., dressing, toileting, transportation);
- Providing supplies (e.g., books/magazines, music, craft projects, cards, sorting materials) for activities, and assistance when needed, for residents' use (e.g., during weekends, nights, holidays, evenings, or when the activities staff are unavailable); and
- Providing a late breakfast to allow a resident to continue a lifelong pattern of attending religious services before eating.

INTERVENTIONS

The concept of individualized intervention has evolved over the years. Many activity professionals have abandoned generic interventions such as "reality orientation" and large-group activities that include residents with different levels of strengths and needs. In their place, individualized interventions have been developed based upon the assessment of the resident's history, preferences, strengths, and needs. These interventions have changed from the idea of "age-appropriate" activities to promoting "person-appropriate" activities. For example, one person may care for a doll or stroke a stuffed animal, another person may be inclined to reminisce about dolls or stuffed animals they once had, while someone else may enjoy petting a dog but will not be interested in inanimate objects. The surveyor observing these interventions should determine if the facility selected them in response to the resident's history and preferences. Many activities can be adapted in various ways to accommodate the resident's change in functioning due to physical or cognitive limitations.

Some Possible Adaptations that May be Made by the Facility ^{10, 11}

When evaluating the provision of activities, it is important for the surveyor to identify whether the resident has conditions and/or issues for which staff should have provided adaptations. Examples of adaptations for specific conditions include, but are not limited to the following:

- For the resident with visual impairments: higher levels of lighting without glare; magnifying glasses, light-filtering lenses, telescopic glasses; use of "clock method" to describe where items are located; description of sizes, shapes, colors; large print items including playing cards, newsprint, books; audio books;
- For the resident with hearing impairments: small group activities; placement of resident near speaker/activity leader; use of amplifiers or headphones; decreased background

noise; written instructions; use of gestures or sign language to enhance verbal communication; adapted TV (closed captioning, magnified screen, earphones);

- For the resident who has physical limitations, the use of adaptive equipment, proper seating and positioning, placement of supplies and materials¹² (based on clinical assessment and referral as appropriate) to enhance:
 - Visual interaction and to compensate for loss of visual field (hemianopsia);
 - Upper extremity function and range of motion (reach);
 - Hand dexterity (e.g., adapted size of items such as larger handles for cooking and woodworking equipment, built-up paintbrush handles, large needles for crocheting);
 - The ability to manipulate an item based upon the item's weight, such as lighter weight for residents with muscle weakness¹³;
- For the resident who has the use of only one hand: holders for kitchen items, magazines/books, playing cards; items (e.g., art work, bingo card, nail file) taped to the table; c-clamp or suction vise to hold wood for sanding;
- For the resident with cognitive impairment: task segmentation and simplification; programs using retained long-term memory, rather than short-term memory; length of activities based on attention span; settings that recreate past experiences or increase/decrease stimulation; smaller groups without interruption; one-to-one activities;

NOTE: The length, duration, and content of specific one-to-one activities are determined by the specific needs of the individual resident, such as several short interventions (rather than a few longer activities) if someone has extremely low tolerance, or if there are behavioral issues.

Examples of one-to-one activities may include any of the following:

- Sensory stimulation or cognitive therapy (e.g., touch/visual/auditory stimulation, reminiscence, or validation therapy) such as special stimulus rooms or equipment; alerting/upbeat music and using alerting aromas or providing fabrics or other materials of varying textures;
- Social engagement (e.g., directed conversation, initiating a resident to resident conversation, pleasure walk or coffee visit);
- Spiritual support, nurturing (e.g., daily devotion, Bible reading, or prayer with or for resident per religious requests/desires);

- Creative, task-oriented activities (e.g., music or pet activities/therapy, letter writing, word puzzles); or
- Support of self-directed activity (e.g., delivering of library books, craft material to rooms, setting up talking book service).
- For the resident with a language barrier: translation tools; translators; or publications and/or audio/video materials in the resident's language;
- For residents who are terminally ill: life review; quality time with chosen relatives, friends, staff, and/or other residents; spiritual support; touch; massage; music; and/or reading to the resident;⁸

NOTE: Some residents may prefer to spend their time alone and introspectively. Their refusal of activities does not necessarily constitute noncompliance.

- For the resident with pain: spiritual support, relaxation programs, music, massage, aromatherapy, pet therapy/pet visits, and/or touch;
- For the resident who prefers to stay in her/his own room or is unable to leave her/his room: in-room visits by staff/other residents/volunteers with similar interests/hobbies; touch and sensory activities such as massage or aromatherapy; access to art/craft materials, cards, games, reading materials; access to technology of interest (computer, DVD, hand held video games, preferred radio programs/stations, audio books); and/or visits from spiritual counselors;¹⁴
- For the resident with varying sleep patterns, activities are available during awake time. Some facilities use a variety of options when activities staff are not available for a particular resident: nursing staff reads a newspaper with resident; dietary staff makes finger foods available; CNA works puzzle with the resident; maintenance staff take the resident on night rounds; and/or early morning delivery of coffee/juice to residents;
- For the resident who has recently moved-in: welcoming activities and/or orientation activities;
- For the short-stay resident: "a la carte activities" are available, such as books, magazines, cards, word puzzles, newspapers, CDs, movies, and handheld games; interesting/contemporary group activities are offered, such as dominoes, bridge, Pinochle, poker, video games, movies, and travelogues; and/or individual activities designed to match the goals of therapy, such as jigsaw puzzles to enhance fine motor skills;
- For the younger resident: individual and group music offerings that fit the resident's taste and era; magazines, books and movies that fit the resident's taste and era; computer and Internet access; and/or contemporary group activities, such as video games, and the opportunity to play musical instruments, card and board games, and sports; and

- For residents from diverse ethnic or cultural backgrounds: special events that include meals, decorations, celebrations, or music; visits from spiritual leaders and other individuals of the same ethnic background; printed materials (newspapers, magazines) about the resident's culture; and/or opportunities for the resident and family to share information about their culture with other residents, families, and staff.

Activity Approaches for Residents with Behavioral Symptoms^{15, 7}

When the surveyor is evaluating the activities provided to a resident who has behavioral symptoms, they may observe that many behaviors take place at about the same time every day (e.g., before lunch or mid-afternoon). The facility may have identified a resident's pattern of behavior symptoms and may offer activity interventions, whenever possible, prior to the behavior occurring. Once a behavior escalates, activities may be less effective or may even cause further stress to the resident (some behaviors may be appropriate reactions to feelings of discomfort, pain, or embarrassment, such as aggressive behaviors exhibited by some residents with dementia during bathing¹⁶). Examples of activities-related interventions that a facility may provide to try to minimize distressed behavior may include, but are not limited to the following:

For the resident who is constantly walking:

- Providing a space and environmental cues that encourages physical exercise, decreases exit behavior and reduces extraneous stimulation (such as seating areas spaced along a walking path or garden; a setting in which the resident may manipulate objects; or a room with a calming atmosphere, for example, using music, light, and rocking chairs);
- Providing aroma(s)/aromatherapy that is/are pleasing and calming to the resident; and
- Validating the resident's feelings and words; engaging the resident in conversation about who or what they are seeking; and using one-to-one activities, such as reading to the resident or looking at familiar pictures and photo albums.

For the resident who engages in name-calling, hitting, kicking, yelling, biting, sexual behavior, or compulsive behavior:

- Providing a calm, non-rushed environment, with structured, familiar activities such as folding, sorting, and matching; using one-to-one activities or small group activities that comfort the resident, such as their preferred music, walking quietly with the staff, a family member, or a friend; eating a favorite snack; looking at familiar pictures;
- Engaging in exercise and movement activities; and
- Exchanging self-stimulatory activity for a more socially-appropriate activity that uses the hands, if in a public space.

For the resident who disrupts group activities with behaviors such as talking loudly and being demanding, or the resident who has catastrophic reactions such as uncontrolled crying or anger, or the resident who is sensitive to too much stimulation:

- Offering activities in which the resident can succeed, that are broken into simple steps, that involve small groups or are one-to-one activities such as using the computer, that are short and repetitive, and that are stopped if the resident becomes overwhelmed (reducing excessive noise such as from the television);
- Involving in familiar occupation-related activities. (A resident, if they desire, can do paid or volunteer work and the type of work would be included in the resident's plan of care, such as working outside the facility, sorting supplies, delivering resident mail, passing juice and snacks, refer to F169, Work);
- Involving in physical activities such as walking, exercise or dancing, games or projects requiring strategy, planning, and concentration, such as model building, and creative programs such as music, art, dance or physically resistive activities, such as kneading clay, hammering, scrubbing, sanding, using a punching bag, using stretch bands, or lifting weights; and
- Slow exercises (e.g., slow tapping, clapping or drumming); rocking or swinging motions (including a rocking chair).

For the resident who goes through others' belongings:

- Using normalizing activities such as stacking canned food onto shelves, folding laundry; offering sorting activities (e.g., sorting socks, ties or buttons); involving in organizing tasks (e.g., putting activity supplies away); providing rummage areas in plain sight, such as a dresser; and
- Using non-entry cues, such as "Do not disturb" signs or removable sashes, at the doors of other residents' rooms; providing locks to secure other resident's belongings (if requested).

For the resident who has withdrawn from previous activity interests/customary routines and isolates self in room/bed most of the day:

- Providing activities just before or after meal time and where the meal is being served (out of the room);
- Providing in-room volunteer visits, music or videos of choice;
- Encouraging volunteer-type work that begins in the room and needs to be completed outside of the room, or a small group activity in the resident's room, if the resident agrees; working on failure-free activities, such as simple structured crafts or other activity with a friend; having the resident assist another person;

- Inviting to special events with a trusted peer or family/friend;
- Engaging in activities that give the resident a sense of value (e.g., intergenerational activities that emphasize the resident's oral history knowledge);
- Inviting resident to participate on facility committees;
- Inviting the resident outdoors; and
- Involving in gross motor exercises (e.g., aerobics, light weight training) to increase energy and uplift mood.

For the resident who excessively seeks attention from staff and/or peers: Including in social programs, small group activities, service projects, with opportunities for leadership.

For the resident who lacks awareness of personal safety, such as putting foreign objects in her/his mouth or who is self-destructive and tries to harm self by cutting or hitting self, head banging, or causing other injuries to self:

- Observing closely during activities, taking precautions with materials (e.g., avoiding sharp objects and small items that can be put into the mouth);
- Involving in smaller groups or one-to-one activities that use the hands (e.g., folding towels, putting together PVC tubing);
- Focusing attention on activities that are emotionally soothing, such as listening to music or talking about personal strengths and skills, followed by participation in related activities; and
- Focusing attention on physical activities, such as exercise.

For the resident who has delusional and hallucinatory behavior that is stressful to her/him:

- Focusing the resident on activities that decrease stress and increase awareness of actual surroundings, such as familiar activities and physical activities; offering verbal reassurance, especially in terms of keeping the resident safe; and acknowledging that the resident's experience is real to her/him.

The outcome for the resident, the decrease or elimination of the behavior, either validates the activity intervention or suggests the need for a new approach.

ENDNOTES

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INVESTIGATIVE PROTOCOL

ACTIVITIES

Objective

To determine if the facility has provided an ongoing program of activities designed to accommodate the individual resident's interests and help enhance her/his physical, mental and psychosocial well-being, according to her/his comprehensive resident assessment.

Use

Use this procedure for each sampled resident to determine through interview, observation and record review whether the facility is in compliance with the regulation.

Procedures

Briefly review the comprehensive assessment and interdisciplinary care plan to guide observations to be made.

1. Observations

Observe during various shifts in order to determine if staff are consistently implementing those portions of the comprehensive plan of care related to activities. Determine if staff take into account the resident's food preferences and restrictions for activities that involve food, and provide ADL assistance and adaptive equipment as needed during activities programs. For a resident with personal assistive devices such as glasses or hearing aides, determine if these devices are in place, glasses are clean, and assistive devices are functional.

For a resident whose care plan includes group activities, observe if staff inform the resident of the activities program schedule and provide timely transportation, if needed, for the resident to attend in-facility activities and help the resident access transportation to out-of-facility and community activities.

Determine whether the facility provides activities that are compatible with the resident's known interests, needs, abilities and preferences. If the resident is in group activity programs, note if the resident is making attempts to leave, or is expressing displeasure with, or sleeping through, an activity program. If so, determine if staff attempted to identify the reason the resident is attempting to leave, and if they addressed the resident's needs. Determine whether the group activity has been adapted for the resident as needed and whether it is "person appropriate."

NOTE: If you observe an activity that you believe would be age inappropriate for most residents, investigate further to determine the reason the resident and staff selected this activity. The National Alzheimer's Association has changed from endorsing the idea of "age-appropriate" activities to promoting "person-appropriate" activities. In general, surveyors should not expect to see the facility providing dolls or stuffed animals for

most residents, but some residents are attached to these items and should be able to continue having them available if they prefer.

Regarding group activities in common areas, determine if the activities are occurring in rooms that have sufficient space, light, ventilation, equipment and supplies. Sufficient space includes enough space for residents to participate in the activity and space for a resident to enter and leave the room without having to move several other residents. Determine if the room is sufficiently free of extraneous noise, such as environmental noises from mechanical equipment and staff interruptions.

For a resident who is involved in individual activities in her/his room, observe if staff have provided needed assistance, equipment and supplies. Observe if the room has sufficient light and space for the resident to complete the activity.

2. Interviews

Resident/Representative Interview. Interview the resident, family or resident representative as appropriate to identify their involvement in care plan development, defining the approaches and goals that reflect the resident's preferences and choices. Determine:

- What assistance, if any, the facility should be providing to facilitate participation in activities of choice and whether or not the assistance is being provided;
- Whether the resident is participating in chosen activities on a regular basis, and if not, why not;
- Whether the resident is notified of activities opportunities and is offered transportation assistance as needed to the activity location within the facility or access to transportation, where available and feasible, to outside activities;
- Whether the facility tried, to the extent possible, to accommodate the resident's choices regarding her/his schedule, so that service provision (for example, bathing and therapy services) does not routinely conflict with desired activities;
- Whether planned activity programs usually occur as scheduled (instead of being cancelled repeatedly); and,
- Whether the resident desires activities that the facility does not provide.

If the resident has expressed any concerns, determine if the resident has discussed these with staff and, if so, what was the staff's response.

Activity Staff Interview

Interview activities staff as necessary to determine:

- The resident's program of activities and related goals;
- What assistance/adaptations they provide in group activities according to the resident's care plan;
- How regularly the resident participates; if not participating, what is the reason(s);
- How they assure the resident is informed of, and transported to, group activities of choice;
- How special dietary needs and restrictions are handled during activities involving food;
- What assistance they provide if the resident participates in any individual (non-group) activities; and
- How they assure the resident has sufficient supplies, lighting, and space for individual activities.

CNA Interview

Interview CNAs as necessary to determine what assistance, if needed, the CNA provides to help the resident participate in desired group and individual activities, specifically:

- Their role in ensuring the resident is out of bed, dressed, and ready to participate in chosen group activities, and in providing transportation if needed;
- Their role in providing any needed ADL assistance to the resident while she/he is participating in group activities;
- Their role in helping the resident to participate in individual activities (if the resident's plan includes these), for example, setup of equipment/supplies, positioning assistance, providing enough lighting and space; and,
- How activities are provided for the resident at times when activities staff are not available to provide care planned activities.

Social Services Staff Interview

Interview the social services staff member as necessary to determine how they help facilitate resident participation in desired activities; specifically, how the social services staff member:

- Addresses the resident's psychosocial needs that impact on the resident's ability to participate in desired activities;

- Obtains equipment and/or supplies that the resident needs in order to participate in desired activities (for example, obtaining audio books, helping the resident replace inadequate glasses or a hearing aid); and
- Helps the resident access his/her funds in order to participate in desired activities that require money, such as attending concerts, plays, or restaurant dining events.

Nurse Interview

Interview a nurse who supervises CNAs who work with the resident to determine how nursing staff:

- Assist the resident in participating in activities of choice by:
 - Coordinating schedules for ADLs, medications, and therapies, to the extent possible, to maximize the resident's ability to participate;
 - Making nursing staff available to assist with activities in and out of the facility;
- If the resident is refusing to participate in activities, how they try to identify and address the reasons; and
- Coordinate the resident's activities participation when activities staff are not available to provide care planned activities.

3. Record Review

Assessment

Review the RAI, activity documentation/notes, social history, discharge information from a previous setting, and other interdisciplinary documentation that may contain information regarding the resident's activity interests, preferences and needed adaptations.

Compare information obtained by observation of the resident and interviews with staff and the resident/responsible party (as possible), to the information in the resident's record, to help determine if the assessment accurately and comprehensively reflects the resident's status. Determine whether staff have identified:

- Longstanding interests and customary routine, and how the resident's current physical, mental, and psychosocial health status affects her/his choice of activities and her/his ability to participate;
- Specific information about how the resident prefers to participate in activities of interest (for example, if music is an interest, what kinds of music; does the resident play an

instrument; does the resident have access to music to which she/he likes to listen; and can the resident participate independently, such as inserting a CD into a player);

- Any significant changes in activity patterns before or after admission;
- The resident's current needs for special adaptations in order to participate in desired activities (e.g., auditory enhancement or equipment to help compensate for physical difficulties such as use of only one hand);
- The resident's needs, if any, for time-limited participation, such as a short attention span or an illness that permits only limited time out of bed;
- The resident's desired daily routine and availability for activities; and
- The resident's choices for group, one-to-one, and self-directed activities.

Comprehensive Care Planning

Review the comprehensive care plan to determine if that portion of the plan related to activities is based upon the goals, interests, and preferences of the resident and reflects the comprehensive assessment. Determine if the resident's care plan:

- Includes participation of the resident (if able) or the resident's representative;
- Considers a continuation of life roles, consistent with resident preferences and functional capacity;
- Encourages and supports the development of new interests, hobbies, and skills;
- Identifies activities in the community, if appropriate;
- Includes needed adaptations that address resident conditions and issues affecting activities participation; and
- Identifies how the facility will provide activities to help the resident reach the goal(s) and who is responsible for implementation (e.g., activity staff, CNAs, dietary staff).

If care plan concerns are noted, interview staff responsible for care planning regarding the rationale for the current plan of care.

Care Plan Revision

Determine if the staff have evaluated the effectiveness of the care plan related to activities and made revisions, if necessary, based upon the following:

- Changes in the resident's abilities, interests, or health;
- A determination that some aspects of the current care plan were unsuccessful (e.g., goals were not being met);
- The resident refuses, resists, or complains about some chosen activities;
- Changes in time of year have made some activities no longer possible (e.g., gardening outside in winter) and other activities have become available; and
- New activity offerings have been added to the facility's available activity choices.

For the resident who refused some or all activities, determine if the facility worked with the resident (or representative, as appropriate) to identify and address underlying reasons and offer alternatives.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation (F248)

This requirement stipulates that the facility's program of activities should accommodate the interests and well-being of each resident. In order to fulfill this requirement, it is necessary for the facility to gain awareness of each resident's activity preferences as well as any current limitations that require adaptation in order to accommodate these preferences.

Criteria for Compliance

The facility is in compliance with this requirement if they:

- Recognized and assessed for preferences, choices, specific conditions, causes and/or problems, needs and behaviors;
- Defined and implemented activities in accordance with resident needs and goals;
- Monitored and evaluated the resident's response; and
- Revised the approaches as appropriate.

If not, cite at F248.

Noncompliance for Tag F248

After completing the Investigative Protocol, analyze the information gained in order to determine whether noncompliance with the regulation exists. Activities (F248) is an outcome-oriented requirement in that compliance is determined separately for each resident sampled. The survey team's review of the facility's activities program is conducted through a review of the individualization of activities to meet each resident's needs and preferences. For each sampled

resident for whom activities participation was reviewed, the facility is in compliance if they have provided activities that are individualized to that resident's needs and preferences, and they have provided necessary adaptations to facilitate the resident's participation. Noncompliance with F248 may look like, but is not limited to the following:

The facility does not have an activity program and does not offer any activities to the resident;

- A resident with special needs does not receive adaptations needed to participate in individualized activities;
- Planned activities were not conducted or designed to meet the resident's care plan;

Potential Tags for Additional Investigation

During the investigation of the provision of care and services related to activities, the surveyor may have identified concerns with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether noncompliance may be present. Some examples of requirements that should be considered include the following (not all inclusive):

- 42 CFR 483.10(e), F164, Privacy and Confidentiality
 - Determine if the facility has accommodated the resident's need for privacy for visiting with family, friends, and others, as desired by the resident.
- 42 CFR 483.10(j)(1) and (2), F172, Access and Visitation Rights
 - Determine if the facility has accommodated the resident's family and/or other visitors (as approved by the resident) to be present with the resident as much as desired, even round-the-clock.
- 42 CFR 483.15(b), F242, Self-Determination and Participation
 - Determine if the facility has provided the resident with choices about aspects of her/his life in the facility that are significant to the resident.
- 42 CFR 483.15(e)(1), F246, Accommodation of Needs
 - Determine if the facility has provided reasonable accommodation to the resident's physical environment (room, bathroom, furniture, etc.) to accommodate the resident's individual needs in relation to the pursuit of individual activities, if any.
- 42 CFR 483.15(f)(2), F249, Qualifications of the Activities Director

- Determine if a qualified activities director is directing the activities program.
- 42 CFR 483.15(g)(1), F250, Social Services
 - Determine if the facility is providing medically-related social services related to assisting with obtaining supplies/equipment for individual activities (if any), and assisting in meeting the resident's psychosocial needs related to activity choices.
- 43 CFR 483.20(b)(1), F272, Comprehensive Assessment
 - Determine if the facility assessed the resident's activity needs, preferences, and interests specifically enough so that an individualized care plan could be developed.
- 43 CFR 483.20(k)(1), F279, Comprehensive Care Plan
 - Determine if the facility developed specific and individualized activities goals and approaches as part of the comprehensive care plan, unless the resident is independent in providing for her/his activities without facility intervention.
- 43 CFR 483.20(k)(2), F280, Care Plan Revision
 - Determine whether the facility revised the plan of care as needed with input of the resident (or representative, as appropriate).
- 43 CFR 483.30(a), F353, Sufficient Staff
 - Determine if the facility had qualified staff in sufficient numbers to assure the resident was provided activities based upon the comprehensive assessment and care plan.
- 43 CFR 483.70(g), F464, Dining and Activities Rooms
 - Determine if the facility has provided sufficient space to accommodate the activities and the needs of participating residents and that space is well lighted, ventilated, and adequately furnished.
- 43 CFR 483.75(g), F499, Staff Qualifications
 - Determine if the facility has employed sufficient qualified professional staff to assess residents and to develop and implement the activities approaches of their comprehensive care plans.

DEFICIENCY CATEGORIZATION (See SOM Appendix P, Part *IV*)

Surveyors should be mindful of the elevated risk of psychosocial harm associated with the regulation at tag F248 that may lead to noncompliance, and consider this during their investigation.

Once the team has completed their investigation, analyzed the data, reviewed the regulatory requirements, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F248 exists, the team must determine the scope and severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The survey team must consider the potential for both physical and psychosocial harm when determining the scope and severity of deficiencies related to activities.

See also the Psychosocial Outcome Severity Guide and Investigative Protocol in Appendix P, Part IV, Section E for additional information on evaluating the severity of psychosocial outcomes.

F250

(Rev.)

§483.15(g) Social Services

§483.15(g)(1) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

Intent §483.15(g)

To assure that sufficient and appropriate social service are provided to meet the resident's needs.

Interpretive Guidelines §483.15(g)(1)

Regardless of size, all facilities are required to provide for the medically related social services needs of each resident. This requirement specifies that facilities aggressively identify the need for medically-related social services, and pursue the provision of these services. It is not required that a qualified social worker necessarily provide all of these services. Rather, it is the responsibility of the facility to identify the medically-related social service needs of the resident and assure that the needs are met by the appropriate disciplines.

“Medically-related social services” means services provided by the facility’s staff to assist residents in maintaining or improving their ability to manage their everyday physical, mental, and psychosocial needs. These services might include, for example:

- Making arrangements for obtaining needed adaptive equipment, clothing, and personal items;

- Maintaining contact with facility (with resident's permission) to report on changes in health, current goals, discharge planning, and encouragement to participate in care planning;
- Assisting staff to inform residents and those they designate about the resident's health status and health care choices and their ramifications;
- Making referrals and obtaining services from outside entities (e.g., talking books, absentee ballots, community wheelchair transportation);
- Assisting residents with financial and legal matters (e.g., applying for pensions, referrals to lawyers, referrals to funeral homes for preplanning arrangements);
- Discharge planning services (e.g., helping to place a resident on a waiting list for community congregate living, arranging intake for home care services for residents returning home, assisting with transfer arrangements to other facilities);
- Providing or arranging provision of needed counseling services;
- Through the assessment and care planning process, identifying and seeking ways to support residents' individual needs;
- Promoting actions by staff that maintain or enhance each resident's dignity in full recognition of each resident's individuality;
- Assisting residents to determine how they would like to make decisions about their health care, and whether or not they would like anyone else to be involved in those decisions;
- Finding options that most meet the physical and emotional needs of each resident;
- Providing alternatives to drug therapy or restraints by understanding and communicating to staff why residents act as they do, what they are attempting to communicate, and what needs the staff must meet;
- Meeting the needs of residents who are grieving; and
- Finding options which most meet their physical and emotional needs

Factors with a potentially negative effect on physical, mental, and psychosocial well being include an unmet need for:

- Dental /denture care;
- Podiatric care;

- Eye Care;
- Hearing services
- Equipment for mobility or assistive eating devices; and
- Need for home-like environment, control, dignity, privacy

Where needed services are not covered by the Medicaid State plan, nursing facilities are still required to attempt to obtain these services. For example, if a resident requires transportation services that are not covered under a Medicaid state plan, the facility is required to arrange these services. This could be achieved, for example, through obtaining volunteer assistance.

Types of conditions to which the facility should respond with social services by staff or referral include:

- Lack of an effective family/support system;
- Behavioral symptoms;
- If a resident with dementia strikes out at another resident, the facility should evaluate the resident's behavior. For example, a resident may be re-enacting an activity he or she used to perform at the same time everyday. If that resident senses that another is in the way of his re-enactment, the resident may strike out at the resident impeding his or her progress. The facility is responsible for the safety of any potential resident victims while it assesses the circumstances of the residents behavior);
- Presence of a chronic disabling medical or psychological condition (e.g., multiple sclerosis, chronic obstructive pulmonary disease, Alzheimer's disease, schizophrenia);
- Depression
- Chronic or acute pain;
- Difficulty with personal interaction and socialization skills;
- Presence of legal or financial problems
- Abuse of alcohol or other drugs;
- Inability to cope with loss of function;
- Need for emotional support;

- Changes in family relationships, living arrangements, and/or resident’s condition or functioning; and
- A physical or chemical restraint.
- For residents with or who develop mental disorders as defined by the “Diagnostic and Statistical Manual for Mental Disorders (DSM-IV),” see [§483.45, F406](#).

Probes: §483.15(g)(1)

For residents selected for a comprehensive or focused review as appropriate:

- How do facility staff implement social services interventions to assist the resident in meeting treatment goals?
- How do staff responsible for social work monitor the resident’s progress in improving physical, mental and psychosocial functioning? Has goal attainment been evaluated and the care plan changed accordingly?
- How does the care plan link goals to psychosocial functioning/well-being?
- Have the staff responsible for social work established and maintained relationships with the resident’s family or legal representative?
- [NFs] What attempts does the facility make to access services for Medicaid recipients when those services are not covered by a Medicaid State Plan?

Look for evidence that social services interventions successfully address residents’ needs and link social supports, physical care, and physical environment with residents’ needs and individuality.

For sampled residents, review the appropriate sections of the current MDS.

DEFICIENCY CATEGORIZATION (See SOM Appendix P, Part IV)

Surveyors should be mindful of the elevated risk of psychosocial harm associated with the regulation at tag F250 that may lead to noncompliance, and consider this during their investigation.

Once the team has completed their investigation, analyzed the data, reviewed the regulatory requirements, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F250 exists, the team must determine the scope and severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The survey team must consider the potential for both physical and psychosocial harm when determining the scope and severity of deficiencies related to social services.

See also the Psychosocial Outcome Severity Guide and Investigative Protocol in Appendix P, Part IV, Section E for additional information on evaluating the severity of psychosocial outcomes.

F310

(Rev. 70, Issued: 01-07-11, Effective: 10-01-10 Implementation: 10-01-10)

§483.25(a)(1) A resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that diminution was unavoidable. This includes the resident's ability to --

- (i) Bathe, dress, and groom;**
- (ii) Transfer and ambulate;**
- (i) Toilet;**
- (iv) Eat; and**
- (v) Use speech, language, or other functional communication systems.**

Interpretive Guidelines §483.25(a)

The mere presence of a clinical diagnosis, in itself, justify a decline in a resident's ability to perform ADLs. Conditions which may demonstrate unavoidable diminution in ADLs include:

- The natural progression of the resident's disease;
- Deterioration of the resident's physical condition associated with the onset of a physical or mental disability while receiving care to restore or maintain functional abilities; and
- The resident's or his/her surrogate's or representative's refusal of care and treatment to restore or maintain functional abilities after aggressive efforts by the facility to counsel and/or offer alternatives to the resident, surrogate, or representative. Refusal of such care and treatment should be documented in the clinical record. Determine which interventions were identified on the care plan and/or could be in place to minimize or decrease complications. Note also that depression is a potential cause of excess disability and, where appropriate, therapeutic interventions should be initiated.

Appropriate treatment and services includes all care provided to residents by employees, contractors, or volunteers of the facility to maximize the individual's functional abilities. This includes pain relief and control, especially when it is causing a decline or a decrease in the quality of life of the resident.

If the survey team identifies a pattern of deterioration in ADLs, i.e., a number of residents have deteriorated in more than one ADL or a number of residents have deteriorated in only one ADL

(one in bathing, one in eating, one in toileting) and it is determined there is deficient practice, cite at F310.

For evaluating a resident's ADLs and determining whether a resident's abilities have declined, improved or stayed the same within the last twelve months, use the following definitions as specified in the State's RAI:

Independent – Resident completed activity with no help or oversight every time during the 7-day look-back period.

Supervision – Oversight, encouragement or cueing provided 3 or more times during the last 7 days.

Limited Assistance - Resident highly involved in activity and received physical help in guided maneuvering of limb(s) or other non-weight bearing assistance 3 or more times during the last 7-days.

Extensive Assistance - While resident performed part of activity over the last 7 days, help of following type(s) was provided 3 or more times;

- a. Weight-bearing support provided 3 or more times; or
- b. Full staff performance of activity during part (but not all) of last 7 days.

Total Dependence - Full staff performance of an activity with no participation by resident for any aspect of the ADL activity. Resident was unwilling or unable to perform any part of the activity over entire 7-day look-back period.

§483.25(a)(1)(i) Bathing, Dressing, Grooming

Interpretive Guidelines §483.25(a)(1)(i)

“Bathing” means how resident takes full-body bath, sponge bath, and transfers in/out of tub/shower. Exclude washing of back and hair.

“Dressing” means how resident puts on, fastens, and takes off all items of clothing, including donning/removing prosthesis.

“Grooming” means how resident maintains personal hygiene, including preparatory activities, combing hair, brushing teeth, shaving, applying make-up, washing/drying face, hands and perineum. Exclude baths and showers.

BATHING, DRESSING, GROOMING

Procedures: §483.25(a)(1)(i)

For each sampled resident selected for the comprehensive review or the focused review, as appropriate, determine:

1. Whether the resident's ability to bathe, dress and/or groom has changed since admission, or over the past 12 months;
2. Whether the resident's ability to bathe, dress and groom has improved, declined or stayed the same;
3. Whether any deterioration or lack of improvement was avoidable or unavoidable by:
4. Identifying if resident triggers CAAs for ADL functional/rehabilitation potential.
 - a. What risk factors for decline of bathing, dressing, and/or grooming abilities did the facility identify?
 - b. What care did the resident receive to address unique needs to maintain his/her bathing, dressing, and/or grooming abilities (e.g., resident needs a button hook to button his shirt; staff teaches the resident how to use it; staff provides resident with dementia with cues that allow him/her to dress him or herself)?
 - c. Were individual objectives of the plan of care periodically evaluated, and if the objectives were not met, were alternative approaches developed to encourage maintenance of bathing, dressing, and/or grooming abilities (e.g., resident now unable to button dress, even with encouragement; will ask family if we may use velcro in place of buttons so resident can continue to dress herself)?

Probes: §483.25(a)(1)(i)

If the resident's abilities in bathing, dressing, and grooming have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided:

- Identify relevant sections of the MDS and consider whether assessment triggers the CAAs and the CAA process was followed.
- Are there physical and psychosocial deficits that could affect improvement in functional abilities?
- Was the care plan driven by resident strengths identified in the comprehensive assessment?
- Was the care plan consistently implemented?
- What changes were made in treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress might have been possible?

TRANSFER AND AMBULATION

§483.25(a)(1)(ii)

Interpretive Guidelines: §483.25(a)(1)(ii)

“Transfer” means how resident moves between surfaces - to/from: bed, chair, wheelchair, standing position. (Exclude to/from bath/toilet.)

“Ambulation” means how resident moves between locations in his/her room and adjacent corridor on same floor. If in wheelchair, self-sufficiency once in chair.

Procedures: §483.25(a)(1)(ii)

Determine for each resident selected for a comprehensive review, or a focused review as appropriate, whether the resident’s ability to transfer and ambulate has declined, improved or stayed the same and whether any deterioration or decline in function was avoidable or unavoidable.

Probes: §483.25(a)(1)(ii)

If the resident’s transferring and ambulating abilities have declined, what evidence is there that the decline was unavoidable:

- What risk factors for decline of transferring or ambulating abilities did the facility identify (e.g., necrotic area of foot ulcer becoming larger, postural hypotension)?
- What care did the resident receive to address risk factors and unique needs to maintain transferring or ambulating abilities (e.g., a transfer board is provided to maintain ability to transfer from bed to wheelchair and staff teaches the resident how to use it)?
- What evidence is there that sufficient staff time and assistance are provided to maintain transferring and ambulating abilities?
- Has resident been involved in activities that enhance mobility skills?
- Were individual objectives of the plan of care periodically evaluated, and if goals were not met, were alternative approaches developed to encourage maintenance of transferring and ambulation abilities (e.g., resident remains unsteady when using a cane, returns to walker, with staff encouraging the walker’s consistent use)?
- Identify if resident triggers CAAs for ADL functional/rehabilitation potential, psychosocial well-being, or mood state and the CAA process is followed.

If the resident's abilities in transferring and ambulating have been maintained, is there evidence that the resident could have improved if appropriate treatment and services were provided?

- Are there physical and psychosocial deficits that could affect improvement in functional abilities?
- Was the care plan driven by resident strengths identified in the comprehensive assessment?
- Was the care plan consistently implemented? What changes were made in treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible?

TOILETING

§483.25(a)(1)(ii)

Interpretive Guidelines: §483.25(a)(1)(iii)

“Toilet use” means how the resident uses the toilet room (or commode, bedpan, urinal); transfers on/off the toilet, cleanses self, changes pad, manages ostomy or catheter, adjusts clothes.

Procedures: §483.25(a)(1)(iii)

Determine for each resident selected for a comprehensive review, or focused review as appropriate, whether the resident's ability to use the toilet has improved, declined or stayed the same and whether any deterioration or decline in improvement was avoidable or unavoidable.

Probes: §483.25(a)(1)(iii)

If the resident's toilet use abilities have declined, what evidence is there that the decline was unavoidable.

- What risk factors for the decline of toilet use abilities did the facility identify (e.g., severe arthritis in hands makes use of toilet paper difficult)?
- What care did resident receive to address risk factors and unique needs to maintain toilet use abilities (e.g., assistive devices to maintain ability to use the toilet such as using a removable elevated toilet seat or wall grab bar to facilitate rising from seated position to standing position)?
- Is there sufficient staff time and assistance provided to maintain toilet use abilities (e.g., allowing residents enough time to use the toilet independently or with limited assistance)?

- Were individual objectives of the plan of care periodically evaluated, and if objectives were not met, were alternative approaches developed to encourage maintaining toilet use abilities (e.g., if resident has not increased sitting stability, seek occupational therapy consult to determine the need for therapy to increase sitting balance, ability to transfer safely and manipulate clothing during the toileting process. For residents with dementia, remind periodically to use the toilet)?
- Identify if resident triggers CAAs for urinary incontinence, and ADL functional/rehabilitation potential and the CAA process was used to assess causal factors for decline or potential for decline or lack of improvement.

If the resident's toilet use abilities have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided?

- Are there physical and psychosocial deficits that could affect improvement in functional abilities?
- Was the care plan driven by resident strengths identified in the comprehensive assessment?
- Was the care plan consistently implemented? What changes were made to treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible?
- Identify if resident triggers CAAs for mood state and psychosocial well-being.

EATING

§483.25(a)(1)(iv)

Interpretive Guidelines: §483.25(a)(1)(iv)

“Eating” means how resident ingests and drinks (regardless of self-feeding skill).

Procedures: §483.25(a)(1)(iv)

Determine for each resident selected for a comprehensive review, or focused review, as appropriate, whether the resident's ability to eat or eating skills has improved, declined, or stayed the same and whether any deterioration or lack of improvement was avoidable or unavoidable.

If the resident's eating abilities have declined, is there any evidence that the decline was unavoidable?

1. What risk factors for decline of eating skills did the facility identify?
 - a. A decrease in the ability to chew and swallow food

- b. Deficit in neurological and muscular status necessary for moving food onto a utensil and into the mouth
 - c. Oral health status affecting eating ability
 - d. Depression or confused mental state
2. What care did the resident receive to address risk factors and unique needs to maintain eating abilities?
 - a. Assistive devices to improve resident's grasp or coordination;
 - b. Seating arrangements to improve sociability;
 - c. Seating in a calm, quiet setting for residents with dementia.
3. Is there sufficient staff time and assistance provided to maintain eating abilities (e.g., allowing residents enough time to eat independently or with limited assistance)?
4. Identify if resident triggers CAAs for ADL functional/rehabilitation potential, feeding tubes, and dehydration/fluid maintenance, and the CAA process was used to assess causal reasons for decline, potential for decline or lack of improvement.
5. Were individual objectives of the plan of care periodically evaluated, and if the objectives were not met, were alternative approaches developed to encourage maintaining eating abilities?

Probes: §483.25(a)(1)(iv)

If the resident's eating abilities have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided:

- Are there physical and psychosocial deficits that could affect improvement in functional abilities?
- Was the care plan driven by resident strengths identified in the comprehensive assessment?
- Was the care plan consistently implemented? What changes are made to treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible?

Interpretive Guidelines: §483.25(a)(1)(v)

“Speech, language or other functional communication systems” is defined as the ability to effectively communicate requests, needs, opinions, and urgent problems; to express emotion, to listen to others and to participate in social conversation whether in speech, writing, gesture or a combination of these (e.g., a communication board or electronic augmentative communication device).

USE OF SPEECH, LANGUAGE, OR OTHER FUNCTIONAL COMMUNICATION SYSTEMS

§483.25(a)(1)(v)

Procedures: §483.25(a)(1)(v)

Determine for each resident selected for a comprehensive review, or focused review, as appropriate, if resident’s ability to communicate has declined, improved or stayed the same and whether any deterioration or lack of improvement was avoidable or unavoidable.

Identify if resident triggers CAAs for communication, psychosocial well-being, mood state, and visual function, and if the CAA process was used to assess causal factors for decline, potential for decline or lack of improvement.

Probes: §483.25(a)(1)(v)

If the resident’s communication abilities have diminished, is there any evidence that the decline was unavoidable:

- What risk factors for decline of communication abilities did the facility identify and how did they address them (e.g., dysarthria, poor fitting dentures, few visitors, poor relationships with staff, Alzheimer’s disease)?
- Has the resident received audiologic and vision evaluation? If not, did the resident refuse such services? (See also §483.10(b)(4).)
- What unique resident needs and risk factors did the facility identify (e.g., does the resident have specific difficulties in transmitting messages, comprehending messages, and/or using a variety of communication skills such as questions and commands; does the resident receive evaluation and training in the use of assistive devices to increase and/or maintain writing skills)?
- What care does the resident receive to improve communication abilities (e.g., nurse aides communicate in writing with deaf residents or residents with severe hearing problems; practice exercises with residents receiving speech-language pathology services; increase number of resident’s communication opportunities; non-verbal means of communication; review of the effect of medications on communication ability)?

- Is there sufficient staff time and assistance provided to maintain communication abilities?
- Were individual objectives of the plan of care periodically evaluated, and if the objectives were not met, were alternative approaches developed to encourage maintenance of communication abilities (e.g., if drill-oriented therapy is frustrating the resident, a less didactic approach should be attempted)?

Probes: §483.25(a)(1)(v)

If the resident's speech, language, and other communication abilities have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided:

- Are there physical and psychosocial deficits that could affect improvement in functional abilities?
- Was the care plan driven by resident strengths identified in the comprehensive assessment?
- Was the care plan consistently implemented?
- What changes were made to treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible?

DEFICIENCY CATEGORIZATION (See *SOM Appendix P*, Part IV)

Surveyors should be mindful of the elevated risk of psychosocial harm associated with the regulation at tag F310 that may lead to noncompliance, and consider this during their investigation.

Once the team has completed their investigation, analyzed the data, reviewed the regulatory requirements, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F310 exists, the team must determine the scope and severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The survey team must consider the potential for both physical and psychosocial harm when determining the scope and severity of deficiencies related to activities of daily living. See also the Psychosocial Outcome Severity Guide and Investigative Protocol in Appendix P, Part IV, Section E for additional information on evaluating the severity of psychosocial outcomes.

F320

(Rev.)

§483.25(f)(2)

(2) A resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern is unavoidable.

Procedures §483.25(f)(2)

For sampled residents whose assessment did not reveal a mental or psychosocial adjustment difficulty, but who display decreased social interaction or increased withdrawn, angry, or depressed behaviors, determine, as appropriate, was this behavior unavoidable.

Probes: §483.25(f)(2)

- Did the facility attempt to evaluate whether this behavior was attributable to organic causes or other risk factors not associated with adjusting to living in the nursing facility?
- What care did the resident receive to maintain his/her mental or psychosocial functioning?
- Were individual objectives of the plan of care periodically evaluated, and if progress was not made in reducing, maintaining, or increasing behaviors that assist the resident to have his/her needs met, were alternative treatment approaches developed to maintain mental or psychosocial functioning?
- Identify if resident triggers CAAs for behavior problem, cognitive loss/dementia, and psychosocial well-being. Consider whether the CAA process was used to assess causal factors for decline, potential for decline or lack of improvement.
- Did the facility use the CAA process for behavior problems, cognitive loss/dementia, and psychosocial well-being to assess why the behaviors or change in mental or psychosocial functioning was occurring?

DEFICIENCY CATEGORIZATION (See SOM Appendix P, Part IV)

Surveyors should be mindful of the elevated risk of psychosocial harm associated with the regulation at tag F320 that may lead to noncompliance, and consider this during their investigation.

Once the team has completed their investigation, analyzed the data, reviewed the regulatory requirements, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F320 exists, the team must determine the scope and severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The survey team must consider the potential for both physical and psychosocial harm when determining the scope and severity of deficiencies related to mental and psychosocial adjustment.

See also the Psychosocial Outcome Severity Guide and Investigative Protocol in Appendix P, Part IV, Section E for additional information on evaluating the severity of psychosocial outcomes.

F353

§483.30 Nursing Services

The facility must have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care.

Intent §483.30

To assure that sufficient qualified nursing staff are available on a daily basis to meet residents' needs for nursing care in a manner and in an environment which promotes each resident's physical, mental and psychosocial well-being, thus enhancing their quality of life.

Procedures §483.30

§483.30(a) and (b) are to be reviewed during the standard survey whenever quality of care problems have been discovered (see Appendix P, Survey Protocol, Task 4, for further information and Task 5C for the investigative protocol to complete this review). In addition, fully review requirements of nursing services during an extended survey or when a waiver of RN and/or licensed nurse (RN/LPN) staffing has been requested or granted. Except as licensed nursing personnel are specifically required by the regulation (e.g., an RN for 8 consecutive hours a day, 7 days a week), the determination of sufficient staff will be made based on the staff's ability to provide needed care to residents that enable them to reach their highest practicable physical, mental and psychosocial well-being. The ability to meet the requirements of §§483.13, 483.15(a), 483.20, 483.25 and 483.65 determines sufficiency of nurse staffing.

§483.30(a) Sufficient Staff

§483.30(a)(1) The facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans:

- (i) Except when waived under paragraph (c) of this section, licensed nurses; and**
- (ii) other nursing personnel.**

§483.30(a)(2) Except when waived under paragraph (c) of this section, the facility must designate a licensed nurse to serve as a charge nurse on each tour of duty.

For Interpretive Guidelines and Probes on §483.30(a) see Tag F354

DEFICIENCY CATEGORIZATION (See SOM Appendix P, Part IV)

Surveyors should be mindful of the elevated risk of psychosocial harm associated with the regulation at tag F353 that may lead to noncompliance, and consider this during their investigation.

Once the team has completed their investigation, analyzed the data, reviewed the regulatory requirements, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F353 exists, the team must determine the scope and severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The survey team must consider the potential for both physical and psychosocial harm when determining the scope and severity of deficiencies related to sufficient staffing. See also the Psychosocial Outcome Severity Guide and Investigative Protocol in Appendix P, Part IV, Section E for additional information on evaluating the severity of psychosocial outcomes.

CMS Manual System

Department of Health &
Human Services (DHHS)

Pub. 100-07 State Operations Provider Certification

Centers for Medicare &
Medicaid Services (CMS)

Transmittal – Advance Copy

Date:

SUBJECT: Revisions to the State Operations Manual (SOM) - Appendix P – Survey Protocol for Long Term Care Facilities

I. SUMMARY OF CHANGES: This instruction revises the instructions to surveyors in Section IV.E of Appendix P, Psychosocial Outcome Severity Guide, to provide additional information to surveyors about assessing for psychosocial harm.

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: (N/A if manual not updated.)

(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix P Survey Protocol for Long Term Care Facilities, Section IV.E, Psychosocial Outcome Severity Guide

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.

E. Psychosocial Outcome Severity Guide

Purpose

The purpose of the Psychosocial Outcome Severity Guide is to help surveyors determine the severity of psychosocial outcomes resulting from the identified noncompliance at a specific F tag. The Guide is used to determine the severity of a deficiency in any regulatory grouping (e.g., Quality of Care, Quality of Life) that resulted in a negative psychosocial outcome.

This Guide is not intended to replace the current scope and severity grid, but rather it is intended to be used in conjunction with the scope and severity grid to determine the severity of outcomes to each resident involved in a deficiency that has resulted in a psychosocial outcome. The team should select the level of severity for the deficiency based on the highest level of physical or psychosocial outcome. For example, a resident who was slapped by a staff member may experience only a minor physical outcome from the slap but suffer a greater psychosocial outcome. In this case the severity level based on the psychosocial outcome would be used as the level of severity for the deficiency.

Overview

Psychosocial outcomes (i.e., mood and behavior) may result from a facility's noncompliance with any regulatory requirement. Although a resident may experience either a negative physical outcome or a negative psychosocial outcome, some may experience or have the potential to experience both types of negative outcomes.

Psychosocial outcomes and physical outcomes are equally important in determining the severity of noncompliance, and both need to be considered before assigning a severity level. The severity level assigned should reflect the most significant negative outcome or highest level of harm/potential harm.

The presence of a given affect (i.e., behavioral manifestation of mood demonstrated by the resident) does not necessarily indicate a psychosocial outcome that is the direct result of noncompliance. A resident's reactions and responses (or lack thereof) also may be affected by pre-existing psychosocial issues, illnesses, medication side effects, and/or other factors. Because many nursing home residents have sadness, anger, loss of self-esteem, etc. in reaction to normal life experiences, the survey team must have determined that the psychosocial outcome is a result of the noncompliance *and not a pre-existing condition for the resident*.

Psychosocial outcomes of interest to surveyors are those caused by the facility's noncompliance with any regulation. This also includes psychosocial outcomes resulting from facility failure to assess and develop an adequate care plan to address a resident's pre-existing psychosocial issues, *leading* to continuation or worsening of the condition.

Instructions

This Guide is designed to be used separately for each resident included in the deficiency. Each resident's psychosocial response to the noncompliance is the basis for determining psychosocial

severity of a deficiency. To determine severity, use the information gathered through the investigative process. Compare the resident's behavior (e.g., their routine, activity, and responses to staff or to everyday situations) and mood before and after the noncompliance.

If the survey team determines that a facility's noncompliance has resulted in a negative psychosocial outcome to one or more residents, the team should use this Guide to evaluate the severity of the outcome for each resident identified in the deficiency (in accordance with the instructions at Task 6). The team should determine severity based on the resident's response in the following circumstances:

- If the resident can communicate a psychosocial reaction to the deficient practice, compare this response to the Guide; or
- If the resident is unable to express her/himself verbally but shows a noticeable non-verbal response that is related to the deficient practice, compare the non-verbal response to the Guide.

Application of the Reasonable Person Concept

There are circumstances in which the survey team may apply the "reasonable person concept" to determine severity of the deficiency. To apply the reasonable person concept, the survey team should determine the severity of the psychosocial outcome or potential outcome the deficiency may have had on a reasonable person in the resident's position (i.e., what degree of actual or potential harm would one expect a reasonable person in a similar situation to suffer as a result of the noncompliance).

NOTE: The reasonable person concept described in this Guide is merely a tool to assist the survey team's assessment of the severity level of negative psychosocial outcomes. Although the reasonable person concept is used in many areas of the law, the application of common law defenses to the assessment of severity pursuant to this Guide would be inappropriate and is expressly precluded.

The survey team should use the reasonable person concept when the resident's psychosocial outcome may not be readily determined through the investigative process:

- When there is no discernable response or when circumstances obstruct the direct evaluation of the resident's psychosocial outcome. Such circumstances may include, but are not limited to, the resident's death, subsequent injury, cognitive impairments, physical impairments, or insufficient documentation by the facility. In this situation, the survey team may use the reasonable person concept to evaluate the severity (Level 2, Level 3, or Level 4) of the deficient practice; or
- When the resident's reaction to a deficient practice is markedly incongruent with the level of reaction the reasonable person would have to the deficient practice. In this situation, the survey team may use the reasonable person concept to evaluate the potential severity (Level 2 or Level 4) of the deficient practice.

Clarification of Terms

“Anger” refers to an emotion caused by the frustrated attempts to attain a goal, or in response to hostile or disturbing actions such as insults, injuries, or threats that do not come from a feared source.¹

“Apathy” refers to a marked indifference to the environment; lack of a response to a situation; lack of interest in or concern for things that others find moving or exciting; absence or suppression of passion, emotion, or excitement.²

“Anxiety” refers to the apprehensive anticipation of future danger or misfortune accompanied by a feeling of distress, sadness, or somatic symptoms of tension. Somatic symptoms of tension may include, but are not limited to, restlessness, irritability, hyper-vigilance, an exaggerated startle response, increased muscle tone, and teeth grinding. The focus of anticipated danger may be internal or external.³

“Dehumanization” refers to the deprivation of human qualities or attributes such as individuality, compassion, or civility.⁴ Dehumanization is the outcome resulting from having been treated as an inanimate object or as having no emotions, feelings, or sensations.

“Depressed mood” (which does not necessarily constitute clinical depression) is indicated by negative statements; self-deprecation; sad facial expressions; crying and tearfulness; withdrawal from activities of interest; and/or reduced social interactions.⁵ Some residents such as those with moderate or severe cognitive impairment may be more likely to demonstrate nonverbal symptoms of depression.

“Humiliation” refers to a feeling of shame due to being embarrassed, disgraced, or depreciated. Some individuals lose so much self-esteem through humiliation that they become depressed.⁶

PSYCHOSOCIAL OUTCOME SEVERITY GUIDE

The following are levels of negative psychosocial outcomes that developed, continued, or worsened as a result of the facility's noncompliance. This Guide is only to be used once the survey team has determined noncompliance at a regulatory requirement. The survey team must have established a connection between the noncompliance and a negative psychosocial outcome to the resident as evidenced by observations, record review, and/or interviews with residents, their representatives, and/or staff.

Areas where the survey team may more likely see psychosocial outcomes when citing a particular deficiency include, but are not limited to, F221/F222, Physical and Chemical Restraints; F223 Abuse; F224 Mistreatment, Neglect, Misappropriation; F225 Investigate and Report Allegations of Abuse; F226 Abuse and Neglect Policies; F241, Dignity; F246, Accommodation of Needs; F248, Activities; F279, Comprehensive Care Plans; F280, Right to Participate in Care Planning; F309, Quality of Care (pain, dementia care); F319, Treatment/Services for Mental/Psychosocial Functioning; F320, No Behavior Difficulties Unless Unavoidable; and F329, Drug Regimen is Free From Unnecessary Drugs. While the survey team may find negative psychosocial outcomes related to any of the regulations, these areas may be more susceptible to a negative psychosocial outcome or contain a psychosocial element that may be greater in severity than the physical outcome.

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/resulted in, or is likely to allow/cause /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 of negative psychosocial outcomes as a result of the facility's noncompliance may include but are not limited to:

- Suicidal ideation/thoughts and preoccupation (with a plan) or suicidal attempt (active or passive) such as trying to jump from a high place, throwing oneself down a flight of stairs, refusing to eat or drink in order to kill oneself.
- Engaging in self-injurious behavior that is likely to cause serious injury, harm, impairment, or death to the resident (e.g., banging head against wall).
- Sustained and intense crying, moaning, screaming, or combative behavior.
- Expressions (verbal and/or non-verbal) of severe, unrelenting, excruciating, and unrelieved pain; pain has become all-consuming and overwhelms the resident.

- Recurrent (i.e., more than isolated or fleeting) debilitating fear/anxiety that may be manifested as panic, immobilization, screaming, and/or extremely aggressive or agitated behavior(s) (e.g., trembling, cowering) in response to an identifiable situation (e.g., approach of a specific staff member).
- Ongoing, persistent expression of dehumanization or humiliation in response to an identifiable situation, that persists regardless of whether the precipitating event(s) has ceased and has resulted in a potentially life-threatening consequence.
- Expressions of anger at an intense and sustained level that has caused or is likely to cause serious injury, harm, impairment, or death to self or others.

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

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

Examples of negative psychosocial outcomes as a result of the facility's noncompliance may include but are not limited to:

- Significant decline in former social patterns that does not rise to a level of immediate jeopardy.
- Persistent depressed mood^{7,8,9} that may be manifested by verbal and nonverbal symptoms such as:
 - Social withdrawal; irritability; anxiety; hopelessness; tearfulness; crying; moaning;
 - Loss of interest or ability to experience or feel pleasure nearly every day for much of the day;
 - Psychomotor agitation¹⁰ (e.g., inability to sit still, pacing, hand-wringing, or pulling or rubbing of the skin, clothing, or other objects), accompanied by a bothered or sad expression;
 - Psychomotor retardation (e.g., slowed speech, thinking, and body movements; increased pauses before answering);
 - Verbal agitation¹¹ (e.g., repeated requests for help, groaning, sighing, or other repeated verbalizations), accompanied by sad facial expressions;
 - Expressions of feelings of worthlessness or excessive guilt nearly every day (not merely self-reproach or guilt about being sick or needing care);

- Markedly diminished ability to think or concentrate;
- Recurrent thoughts of death (not just fear of dying) or statements without an intent to act (e.g., “I wish I were dead” or “my family would be better off without me”).
- Expressions (verbal and/or non-verbal) of persistent pain or physical distress (e.g., itching, thirst) that has compromised the resident’s functioning such as diminished level of participation in social interactions and/or ADLs, intermittent crying and moaning, weight loss and/or diminished appetite. Pain or physical distress has become a central focus of the resident’s attention, but it is not all-consuming or overwhelming (as in Severity Level 4).
- Chronic or recurrent fear/anxiety that has compromised the resident’s well-being and that may be manifested as avoidance of the fear-inducing situation(s) or person(s); preoccupation with fear; resistance to care and/or social interaction; moderate aggressive or agitated behavior(s) related to fear; sleeplessness due to fear; and/or verbal expressions of fear. Expressions of fear/anxiety are not to the level of panic and immobilization (as in Severity Level 4).
- Ongoing, persistent feeling and/or expression of dehumanization or humiliation that persists regardless of whether the precipitating, dehumanizing event(s) or situation(s) has ceased. The feelings of dehumanization and humiliation have not resulted in a life-threatening consequence.
- Apathy and social disengagement such as listlessness; slowness of response and thought (psychomotor retardation); lack of interest or concern especially in matters of general importance and appeal, resulting from facility noncompliance.
- Sustained distress (e.g., agitation indicative of under stimulation as manifested by fidgeting; restlessness; repetitive verbalization of not knowing what to do, needing to go to work, and/or needing to find something).
- Anger that has caused aggression that could lead to injuring self or others. Verbal aggression can be manifested by threatening, screaming, or cursing; physical aggression can be manifested by self-directed responses or hitting, shoving, biting, and scratching others.

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

Severity 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.

Examples of negative psychosocial outcomes as a result of the facility's noncompliance may include but are not limited to:

- Intermittent sadness, as reflected in facial expression and/or demeanor, tearfulness, crying, or verbal/vocal agitation (e.g., repeated requests for help, moaning, and sighing).
- Feelings and/or complaints of discomfort or moderate pain. The resident may be irritable and/or express discomfort.
- Fear/anxiety that may be manifested as expressions or signs of minimal discomfort (e.g., verbal expressions of fear/anxiety; pulling away from a feared object or situation) or has the potential, not yet realized, to compromise the resident's well-being.
- Feeling of shame or embarrassment without a loss of interest in the environment and the self.
- Complaints of boredom and/or reports that there is nothing to do, accompanied by expressions of periodic distress that do not result in maladaptive behaviors (e.g., verbal or physical aggression).
- Verbal or nonverbal expressions of anger that did not lead to harm to self or others.

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

Severity Level 1 is not an option because any facility practice that results in a reduction of psychosocial well-being diminishes the resident's quality of life. The deficiency is, therefore, at least a Severity Level 2 because it has the potential for more than minimal harm.

ENDNOTES

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³ American Psychiatric Association (1994). *Diagnostic and statistical manual of mental disorders (Fourth Edition)*. Washington, DC: Author.

⁴ Random House. (1981).

⁵ Minimum Data Set Version 2.0, Section E.

⁶ Corsini, R. (1999). *The Dictionary of Psychology*. Ann Arbor, MI: Taylor and Francis.

- ⁷ Alexopoulos, G., Abrams, R., Young, R., & Shamoian, C. (1988). Cornell scale for depression in dementia. *Biological Psychiatry*, 23, 271-284.
- ⁸ Brink, T.L., Yesavage, J.A., Lum, O., Heersema, P., Adey, M., & Rose, T.L. (1982). Screening tools for geriatric depression. *Clinical Gerontologist*, 1, 37-43.
- ⁹ Warren, W.L. (1994). *Revised Hamilton Rating Scale for Depression (RHRSD)*. Los Angeles, CA: Western Psychological Services.
- ¹⁰ Cohen-Mansfield, J. (2003). Agitation in the elderly: Definitional and theoretical conceptualizations. In D.P. Hay, D. Klein, L. Hay, G. Grossberg, & J.S. Kennedy (Eds.) *Agitation in Patients with Dementia: A Practical Guide to Diagnosis and Management* (pp. 1-22). Washington, DC: American Psychiatric Publishing Inc.
- ¹¹ Cohen-Mansfield, J. (2003). Agitation in the elderly: Definitional and theoretical conceptualizations.