F757
(Rev.)

§483.45(d) Unnecessary Drugs—General.
Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—

§483.45(d)(1) In excessive dose (including duplicate drug therapy); or

§483.45(d)(2) For excessive duration; or

§483.45(d)(3) Without adequate monitoring; or

§483.45(d)(4) Without adequate indications for its use; or

§483.45(d)(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

§483.45(d)(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.

INTENT

The intent of these requirements is to ensure each resident's entire drug/medication regimen is managed and monitored to promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being.

NOTE:

- ***For concerns related to psychotropic medications only, including the unnecessary medication requirements, surveyors should assess compliance with §483.10(e), §483.12(a), and §§483.45(c) and (e), F605.***
- ***This guidance uses the terms "medications," and, "drugs," interchangeably.***
- ***For purposes of this guidance, references to "the pharmacist" mean the facility's licensed pharmacist, whether employed directly by the facility or under arrangement.***

The regulations and guidance are not intended to supplant the judgment of a practitioner in consultation with facility staff, the resident, and his/her representatives and in accordance with professional standards of practice. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents. For example, a resident's medical record should contain documentation that demonstrates how the practitioner arrived at their decision(s) in accordance with the professional standards of practice.

DEFINITIONS

"Adequate Indications for use" *refers to the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident's condition and therapeutic goals, and after any safer treatments have been deemed clinically contraindicated. Also, adequate indication for use means that the medication administered 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.

"Adverse consequence" *refers to unwanted, unintended, or dangerous effects that a drug may have, 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) (adapted from The Merck Manual Professional Version, http://www.merckmanuals.com/professional/clinical-pharmacology/adverse-drug-reactions/adverse-drug-reactions.)*

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" *refers to* 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, anti-psychotics, antiemetics, muscle relaxants; and
- Certain medications used to treat cardiovascular conditions, Parkinson's disease, urinary incontinence, gastrointestinal issues and vertigo.

"Neuroleptic Malignant Syndrome (NMS)" *refers to* a syndrome related to the use of medications, 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.

"Serotonin Syndrome" *refers to* 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.

GUIDANCE

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, arresting or slowing a disease process, reducing or eliminating symptoms, or as part of diagnosing or preventing a disease or symptom.

Comprehensive Assessment

The indications for initiating, maintaining, or discontinuing medication(s) are

determined by evaluating the resident's physical, behavioral, mental, and psychosocial signs and symptoms in order to identify and rule out any underlying medical conditions, including the assessment of relative benefits and risks, and the preferences and goals for treatment. The resident's medical record should include documentation of this evaluation and the rationale for chosen treatment options.

Additionally, the facility should ensure that the initiation or change in a medication is not:

- *Due to a medical condition or problem (e.g., pain, fluid or electrolyte imbalance, infection, obstipation, medication side effect or polypharmacy) that can be expected to improve or resolve as the underlying condition is treated or the offending medication(s) are discontinued;*
- *Due to environmental stressors alone, that can be addressed to improve the symptoms; and*
- *Due to psychological stressors alone, that can be expected to improve or resolve as the situation is addressed.*

Circumstances that warrant evaluation of a resident's underlying medical condition and medication(s) include:

- *Admission or re-admission: Some residents may be admitted to the facility on medications that were started in the hospital or the community without a clear documented indication for why the medication was begun or should be continued. The prescribing practitioner and the IDT should subsequently determine if continuing the medication is justified by conducting a comprehensive evaluation;*
- *A new or worsening change in condition/status;*
- *An irregularity identified in the pharmacist's medication regimen review. See F756 for guidance related to the medication regimen review; and*
- *New medication order as an emergency measure – When a resident is experiencing an acute medical problem or emergency and the acute phase has stabilized, the staff and prescriber should consider whether medications are still relevant.*

Determining the Necessity for use of Medications

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 have serious side effects, such as changes in vital signs/lab values, confusion, immobility, falls, and hip fractures, which can be especially dangerous for elderly residents, in addition to an increased risk of death. American Geriatrics Society 2023 updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults provides information on safely prescribing medications for older adults, https://agsjournals.onlinelibrary.wiley.com/doi/full/10.1111/jgs.18372.

NOTE: *Instances of prescribing antibiotics unnecessarily should be cited at §483.45(d), F757. The findings may support citing F881 as well, in which case the surveyor must also show that the facility is not implementing part or all of the Antibiotic Stewardship Program (e.g., antibiotic use protocols that utilize an infection assessment tool, monitoring of antibiotic use, or feedback and education to prescribing providers).*

Resident's Right to be Informed

In accordance with the requirements at §483.10(c), residents have the right to be informed of and participate in their treatment. Prior to initiating or increasing a medication, the resident, family, and/or resident representative must be informed of the benefits, risks, and alternatives for the medication, in advance of such initatiation or increase. The resident has the right to accept or decline the initiation or increase of a medication. To demonstrate compliance, the resident's medical record must include documentation that the resident or resident representative was informed in advance of the risks and benefits of the proposed care, the treatment alternatives or other options and was able to choose the option he or she preferred. A written consent form may serve as evidence of a resident's consent to medication, but other types of documentation are also acceptable. If a medication has been initiated or increased, and there is not documentation demonstrating compliance with the resident's right to be informed and participate in their treatment, noncompliance with §483.10(c) exists and F552 must be cited.

Dose and Duration

The dose and duration of medications, in accordance with §483.45(d)(1) and (d)(2), are 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 (IDT) about the resident, including the resident's preferences and goals, the type of medication(s), and therapeutic goals being considered or used.

***Dose** refers to 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.*

***Polypharmacy** refers to the use of five or more medications for an individual which can increase the risk of adverse outcomes such as falls, frailty, disability, and mortality in older adults. Polypharmacy also increases the possibility of prescribing cascades when additional drugs are prescribed to treat the adverse effects of one of the current medications.*

***Duplicate therapy** refers to two or more medications of the same pharmacological class/category without a clear distinction of when one medication should be administered over another. 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 medication containing the same ingredient, use of more than one drugs within the same class, or medications from different therapeutic categories with similar effects or properties.*

The risk for polypharmacy and duplicate therapy is particularly high during transitions of care, especially if medications are not tracked closely between locations or within the care settings. Documentation is necessary to clarify the rationale for each medication and the approach to monitor the benefits and any adverse consequences.

***Excessive dose** refers to 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, and accepted standards of practice for a resident's age and condition.

***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..*

The clinical rationale for continued use of a medication(s) should be documented in the medical record. Examples of inappropriate duration that should be cited for non-compliance may include:

- *A medication was initiated because of a time-limited condition (for example, delirium, pain, infection, nausea and vomiting, cold and cough symptoms, or itching). However, failure to review whether the underlying cause has resolved led to excessive duration, because the medication was not discontinued when the condition resolved or there was no documentation indicating why continued use was still relevant.*
- *A medication was administered beyond the stop date established by the prescriber, without evidence of clinical indication for continued use of the medication.*

Monitoring and Adverse Consequences

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, in accordance with §483.45(d)(3) and (d)(5), as well as documenting medication management steps. Monitoring and accurate documentation of the resident's response to any treatment (such as, lab results, vital signs, progress notes, behavior flow sheets, medication administration records and the consultant pharmacist's drug regimen review) is essential to evaluate the ongoing effectiveness, benefits as well as risks of medications.

***Note:** The facility's pharmacist is a valuable source of information about medications. The pharmacist and attending physician must adhere to the requirements for reporting and responding to identified irregularities (See F756 Drug Regimen Review).*

When there are multiple prescribers, 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 be clinically indicated and documented in the resident's medical record. If it is determined through monitoring that changes in the resident's treatment plan need to be made, surveyors must review the medical record to determine whether the prescribing practitioner provided a rationale for continued use or discontinuation. Without a rationale, the use of the medication(s) may be unnecessary and therefore, noncompliant.

The surveyor must review documentation to confirm that residents are being adequately monitored and re-evaluated for adverse consequences and the need for tapering. Adverse consequences related to medications are common enough to warrant serious attention and close monitoring, and can range from minimal harm to functional decline, hospitalization, permanent injury, and death.

One of the existing mechanisms to warn prescribers about risks associated with medications is the Food and Drug Administration (FDA) requirement that manufacturers include 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: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program or search for "FDA Safety Alerts for Human Medical Products." Manufacturers are required to place statements about serious problems or contraindications in a prominently displayed box ("black box") in the medication labelling. The boxed warning is reserved for prescription drugs that pose a significant risk of serious or life-threatening adverse effects, based on medical studies. Use of a tool, such as the CMS Adverse Drug Event Trigger Tool, may assist in identifying resident risk factors and triggers for adverse drug events as well as in determining whether a facility has systems and processes in place to minimize risk factors and mitigate harm to residents. This tool and other resources are available on the CMS Adverse Events in Nursing Homes website, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Adverse-Events-NHs. Additionally, as part of a facility's QAPI program, a facility may track its use of certain classes of medications through reports from the long-term care pharmacist which could identify trends and reduce adverse events.

INVESTIGATIVE PROCEDURES

Use the Unnecessary Medications, Chemical Restraints/Psychotropic Medications, and Medication Regimen Review Critical Element (CE) Pathway, along with the above interpretive guidance, when determining if the facility meets the requirements or when investigating concerns.

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 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.

Use the table below to guide observations, record review, and interviews with the resident or representative and relevant staff. Symptoms and signs described in the table may also be related to a resident's condition or disease. The surveyor may seek clarification about the basis of specific signs and symptoms from the attending physician and/or pharmacist.

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT
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	Review the record (including the care plan, comprehensive assessment, and other parts of the record as appropriate) to determine whether it reflects the following

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT
in condition or currently has signs and symptoms, such as: • Anorexia and/or unplanned weight loss, or weight gain • Apathy • Behavioral changes, unusual patterns (including increased expressions or indications of distress, social isolation or withdrawal) • 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 • Lethargy • Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia (including delirium), inability to concentrate) • Psychomotor agitation (e.g., restlessness, inability to sit still, pacing, hand-wringing, or pulling or rubbing of the skin, clothing, or other objects). • Psychomotor retardation (e.g., slowed speech, thinking, and body movements) • Rash, pruritus • Respiratory difficulty or changes • Sedation (excessive), insomnia, or sleep disturbance • Seizure activity • Urinary retention or incontinence If observations or record review indicate symptoms or changes in condition that may be related to	elements related to medication management for the resident: • Clinical indications for use of the medication • Implementation of person-centered, non-pharmacological approaches to care • 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: o Response to medications and progress toward therapeutic goals and resident's goals o Emergence of medication-related adverse consequences • Adverse consequences, if present and potentially medication-related, note if there was: o Recognition, evaluation, reporting, and management by the IDT o Physician action regarding potential medication-related adverse consequences • The resident's goals and preferences for medications and treatments

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	REVIEW FOR HOW THE IDT MANAGED MEDICATIONS FOR THE RESIDENT
medications, determine whether the facility considered medications as a potential cause of the change or symptom.	

Interview the resident, his or her family, and representative(s) and the IDT, as needed to gather information about use of medications and any possible side effects in the *facility*. Evaluate if the resident may have experienced psychosocial harm related to side effects of medications.

For a resident who is unable to communicate psychosocial outcomes related to medication side effects, the surveyor should consider how a reasonable person *in the resident's condition* would experience the changes caused by medication side effects as explained in the Psychosocial Outcome Severity Guide, on the CMS Nursing Homes Survey Resources website.

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.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

- *F552, Right to be Informed/Make Treatment Decisions*
- *F553, Right to Participate Planning Care*
- *F580, Notification of Changes*
- *F656, Develop/Implement Comprehensive Care Plan*
- *F710, Physician Supervision*
- *F756, Drug Regimen Review*
- *F841, Medical Director*
- *F881, Antibiotic Stewardship Program*

DEFICIENCY CATEGORIZATION

Examples of Level 4, immediate jeopardy to resident health and safety include, but are not limited to:

- Facility failure to take appropriate action (e.g., suspending administration of the anticoagulant) in response to an elevated International Normalized Ratio (INR) for a resident who is receiving warfarin, resulting in either the potential or actual need to transfuse or hospitalize the resident.
- Failure to respond appropriately to an INR level that is above or 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 antidepressant, leading to the addition of medications with additive serotonin effect or medication to suppress the symptoms.

- Failure to recognize and respond to signs and symptoms of neuroleptic malignant syndrome (NMS).
- In the presence of initial gastrointestinal bleeding, i.e. blood in stool, 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.

Examples of Level 3, actual harm that are not immediate jeopardy include, but are not limited to:

- The facility failed to monitor the side effects of a resident's new medication regimen as the source of a resident's recent nausea. Instead of adjusting the current regimen, the prescriber added a medication to treat the nausea, which caused agitation and insomnia.
- *A resident had been sick and taking in less fluids. Staff failed to monitor the resident's blood pressure when the resident mentioned feeling lightheaded. The resident continued to receive prescribed blood pressure medications without adequate monitoring which led to a low blood pressure causing the resident to fall and sustain a serious injury.*

Examples of Level 2, *no* actual harm, with potential for more than minimal harm, that is not immediate jeopardy, include but are not limited to:

- Facility failure to identify and act upon minor symptoms of allergic response to medications, such as a rash with mild itching to the abdomen and no other symptoms, causing minimal discomfort.
- Facility failure to monitor for response or for the emergence or presence of adverse consequences for a resident who has not yet experienced an adverse consequence or decline in function, such as by monitoring hydration status and basic metabolic profile for a resident receiving diuretics or ACE inhibitors.

Severity Level 1:
Severity Level 1 does not apply for this regulatory requirement because 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.

RESOURCES AND TOOLS
The following resources and tools provide information on medications including 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. Additionally, the list includes some of the recognized clinical resources available for understanding the overall treatment and management of medical problems, symptoms and medication consequences and precautions.

- U.S. Department of Health and Human Services, National Institute of Mental Health Web site, which includes publications and clinical research information, www.nimh.nih.gov

- MedlinePlus, https://www.nlm.nih.gov/medlineplus/druginformation.html
- National Library of Medicine Drug Information Portal, http://druginfo.nlm.nih.gov/drugportal/drug/categories (medication class information).
- 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
- The University of Maryland Medical Center Drug Interaction Tool, http://umm.edu/health/medical/drug-interaction-tool
- American Medical Directors Association, www.amda.com
- American Society of Consultant Pharmacists, www.amda.com

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