

Pharmacy Services



Division of Nursing Homes

§483.45 Pharmacy Services Overview

The Pharmacy Services section of Appendix PP contains all Pharmacy Services requirements and interpretive guidelines (IG) found within the following regulatory sections and tags:

- §483.45(a) and (b)(1)-(3), **F755**—Pharmacy Services
- §483.45(c)(2), (4), and (5), **F756**—Drug Regimen Review
- §483.45(d)(1)-(5), **F757**—Unnecessary drugs
- §483.45(c)(3) and (e), **F758**—Psychotropic drugs
- §483.45(f)(1), **F759**—Medication errors [not 5 percent or greater]
- §483.45(f)(2), **F760**—Medication errors [significant medication errors]
- §483.45(g) and (h)(1) and (2), **F761**—Labeling and Storage of Drugs and Biologicals

§483.45 Pharmacy Services Overview

- F756 Drug Regimen Review
- F757 Unnecessary Medications
- F758 Psychotropic Medications

§483.45(c), F756 – Drug Regimen Review

§483.45(c) Drug Regimen Review

- (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.
- (2) This review must include a review of the resident's medical chart.
- (4) The pharmacist must report any irregularities to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon.
 - (i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug.
 - (ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified.
 - (iii) The attending physician must document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.
- (5) The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

§483.45(c), F756 – Drug Regimen Review

Medication regimen review (MRR) component of the pharmaceutical services systems includes:

- A pharmacist's review of the resident's medication regimen and medical record; and
- Acting upon identified irregularities.



F756 – New Requirements

483.45(c)(2)

Medication regimen review (MRR) must include a review of the resident's medical chart

- To identify irregularities; and
- To identify clinically significant risks and/or actual or potential adverse consequences.



F756 – New Requirements

483.45(c)(4)

Irregularities: the use of medication that is inconsistent with accepted standards of practice for providing pharmaceutical services, not supported by medical evidence, and/or that impedes or interferes with achieving the intended outcomes of pharmaceutical services.

F756 – New Requirements

483.45(c)(4)

Pharmacist must report irregularities to the:

- Attending physician;
- Director of nursing; and
- Facility medical director.



F756 – New Requirements

483.45(c)(4)

- Irregularities must be documented in a separate, written report.
- Attending physician must:
 - Document irregularities were reviewed; and
 - What action will be taken.

483.45(c)(5) F756 – New Requirements

483.45(c)(5)



- Each facility must develop and maintain policies and procedures, which include:
 - Time frames for steps in the process; and
 - Steps to take when immediate action is required.
- Policies and procedures should also address:
 - Anticipated stays that are less than 30 days; and
 - Identified acute changes of condition.

F756 Examples of Noncompliance

An example of noncompliance that demonstrates severity at Level 4 includes, but is not limited to:

During the survey, a resident was observed lying in bed, asleep, for multiple hours each day. On two occasions, he was observed to refuse to eat the meal that had been brought to his room, missing the meal altogether.

Record review showed that the resident had a diagnosis of dementia and was prescribed an antipsychotic medication 2 ½ months prior. The record also revealed that since the medication had been started, the resident experienced persistent lethargy and drowsiness, spent most of his day napping in his room not participating in activities that he had before regularly attended, had stopped eating his meals in the dining room with the other residents, and had experienced an unplanned severe weight loss of 8% of his usual body weight.

During an interview with facility nursing staff, the surveyor was told that the resident was previously difficult to deal with and combative at times but the resident had become more “cooperative” and “docile” since being prescribed the anti-psychotic medication.

During interviews with the pharmacist, DON, and facility medical director it was confirmed that two MRRs were conducted in the last two months but no potential drug irregularities were identified or reported to indicate that the resident’s regimen could be causing or associated with new, worsening, or progressive signs and symptoms.

F756 Examples of Noncompliance

An example of Level 3, Actual harm (physical or psychosocial) that is not immediate jeopardy, includes, but is not limited to:

The pharmacist's MRR failed to identify the indication for continued use for opioid analgesics that had been prescribed for a resident's acute pain which had resolved. As a result of prolonged duration of use, the resident continued to be or became more lethargic and/or withdrawn.

F756 Examples of Noncompliance

An example of Level 2, No actual harm with a potential for more than minimal harm that is not immediate jeopardy, may include but is not limited to:

The pharmacist's MRR failed to evaluate and report on the potential adverse consequences of a medication that may increase the possible side effects of another clinically appropriate medication that had been prescribed. The resident had not yet experienced side effects from the combined medications.

F756 Examples of Noncompliance

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

The failure of the facility to perform the medication regimen review according to the regulatory requirements creates the potential for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

§483.45(d), F757 Unnecessary Drugs and §483.45(c) and (e), F758 Psychotropic Drugs

- No new requirements for Unnecessary Medications.
- Interpretive Guidelines (IGs) for the two tags of F757 and F758 have been combined to avoid unnecessary duplication.

§483.45(c)(3) and (e), F758 Psychotropic drugs

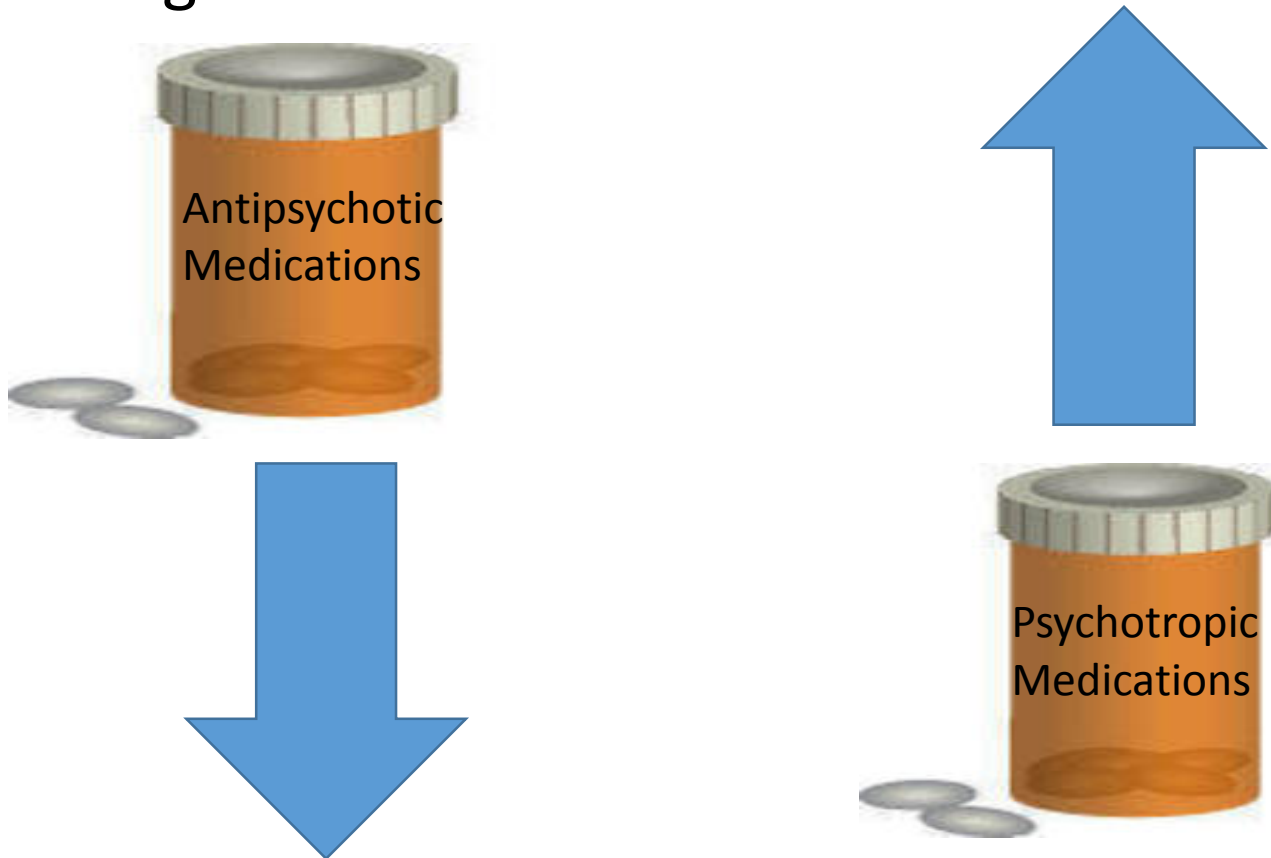
The requirements at 483.45 contain a new psychotropic medication category which replaces the anti-psychotic medication category and expands the types of drugs to which the requirements at 483.45(e) apply.

*§483.45(c)(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. **These drugs include, but are not limited to, drugs in the following categories:***

- (i) Anti-psychotic;*
- (ii) Anti-depressant;*
- (iii) Anti-anxiety; and*
- (iv) Hypnotic.*

§483.45(c)(3) and (e), F758 Psychotropic drugs

The expansion of medication categories addresses the concern that as use of antipsychotic medications decreases, use of other psychotropic medications might increase.



F758 Psychotropic Drugs

- Other medications which may affect brain activity include:
Central nervous system agents, mood stabilizers, anticonvulsants, muscle relaxants, anti-cholinergic medications, antihistamines, NMDA receptor modulators, and OTC natural and herbal products
- Increased confusion or over-sedation could occur with these medications so, as with all medications, the facility must monitor for adverse consequences.

§483.45(c)(3) and (e), F758 Psychotropic drugs

Requirements which applied to anti-psychotic medications now apply to all psychotropic medications:

§483.45(e) Psychotropic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that--

(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;

(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;

NOTE: Gradual dose reductions may not be appropriate for specific, enduring, progressive, or terminal conditions such as chronic depression, Parkinson's disease psychosis, or recurrent seizures.

§483.45(c)(3) and (e), F758 Psychotropic drugs

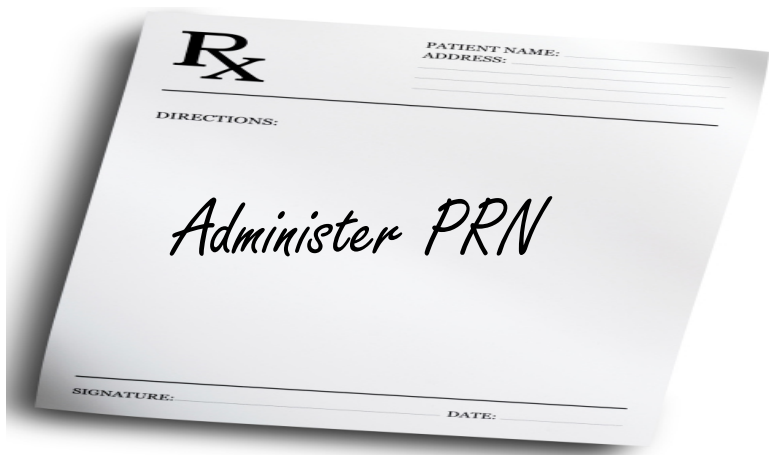
- The regulations and guidance concerning psychotropic medications are not intended to replace the judgment of a physician or prescribing practitioner.
- The regulations and guidance are intended to ensure psychotropic medications are used only when the medication(s) is appropriate to treat a resident's specific, diagnosed, and documented condition and the medication(s) is beneficial to the resident, as demonstrated by monitoring and documentation of the resident's response to the medication(s).



F758 PRN Limitations

Two types of PRN limitations:

- PRN orders for psychotropic medications, *excluding* anti-psychotics.
- PRN orders for anti-psychotic medications *only*.



F758 PRN Limitations

PRN orders for psychotropic medications, excluding antipsychotics:

- Limited to 14 days
- May be extended beyond 14 days if the attending physician or prescribing practitioner believes it is appropriate to extend the order.
- Must have a documented rationale by the attending physician or prescribing practitioner for the extended time period in the medical record, including a specific duration.



F758 PRN Limitations

PRN orders for antipsychotic medications only:

- Limited to 14 days, without exception
- If the attending physician or prescribing practitioner wishes to write a new order for the PRN antipsychotic, the attending physician or prescribing practitioner must first evaluate the resident to determine if the new order for the PRN antipsychotic is appropriate.



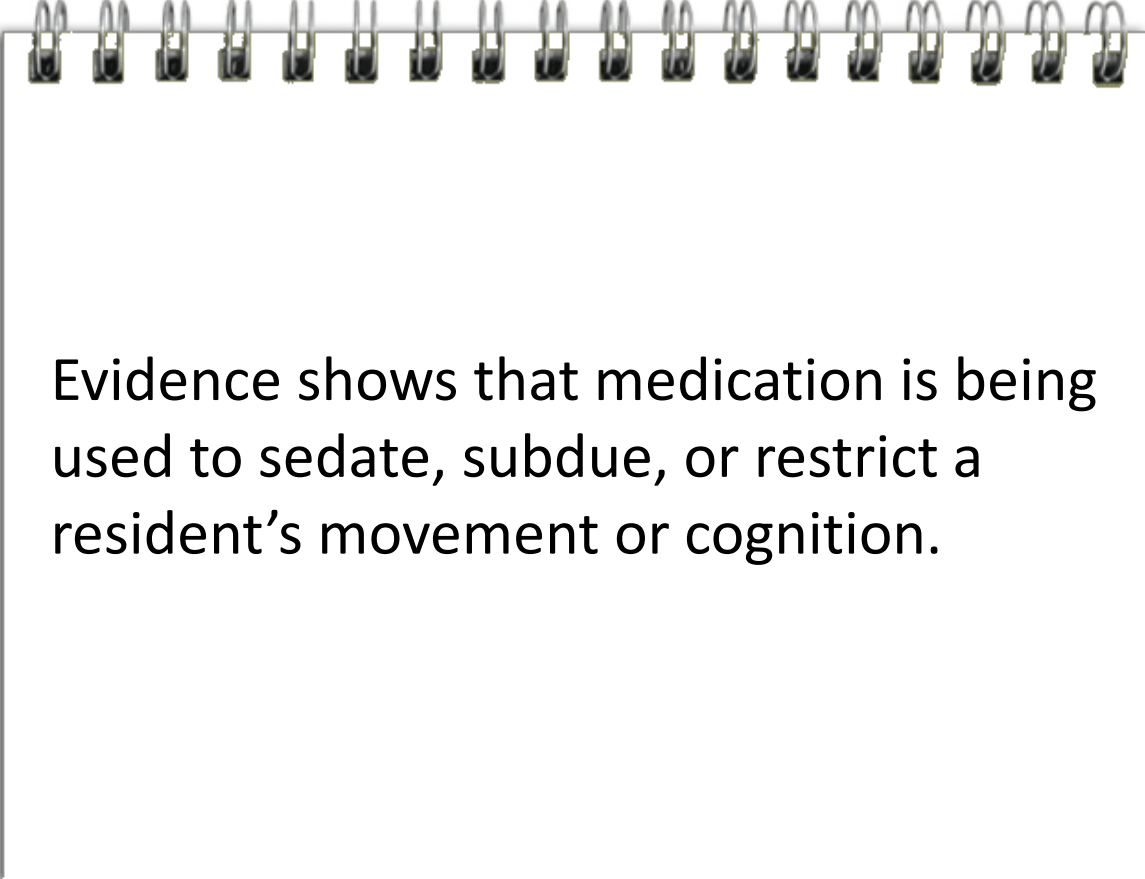
F758 PRN Limitations

Evaluate the resident before deciding whether to write a new order for a PRN antipsychotic medication.

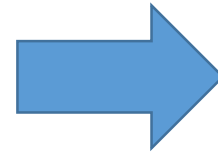
- Is the antipsychotic medication still needed on a PRN basis?
- What is the benefit of the medication to the resident?
- Have the resident's expressions or indications of distress improved as a result of the PRN medication?



F758 Psychotropic Drugs/Chemical Restraints



Evidence shows that medication is being used to sedate, subdue, or restrict a resident's movement or cognition.



Assess compliance with 483.10 and 483.12, F605, Right to be Free From Chemical Restraints

F757 and F758

IG General Revisions:

- IG uses more person-centered language, e.g. “expressions or indications of distress”, “non-pharmacological approaches to care.”
- Emphasis on documentation to demonstrate appropriate use and adequate monitoring of medications.

F757 and F758

F757 or F758?



§483.45(c)(3) and (e), F758 Psychotropic drugs

If identified concerns involve psychotropic medications, investigate compliance with F758.

For all other medication concerns, investigate compliance with F757.

Deficiency Categorization Examples

For F757:

An example of noncompliance that demonstrates severity at Level 4 includes, but is not limited to:

Facility failure to take appropriate action (e.g., suspending administration of the anticoagulant) in response to an elevated INR for a resident who is receiving warfarin, resulting in either the potential or actual need to transfuse or hospitalize the resident.

Deficiency Categorization Examples

For F758:

An example of noncompliance that demonstrates severity at Level 4 includes, but is not limited to:

Failure to recognize that use of an antipsychotic medication, originally prescribed for agitation, has caused significant changes in the resident's quality of life. The resident no longer participates in activities that he or she previously enjoyed, has difficulty concentrating and carrying on conversations, and spends most of the day isolated in their room, sleeping in a recliner or in bed. Use of the antipsychotic medication without an adequate clinical indication, GDR attempts, and non-pharmacological approaches resulted in psychosocial harm.

Deficiency Categorization Examples

For F758:

An example of Level 3, Actual harm (physical or psychosocial) that is not immediate jeopardy, includes, but is not limited to:

Failure to evaluate a resident for a GDR for a psychotropic medication originally prescribed to treat delirium. Delirium symptoms subsided but the resident remained drowsy and inactive.

Deficiency Categorization Examples

For F757:

An example of Level 2, No actual harm with a potential for more than minimal harm that is not immediate jeopardy, may include but is not limited to:

Facility failure to identify and act upon minor symptoms of allergic response to medications, such as a rash.

Deficiency Categorization Examples

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.

Surveyor Tools



- Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review Critical Element Pathway (CMS-20082)
- Psychosocial Severity Outcome Guide—Appendix P
- Appendix Q of the State Operations Manual—Immediate Jeopardy

Thank you

For your continued efforts towards our shared goal in providing quality care to America's nursing home residents



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