



## 483.45 Pharmacy Services



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Welcome. This is the Pharmacy Services section of the training.

# Pharmacy Services

Ftag	Tag Subject	Key Change to Regulation or Interpretive Guidelines	Significant Change or Technical Correction
F755	Pharmacy Services	Clarified language related to disposal of Fentanyl patches	Significant
F757	Drug Regimen is Free from Unnecessary Drugs	Added language related to antibiotic stewardship and F881	Significant
F758	Free from Unnecessary Psychotropic Medications/ PRN Use	Clarification of other classes of drugs not listed in the regulation and how they are affected by the psychotropic medication requirements; Added language on potential misdiagnoses, such as schizophrenia, in order to prescribe antipsychotics.	Significant

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For the Pharmacy Services regulatory section, we have made small but significant changes to guidance at F755 Pharmacy Services, F757 Unnecessary Medications and F758 Unnecessary Psychotropic Medications and PRN Use

There were no new Phase 3 regulations for these tags but changes to guidance were made for clarification and in response to questions from nursing home stakeholders. Language was changed regarding disposal of used fentanyl patches and antibiotic stewardship requirements. For F758 guidance, new language has been added regarding other classes of medications not specifically listed in the psychotropic medication regulation. We also added language related to potential misdiagnosing of residents with a condition for which antipsychotics are an approved use such as schizophrenia. The new diagnosis then excludes the resident from the long-stay anti-psychotic quality measure.

## Changes to Pharmacy Services F755

### Revised guidance on disposal of used Fentanyl patches

- The Food and Drug Administration instructions to fold used patch and flush down toilet are not always appropriate for nursing homes.
- The Environmental Protection Agency does not currently ban flushing of pharmaceuticals (unless considered hazardous—Fentanyl patches are not classified as hazardous), but state and local laws may restrict flushing of pharmaceuticals.
- Nursing homes may use drug disposal systems if they can show the system minimizes accidental exposure and diversion.
- Disposal of fentanyl patches in common areas or resident room trash cans or sharps containers would not be compliant as these methods do not prevent accidental exposure or diversion.

At F755, we revised the guidance on disposal of used Fentanyl patches. We explain how the Food and Drug Administration instructions to fold the used patch and flush down the toilet are not always appropriate for nursing homes. We also explain that the Environmental Protection Agency does not currently ban flushing of pharmaceuticals unless they are considered hazardous—Fentanyl patches are not classified as hazardous. However, state and local laws may restrict flushing of pharmaceuticals. The guidance states that nursing homes may use drug disposal systems for fentanyl patches if they can show that the system minimizes accidental exposure and diversion. Lastly, this guidance states that disposal of fentanyl patches in common areas or resident room trash cans or sharps containers would not be compliant as these methods do not prevent accidental exposure or diversion.

## Key Changes to Pharmacy Services F757 and F758

Key Elements of Non-compliance for F757 and F758-- new guidance directs surveyors to consider F881 if unnecessary antibiotic use also indicates that a facility is not implementing part or all of the antibiotic stewardship program.



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In the Key Elements of Non-compliance section of the guidance for F757 and F758, a “Note” has been added. The note directs the survey team to consider whether a facility is compliant with F881, the tag for the Antibiotic Stewardship Program, if the team has found evidence of unnecessary antibiotic use. The unnecessary antibiotic use could indicate that a facility is not implementing part or all of an antibiotic stewardship program, **which entails** using protocols that utilize an infection assessment tool, monitoring of antibiotic use, or feedback and education to prescribing providers.

## Key Changes to F758

### F758 Unnecessary Psychotropic/PRN use:

- In November 2017, the regulations and guidance expanded the category of antipsychotic medications to psychotropic medications (antipsychotics, anti-depressants, anti-anxiety drugs, hypnotics) to address the concern that use of other psychotropic medications may increase as nursing homes attempt to decrease antipsychotic use.
- Guidance also describes other medications which affect brain activity -- may be clinically indicated but can also have adverse consequences.
- The use of these “other medications” is subject to the psychotropic medication requirements if documented use appears to be a substitution for another psychotropic medication rather than for the original or approved indication.
- For example, a seizure medication is being given to a resident with no history of seizures but the medical record shows the medication is given to treat agitation. The use of the seizure medication should be consistent with the psychotropic medication requirements under §483.45(e)

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The Phase 2 regulations and guidance released in November of 2017 expanded the category of antipsychotic medications to the new category of psychotropic medications. The regulation defines a psychotropic medication as any drug that affects brain activities associated with mental processes and behavior. This new category includes medications in the categories of anti-psychotics, anti-depressants, anti-anxiety medications, and hypnotics. This change was made out of concern that use of psychotropic medications other than anti-psychotics could increase as nursing homes attempt to decrease use of antipsychotic medications through efforts such as the National Partnership to Improve Dementia Care. The guidance also described other medications which affect brain activity. These medications may be clinically indicated but can also have adverse consequences. New guidance explains that these “other” medications are subject to the psychotropic medication requirements if documented use appears to be a substitution for another psychotropic medication rather than for the approved or original indication. An example could be a seizure medication which is being given to a resident with no history of seizures. However, the medical record shows the medication is prescribed and given to treat symptoms of agitation. In this case, the use of the seizure medication should be consistent with the psychotropic medication

requirements under Section 483.45(e).

## Additional Changes to Pharmacy Services F758

- Language was added to the gradual dose reduction section:

*Dose reductions should occur in modest increments over adequate periods of time to minimize withdrawal symptoms and to monitor symptom recurrence. Compliance with the requirement to perform a GDR may be met if, for example, within the first year in which a resident is admitted on a psychotropic medication or after the prescribing practitioner has initiated a psychotropic medication, a facility attempts a GDR in two separate quarters (with at least one month between the attempts), unless clinically contraindicated.*

- Resources for gradual dose reduction information were added.



We also added language related to the gradual dose reduction guidance in F758. We added language to further describe gradual dose reductions which states that:

*Dose reductions should occur in modest increments over adequate periods of time to minimize withdrawal symptoms and to monitor symptom recurrence.*

Resources were also added to provide information on gradual dose reductions.

## Additional Changes to Pharmacy Services F758

- Added language about the potential misdiagnosis of residents with a condition for which antipsychotics are an approved use (e.g., new diagnosis of schizophrenia) which excludes the resident from the long-stay antipsychotic quality measure.
- For this potential misdiagnosis issue, surveyors should consider investigating:
  - §483.21(b)(3)(i), F658, to determine if the practitioner's diagnosing practices meet professional standards.
  - §483.20(g), F641 to determine if the facility completed an assessment which accurately reflects the resident's status.

We added language to address situations CMS has identified where residents are potentially misdiagnosed with a condition for which antipsychotics are an approved use, such as a new diagnosis of schizophrenia. This diagnosis excludes the resident from the long-stay antipsychotic quality measure.

When investigating a potential misdiagnosis, surveyors should consider section 483.21(b)(3)(i), F658 to determine if the practitioner's diagnosing practices meet professional standards and section 483.20(g), F641 to determine if the facility completed an assessment which accurately reflects the resident's status. Language was also added to the guidance for F658 and F641 to align with the changes in F758.

## Additional Changes to Pharmacy Services F758

- Added language to direct surveyors to evaluate if a resident experienced psychosocial harm related to side effects of medications.
- Did side effects such as sedation, lethargy, agitation, mental status changes, or behavior changes:
  - affect a resident's abilities to perform activities of daily living or interact with others,
  - cause the resident to withdraw or decline from usual social patterns,
  - show the resident has decreased engagement in activities, and/or
  - cause diminished ability to think or concentrate.
- Updated the deficiency categorization section.

We added language to the section on investigating concerns and the side effects table which directs surveyors to evaluate if a resident has experienced psychosocial harm related to side effects of medications. Surveyors should look at whether side effects such as sedation, lethargy, agitation, mental status changes, or behavior changes affected:

- the resident's abilities to perform activities of daily living or to interact with others
- cause the resident to withdraw or decline from usual social patterns
- show the resident has decreased engagement in activities, and/or
- cause diminished ability to think or concentrate.

Lastly, we updated the deficiency categorization section to ensure the examples show the appropriate severity level.

Congratulations! You have successfully completed this section of the training.

## Thank You

If you have questions about this training please send them to:

[DNH\\_TriageTeam@cms.hhs.gov](mailto:DNH_TriageTeam@cms.hhs.gov)



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Thank you for your continued efforts towards our shared goal in providing quality care to America's nursing home residents.