#### Appendix PP and the Role of the Consultant Pharmacist

Brian Bell Consultant Pharmacist

#### MPhA Consultant Seminar 2024

Presented by Brian Bell, Consultant Pharmacist

#### Financial Disclosure and CE Info

Brian Bell declares that he has no current affiliations or financial relationships with any ineligible companies relevant to the subject matter of this continuing pharmacy education activity within the past 24 months.

The University of Mississippi School of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

ACPE Universal Activity Number: **0032-9999-24-015-L01-P** Activity type: **knowledge-based** 

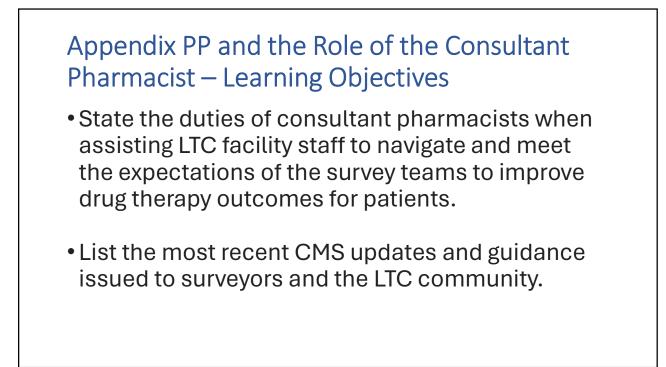
Credits: 2.0 contact hour (0.2 CEU)

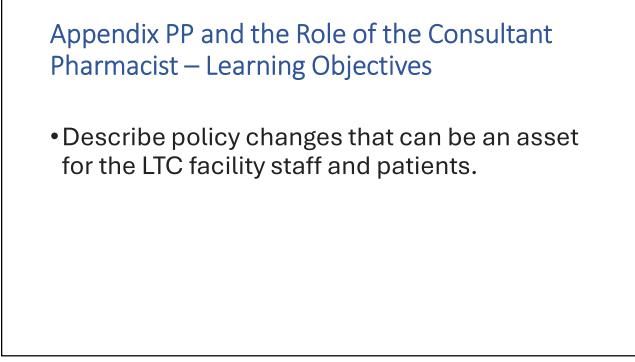


Appendix PP and the Role of the Consultant Pharmacist – Learning Objectives

- Describe the role and expectations of the consultant pharmacist.
- Describe the standards and policies of the Centers for Medicare & Medicaid Services (CMS) State Operations Manual and how they apply to the consultant pharmacist in the long-term care (LTC) setting.

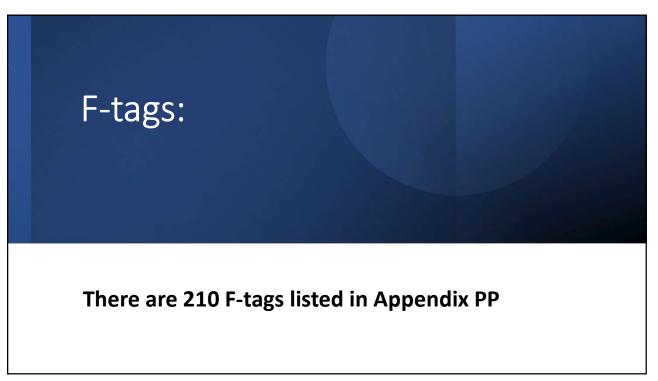
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#### **State Operations Manual**

Appendix PP - Guidance to Surveyors for Long-Term Care Facilities



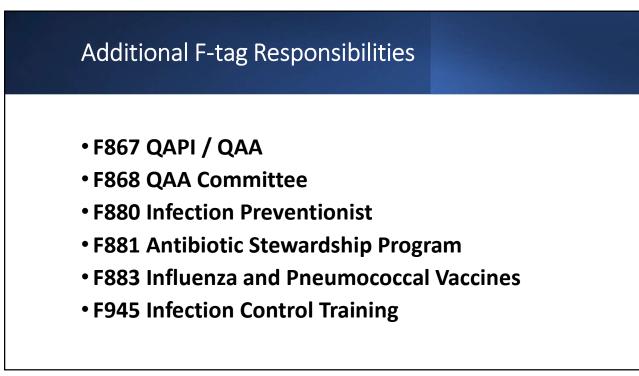
#### F-tags: Pharmacy Services

#### 7 F-tags fall under Pharmacy Services



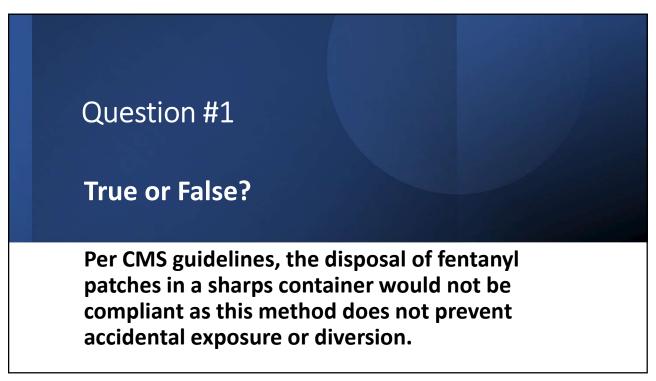
#### Additional F-tag Responsibilities

- F554 Right to Self Administer
- F578 Right to Request, Refuse, and / or D/C Treatment
- F580 Notification of Changes
- F605 Right to be Free From Any Physical or Chemical Restraints
- F693 Enteral Nutrition (Peg Tube)
- F697 Pain Management
- F744 Treatment / Service for Resident With Dementia



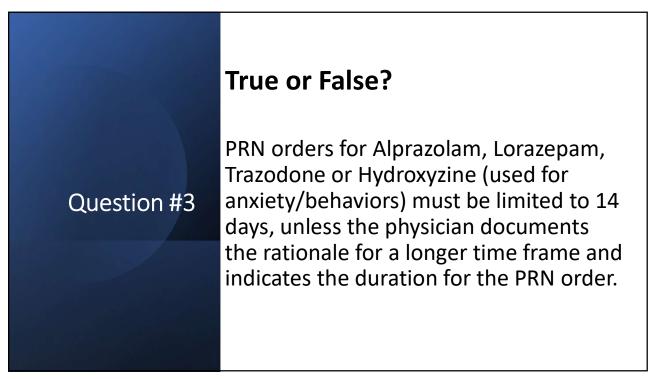
# Questions?

#### **10** Questions for the Consultants



Which of the following methods is acceptable for the attending physician to document a response to the DRR?

- a) Pharmacist writes DRR recommendation in the medical record and the physician responds directly on the medical record.
- b) Pharmacist writes DRR recommendation on a separate form, physician writes response in the medical record.
- c) Pharmacist writes DRR recommendation on a separate form, physician writes response on the form and form is placed in the medical record.
- d) All of the above are acceptable.



#### True or False?

If Valproic acid is ordered and the medical record shows no history of seizures but there is documentation that the medication is being used to treat mood disorder, then the facility should treat valproic acid as a psychotropic medication including monitoring appropriately and attempting gradual dose reductions as required per CMS regulations.

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## Question #5

#### True or False?

A facility must employ a full time Infection Preventionist to oversee the Antibiotic Stewardship Program.

Ms. White is an 83 year old resident of Acme Nursing and Retirement Center. She has recently started having some aggressive behaviors in the evening and the attending physician orders quetiapine 25mg HS. There is no clear diagnosis for the quetiapine so you ask the prescriber to clarify diagnosis/indication. The prescriber documents schizophrenia as the diagnosis.

**True or False?** Schizophrenia is a disease state that antipsychotic medication treats, and CMS survey teams will accept the diagnosis of schizophrenia due to a physician documenting it in the record.

#### Question #7

Ms. White is prescribed levofloxacin 750mg QD X 14 days but there is no indication she has an infection and there is no documentation on the rationale for use. The facility's Consultant Pharmacist fails to find this irregularity in the monthly drug regimen review. A CMS survey team completed a survey a few weeks later and found this order. What F-tag(s) could be cited:

- a) F881 Antibiotic Stewardship
- b) F757 Unnecessary Medication
- c) F756 Drug Regimen Review
- d) All 3 F-tags could be cited

#### True or False?

Ms. White has her medications administered by peg tube. Prior to medication administration, the nurse must check for proper peg tube placement. The nurse can use two methods to confirm that the peg tube is still in position, injecting air into the tube and listening for air escaping from the stomach with a stethoscope or by inserting the syringe into the tube and slowly drawing back residual content from the stomach.

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#### Question #9

If the nurse fails to confirm the peg tube placement, is this considered a 'medication error'?

- A) Yes
- B) No
- C) Maybe, depending on the circumstances

#### True of False?

If a glucometer is used for more than one resident, the device is cleaned and disinfected after every use according to manufacturer's instructions. If manufacturer does not provide instructions for cleaning and disinfection, then the device should not be used for more than one resident.





# Enforcement implementation in October 2022

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#### Mega Rule was proposed on July 16, 2015. Final Mega Rule published on September 26, 2016.

 Rewrites all LTC regulations required for participation in Medicare/Medicaid programs

# Original Mega Rule Phase-In Timeline

Phase 1 – November 28, 2016 Phase 2 – November 28, 2017 Phase 3 – November 28, 2019

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# Mega Rule Revised Guidelines / Clarifications

Notice provided June 29, 2022





#### F755 – Pharmacy Services Questions

- 1) True or False: A facility has the choice to utilize the services of a consultant pharmacist or a nurse practitioner to consult on the provision of pharmaceutical services.
- **2) True or False:** If a facility qualifies under rule 87.1, the facility can choose to not provide pharmaceutical services.
- 3) True or False: Narcotic reconciliation procedures are outlined and discussed under F755 Pharmacy Services .

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#### F755 – Pharmacy Services Definition

A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

#### F755 – Pharmacy Services Definition

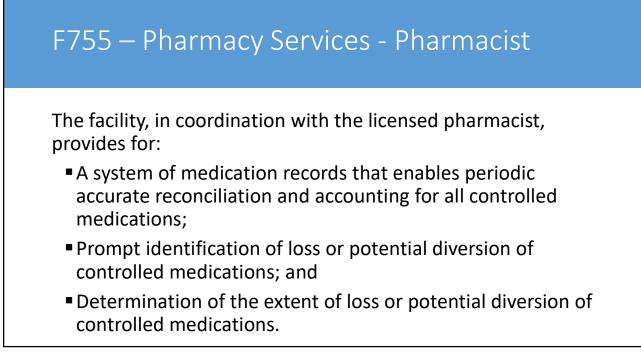
The facility must employ or obtain the services of a licensed pharmacist who:

- (1) Provides consultation on all aspects of the provision of pharmacy services in the facility.
- (2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and are periodically reconciled.

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#### F755 – Pharmacy Services - Pharmacist

The licensed pharmacist collaborates with facility leadership and staff to coordinate pharmaceutical services within the facility, guide development and evaluation of pharmaceutical services procedures, and help the facility identify, evaluate, and resolve pharmaceutical concerns which affect resident care, medical care or quality of life.





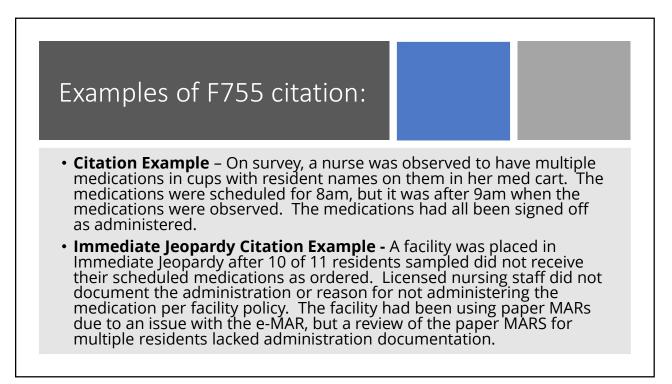
#### Fentanyl Patch Destruction - New Guidance

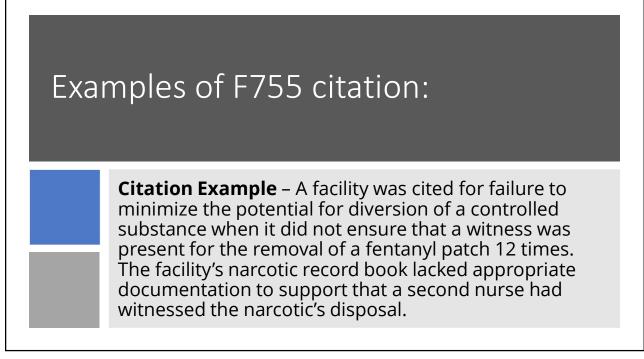
#### **Per the Appendix PP:**

Fentanyl transdermal patches present a unique situation given the multiple boxed warnings, and the substantial amount of fentanyl remaining in the patch after removal, creating a potential for abuse, misuse, diversion, or accidental exposure. Due to the life-threatening risks associated with exposure to or ingestion of the patch, the Food and Drug Administration (FDA) and manufacturer instructions recommend consumers dispose of used fentanyl patches by folding the patch in half with the sticky sides together and flushing the patch down the sink or toilet,

https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=e15a7e9b-8025- 49dd-9a6d-bafcccf1959f&type=display. The Environmental Protection Agency Advanced Copy bans flushing of pharmaceuticals if they are considered hazardous waste pharmaceuticals; fentanyl patches are not in this category, https://www.epa.gov/hw/defining-hazardous-waste-listed-characteristic-andmixedradiological-wastes#PandU









# F756 – DRR Questions 1) True or False: When performing a DRR, the consultant pharmacist can choose not to review the resident's chart but only review the MAR. 2) True or False: Irregularities identified must be reported in writing only if there is a significant medication error. 3) True or False: Irregularities identified must be reported to the attending physician, the medical director and the DON.

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#### F756 – Drug Regimen Review Definition

"Medication Regimen Review (MRR)" or Drug Regimen Review is a thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences and potential risks associated with medication.

#### F756 – Drug Regimen Review Definition

The MRR includes review of the medical record in order to prevent, identify, report, and resolve medicationrelated problems, medication errors, or other irregularities. The MRR also involves collaborating with other members of the IDT, including the resident, their family, and/or resident representative.

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#### F756 – Objectives of the DRR

An objective of the DRR (or MRR) is to try to minimize or prevent adverse consequences by identifying irregularities including, for example: syndromes potentially related to medication therapy, emerging or existing adverse medication consequences (e.g., drug reactions or medication errors).

#### F756 – Chart Review

# The pharmacist must review the resident's medical chart.

#### F756 – Sources for the Consultant

#### Possible sources to obtain this information include:

- Resident's chart (required to review)
- Medication administration records (MAR)
- Progress, nursing and consultants' notes
- Resident Assessment Instrument (RAI)
- Laboratory and diagnostic test results
- Quality Measures/Quality Indicator reports
- Resident or family members

#### F756 – Conducting a DRR

#### The pharmacist's review considers factors such as:

• Whether the physician and staff have documented objective findings, diagnoses, symptom(s), and/or resident goals and preferences to support indications for use;

• Whether the physician and staff have identified and acted upon, or should be notified about, the resident's allergies and/or potential side effects and significant medication interactions;

• Whether the medication dose, frequency, route of administration, and duration are consistent with the resident's condition, manufacturer's recommendations, and applicable standards of practice;

• Whether the physician and staff have documented progress towards, decline from, or maintenance of the resident's goal(s) for the medication therapy;

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#### F756 – Conducting a DRR

• Whether the physician and staff have documented any attempts for gradual dose reduction (GDR) or added any non-pharmacological approaches, in an effort to reduce or discontinue a drug;

• Whether the physician and staff have obtained and acted upon laboratory results, diagnostic studies, or other measurements (such as bowel function, intake and output) as applicable;

• Whether medication errors exist or circumstances exist that make them likely to occur;

• Whether the physician and staff have noted and acted upon possible medication related causes of recent or persistent changes in the resident's condition such as worsening of an existing problem or the emergence of new signs or symptoms.

#### F756 – Reporting

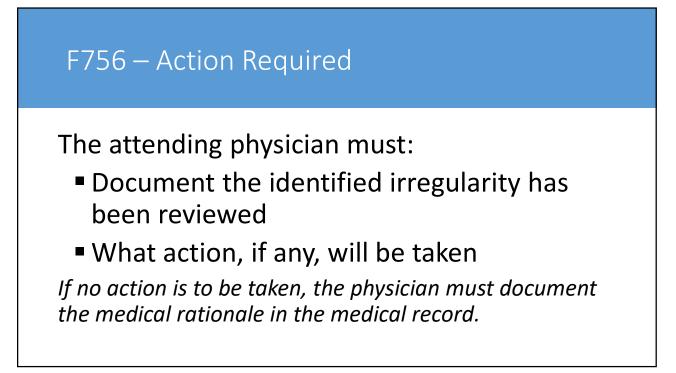
The pharmacist must report any irregularities to:

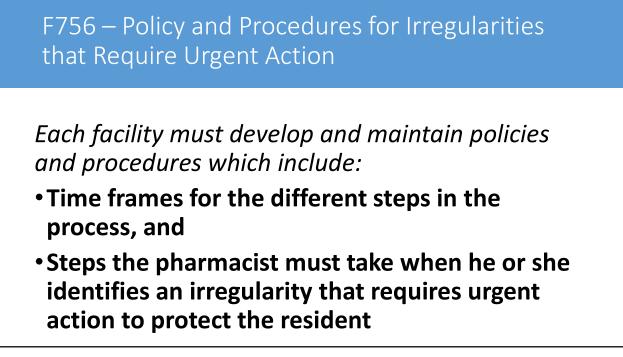
\*Attending physician\*Medical Director\*Director of Nursing

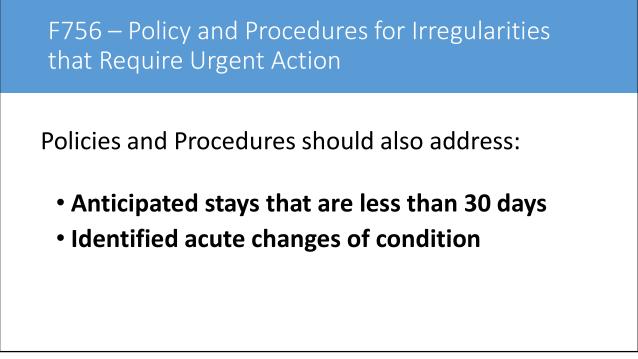
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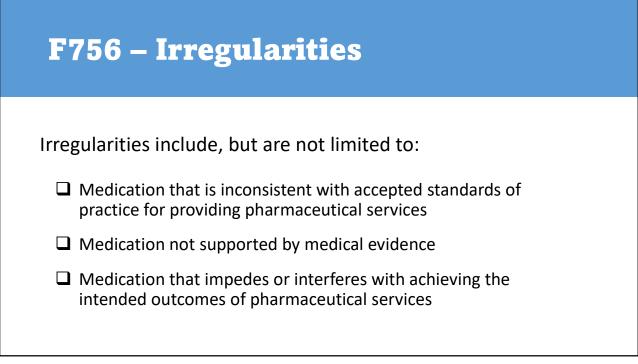
#### F756 – Reporting

Any irregularity identified must be recorded in writing and must include at a minimum the resident's name, the relevant drug, and the irregularity identified by the pharmacist.









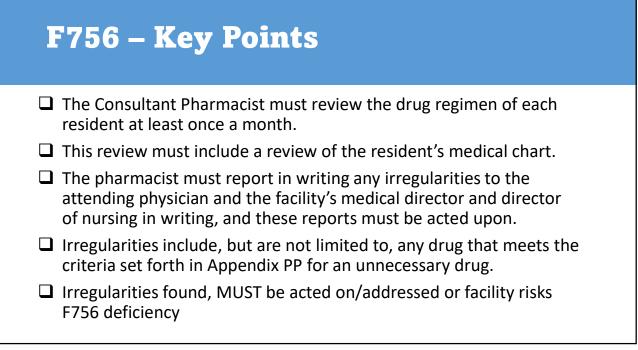
#### **F756 – Examples of Irregularities**

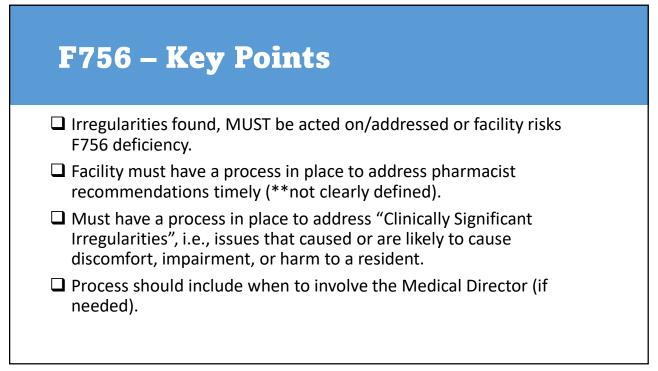
- The use of a medication without identifiable evidence of adequate indications for use.
- The use of an appropriate medication that is not helping attain the intended treatment or resident's goals because of timing of administration, dosing intervals, sufficiency of dose, techniques of administration, or other reasons.
- The use of a medication in an excessive dose (including duplicate therapy) or for excessive duration, thereby placing the resident at greater risk for adverse consequences or causing existing adverse consequences.

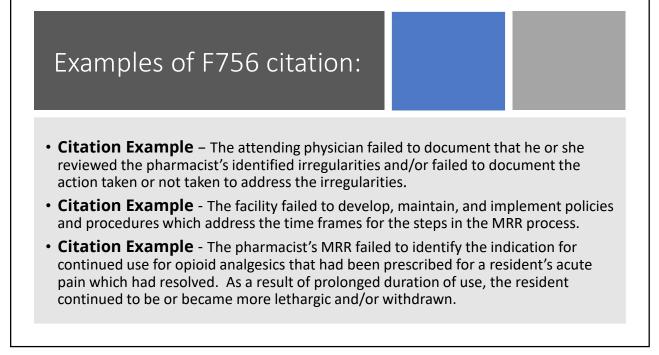
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#### **F756 – Examples of Irregularities**

- The presence of an adverse consequence associated with the resident's current medication regimen.
- The use of a medication without evidence of adequate monitoring; i.e., either inadequate monitoring of the response to a medication or an inadequate response to the findings.
- Presence of medication errors or the risk for such errors.
- Presence of a clinical condition that might warrant initiation of medication therapy.









#### F757 – Questions

- 1) True or False: Warfarin is dosed with a PT / INR lab Q month ordered. This lab monitoring meets CMS' requirement for monitoring residents on anticoagulant medication.
- 2) True or False: When furosemide is dosed, the resident should be monitored for edema with the results documented in record.
- **3) True or False:** OTC medication orders do not require a documented medical diagnosis in the record.

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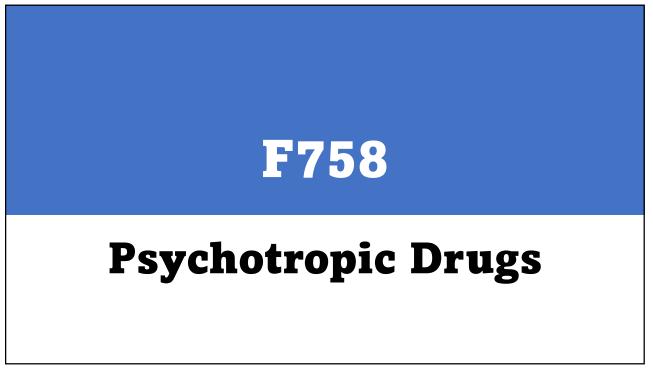
#### F757 – Unnecessary Medication Definition

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

- \* In excessive dose (including duplicate drug therapy)
- \* For excessive duration
- \* Without adequate monitoring
- \* Without adequate indications for its use
- \* In the presence of adverse consequences which indicate the dose should be reduced or discontinued

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Examples of F757 citation:				
• <b>Citation Example</b> – 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.				
<ul> <li>Citation Example – Facility failure to identify and act upon minor symptoms of allergic response to medications, such as a rash.</li> </ul>				



# F758 Psychotropic medication definition

A psychotropic drug is **any drug that affects** brain activities associated with mental processes and behavior.

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#### F758 Psychotropic drugs

These drugs include, **but are not limited to**, drugs in the following categories:

- 1. Anti-psychotic
- 2. Anti-depressant
- 3. Anti-anxiety
- 4. Hypnotic

#### F758 Psychotropic drugs

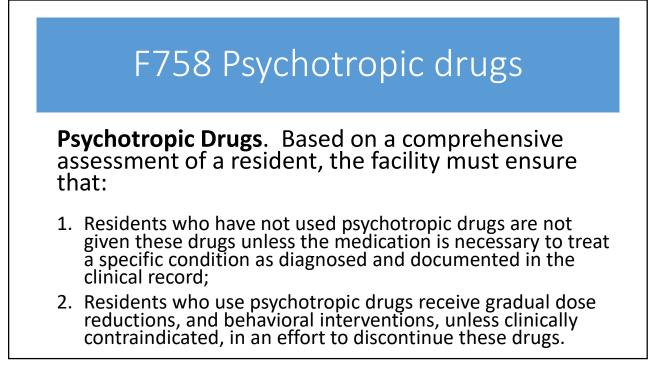
Other medications which may affect brain activity include:

- central nervous system agents
- mood stabilizers
- anticonvulsants
- muscle relaxants
- anti-cholinergic medications
- antihistamines
- NMDA receptor modulators
- OTC natural and herbal products

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#### Per Appendix PP:

- Categories of medications which affect brain activity include antihistamines, anticholinergic medications and central nervous system agents used to treat conditions such as seizures, mood disorders, pseuodobulbar affect, and muscle spasms or stiffness. The requirements pertaining to psychotropic medications apply to these types of medications when their documented use appears to be a substitution for another psychotropic medication.
- For example, if a resident is prescribed valproic acid and the medical record shows no history of seizures but there is documentation that the medication is being used to treat agitation or other expressions of distress, then the use of valproic acid should be consistent with the psychotropic medication requirements under §483.45(e).
- Residents who take these medications must be monitored for any adverse consequences, specifically increased confusion or over-sedation, as required by §483.45(d)(3). Concerns related to the use of the medications noted here would be investigated at F757, Unnecessary Medications, if the medication is being used for its original or approved indication and not primarily as a psychotropic medication.



## Updated F758 – Free from Unnecessary Psychotropic Meds / PRN Use

Clarification on the definition of psychotropic medication, PRN use and schizophrenia - New guidance

# F758 Gradual Dose Reduction

"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.

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#### F758 Gradual Dose Reduction

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.

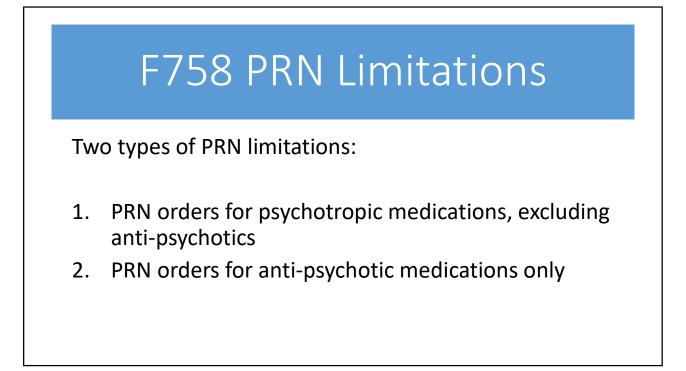
## F758 Psychotropic drugs

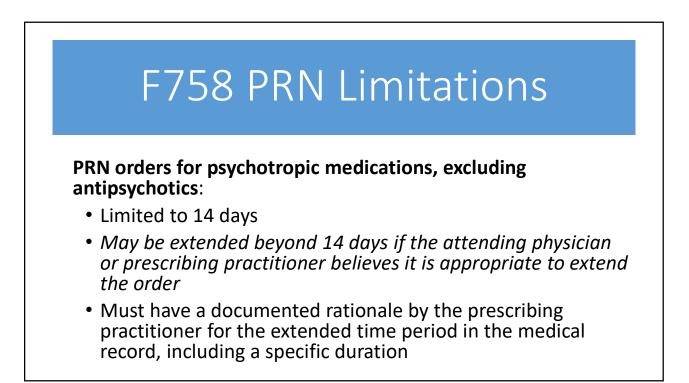
**NOTE:** Gradual dose reductions may not be appropriate for specific, enduring, progressive, or terminal conditions such as chronic depression, Parkinson's disease psychosis, or recurrent seizures.

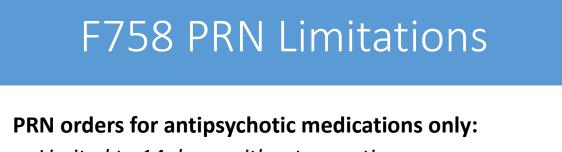
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### F758 Psychotropic drugs

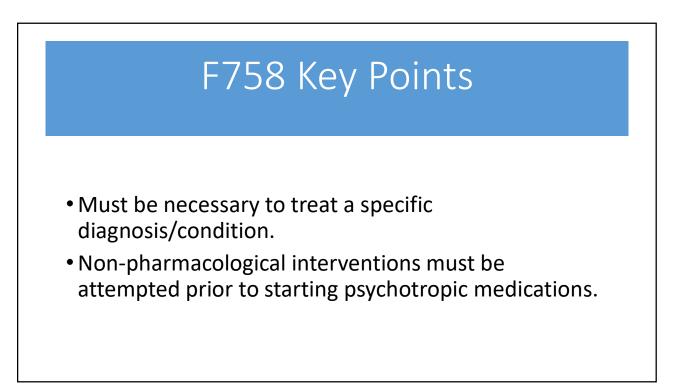
The regulations and guidance are intended to ensure psychotropic medications are used only when the medication(s) is appropriate to *treat a resident's specific, diagnosed, and documented condition* and the medication(s) *is beneficial to the resident,* as demonstrated by monitoring and documentation of the resident's response to the medication(s).

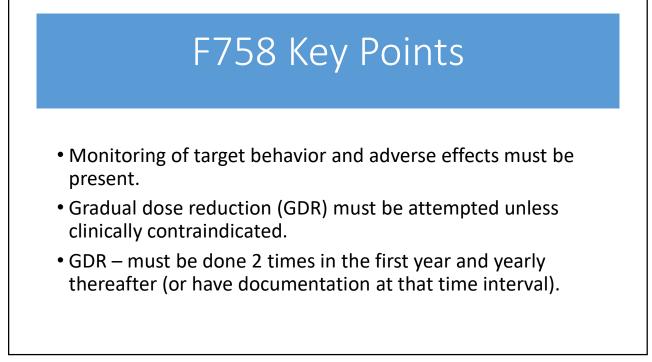


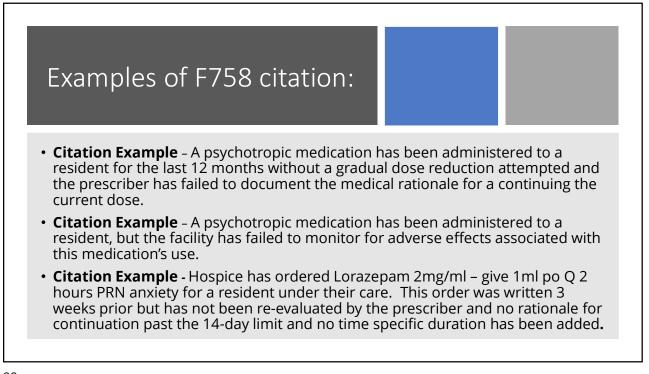




- Limited to 14 days, without exception
- If the prescribing practitioner wishes to write a new order for the PRN antipsychotic, they must first evaluate the resident to determine if the new order for the PRN antipsychotic is appropriate



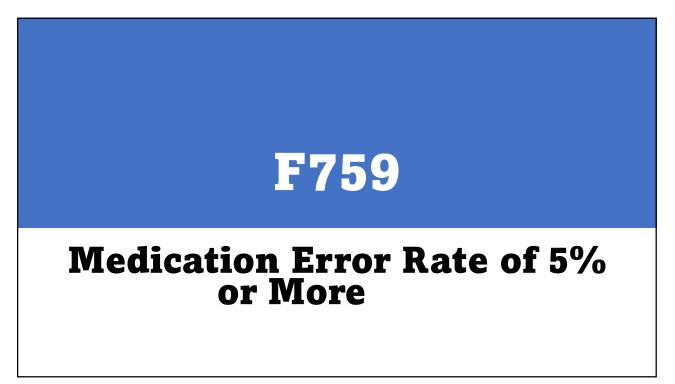




# F757 or F758?

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

For all other medication concerns, investigate compliance with F757.





### F579

Ensure facility medication error rates are NOT 5% or greater

Surveyors may identify errors from multiple sources: MAR discrepancies, watching medication pass, interviewing resident

#### Non-significant medication error:

- Omission of docusate, artificial tears, etc.
- Wrong time of dose: dosed docusate at 8am but scheduled for 8pm



### Free From Significant Medication Errors

## **F760 Significant Med Error**

**Significant** - means one which causes the resident discomfort or jeopardizes his or her health and safety.

- Omission of digoxin, insulin, etc.
- Administered insulin to the wrong resident, etc.
- Significant medication errors cited under F760 (regardless of 5% error)

# **F761**

## Label / Store Drugs

F761-Label/Store Drugs

- Labeled in accordance with professional principles, expiration date, cautionary instructions.
- Ensure medications and biologicals are stored at their appropriate temperatures according to manufacturer and/or USP guidelines for temperature ranges.
- Facility should ensure that medications and biologicals for expired and/or discharged residents are stored separately, away from use, until destroyed or disposed of.





### F881 Antibiotic Stewardship

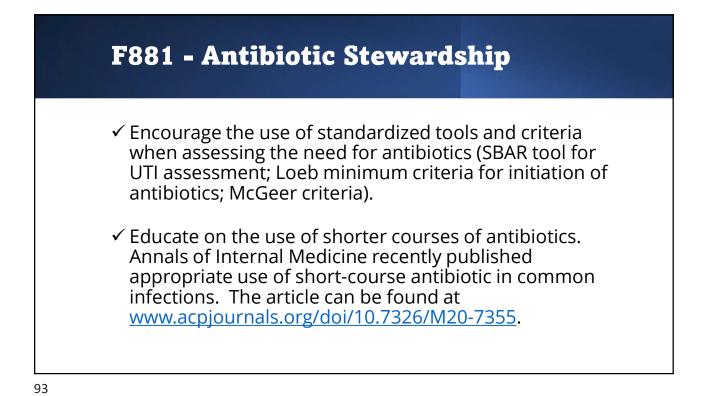
The intent of the Antibiotic Stewardship Program is to ensure:

- Residents who require antibiotics are prescribed the appropriate antibiotic to optimize the treatment of infections with the correct indication, dose and duration.
- The risk of adverse events is reduced by ensuring that unnecessary/inappropriate antibiotic use does not occur, which could lead to the development of antibiotic-resistant organisms.
- That the facility has developed, promoted and implemented a facility-wide system to monitor the use of antibiotics.

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### **F881 - Antibiotic Stewardship**

The Antibiotic Stewardship Program should include antibiotic use protocols that utilize an infection assessment tool, have ongoing monitoring of antibiotic use, and feedback and education to prescribing providers.



F881 - Antibiotic Stewardship

The consultant pharmacist is expected to conduct the MRR at least monthly, and to include a review of the resident's medical record. That review should include the assessment, monitoring and communication of antibiotic use.

### **Per Appendix PP:**

 If there are concerns with the ASP, surveyors must include at least one resident on an antibiotic in the resident sample Advanced Copy to assess whether the resident(s) is being prescribed an antibiotic(s) unnecessarily and whether there were any negative outcomes such as an adverse drug event. Instances of prescribing antibiotics unnecessarily should be cited at F757. These findings may support citing F881, as well, in which case the surveyor must also show that the facility does not have or is not implementing an ASP.

• F756 can also be cited (Drug Regimen Review).

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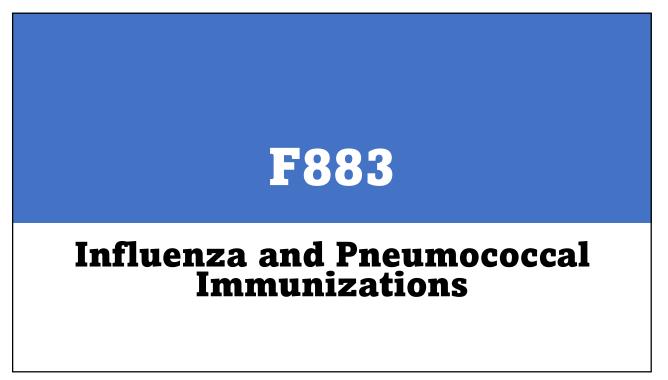
## F881 - Antibiotic Stewardship

#### The facility must:

- 1. Develop and implement antibiotic use protocols to address the treatment of infections by ensuring that residents who require antibiotics are prescribed the appropriate antibiotics;
- 2. Develop and implement antibiotic use protocols that address unnecessary or inappropriate antibiotic use thereby reducing the risk of adverse events, including the development of antibiotic-resistant organisms; and/or
- 3. Develop, promote and implement a facility-wide system to monitor the use of antibiotics

### **Per the Appendix PP:**

If there are concerns with the Antibiotic Stewardship Program, surveyors must include at least one resident on an antibiotic in the resident sample to assess whether the resident(s) is being prescribed an antibiotic(s) unnecessarily and whether there were any negative outcomes such as an adverse drug event. Instances of prescribing antibiotics unnecessarily should be cited at F757. These findings may support citing F881, as well, in which case the surveyor must also show that the facility does not have or is not implementing an ASP.



### F883 – Influenza and Pneumococcal Immunizations

For both influenza and pneumococcal immunizations, facilities are required to do several things:

- Provide residents with education on both the benefits and potential side effects risk of the immunization.
- Provide resident / representative with the opportunity to refuse.
- For influenza, residents must be offered the immunization between October 1 and March 31 on an annual basis.
- Pneumococcal immunizations, facilities are expected to follow CDC and ACIP (Advisory Committee on Immunization Practices) recommendations.
- Facilities need to have a protocol in place for the administration of PPSV23 and PCV13.
- Document education provided, immunization dosed (or not dosed with the reason).



#### F605: KEY ELEMENTS OF NONCOMPLIANCE

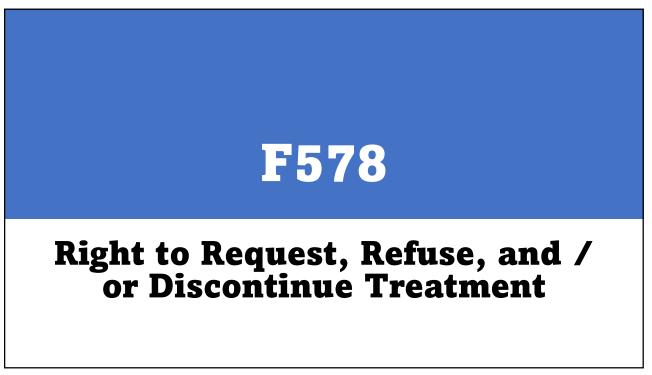
To cite deficient practice at F605, the surveyor's investigation will generally show that the facility has failed, in one or more areas, to do any one or more of the following:

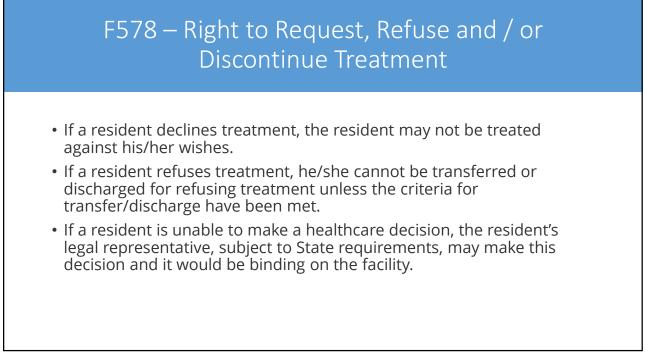
- Assure that the resident is free from restraints imposed for discipline or staff convenience (convenience can be caused intentionally or unintentionally by staff);
- Identify medical symptoms that were being treated with the use of a chemical restraint;
- If a chemical restraint is in use, the facility:
  - Provides the least restrictive alternative for the least time possible, including and as appropriate, developing and implementing a plan for gradual dose reduction, in the absence of identified and documented clinical contraindications;
  - Monitors and evaluates the resident's response to the medication; and
  - Discontinues the use of the medication when the medical symptom is no longer being treated, unless reducing or eliminating the use of the medication may be clinically contraindicated

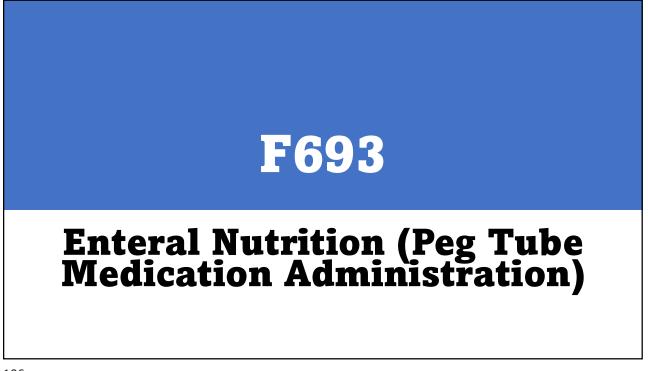


### F554 – Right to Self Administer

The resident has a right to self-administer medications if the IDT has determined that it is clinically appropriate and safe for the resident to do so.

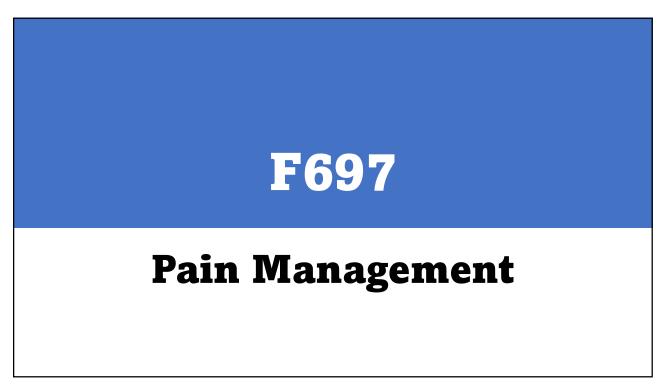






### F693 – Peg Tube Administration

- The standard of practice is that crushed medications should not be combined and given all at once via feeding tube.
- Crushing and combining medications may result in physical and chemical incompatibilities leading to an altered therapeutic response, or cause feeding tube occlusions when the crushed medications are combined and administered via feeding tube.
- Flushing the feeding tube between each medication is also standard of practice.



### F697 – Pain Management

The facility must ensure that pain management is provided to residents who require such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

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#### F697 – Pain Management

- Risk are even greater for adults aged 65 and older (high risk for falls and hip fractures, cognitive impairment/confusion, daytime fatigue, and delirium.
- If concurrent use of opioids and benzodiazepines is clinically indicated for an individual resident, the resident should be closely monitored for adverse consequences.

Consultant Pharmacist – Role in risk mitigation

#### How can we help the homes avoid these tags?

- Policy and procedures
  - Verify P&P in place and are being followed
  - Be a part in developing / updating policies and practices
- Educate the nursing staff and prescribers
  - Facility policies
  - Medication issues (empty stomach, do not crush, etc.)
  - Medication pass observations / education
  - Antibiotics (UA with C&S, durations, adverse effects, etc.)
  - In-services
- Monitoring and reviewing documentation
  - Review clinical notes for medication adverse effects and effectiveness (nurse and prescriber)
  - Audit MAR to verify documentation (missing dosing, insulin sites, etc.)
  - Psychotropic monitoring (target behavior, adverse effects)
  - Anticoagulant monitoring (bleeding)
  - Diabetic monitoring (glucose, etc.)
- Medication procurement / storage
  - Review ordering / reordering process
  - Audit medication availability and storage
  - Verify medication is being stored securely, accounted for (control substances)