



Guardian Consulting Services, Inc.  
Consultant Pharmacists for Healthcare Facilities

## Pharmacy F-Tag and Survey Updates - *What You Need To Know!*

*Presented by:*

**Dr. William C. Hallett, Pharm.D., MBA, BCGP, C-MTM**  
*President/CEO – Guardian Consulting Services, Inc.*

[whallett@guardianconsulting.com](mailto:whallett@guardianconsulting.com)

(855) 625-6235

---

---

---

---

---

---

---

---



Guardian Consulting Services, Inc.  
Consultant Pharmacists for Healthcare Facilities

## Goals for the Day

1. Review the Pharmacy related sections of the recently released updates to the State Operations Manual
2. Provide an overview of what we are seeing and experiencing in recent surveys
3. Outline practical compliance strategies

---

---

---

---

---

---

---

---



Guardian Consulting Services, Inc.  
Consultant Pharmacists for Healthcare Facilities

## State Operations Manual (SOM) Appendix PP

**Better known as the F-Tags**

- **AKA the “Guidance to Surveyors”**
- Full re-write released June 30<sup>th</sup>, 2017; went into effect **November 28, 2017**
- Written to accompany the November 2016 Final Rule, AKA the “Mega Rule” Regulations
- **696 Total Pages** of Regulations and Guidance
- This re-write represents a total re-numbering (and expansion!) of the F-Tags as we had known them!

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### State Operations Manual Appendix PP Update

#### Pharmacy Related Ftags Crosswalk:

F755: Pharmacy Services (Formerly F425)  
F756: Drug Regimen Review (Formerly F428)  
F757/F758: Unnecessary Medications/Psychotropic Medications (Formerly F329 plus NEW)  
F759/F760: Medication Errors (Formerly F332/F333)  
F761: Labeling and Storage of Medications (Formerly F431)  
F881: Infection Prevention and Control Program; Antibiotic Stewardship (NEW)  
F883: Influenza and Pneumococcal Immunizations (Formerly F334)

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### State Operations Manual Appendix PP Update

**F757 Unnecessary Medications**  
**F758: Psychotropic Medications**

**For all the changes, it's (mostly) still all  
about (preventing mis)use in *DEMENTIA*.**

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### F757: Unnecessary Medications and F758: Psychotropic Medications – 28 Pages

F757

§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.

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### F758: Psychotropic Medications

**F758**

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

**§483.45(e)(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;

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

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### F758: Psychotropic Medications, *continued...*

**§483.45(c)(3)** *Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and*

**§483.45(c)(4)** *PRN orders for psychotropic drugs are limited to 14 days. Except as provided in §483.45(c)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.*

**§483.45(c)(5)** *PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.*

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### F758: Psychotropic Medications

#### Key requirements, restated: Specific Conditions; GDR; Time Limits on PRN's

*With regard to psychotropic medications, the regulations additionally require:*

- *Giving psychotropic medications only when necessary to treat a specific diagnosed and documented condition;*
- *Implementing GDR and other non-pharmacologic interventions for residents who receive psychotropic medications, unless contraindicated; and*
- *Limiting the timeframe for PRN psychotropic medications, which **are not** antipsychotic medications, to 14 days, unless a longer timeframe is deemed appropriate by the attending physician or the prescribing practitioner.*
- *Limiting PRN psychotropic medications, which **are** antipsychotic medications, to 14 days and not entering a new order without first evaluating the resident.*

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

## F758: Psychotropic Medications

### Definition of a psychotropic drug:

*"Psychotropic drug" is defined in the regulations at §483.45(c)(3), as "any drug that affects brain activities associated with mental processes and behavior." Psychotropic drugs include, but are not limited to the following categories: anti-psychotics, anti-depressants, anti-anxiety, and hypnotics.*

### Gradual Dose Reduction Requirements:

Within the first year in which a resident is admitted on a *psychotropic* medication or after the *prescribing practitioner* has initiated a *psychotropic* 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.

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

## F758: Psychotropic Medications

### Determining when GDR is "Clinically Contraindicated":

For any individual who is receiving a *psychotropic* medication to treat a disorder other than *expressions or indications of distress* related to dementia (for example, schizophrenia, bipolar mania, depression with psychotic features, or another medical condition, other than dementia, which may cause psychosis), the GDR may be considered *clinically contraindicated* for reasons that include, but that are not limited to:

- 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 exacerbate an underlying medical or 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 exacerbate an underlying medical or psychiatric disorder.

**Enduring Conditions: Psychotropic medications may be used to treat an enduring (i.e., nonacute; chronic or prolonged) condition.**

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

## F758: Psychotropic Medications

### Documenting "Clinically Contraindicated":

**Scenario 1: Chronic Enduring Condition such as Schizophrenia, Bipolar Disorder, Major Depression:**

*"Continue Seroquel for chronic enduring condition of Bipolar disorder. Gradual dose reduction clinically contraindicated, resident highly likely to deteriorate and become a danger to self and others."*

**Scenario 2: Other chronic conditions OTHER THAN DEMENTIA that result in psychosis**

*"Continue Risperdal for chronic psychosis related to Traumatic Brain Injury. Gradual dose reduction clinically contraindicated, resident highly likely to deteriorate and become a danger to self and others."*

**\*\* In ALL OTHER SCENARIOS: Gradual Dose Reduction (GDR) in an effort to D/C MUST be attempted and fail in 2 consecutive quarters before GDR can be considered "Clinically Contraindicated".**

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### F758: Psychotropic Medications

#### Recent Survey Activity and Recommendations:

1. **REMEMBER: The focus remains on DEMENTIA**
  - a) *Make sure you are identifying residents on psychotropics that have the word "Dementia" in the diagnosis. These WILL be the easy targets.*
2. **Be prepared to defend appropriate, long term use without GDR use in Major Depression**
3. **Beware of "Class Shifting"**
  - a) *Anxiolytics (ex: Ativan, Xanax), Anticonvulsants for behaviors, and Antidepressants (for uses other than depression) are becoming just as big a focus!*
4. **Don't fall into the trap of "Diagnosis Drift"**
  - a) *Don't write Schizophrenia (or Bipolar Disorder) unless the diagnosis is REAL*
  - b) *Key: Understanding the difference between the Survey Process and the CMS Five Star Quality Measures on Antipsychotics*
5. **Run and analyze reports from your EMR, or.....**

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### F758: Psychotropic Medications

#### Guidance on PRN Antipsychotics and Psychotropics

#### PRN Psychotropics (Other than Antipsychotics):

- 14 days, may be extended beyond 14 days provided rationale is documented by the practitioner and the time duration is specified.
  - *This INCLUDES sleep induction meds such as Zolpidem (Ambien).*

#### PRN Antipsychotics:

- Max 14 days, *no exceptions*. If the practitioner wishes to write a new PRN order, may only do so after "evaluating the resident".
  - *Hospice is NOT excluded from this guidance.*

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### F758: Psychotropic Medications

#### Definition of "Evaluating" = "directly examining the resident"

*The required evaluation of a resident before writing a new PRN order for an antipsychotic entails the attending physician or prescribing practitioner directly examining the resident and assessing the resident's current condition and progress to determine if the PRN antipsychotic medication is still needed. As part of the evaluation, the attending physician or prescribing practitioner should, at a minimum, determine and document the following in the resident's medical record:*

- *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?*

**Compliance Strategy:** *Continue to avoid PRN antipsychotics and psychotropics to the absolute greatest extent possible.*

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

## F758: Psychotropic Medications

### Examples of Key Elements of Noncompliance

#### *Psychotropic Medications*

- Failure to present to the attending physician or prescribing practitioner the need to attempt GDR in the absence of identified and documented clinical contraindications; or
- Use of psychotropic medication(s) without documentation of the need for the medication(s) to treat a specific diagnosed condition; or
- PRN psychotropic medication ordered for longer than 14 days, without a documented rationale for continued use; or
- Failure to implement person-centered, non-pharmacological approaches in the attempt to reduce or discontinue a psychotropic medication; or
- Administering a new PRN antipsychotic medication for which the resident had a previous PRN order (for 14 days) but the medical record does not show that the attending physician or prescribing practitioner evaluated the resident for the appropriateness of the new order for the medication.

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

## State Operations Manual

### F755: Pharmacy Services – 14 pages

#### F755

##### §483.45 Pharmacy Services

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.70(g). The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

§483.45(a) Procedures. 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.

§483.45(b) Service Consultation. The facility must employ or obtain the services of a licensed pharmacist who—

§483.45(b)(1) Provides consultation on all aspects of the provision of pharmacy services in the facility.

§483.45(b)(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

§483.45(b)(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

## F755: Pharmacy Services

### Consultant Pharmacist's responsibility for oversight of Controlled Drug recordkeeping:

§483.45(b)(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

§483.45(b)(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

*NOTE: The pharmacist is not required by these regulations to perform the reconciliation of medications, but rather to evaluate and determine that the facility maintains an accurate account of all controlled medications and completes the reconciliation according to its procedures, consistent with State and federal requirements.*

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### F755: Pharmacy Services

#### Borrowing of Medications as a source of medication errors:

*NOTE: Facility staff may encounter situations in which a medication is not available in the resident's supply or the facility's emergency medication supply and then decide to "borrow" medications from another resident's supply. This practice of borrowing medications from other residents' supplies is not consistent with professional standards and contributes to medication errors. Concerns about whether the facility has a system in place to ensure each resident has a sufficient supply of medications for timely administration should be cited under this tag Pharmacy Services (F755). However, if staff borrow any medication from another resident's supply due to failure to order the medication and/or not following the facility's system for reordering medications, refer to §483.21, F658, Services Provided Meet Professional Standards. Instances of "borrowing" would not be considered to be drug diversion.*

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### F755: Pharmacy Services

#### Recent Survey Experience and Compliance Strategies:

1. Medication Room Inspection is still (often) FIRST
  - a) Cleanliness counts!
  - b) Focus: Expired meds; Refrigerators; Ekits; Narc Boxes
2. Expanded checks on controlled substance accountability
  - a) Checks of narc box locks; refrigerated narcs
  - b) Presence of expired/discontinued narcs on unit
  - c) Examining descending counts sheets for missing signatures
3. Separate BNE Inspections
  - a) Often occur on day of scheduled narcotic inspections
  - b) Includes checks of how discontinued controlled substances are stored after collection and awaiting destruction
  - c) Make sure your policies and procedures are in order!

1) Applicable regulations appear at Title 10 NYCRR 80.49 and 80.50

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### F756: Drug Regimen Review – 10 pages

F756

§483.45(c) Drug Regimen Review.

§483.45(c)(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

§483.45(c)(2) This review must include a review of the resident's medical chart.

§483.45(c)(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.

§483.45(c)(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.

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### F756: Drug Regimen Review

:

#### Time Frames for Response to DRR's; Handling of "Urgent" findings

*Facilities must develop policies and procedures to address the MRR. The policies and procedures must specifically address:*

- The appropriate time frames for the different steps in the MRR process; and
- The steps a pharmacist must follow when he or she identifies an irregularity that requires immediate action to protect the resident and prevent the occurrence of an adverse drug event.

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### F756: Drug Regimen Review Documentation of Drug Regimen Review

#### Regulation:

*(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.*

#### Guidance:

*The pharmacist must document any identified irregularities in a separate, written report. The report may be in paper or electronic form. If no irregularities were identified during the review, the pharmacist includes a signed and dated statement to that effect.*

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### F756: Drug Regimen Review

#### Response to Drug Regimen Review:

*The medical record must show documentation that the attending physician reviewed any irregularities identified by the pharmacist. For those issues that require physician intervention, the attending physician either accepts and acts upon the report and recommendations or rejects all or some of the report and should document his or her rationale of why the recommendation is rejected in the resident's medical record. It is not acceptable for an attending physician to document only that he/she disagrees with the report, without providing some clinical basis for disagreeing.*

#### Compliance methods:

- Write up DRR in EMR, physician responds in EMR  
*Problem: EMR's lack ability to track "open" DRR's!*
- Write up DRR on paper, scan to EMR or file on paper chart *AFTER* physician responds (*Keep copies in binder in Nursing Office!*)
- Write up DRR on paper, physician responds, maintain in binder until after survey, THEN scan to EMR or file with paper chart.

---

---

---

---

---

---

---

---





Guardian Consulting Services, Inc.  
Consultant Pharmacists for Healthcare Facilities

### F756: Drug Regimen Review

#### Recent Survey Activity and Recommendations:

1. So far, little to no action on “prescriber response on chart”
2. Have your Medication Regimen Review policy READY.
  1. Remember: Policy must specify TIMEFRAMES.
3. Common practice: Surveyors request “6 Residents/Last 6 Months”
  - a) Surveyor requests just ONE resident? *Usually indicates there is an issue/concern.*
4. Using an EMR? Make sure you remind where the DNS/ designee where consultant Pharmacist signs

---

---

---

---

---

---

---

---



Guardian Consulting Services, Inc.  
Consultant Pharmacists for Healthcare Facilities

### F759/F760: Medication Errors – 12 Pages

#### F759

§483.45(f) Medication Errors.  
The facility must ensure that *its*—

§483.45(f)(1) Medication error rates *are not* 5 percent or greater; and

#### F760

The facility must ensure that *its*—  
§483.45(f)(2) Residents are free of any significant medication errors.

Overall – 12 pages of excellent guidance that can be useful as a “Med Pass Teaching” guide!

---

---

---

---

---

---

---

---



Guardian Consulting Services, Inc.  
Consultant Pharmacists for Healthcare Facilities

### F759/F760: Medication Errors

#### Definitions:

“Medication Error” means the observed or identified preparation or administration of medications or biologicals which is not in accordance with:

1. The prescriber’s order;
2. Manufacturer’s specifications (not recommendations) regarding the preparation and administration of the medication or biological; or
3. Accepted professional standards and principles which apply to professionals providing services. Accepted professional standards and principles include the various practice regulations in each State, and current commonly accepted health standards established by national organizations, boards, and councils.

“Significant Medication Error” means one that causes the resident discomfort or jeopardizes his or her health and safety.

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

## F759/F760: Medication Errors

### Calculating Med Error Rates:

Medication Error Rate = Number of Errors Observed divided by the Opportunities for Errors (doses given plus doses ordered but not given) X 100.

The error rate must be 5% or greater in order to cite F759. Rounding up of a lower rate (e.g., 4.6%) to a 5% rate is not permitted. A medication error rate of 5% or greater may indicate that systemic problems exist. The survey team should consider investigating additional potential noncompliance issues, such as F755– Pharmacy Services, related to the facility's medication distribution system.

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

## F759/F760: Medication Errors

### Guidance on administering crushed meds by ORAL and via the GT routes individually:

The standard of practice is that crushed medications should not be combined and given all at once, either orally (e.g., in pudding or other similar food) or 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 medications are administered via feeding tube. Additionally, a resident may not want or may be unable to finish eating the food into which combined crushed medications were added or the resident's feeding tube could malfunction, all of which could prevent complete administration of the crushed medications. In these situations, staff would not know which medications the resident actually received because they were crushed and combined but not fully administered.

**Some good news....**

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

## F759/F760: Medication Errors

**From a November 14<sup>th</sup>, 2017 correspondence to the American Society of Consultant Pharmacists Memorandum – CMS will be reversing its guidance on administering crushed ORAL medications separately:**

We will be revising the interpretive guidance to convey that best practice would be to separately crush and administer each medication with food to address concerns with physical and chemical incompatibility of crushed medications and ensure complete dosaging of each medication. However, separating crushed medications may not be appropriate for all residents and should not be counted as a medication error unless there are instructions not to crush the medication(s). Facilities should use a person-centered, individualized approach to administering all medications. If a surveyor identifies concerns related to crushing and combining oral medications, the surveyor should evaluate whether facility staff have worked with the resident/representative and appropriate clinicians (e.g., the consultant pharmacist, attending physician, medical director) to determine the most appropriate method for administering medications which considers each resident's safety, needs, medication schedule, preferences, and functional ability.

---

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### **F759/F760: Medication Errors**

***Additional areas covered in this guidance:***

- Giving adequate fluid with medications  
– *Metamucil, Alendronate, Potassium*
- Medications that *\*must\** be taken with food or antacids
- Potential for adverse consequences from herbal and dietary supplements
- Proper eye drop administration
- Metered Dose Inhaler procedures

---

---

---

---

---

---

---



**Guardian Consulting Services, Inc.**  
Consultant Pharmacists for Healthcare Facilities

### **Pharmacy F-Tag and Survey Updates - *What You Need To Know!***

***Presented by:***

**Dr. William C. Hallett, Pharm.D., MBA, BCGP, C-MTM**

*President/CEO – Guardian Consulting Services, Inc.*

[whallett@guardianconsulting.com](mailto:whallett@guardianconsulting.com)

(855) 625-6235

---

---

---

---

---

---

---