




## Drug Regimen Review

F428 CFR 483.45  
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**Objectives**

At the conclusion of this presentation you will be able to:


- Identify the revisions to the Long Term Care (LTC) regulations that impact the Pharmacy Consultant's role
- Identify criteria for compliance with the pharmacy conditions of participation
- Identify the components of a Pharmacy Review
- Identify the most frequently cited pharmacy tags

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**Disclosure**

- Ms. Cass has no actual or potential conflict of interest with this presentation.


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**Final Rule to Reform the Requirements for Long Term Care Facilities (LTC)**

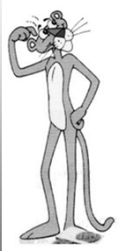
Background

- LTC requirements are health & safety standards a LTC facility must meet in order to participate in Medicare/Medicaid program
- Requirements found at 42 CFR 483 Subpart B
- Appendix PP


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**Changes**

- Last update- 1991
- 9800 public comments that resulted in revisions
- Final product represents advances in service delivery & implements sections of ACA



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**Themes of the Final LTC Rule**

- Person Centered Care
- Quality
- Facility Assessment, Competency Based Approaches
- Alignment with HHS priorities
- Implementation of legislation

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## HHS Initiatives: Crosscutting Priorities

- Reducing unnecessary hospital re-admissions;
- Reducing the incidences of healthcare acquired infections;
- Improving behavioral healthcare; and
- *Safeguarding nursing home residents from the use of unnecessary psychotropic medications*

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## Implementation of Legislation

- Sections of ACA:
  - Section 6102(b): Compliance and ethics program
  - Section 6102(c): QAPI
  - Section 6703(b)(3): Reporting to law enforcement suspicion of a crime
  - Section 6121: dementia and abuse training
  - IMPACT ACT: D/C planning requirements for SNF's

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## Phased in Implementation

- Phase 1 (November 28, 2016) minor changes to survey process and requirements
- Phase 2 (November 28, 2017) foundational elements and new survey process released (i.e. Interpretive Guidance (IG))
- Phase 3 (November 28, 2019) Implementation of system approaches to quality

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## Impact to Pharmacy Services

- Phase 1 (November 28, 2016)
  - Freedom from unnecessary medications and medication errors protection continues

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## Phase 2, November 28, 2017

- New Interpretive Guidance (IG)
- New F Tag numbering
- Revised automated LTC survey process

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## Impact to Pharmacy Services

Phase 2 (November 28, 2017 implementation)

**F329, 483.45(d) Unnecessary Drugs**

- Requires facilities to ensure that 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 .....and GDR and behavioral interventions are conducted to discontinue the drug(s)
  - Dementia Care Focused Surveys
  - PRN usage of psychotropic medications: 14 days
  - **NOTE: DIFFERENCE BETWEEN PRN PSYCHOTROPIC AND ANTIPSYCHOTIC**
- NO changes to GDR...AP...within first year, GDR in two separate quarters with at least one month between attempts and annually thereafter, unless clinically contraindicated

**F425, 483.45 Pharmacy Services: Changes limited to numbering**

**F428, 483.45 (c) Drug Regimen Review**

- Data Regimen Review: GDRS must include a review of the resident's clinical record
- Defines Psychotropic drug to include, anti-psychotic, anti-depressant, anti-anxiety, and hypnotic
- In addition to reporting irregularities to the attending MD, irregularities must also be reported to the medical director and include:
  - Irregularities refer back to 483.45(d), F329
  - Irregularities must be documented in a separate report and documented to the attending MD, medical director and DNS and include at a minimum, resident's name, relevant drug and irregularity identified
  - Alerts must respond and if no action, rationale for each
- Facility must develop and maintain P-P that includes, above with time frames for the process (that the facility will be accountable to) and steps the pharmacist must take that requires mandatory action

**F431, 483.45(b) Service Consultation: Changes limited to numbering**

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**DPH** Phase 2, F329

**§483.45(e) Psychotropic Drugs.**  
 [§483.45(e)(1)-(5) will be implemented beginning November 28, 2017 (Phase 2)]  
**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;

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**DPH** Phase 2, F329

- (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
- (4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in §483.45(e)(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.
- (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.

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**DPH** Phase 3, November 28, 2019

Ongoing implementation



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**DPH** F329, OIG Report reference

Adverse consequences related to medications are common enough to warrant serious attention and close monitoring. An Office of the Inspector General (OIG) report on adverse events in skilled nursing facilities (SNFs) found one in five SNF residents experienced at least one adverse event and 37 percent of these adverse events were related to medications.<sup>5</sup> The report found 66 percent of medication-related adverse events to be preventable because the events often occurred due to substandard treatment or insufficient monitoring. Additionally, the OIG found that the use of multiple medications often complicated the determination of the primary cause of events, particularly when the primary cause was related to another medication.

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**DPH** Knowledge Check

True or False  
 The most significant revisions to the LTC requirements, specific to pharmacy services will be implemented November 29, 2019


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**DPH** Knowledge Check

Effective 11/28/17, PRN orders for psychotropic drugs are limited to:

- A. Monthly for the first 90 days and every 60 days thereafter
- B. 14 days
- C. 14 days or documentation in medical record for rationale to extend beyond 14 days by prescriber or attending


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 **Knowledge Check**

True or False


Effective November 28, 2017, any irregularities, including unnecessary drugs identified during the drug regimen review must be documented and submitted in a separate report to the attending physician and the director of nurses.

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 **Pharmacy Review**


- Facility is required to employ or contract for pharmacy services
- Collaboration with facility and medical director to
  - Develop and maintain all P.P for pharmacy services
    - \* Reviewing, transcribing and reconciling medication orders
  - IV procedures
    - \* Warners, is consulting pharmacist involved
  - Emergency Room
    - \* Does it capture the specific needs of the facility to meet the needs of the residents
    - \* Types of medications, amounts, doses, strengths, record keeping, monitoring for expirations
  - Medication administration and errors
    - \* Medication pass
      - \* Role in reviewing medication errors... RCA
  - ID team role: RCP
  - Role on Medical Staff
    - \* Recommending the types of medication delivery systems to mitigate risk of errors
    - \* Participation in meetings
  - Drafting schedules for administering medications
    - \* In some facilities... is a two hour window enough when one nurse is administering medications to, in other many cases, 30 residents? Can consideration be given to staggered dosing and do you have input....
  - Role in QAPI
  - Drug reconciliation
  - Labeling of drugs and biologicals
  - System for storage of controlled drugs in accordance with state and federal laws and regulations
  - Medical Marijuana

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 **Compliance Criteria**


- The services of a pharmacist who provides consultation regarding all aspects of pharmaceutical services has been arranged
- Each resident receives medications and/or biologicals as ordered by the prescriber
- Policies and procedures for implementation for pharmaceutical services have been developed and revised as applicable
- Medication administration is consistent with applicable state laws and regulations

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 **Drug Regimen Review**


- Intent: to ensure that each resident's achieves their highest practicable level of functioning
- Monthly (at least, may be more frequent depending on resident condition or risks) review
  - Includes residents on respite care, end of life care, anticipated stay less than 30 days, and sig change

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 **Drug Regimen Review**

- Considerations for monthly review:
  - MD and staff have documented objective findings appropriate diagnosis to support indication for use
  - Allergies
  - Potential side effects
  - Dose, frequency, route, duration consistent with resident diagnosis/condition, manufacturer's recommendations, and standards of practice
  - Have MD and staff documented progress toward goal of specific medication therapy
  - Labs, diagnostic studies, or other measurement tools (I+O, bowel function)
  - Medication errors exist or circumstances exist to make them likely to occur
  - Staff are monitoring for worsening of an existing problem
  - Potential interactions of medications
  - IDENTIFICATION OF UNNECESSARY MEDICATIONS

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 **F329 Unnecessary Medications**

- Use of medication without identifiable evidence of adequate indications for use
- Use of medication to treat a clinical condition without identifiable evidence that safer alternatives or more clinically appropriate medications have been considered
- Appropriateness of timing of administration, dosing intervals, sufficiency of dose, techniques of administration, or other reasons
- *Safeguarding nursing home residents from the use of unnecessary psychotropic medications (HHS Priority)*

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## Unnecessary Medications

**Unnecessary Meds/Med Regimen Review Critical Element Pathway**

Use for a sampled resident who has potentially unnecessary medication and has experienced a potential adverse outcome to determine whether facility practices are in place to identify, evaluate, and intervene for potential or actual unnecessary medications.

**\*\*If the resident has a diagnosis of dementia and is receiving any psychopharmacological medications (including but not limited to antipsychotic medications) the surveyor should refer to the checklist "Care for a Resident with Dementia" as a guide to determine the facility's compliance at F309.\*\***

**Review the following to guide your observations and interviews**

- Review all of the cases currently ordered and/or discontinued by the prescriber going back to the most recent signed requisition. (Refer to the guidance at F329 of the SDH, Appendix PP, Utilize Tables I and II). Dementia if the facility:
  - Documents an acceptable clinical indication for use
    - The following are not appropriate reasons to use antipsychotics
      - Wandering, restlessness or mild anxiety
      - Post-fall-care or assistance or assistance to surroundings
      - Incontinent
      - Incontinence
      - Sadness or crying alone that is not related to depression or other psychiatric disorders
      - Tidying up surroundings
      - Uncooperativeness (e.g., refusal difficulty receiving care)
  - Demonstrates monitoring for each medication as appropriate
    - The following high risk needs should be monitored
      - Narcotics - assess pain, implement bowel program
      - Anticholinergic -blurred vision, PT/DTX, interaction with other medications
      - Diuretic- edema, K<sup>+</sup> level, signs of electrolyte imbalance
      - Track appropriate behaviors for all psychotropic medications
        - Hypotension, causes for incontinence, loss of sleep
        - Subsidence, delirious/ delirium, effectiveness
    - Demonstrates appropriate dosing of each medication
      - In these documentation of a rationale for any med that exceeds the manufacturer's recommendations, clinical practice guidelines, evidence based

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## Unnecessary Medications

**Unnecessary Meds/Med Regimen Review Critical Element Pathway**

**Review the following to guide your observations and interviews (continued)**

- Did the pharmacist conduct a MRE (medication regimen review)?
  - Did the pharmacist identify and report any need for simplification?
  - Did the MD and DON act on the reported simplification?
- Aligns.
- The most recent comprehensive MDR-CAAS (focus on areas pertinent to the needs ordered such as adverse consequences and behaviors, etc.), and
- Care plan for high risk needs and individualized interventions, including non-pharmacological interventions.

**Observation**

Make observations as appropriate, over various shifts to corroborate the information obtained during the record review. You may also find it important to make further observations for information obtained from staff interviews. Potential pertinent observations are listed below. If further guidance is needed, surveyors should refer to the regulation and life as they conduct the observations.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li><input type="checkbox"/> Are care planned interventions implemented for needs that pose a high risk for adverse consequences?</li> <li><input type="checkbox"/> Are non-pharmacological interventions being used?</li> <li><input type="checkbox"/> Observe for need effectiveness such as:                             <ul style="list-style-type: none"> <li>Anaphylaxis - is pain relieved?</li> <li>Psychomotor - is identified behavior/need addressed?</li> <li>How does staff respond and interact with the resident?</li> <li>Does staff address the resident request for a need appropriately?</li> <li>Does the resident show signs of behavior concerns?</li> <li>Does staff appropriately interact when the resident shows mood or behavior concerns (e.g., redirected, invited to an activity)?</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li><input type="checkbox"/> Observe for side effects and/or adverse consequences that may be related to the resident's current medication regimen                             <ul style="list-style-type: none"> <li>Apparent unexplained weight changes, edema;</li> <li>Behavioral changes or unusual behavior patterns;</li> <li>Mental status changes or decline in physical functioning;</li> <li>Seclusion (excessive), changes in alertness;</li> <li>Incontinence or sleep disturbances;</li> <li>Falls, pressure;</li> <li>Bleeding or bruising, spontaneous or unexplained;</li> <li>Frequent changes;</li> <li>Bowel dysfunction, urinary retention, incontinence;</li> <li>Delirium or swallowing difficulty;</li> <li>Falls, dizziness, or headache, and</li> </ul> </li> </ul> |
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## F329

For one medical record reviewed, the facility failed to identify adequate indications for the implementation of an antipsychotic medication and consistently monitor one resident's behaviors subsequent to initiation of antipsychotic therapy. The findings are based on review of the clinical record and a review of policy and procedures and include the following:

Resident #1A was admitted with diagnosis inclusive of syncope, hypertension, and cellulitis. MDS assessments dated 10/15/02, 10/24/02, 11/8/02 and 12/8/02 identified no behavioral problems. Behavioral health consults from 12/18/02 through 1/15/03 identified that the resident was referred for anxiety and agitation that was more pronounced on the evening shift. The consults indicated that delusional and paranoid behaviors were present with the diagnosis of dementia with delusions assigned. Serenol was added with the dose increased to 50 milligrams (mg) at 1:00PM on 1/15/03 and 100mg at 5:00PM on 1/24/03.

According to the Physician's Desk Reference 2002, Edition 56, 2002, page 685, Serenol is indicated for the treatment of schizophrenia with warnings and/or precautions that included orthostatic hypotension, neuroleptic malignant syndrome, tardive dyskinesia, and the development of cataracts. Review of the policy and procedure for antipsychotic drugs indicates that antipsychotic drugs should not be used unless the clinical record documents that the resident's organic mental syndrome with associated psychotic behaviors have been quantitatively and objectively documented.

Although review of the behavioral health consults indicated delusional and paranoid behavior, review of the nurse notes, MDS assessments, and physician progress notes from 10/15/02 through 1/15/03 failed to identify any such behaviors. Additionally, documentation was lacking which identified any target behaviors to support the administration of Serenol. During an interview with the Medical Director on 7/25/03, he stated that the resident "got a little frustrated and combative at times". Additionally, he stated that Serenol helps with sleep and that's why it was ordered.

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## What has been your role when non-compliance has been identified?

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## Medication Storage

**Medication Storage and Labeling**

- Medications and biologicals in medication rooms, carts, boxes, and refrigerators were maintained within:
  - Secured (locked) locations, accessible only to designated staff;
  - Clean and sanitary conditions; and
  - Proper temperatures in accordance with manufacturer specifications.
- Schedule II controlled medications (excluding single-unit packaging in minimal quantities that can readily be detected if missing) were maintained within a separately locked permanently affixed compartment.
- Sufficiently detailed records of receipt and disposition of controlled medications were maintained to enable an accurate reconciliation.
- All medication records were in order and an account of all controlled medications was maintained and periodically reconciled.
- Were medications and biologicals labeled in accordance with currently accepted professional principles, and include:
  - Appropriate accessory and cautionary instructions, and
  - Expiration date, when applicable.

Unit or area where the medication storage task was conducted: \_\_\_\_\_

1. Are all medications and biologicals stored and labeled properly (medication rooms, carts, boxes, refrigerators)?  Yes  No **F431**

Notes

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## Knowledge Check

Which of the following is not a requirement of Pharmacy Services in LTC facilities?

- Provide routine and emergency medication and biologicals (or obtain them under an agreement)
- The facility must have procedures for pharmaceutical services to meet the residents needs that assure the accurate acquisition, receipt, dispensing, and administration of all medications and biologicals
- The Consultant Pharmacist determines who shall administer medications
- The facility must have a licensed pharmacist who provides consultation and oversees all aspects of the pharmaceutical services


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 **Knowledge Check**

Which of the following are components of the drug regimen review:

1. Reviewing for unnecessary drugs in the resident's medication regime
2. Whether the medication dose, frequency, route of administration, and duration are ordered and administered in accordance with standards of care
3. Reviewing for medication errors or assessing to see if circumstances exist that make an error likely to occur
4. Reviewing to ascertain if the physician has ordered and/or staff have obtain laboratory results as applicable


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 **Frequency of Pharmacy Citations**

F329; FY 2016


- 12<sup>th</sup> most frequently cited citation, 11.9% of providers, 5.7% of surveys
- Region 1 Frequency: 127 citations for F329
  - CT: 76
  - Maine: 13
  - Massachusetts: 20
  - New Hampshire: 1
  - Rhode Island: 9
  - Vermont: 8

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 **Why so many more in CT???**

- Review of 2016 citations
  - QIS
  - No themes
    - Failure to monitor behaviors
    - No indication for use
    - Failure to complete an AIMS
    - GDR: rare
    - In several, F428 cited. While the pharmacy consultant's report identified the need, the facility did not act
  - Can we talk.....
    - Orthostatic blood pressures and antipsychotic medications


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 **Citation Frequency**

F425, Pharmaceutical Services

- Cited 41 times in Region 1
  - CT: 8
  - Maine: 6
  - Massachusetts: 18
  - New Hampshire: 2
  - Rhode Island: 6
  - Vermont: 1


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 **Citation Frequency**

F428, Drug Regimen Regime

- Cited 45 times in Region 1
  - CT: 21
  - Maine: 4
  - Massachusetts: 7
  - New Hampshire: 1
  - Rhode Island: 5
  - Vermont: 7

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 **Citation Frequency**

F431, Drug Record/Labelling/Store Drugs and Biologicals

- Cited 153 times in Region 1
  - CT: 43
  - Maine: 19
  - Massachusetts: 72
  - New Hampshire: 9
  - Rhode Island: 1
  - Vermont: 9

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**Knowledge Check**

Within Pharmacy Services, what s the most frequently cited citation?

1. F329
2. F425
3. F428
4. F431

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**Investigation**

**Allegation:**  
The resident was on 3 different medications that put him at risk for bleeding. The resident was not monitored properly.

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**Fact Pattern**

- Admission diagnoses:
  - Chopart's amputation
  - Paroxysmal atrial fibrillation
  - CAD
  - Hx of MI
- Review of hospital documentation identified early in admission, melena
- Hospital d/c orders and carried over to LTC facility included:
  - ASA 81 mg, qd
  - Xarelto 20 mg, qd
  - Plavix 75 mg, qd


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**Discussion/Conclusion**

- Review of the clinical record
  - Admission assessment
  - MD progress notes
  - RCP
  - Bowel records
  - Nurse notes
- Interviews
  - MD and APRN

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**Questions**



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