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Disclosure Statement

Norman Pillsbury, Pharm.D., BCPS has disclosed that he has no relevant financial disclosures. No one else in a position to control content has any financial relationships to disclose.

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

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Objectives

At the completion of this activity, the participant will be able to:

- Describe the primary and secondary responsibilities of a consultant pharmacist in the long term care setting
- Discuss the Federal Indicators used in performing a Medication Regimen Review
- Discuss Beer's Criteria and apply it to long term care practice

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Professionalism

- **A Consultant Pharmacist should:**
  - Conduct an entrance conference upon arrival to the facility and an exit conference when consultant pharmacist services are completed for that month with nursing and administrative leadership. Key point to establish a good working relationship with your facility leadership.
  - Provide assistance (by telephone if necessary, ensuring HIPAA requirements) with issues or questions that arise regarding from the survey team at the facility. Consultant Pharmacists will request attendance by facility representative when having discussions with surveyors.

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Discussion Points

- Expectations for Consultant Pharmacist visit
- General Pharmacy Concerns (service, delivery, billing)
- Cost Savings Opportunities
  - Patient Specific Therapeutic Interchange
  - Utilization Management Review

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Discussion Points

- Clinical Focus
  - Eliminate Inappropriate Antipsychotic Utilization
  - Eliminate High Risk Meds in the Elderly
  - Avoidance of Re-Hospitalization
  - Implementation of MegaRule and the IMPACT Act
  - Antimicrobial Stewardship
- Survey preparation and survey readiness

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Clinical Evaluation, Assessment, and Recommendations

- The State Operations Manual F-Tags 756 (Drug Regimen Review), 757 and 758 (Unnecessary Drugs) and 881 (Antibiotic Stewardship Program) integrate regulatory compliance with appropriate pharmaceutical care through the care process. As such, a Consultant Pharmacist should:
  - Assist the facility maintain each resident's highest practicable level of physical, mental and psychosocial well-being and prevent or minimize, adverse consequences of medication therapy to the extent possible.
  - Support the appropriate use of a psychotropic drug, any drug that affects brain activities associated with mental processes and behavior, including but not limited to antipsychotics, antidepressants, antianxiety drugs, and hypnotics.
  - Assume responsibilities as a crucial member of each facility's Antibiotic Stewardship Committee.

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Clinical Evaluation, Assessment, and Recommendations

- The State Operations Manual F-Tags 756 (Drug Regimen Review), 757 and 758 (Unnecessary Drugs) and 881 (Antibiotic Stewardship Program) integrate regulatory compliance with appropriate pharmaceutical care through the care process. As such, a Consultant Pharmacist should:
  - Collaborate with facility interdisciplinary team including the facility Medical Director and other key prescribers.
  - Provide quarterly reports reflecting facility-level drug utilization and clinical management trends, with corresponding recommendations to improve clinical care delivered and potential savings using preferred drug management and formulary compliance.
  - Offer Medication-Related Education.
  - Participate in facility clinical meetings, when feasible.

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Regulatory Compliance

A Consultant Pharmacist should:

- Complete monthly medication regimen reviews using available resources and provide written reports of these reviews to the Facility Administrator, Director of Nursing, Medical Director and all residents' prescribers.
- Assist the facility in establishing a procedure to perform MRR on all residents (without exception) who are anticipated to stay in the facility less than 30 days, or who experience an "acute" change of condition, as identified by facility staff.
- Provide reports to the Facility Quality Assurance Performance Improvement Committee regarding the status of the facility's pharmaceutical services.

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Regulatory Compliance

A Consultant Pharmacist should:

- Aid the facility in developing and implementing policies and procedures to ensure compliance with federal and state regulations related to ordering, storage, handling, labeling, destruction and administration of drugs and biologicals.
- Measure the response to Consultant Pharmacist recommendations from previous visits, and based on subsequent follow-up by the facility, escalate unresolved issues as necessary.

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Regulatory Compliance

A Consultant Pharmacist should:

- Evaluate facility documentation related to behavior and adverse effect monitoring for psychotropic medications.
- Assess appropriate utilization and documentation of non-pharmacologic interventions (including multiple), either instead of, or in conjunction with, medication therapy.
- Check, using representative sampling, medication storage and labeling in common storage areas (medication carts, medication refrigerators, medication rooms).

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Regulatory Compliance

A Consultant Pharmacist should:

- Analyze controlled substance utilization, reconciliation and documentation.
- Routinely review Emergency Drug Supply contents with facility Medical Director for appropriateness.

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F309	F675 – Quality of life F684 – Quality of care F697 – Pain management	F698 – Dialysis F744 – Dementia care
F329	F757 – Unnecessary drugs - general	F758 – Psychotropic drugs
F334	F883 – Influenza and pneumococcal immunizations	
F425	F755 – Pharmacy services	
F428	F756 – Drug regimen review	F758 – Psychotropic drugs
F431	F755 – Pharmacy services F761 – Labeling/storage of drugs and biologicals	
F441	F880 – Infection control F881 – Antibiotic stewardship F882 – Infection preventionist	

Centers for Medicare and Medicaid Services. Federal Regulatory Groups for Long Term Care Facilities. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/List-of-Revised-FTags.pdf

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Medication Regimen Review (F756)

- Irregularities must be documented on a separate, written report that is sent to the attending physician, medical director, and director of nursing
  - Must include the resident's name, relevant drug, and irregularity identified
  - Irregularities must be acted upon

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Have a strategy on how to assess your patient medication profile.

- Assess documentation on the medication administration record (MAR)
- Assess allergies and diagnosis
- Labs and monitoring
- Unnecessary Medications (Beers Drugs)
- Disease State Management
- Psychotropics

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Medication Regimen Review (F756)

- **Irregularities include but not limited to criteria of Unnecessary Drugs**
  - Attending physician must document in the medical record that the identified irregularity has been reviewed, and what, if any, action has been taken to address it or rationale for no change
  - Facility must develop and maintain policies and procedures for monthly DRR including time frames for the different steps and what the pharmacist must do when an irregularity that requires urgent action is identified.

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Medication Regimen Review (F756)

- **The Consultant Pharmacist's Medication Regimen Review (MRR) is part of the resident's permanent health record**
  - Consultant pharmacist require access to the entire health record
  - The facility staff should assure that the attending physician, the Director of Nursing ***AND*** the Medical Director receive copies of the MRRs
  - The MRR is part of the residents' permanent health record
  - The attending physician's response to irregularities identified by the consultant pharmacists are part of the residents' permanent health record.

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Medication Regimen Review (F756)

- **The Consultant Pharmacist's Medication Regimen Review (MRR) is part of the resident's permanent health record**
  - The attending physician's response to irregularities identified by the consultant pharmacists are part of the residents' permanent health record
  - If the attending physician makes no change in the medication based on the Consultant pharmacist's findings, his/her rationale must be entered into the resident's permanent health record.
  - If the attending physician does not respond to the consultant pharmacist's recommendation in a timely manner, the irregularity will be referred to the Medical Director

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Medication Regimen Review (F756)

- Definition of irregularity: includes, but not limited to any drug that meets "unnecessary drug" criteria
- Must now be reported (in a separate report) to the facility's ***Medical Director***, in addition to attending physician and DON
- 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***

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Medication Regimen Review (F756)

- When the Consultant Pharmacist identifies an urgent medication irregularity during MRR that requires immediate action, the consultant pharmacist will notify the nurse and request the facility contact the attending physician to communicate the issue and obtain direction or new orders.
  - If the attending physician has not responded by the time the consultant pharmacist has completed his/her consultation for the day, the issue will be escalated to the Medical Director for immediate action.

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Medication Regimen Review (F756)

- If an irregularity does not require urgent action but should be addressed before the consultant pharmacist's next monthly MRR, the facility staff and the consultant pharmacist will confer on the timeliness of attending physician responses to identified irregularities based on the specific resident's clinical condition

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Suggested Timeframes for Monthly Medication Regimen Reviews

- Urgent Irregularities: before Consultant Pharmacist Leaves facility for the day
  - If the attending physician has not responded during the consultation visit, the urgent issue will be escalated to the Medical Director for action before the pharmacist exits for the day
- Medication Regimen Review Report and Summary Submission: Complete reports provided to the facility within 72 hours of Completion or within three business days.

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Suggested Timeframes for Monthly Medication Regimen Reviews

- Facility staff provides MRR reports to attending physician, Medical Director, and Director of Nursing within 72 hours of receipt or within three business days or following facility policy
- Responses to MRR by the attending Physician if not urgent: the next physician visit to the facility

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Medication Regimen Review (F756)

- Now incorporates language that MRR must include:
  - "Review of all of the resident's medical charts in the facility at least monthly".
  - Collaboration with other members of the interdisciplinary team, including the resident, their family, and/or resident representative

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Medication Regimen Review (F756)

- The requirement for the MRR applies to all residents (whether short or long-stay) without exception."
- Facility MRR policies and procedures should address residents who:
  - Are anticipated to stay less than 30 days
  - Experience an acute change of condition and for whom an immediate MRR is requested after appropriate staff have notified the resident's physician, the medical director, and the director of nursing about the acute change

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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IMPACT Act Medication Reconciliation Measure: Drug Regimen Review (DRR) Elements

- Intent is to document whether SNF providers conducted a DRR [for all residents on a Medicare Part A (PPS) stay]: a) upon admission, or as close to the actual time of admission as possible; and b) throughout the Medicare Part A stay, to identify, prevent, and address "in a timely manner" any potential (or actual) clinically significant medication issues

Centers for Medicare and Medicaid Services. Skilled Nursing Facility Quality Reporting Program Provider Traininghttps://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Training

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IMPACT Act Medication Reconciliation Measure: Drug Regimen Review (DRR) Elements

- In a timely manner" means, for any potential (or actual) clinically significant medication issues, the issues must be:
  - communicated to the prescriber; ***AND***
  - addressed by the prescriber and any prescribed/recommended actions by the prescriber completed by the facility **by midnight of the next calendar day**

Centers for Medicare and Medicaid Services. Skilled Nursing Facility Quality Reporting Program Provider Training. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Training

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What is a "Potential or Actual Clinically Significant Medication Issue" (per CMS)?

"Any circumstance that does not require this immediate attention ***is not considered a potential or actual clinically significant medication issue*** for the purpose of the DRR items"

Centers for Medicare and Medicaid Services. Skilled Nursing Facility Quality Reporting Program Provider Training. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Training

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What is a "Potential or Actual Clinically Significant Medication Issue" (per CMS)?

- A clinically significant medication issue is a potential or actual issue that, in the clinician's professional judgment, warrants:
  - physician (or physician-designee) communication

AND

  - completion of physician's (or designee's) prescribed/recommended actions by midnight of the next calendar day (at the latest)"

Centers for Medicare and Medicaid Services. Skilled Nursing Facility Quality Reporting Program Provider Training. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Training

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F757- Unnecessary Drugs

- Unchanged from previous Appendix PP versions except for numbering
- Unnecessary Drug = any drug used:
  - in excessive dose
  - for excessive duration
  - without adequate monitoring/indications for use
  - in presence of adverse consequences
  - any combination above

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Beers Medications

- Landmark article that identifies potentially inappropriate medications in the elderly.
- Initial purpose was a guideline assist in choosing the most appropriate therapy for our elderly patient
- Recently "integrated" into the Mega Rule where there is language of the Beer's Medication and Unnecessary Drugs.
- Beer's Medications maybe appropriate is the benefit outweighs the risks.

American Geriatrics Society. American Geriatrics Society 2019 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults. American Geriatrics Society. JAGS. 2019.

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F758- Psychotropic Drugs

- Any drug affecting mental processes and behavior, including but not limited to:
  - antipsychotics
  - antidepressants
  - anti-anxiety drugs
  - hypnotics
- Only if necessary for diagnosed condition
- Gradual dosage reduction (GDR) and behavioral interventions

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F758- Psychotropic Drugs

- Only if necessary to treat diagnosed and documented condition
- 14 day restrictions:
  - Non-antipsychotic psychotropic drugs (but can be extended if appropriate documentation and duration indicated on order)
  - Antipsychotic drugs cannot extend without evaluation

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Active Learning Question 1

A Unnecessary Medication is any medication used:

A) in excessive doses
B) for excessive duration
C) without adequate monitoring
D) in the presence of adverse events
E) All the above

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Active Learning Question 2

Which medication would not be considered a "Psychotropic Medication under F758?

A) Quetiapine
B) Lorazepam
C) Melatonin
D) Valproic Acid
E) Zolpidem

Many Roles that the Consultant Pharmacists

- Participation in various meeting
  - QAPI Meetings Quarterly
  - Psychotropic Meeting
  - Antimicrobial Stewardship Meetings
  - Deprescribing Meetings

Quality Assurance and Performance Improvement (QAPI) Meetings

- **Each skilled facility must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program.**
  - Tracking medical errors and adverse events and analyzing their causes
  - Regular review and analysis of data from DRR
- **PI activities must include:**
  - Implement preventive actions and mechanisms that include feedback and learning throughout the facility
- **The QAPI committee must**
  - Implement preventive actions and mechanisms that include feedback and learning throughout the facility

Psychotropic Meetings (F758)

- Monthly or quarterly meeting to discuss and assess patients on psychotropic medications
- Team discussed dosage reductions that have been implemented in the past and dosage reductions that are due.
- Gradual dosage reductions are mandated twice in the first year from the time the psychotropic medication is started, but not in consecutive quarters and yearly, unless contraindicated
- Consultant pharmacists can track that data and present at these meetings.

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Antimicrobial Stewardship (F881)

- Coordinated interventions to improve and measure the appropriate use of antimicrobials by promoting selection of the optimal antimicrobial drug regimen, dose, duration of therapy, and route of administration.
- Antimicrobial stewards seek to achieve optimal clinical outcomes, minimize toxicity and other adverse events, reduce health care costs for infections, and limit development of resistance to antimicrobials.

The Infectious Disease Society of America (IDSA). Antimicrobial Resistance. http://www.idsociety.org/Stewardship_Policy/#sthash.WYHnaDpu.dpuf

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Antimicrobial Stewardship (F881)

- The CDC believes that the key antimicrobial stewardship leaders in nursing homes are the:
  - Medical Director
  - Director of Nursing
  - Consultant Pharmacist
- Each nursing home should individualize selection for this team and utilize staff they feel are in the best position to effect change
- Track infections, antibiotic prescribing patterns, duration of antibiotic use, costs, and outcomes on a monthly basis

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Antimicrobial Stewardship (F881)

- **Consultant Pharmacists can become involved by:**
  - Providing education to staff about the different types of antibiotics and their appropriate use
  - Reviewing antibiotic prescriptions as part of the drug regimen review for new medications and ensure they are ordered appropriately
  - Participating in the development of the facility's antimicrobial stewardship policies and procedures

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Antimicrobial Stewardship (F881)

- **Consultant Pharmacists can become involved by:**
  - Assisting in the establishment of laboratory testing protocols to monitor for adverse events and drug interactions related to use of antibiotics and other high risk medications (e.g., warfarin)
  - Reviewing microbiology culture results and provide feedback to prescribers on initial antibiotic selection

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf.

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Desprescribing

- Deprescribing involves intentionally decreasing or discontinuing medications that are potentially harmful or no longer beneficial.

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Who is involved in Deprescribing Efforts

- Family members may have valuable historical information
- Front-line caregivers have more frequent interaction with residents
- Prescribers and specialists can use information obtained from others when making clinical decisions
- Consultant pharmacists

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Looking at the Medication List

Have there been any changes in the medication list?	• Do we know the indication for each medication? • Do we know why something was stopped or started? • Was the medication changed during a hospitalization or a change in setting?
Are there any apparent duplications?	• If a different medication was used in the hospital, was it continued after discharge? Was the original medication discontinued or is there now a duplication?
Does the medication need a stop date or should it be discontinued?	• Is this medication usually used for a limited duration (e.g., antibiotics, cough and cold, heparin) and has the full course of treatment been completed? • Was the medication ordered for an illness that has now resolved (e.g., acute pain, acute behavior, wound)?

Thompson W et al. Tools for deprescribing in frail older persons and those with limited life expectancy: a systematic review. J Am Geriatr Soc. 2019; 67:172-180.

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Looking for Changes in the Resident

Is there a new symptom or functional change?	• Is the new problem a known side effect of a medication (e.g., falls, weight loss)? • Did it happen about the same time as a medication change?
Does the treatment seem to be having no impact?	• Is a drug-drug interaction causing the treatment to be less effective? • Does the medication or current dose need to be reevaluated?
Has illness or frailty progressed significantly?	• Are all of the chronic medications still needed? • Is the current dose still safe and effective? • What are the palliative or end of life wishes of the resident?

Thompson W et al. Tools for deprescribing in frail older persons and those with limited life expectancy: a systematic review. J Am Geriatr Soc. 2019; 67:172-180.

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Many Roles that the Consultant Pharmacists (F755 and F761)

- Aid the facility in developing and implementing policies and procedures to ensure compliance with federal and state regulations related to ordering, storage, handling, labeling, destruction and administration of drugs and biologicals.
- Audit of the medication rooms and medication carts for proper labeling, expired / discontinued medications, and date opened designation of insulins, ophthalmics, and inhalers.
- Provide a written report on your findings to the facility leadership.

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Many Roles that the Consultant Pharmacists (F755 and F761)

- Maintenance of the Policy and Procedures as it related to the Emergency Boxes or Automated Dispensing Machines.
- Routinely review Emergency Drug Supply contents with facility Medical Director and Pharmacy Leadership for appropriateness.
- Periodic Optimization of Inventory

Centers for Medicare and Medicaid Services. State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

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Many Roles of the Consultant Pharmacists

- Drug information resource
- Customer Service
- Managing costs for your facility

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Typical Day of a Consultant Pharmacist

- There is no typical day
- Unpredictable
- Many different hats to wear
- Never the same two days in a row

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Professional Responsibilities of a Consultant Pharmacist in Long-Term Care