Strategies and requirements for medication use in the long-term care setting: Part 1: Regulations Governing Medication Use

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Objectives

- Discuss federal regulations regarding medication use in long-term care facilities
- Explain Alabama laws on medication use in long-term care facilities

What we will cover this morning

- **Pharmacy Services**
- **F Tags relevant to medications**
- **Alabama pharmacy law specific to long-term care**
- **Non-regulation examples of when medications can be used**
- **Every mention of a medication**
- **Overly detailed requirements of the consultant pharmacist**

From the context of what a non-pharmacist needs in LTC should be familiar with

Medication-Related Adverse Events

2014 Office of the Inspector General report

- 1 in 3 SNF residents experienced an adverse event
  - 37% were medication-related
- 66% of all medication-related events were preventable

Risk Factors	Consequences
• Complex regimens • # of medications • Medication types • Age-related physiologic changes • Co-morbidities	• ↑ LTC stay • Hospitalization • Critical interventions • Permanent harm • Death

Medication Self-Administration

- ✓ Medications is appropriate/ safe for self-administration
- ✓ Able to swallow
- ✓ Able to open bottles
- ✓ Can correctly name medication and knows what it is prescribed for
- ✓ Can follow directions and tell time to know when to take

- ✓ Knows dose, timing, & signs of side effects
- ✓ Knows when to report side effects to staff
- ✓ Understands what refusal of medication is
- ✓ Able to ensure medication is stored safely and securely

F554 (§483.10(c)7– The right to self-administer medications if the interdisciplinary team (IDT) has determined that this practice is clinically appropriate.

Medication Self-Administration

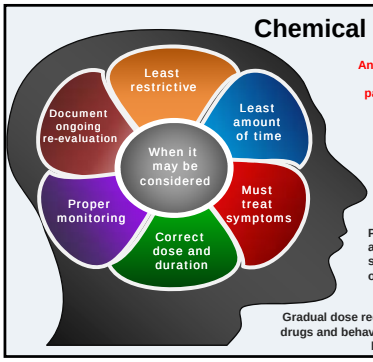
- Medication errors that occur with self-administration are not counted in facility's error rate
- May be asked by surveyors how staff determine if a patient can safely self-administer medications
- Surveyors will evaluate if request was honored
- Interdisciplinary team **must** be involved in this decision

F602 §483.12: The resident has the right to be free from abuse, neglect, misappropriation of a resident's property, and exploitation. This includes ……chemical restraint not required to treat the resident's medical symptoms

"Misappropriation"

- Example: diversion of a resident's medication(s)
  - Clue – patient's pain not relieved on a specific shift, but is relieved on other shifts
- Surveyor will report any allegations to administrator and conduct observations related to the allegation
  - What policies address medication safeguarding and access, monitoring, administration, documentation, reconciliation, and destruction of controlled substances
  - Does pharmacist have established system of records for receipt and disposition of all controlled drugs?
    - Are these in order?
    - Is an account of all controlled drugs maintained and periodically reconciled?
  - Does resident's clinical record provide accurate documentation of administration of a controlled medication and resident outcomes related to the medication administration

Chemical Restraints §483.12(a)



Any medication that restricts the patient's movement or cognition, sedates the patient, and is not accepted standard of practice for a medical or psychiatric condition

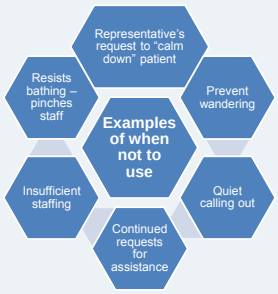
Every medication must have an indication documented in the patient's record

Clinical record must reflect the rationale for continued administration.

PRN orders are not administered unless absolutely necessary to treat a diagnosed specific symptom and are discontinued once indication is no longer present

Gradual dose reductions for psychotropic drugs and behavioral interventions should be utilized

Chemical Restraints



F655 Baseline Care Plans §483.21(a)

- Must:
  - Be developed within 48 hours of admission
  - Include physician orders and initial goals
  - Be provided to the resident and representative
    - Including a summary of medications

F661 Discharge Summary §483.21(c)

- Must include a reconciliation of all pre-discharge medications with post-discharge medications
  - Prescription and over-the-counter
  - Includes drug name, dosage, frequency, route, and indication
  - All discrepancies must be addressed and resolved
    - Example: Antibiotic course prescribed for a UTI may have already been completed and does not need to be taken at home
- Given to resident at the time they leave facility

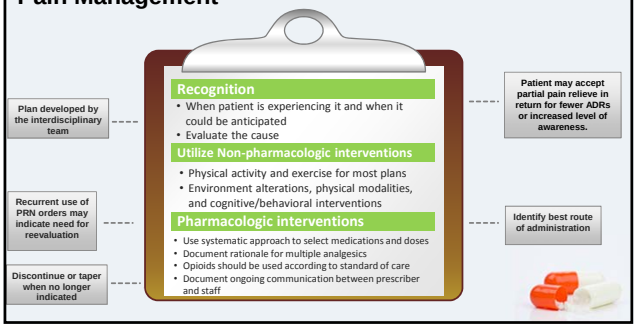
F690 Incontinence §483.25(e)

- Assess for causal medications (anticholinergics, diuretics)
  - Adjust as/if needed
- Must provide resident with risks vs. benefits (e.g. anticholinergic effects) before treating with medications

F697 Pain Management §483.25(k)

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

Pain Management



F711 Physician Visits §483.30(b)

The Physician Must

- Review total program of care – including medications and treatments – at each visit
- Write/sign/date progress notes
- Sign and date all orders
- Document

Signed Orders Exceptions
Influenza and pneumococcal vaccines (if per policy)

Non-Physician Practitioners
As allowed by state law

Faxed Orders
Physician retains original or is sent to facility later
Facility photocopies fax
Not requires for physician to re-sign.

E- Signatures Acceptable

Pharmacy Services §483.45

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

(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.

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

(c) The regimen of each resident must be reviewed at least once a month by a licensed pharmacist

Pharmacy Services

(d) Each resident's drug regimen must be free from unnecessary drugs

(e) Psychotropic drugs

(f) The facility must insure that its (1) medication error rates are not ≥ 5% and (2) residents are free of any significant medication errors

(g) Drugs used in the facility must be labeled in accordance with currently accepted professional principles, including appropriate accessory and cautionary instructions and expiration date (when applicable)

(h) Storage of Drugs and Biologicals

The CMS Definition of "Pharmaceutical Services"

01 The process of receiving and interpreting prescriber's orders

Acquiring, receiving, storing, controlling, reconciling, compounding, dispensing, packaging, labeling, distributing, administering, monitoring responses to, using, and/or disposing of all medications, biologicals, and chemicals

02 The provision of medication-related information to health care professionals and residents.

03 The process of identifying, evaluating, and addressing medication-related errors

04 The provision, monitoring, and/or the use of medication-related devices

05

Other Pharmacist Services

- Develop medication-related documentation procedures
- Identify appropriate abbreviations for use
- Guide medication selection according to state and federal laws and regulations

Pharmaceutical Services Procedures

Provision of Routine and/or Emergency Medications

The facility must provide or obtain routine and emergency medications and biologicals in order to meet the needs of each resident.

All medications should be administered in a ***timely*** manner

- Procedure for when/how/who contacts pharmacy for:
  - Original routine medication order
  - Emergency medication order
  - Refills
- Procedures should state how staff who administer medications:
  - Ensure resident's have sufficient supply.
  - Monitor the delivery and receipt of medications when ordered
  - Determine the appropriate action when a medication is not available for administration
    - When is the prescriber contacted?
    - When is the pharmacist contacted?
- Procedures must include a process for the timely ordering and reordering of medications
- "Borrowing" from another resident's supply is prohibited
- Medications may only be obtained from FDA approved sources

Factors Determining Timeliness

These factors should be used to guide acquisition procedures

Emergency Supply Procedures

- Which agents
- How much
- Dosages/strengths
- Location/storage
- Authorized personnel
- Record keeping
- Expiration date monitoring
- Restocking

Facility/pharmacy in Alabama determine appropriate days supply to keep in kit – most maintain a **2 day** supply

Alabama Law Regarding Emergency Kits

- May contain controlled substances
- Facility/pharmacy determine appropriate days supply
  - Most use a maximum of 2 days supply
- Responsibility for proper control and accountability is with facility and DEA registrant providing the drug
  - Both should maintain complete/accurate records
  - List of contents shall be maintained at both the institution and the pharmacy supplying the drugs.
- Access must be limited
- May only be used upon written or telephone orders of attending physician – must sign telephone order as soon as possible after giving order

Pharmaceutical Services Procedures

Medication Receiving Procedures

- How receipt occurs
  - From dispensing pharmacies
  - From family (if allowed)
- How staff will be identified and authorized to receive medications
- How access to medications is controlled until they are delivered to secured storage area
- Who is responsible for assuring that medications are put into the resident's specific storage area

Pharmaceutical Services Procedures

Medication Administration Procedures

Providing continuity of staff
Avoid unnecessary interruptions in administration.

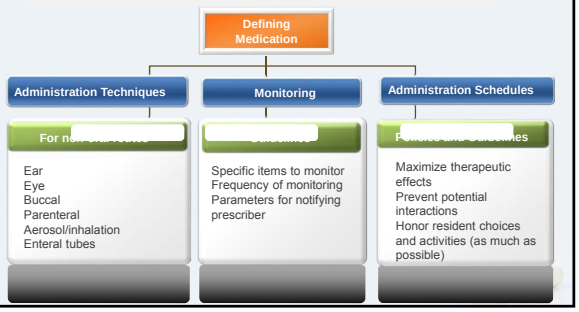
Report medication errors
Including how and to whom

Authorized personnel
Who can administer medications – including parenteral administration

Assuring the 5 R's
The right dose, right person, right route, right dosage form, and at the right time

- Identifying personnel who are authorized to access medications
- Competency of personnel authorized to administer medications
- Training on equipment used for medication administration or monitoring

Other Administration Procedures



Pharmaceutical Services Procedures

Medication Disposition Procedures

- Timely identification and removal
- Storage method for medications awaiting final disposition
- Control and accountability
- Documentation
  - Including: patient name, medication name, strength, prescription #, quantity, date of disposition, and involved personnel
- Methods
  - Should prevent diversion and accidental exposure
  - Consistent with laws, regulations, and standards of practice

Alabama Law: Drug Destruction

- All drugs unused because discontinued or resident is discharged or dies must be destroyed within 30 days
  - Exception If drugs are able to be donated to charitable clinic
- If resident is sent to the hospital – drugs can be retained until resident returns. Any drugs not reordered upon return to facility must be destroyed
- PRN medications should be destroyed after 90 days if they have not been used in that period of time
- Medications should be destroyed upon expiration of the drug
- Drugs can be destroyed on site or picked up by environmental agency that provides a service
  - Record must indicate name/address of facility, date of destruction/date drugs picked up, method of destruction, prescription number, drugstore name from which medication dispensed, resident's name, strength destroyed, amount destroyed, and reason for destruction

Pharmacist Services

- Alabama law requires a consultant pharmacist who:
  - Provides consultation on all aspects of provision of pharmacy services in facility
  - Establishes a system of records of receipt and disposition of all controlled substances in sufficient detail to enable accurate reconciliation
  - Determines records are in order and that an account of all controlled substances is maintained and periodically reconciled

Pharmacist Services

Procedures
Develop/implement/evaluate/revise procedures for provision of all pharmaceutical services

Coordination
Coordinate pharmaceutical services if/when multiple providers are utilized (e.g. hospice, infusions, pharmacies, compounding)

IV medications
Develop IV therapy procedures

Emergency Supply
Determine contents of emergency supply. Monitor use, replacement, and disposition of supply

Issue Resolution
Develop mechanisms for communicating, addressing, and resolving issues related to pharmaceutical services

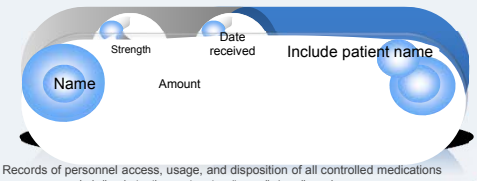
Feedback
Provide feedback on performance and practices related to medication administration and errors

Pharmacist Services

- Develop procedure/guidance when to contact prescriber on medication issues and/or ADRs (including what information to gather)
- Develop medication order process
- Recommend standardized packaging (bottles, bubble packs, tear strips)
- Develop procedures related to automated medication delivery devices or cabinets
- Work with quality assurance
- Recommend drug information resources
- Identify educational needs

Controlled Substances

Must have a system to account for receipt and disposition of controlled substances



Keep Records of personnel access, usage, and disposition of all controlled medications
Including destruction, waste, return (to supplier), or disposal
Periodic reconciliation of records of receipt, disposition, usage, and inventory of all controlled substances
Resolve discrepancies. Make referrals to law enforcement as needed

F756 Drug Regimen Review §483.45(c)

Frequency
- **At least once per month!**
- By a licensed pharmacist only

Report Irregularities
- To attending physician and medical director
- Physician must document in medical record that the irregularity has been reviewed and what (if any) action has been taken
- If no action taken – physician must document the rationale

Procedures
- Facility must have polices and procedures for monthly review

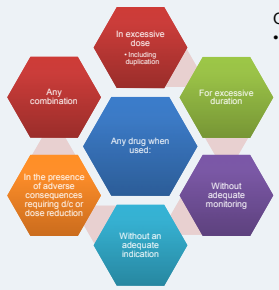
Documentation
- Irregularities
- Absence of irregularities
- Continued irregularities do not have to be documented if a physician has already documented clinical rationale

Drug Regimen Review requirements also are part of Alabama Law

Drug Regimen Review: Required Identifications

- Unnecessary drugs
- Resident response to cited irregularity
- Absence or inadequate indications
- Potential serious adverse consequences – including if/how benefit may outweigh risk
- Potential serious interactions
- Excessive doses and durations
- Duplicate therapy
- Inadequate monitoring
- Drug-induced sign or symptom
- Allergy clarification

F757 Unnecessary drugs §483.45(d)



Other areas of evaluation
- Medication allergies

F758 Psychotropic Drugs §483.45(e)

If not on before – do not give unless needed to treat a condition that is diagnosed and documented in the clinical record

Gradual dose reductions and behavioral interventions must be used in an effort to discontinue these medications unless clinically contraindicated

Administration secondary to a PRN order is only used when needed to treat a condition that is diagnosed and documented in the clinical record

PRN orders are limited to 14 days.
- If more than 14 days is required, the rationale must be documented in the clinical record with a specific duration
- Antipsychotics renewals require prescriber revaluation of the resident

Consideration of other factors that may be causing expressions or distress must occur before psychotropic medications are given

Examples of Medication Use Noncompliance

- No documented clinical reason for using a drug causing an adverse consequence
- Not considering risks/benefits of lower risk medications when giving high-risk drugs
- Not considering other factors that may cause indications of distress before giving a psychotropic medication
- Giving a psychotropic medication without a documented clinical reason
- Failing to use non-pharmacologic (unless contraindicated) to help discontinue psychotropic drugs
- Prescribing/giving a drug to a patient with an allergy without clarification documentation
- No documented reason for duplicate therapy
- Failure to monitor medication response for safety and efficacy
- Not acting when medication does not appear to work or when it appears to cause an adverse consequence.
- Use of excessive doses or durations without documented clinical rationale

F759 and F760 Medication Errors

- §483.45(f)(1)
  - Medication error rates should not be **≥ 5%**
- §483.45(f)(2)
  - Residents are free of any significant medication errors

Medication Error: Observed or identified preparation or administration of medications which is not in accordance with:

- The prescriber's order
- Manufacturer's specifications regarding preparation or administration
- Accepted professional standards and principles

Significant errors are those that cause discomfort or jeopardize safety.

Significant vs. Non-Significant Medication Errors

SIGNIFICANT OMISSIONS
Metoprolol or furosemide

WRONG DOSE
Opioids
Drugs with narrow therapeutic windows

OTHERS
Look-alike, sound-alike substitutes

NON-SIGNIFICANT OMISSIONS
Multivitamin or artificial tears

WRONG DOSE
Calcium carbonate

OTHERS
Minor delays in drug administration as timing is not specified for a specific rationale

Other Potential Medication Errors

F761 Labeling of Medications §483.45(g)

Medications must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

F761 Labeling of Medications §483.45(g)

Minimum Labeling Requirements

Average Medication	Multiuse Preparations	IV Infusions	OTC Medications in Bulk Containers
• Drug name • Dose • Strength • Expiration date (if applicable) • Patient name • Appropriate instructions and precautions	• E.g. – inhalers, eye drops, topical • Patient name • Multi-use vials- date of access	• Medication name • Medication volume • Patient name • Infusion rate • Name/quantity of each additive • Date prepared • Compounder initials • Date/time of administration • Initials of person administering drug • Appropriate precautions • Expiration date/time	• Original manufacturer's or pharmacy-applied label • Drug name • Strength • Quantity • Accessory instructions • Lot number • Expiration date

Additional Drug Labeling Requirements by Alabama Law

- All drugs should be properly and plainly labeled
  - Name/strength
  - Resident's name
  - Ordering physician
  - Date of filling
  - Directions
  - Rx number
  - Expiration date
  - # dosage forms
  - Auxiliary labels
- Unit doses – name/strength, control number, expiration date
- OTC drugs should have name/strength –
  - Other information included at discretion of facility
- Contents of all individual prescriptions must be kept in original container bearing original prescription label

F761 Storage of Medications §483.45(h)

- All medications must be stored in locked compartments under proper temperature controls and only authorized personnel are permitted access to the keys
  - Examples – locked cart, locked cabinets, locked refrigerator, locked drawer
- Schedule II-V controlled substances must be stored separately
  - Exception – when single unit packaging are used
  - Alabama Law requires Schedule II drugs be stored separately.
- Access control
  - Keys, security codes or cards, fingerprints, other technologies
  - Access system for Schedule II medications must not be the same.

Alabama Laws on Medication Storage

- Drug or medicine room must be under the direct supervision and direction of a consulting pharmacist OR a member of the medical staff who must be licensed to practice medicine
- Facility must maintain readily traceable records of receipt and disposition of all controlled substances

Alabama Law on Automated Dispensing Cabinets

- Must be approved by the Alabama Board of Pharmacy
  - Notification should be submitted at least 30 days prior to use
- A pharmacist does not have to be physically on site, but pharmacist of managing pharmacy must have access to equipment and all transaction information
- Access to drugs and information is secured through use of positive identification
- Access is limited to: licensed nurses, pharmacists, pharmacy technicians, or authorized field service personnel (for maintenance purposes in presence of other authorized person)
- Can be restocked only by pharmacist or pharmacy technician
  - May also be restocked by licensed nurse of the facility or other licensed healthcare personnel
- Requires quarterly inventory
- Generally linked to patient medication profile

Alabama Law on STAT Medication Cabinets

- Nursing facilities may maintain one “stat” cabinet
- Can keep a minimum amount of stock medications that may be needed quickly or after regular duty hours
  - Additional cabinets must be approved by the State Board of Health
- There shall be a minimum # of doses of any medication based upon the established needs of the facility
- There must be a list of contents (approved) with name/strength of the drug and quantity of each
- Records must show amount received, name of resident, amount used, prescribing physician, time of administration, name of person removing/using medication, balance on hand
- Must have written procedures for use of cabinet
- Pharmacist must inspect cabinet at least once a month, replace outdated drugs, reconcile prior use. Information obtained included in a monthly report.

Regulation Take Home Points

- There are a lot of regulations on medications in the LTC setting
- Facilities must supply medications that meet the needs of their residents in a timely manner
- All drugs must have a clear indication, regular monitoring
- Avoid anything that could be considered a chemical restraint
- Facilities need policies and procedures for (almost) everything regarding medication use

Questions – At the End