The CMS State Operations Manual Overview and Changes
Overview of the CMS State Operations Manual

- Executive Summary
- Historical Perspective
- The Requirements
  - Pharmacy Services
  - Labeling and Storage of Drugs and Biologicals
  - Medication Regimen Review
  - Unnecessary Drugs
- Interpretive Guidelines for Compliance with Requirements
- The Survey Process, with Example
These new FTags apply to LTC residents of all ages, not just residents older than 65 years, for whom federally-mandated DRR is currently required.
Executive Summary: Synopsis of Regulation F425

- The facility must employ or contract for the services of a pharmacist to provide consultation on all aspects of pharmaceutical services.
  - Facility and Pharmacist must identify how they will collaborate for effective consultation.
  - Pharmacist is responsible for assisting the facility to obtain and maintain appropriate pharmaceutical services.
Executive Summary: Synopsis of Regulation F431

- All drugs and biologicals are securely stored
  - Under proper temperature control
  - Access only by authorized personnel
- Schedule II Controlled Substances and other drugs subject to abuse are secure
  - Facility must provide separately locked compartments
- Medications are properly labeled in accordance with accepted professional principles
  - Appropriate accessory and cautionary instructions
Executive Summary
Synopsis of Regulation F428

Drug Regimen Review

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

- A more frequent review may be necessary depending upon the resident’s condition and the risks for adverse consequences related to current medications.

(2) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

The new FTags take a holistic approach to medication management stressing the importance of the whole care process – medication use is just one component of the care process and plan of care.
Executive Summary: Synopsis of Regulation F329

- Assure that medication therapy is appropriate for the individual resident:
  - Adequate indication for use;
  - Appropriate dose;
  - Behavioral interventions and gradual dose reductions with antipsychotics;
  - Appropriate duration;
  - Monitoring for therapeutic effect and adverse consequences;
  - Reduction of dose or termination of medication in drug-related adverse consequences.
Historical Perspective Of Pharmacy Responsibilities in Long Term Care

- 1974 – Monthly pharmacist-conducted Drug Regimen Review (DRR) in SNFs
- 1980 – Indicators for Surveyor Assessment of DRR
- 1987 – DRR in ICFs
- 1990 – Implementation of OBRA 1987
  - Appropriate use of antipsychotics
  - Unnecessary drugs
  - DRR Indicators updated and expanded
- 1999 – Interpretive Guidelines changes
  - Drug therapy guidelines (Beer’s Criteria)
  - Medication error defined
  - DRR Indicators updated and expanded
- December 18, 2006 – New SOM
Pharmacist collaborates with facility to:

- Develop, implement, evaluate, and revise procedures;
- Coordinate pharmaceutical services with pharmacy, infusion, hospice, Part D prescription drug plans (PDPs);
- Develop infusion therapy procedures;
- Determine contents of emergency drug supply;
- Develop a mechanism for communicating, addressing, resolving issues related to pharmaceutical services;
Pharmacist collaborates with facility to:

- Assure medications are requested, received, and administered in a timely manner as ordered;
- Provide feedback related to medication administration and medication orders;
- Participate in the interdisciplinary team to address and resolve medication-related needs or problems;
- Establish procedures for Medication Regimen Review (MRR);
- Establish procedures for MRR for residents who stay for less than 30 days or experience a change of condition.
The F431 Surveyor Guidelines: Drug Storage

- Secure all medications in a locked storage area
- Limit access to authorized personnel
- Access to medications may be controlled by keys, security codes or cards, and other technology
- Schedule II medications must be maintained in separately locked, permanently affixed compartments
  - Cannot be the same access system used to obtain non-scheduled medications
    - Unit dose packaging systems are exceptions
- During medication pass, medications must be under the direct observation or locked
- Facility must provide for safe and controlled storage of medications for residents who self-medicate
Labeling of medications and biologicals dispensed by the pharmacy must comply with Federal and State requirements and accepted pharmaceutical principles

- For medications designed for multiple administrations, label is affixed to promote administration
- Infusion medication labels include name and volume of solution, infusion rate, name and quantity of each additive, date of preparation, compounding initials, date & time of administration, initials of person administering, ancillary precautions, beyond use date
- Labels for over-the-counter medication in bulk containers must be the manufacturer’s or pharmacy-applied label
- Facility ensures medication labeling in response to order changes is accurate and consistent with state requirements
Medication Regimen Review

- A thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication.
- The review includes preventing, identifying, reporting, and **resolving medication-related problems**, medication errors, or other irregularities, and collaborating with other members of the interdisciplinary team.

The Consultant Pharmacists’ recommendations are considered part of each resident's clinical record and are maintained either in the chart or within the facility, and readily available. The Interdisciplinary Care Team is encouraged to review and get pharmacists’ input on residents' problems/issues.
The essential components of the MRR are unchanged but the scope has increased to include:

- Identification of irregularities through review of:
  - Medication administration records (MAR), prescribers’ orders, progress, nursing and consultants’ notes, Resident Assessment Instrument (RAI), laboratory and diagnostic test results, and behavioral monitoring information.

- Pharmacist consideration of whether physician and staff have:
  - Documented indications for use (not just an indication on the chart)
  - Identified allergies, potential side effects, and medication interactions
  - Documented progress toward, or maintenance of, goals of medication therapy
  - Acted upon laboratory results and diagnostic studies
  - Acted upon possible medication-related causes of worsening in the residents’ condition.

The focus has shifted to achievement of measurable outcomes.
F428 MRR Conditions Requiring Identification of Irregularities

Changes that may be related to medication use that need to be evaluated by the consultant pharmacist during MRR include:

- Anorexia
- Behavioral changes
- Bowel Function changes
- Confusion, cognitive decline
- Dehydration, fluid/electrolyte imbalance
- Depression, mood disturbances
- Dysphagia, swallowing difficulty
- Excessive sedation, sleep disturbances
- Evidence of impaired coordination
- Gastrointestinal bleeding
- Generalized aching or pain
- Rash, pruritis
- Seizure activity
- Spontaneous or unexplained bleeding, bruising
- Unexplained decline in functional status (e.g. ADLs, vision)
- Urinary retention or incontinence
Location and Notification of MRR Findings

- The pharmacist must:
  - Document identification of irregularity;
  - Report irregularity to attending physician or director of nursing;
- Timeliness of notification depends on severity;
- If no irregularities found, pharmacist signs and dates a statement indicating that no irregularities were found;
- Pharmacist’s findings are considered part of each resident’s clinical record.
*NEW – Response to MRR Irregularities

- Physician is not required to order recommended treatments unless he/she determines they are medically valid/indicated;

- If recommendation requires physician intervention, then:
  - Physician accepts and acts upon suggestion
  - or
  - Physician rejects and provides “some basis for disagreeing”*

- If attending physician does not concur or take action, and if there is potential for serious harm, the facility and consulting pharmacist are to contact the medical director.
The F329 Surveyor Guidelines: Unnecessary Drugs

- General. Each resident’s drug regimen must be free from unnecessary drugs, defined as drug used:
  - In excessive dose, and/or
  - For excessive duration, and/or
  - Without adequate monitoring, and/or
  - Without adequate indications for use, and/or
  - In presence of adverse consequences which indicate need for dose reduction or drug discontinuation

- Antipsychotic drugs. Based on comprehensive assessment, facility must ensure that:
  - Non-antipsychotic drug users are not given drug unless necessary to treat specific condition as diagnosed and documented in clinical record; and,
  - Antipsychotic users receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in effort to discontinue drugs.
Unnecessary Drugs: Intent – and New Scope - of Requirement

Each resident’s *entire* drug/medication regimen be managed and monitored to achieve the following goals:

- Medication regimen helps promote resident’s highest practicable mental, physical and psychosocial well-being;
- Resident receives only “clinically indicated” medications in appropriate doses and for appropriate durations;
- Non-pharmacologic interventions considered and used when indicated, instead of or in addition to medications;
- Clinically significant adverse consequences are minimized;
- Potential contribution of medication regimen to unanticipated decline or newly emerging symptom is recognized and evaluated, and regimen is modified when appropriate.
Medication Management Considerations: Unnecessary Drugs Surveyor Guidance

- Indications for use of medication;
- Monitoring for efficacy and adverse consequences;
- Dose (including duplicate therapy);
- Duration
- Tapering of a medication dose: gradual dose reduction of antipsychotic medications;
- Prevention, identification and response to adverse consequences.
Medication Issues of Particular Relevance

- 73 drugs and/or drug classes listed, including:
  - NSAIDs
  - Opioids
  - Antibiotics
  - Anticonvulsants
  - Antidepressants
  - Antidiabetic medications
  - Antipsychotics
  - Anxiolytics
  - Antihypertensives
  - ACE Inhibitors
  - Beta-blockers
  - Calcium channel blockers
  - Statins
  - PPIs
  - Steroids
  - Erythropoiesis stimulants

- Issues and Concerns include:
  - Dosage/adverse consequences
  - Monitoring
  - Adverse consequences
  - Indications
  - Interactions
  - Duration
  - Interactions/adverse consequences
  - Indications/contraindications
  - Monitoring/adverse consequences
### Example - Medication Issues of Particular Relevance: Anticonvulsants

<table>
<thead>
<tr>
<th>Anticonvulsants</th>
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<tbody>
<tr>
<td><strong>Indications</strong></td>
<td>Indefinite continuation based on confirmation of condition and its causes.</td>
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<tr>
<td><strong>Duration</strong></td>
<td>If used to manage behavior, requires attempts at gradual dose reduction or tapering.</td>
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<tr>
<td><strong>Monitoring</strong></td>
<td>Monitor serum drug concentrations when appropriate; Monitor for effectiveness and adverse consequences when used in behavior.</td>
</tr>
<tr>
<td><strong>Adverse Consequences</strong></td>
<td>Liver dysfunction, blood dyscrasias and skin rashes; Nausea/vomiting; CNS toxicity.</td>
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The Survey Process for each FTag has its own set of the following:

- Investigative protocol
- Surveyor guidelines defining compliance with requirements
- Determination of compliance or noncompliance with requirements
- Scope and severity deficiency categorization
- Enforcement remedies
Investigative Protocol: Unnecessary Medications – Medication Regimen Review

- Determine whether resident receives:
  - Only clinically indicated medications in dose and for duration to meet assessed needs;
  - Non-pharmacologic interventions when indicated, instead of, or, in addition to, medication;
  - Gradual dose reductions (antipsychotics) or tapering of other medications as warranted;
  - Evaluation of contribution of medication regimen to unanticipated decline or newly emerging or worsening symptom.

- Determine if facility in collaboration with prescriber:
  - Identifies monitoring parameters for effectiveness and adverse consequences of medications;
  - Recognizes/evaluates changes in clinical condition to determine if medication related, and if so, follows-up to modify medication regimen.
Investigative Protocol: Unnecessary Medications – Medication Regimen Review

- Determine if pharmacist
  - Performed monthly MRR and identified any existing irregularities with indication, dose, duration and potential for, or existence of, adverse consequences;
  - Reported identified irregularities to attending physician and director of nursing;
- Determine if facility/practitioner
  - Acted on the report of any irregularity.
Surveyor Guidelines: Compliance with MRR Requirements

- Determine if pharmacist had identified and reported to director of nursing and attending physician any irregularities with medication regimen.
- Determine whether attending physician and director of nursing acted on any irregularities.
- Determine if pharmacist identified suspected adverse consequence, and the attending physician did not respond, did staff follow-up with the attending physician.
Determination of Compliance with Unnecessary Drug Requirement

Compliance
- Assessed causes of condition/symptoms requiring treatment;
- Medication therapy indicated and therapeutic goals identified;
- Appropriate doses and durations;
- Gradual dose reductions and behavioral interventions, unless clinically contraindicated;
- Monitored for therapeutic goal and adverse consequences;
- Adjusted dose or terminated therapy in response to adverse consequence.

Noncompliance
- Inadequate indications for use;
- Inadequate monitoring;
- Excessive dose, including duplicate therapy;
- Excessive duration;
- Adverse consequences;
- No gradual dose reduction or behavioral intervention with antipsychotics.
“Scope and Severity” Deficiency Categorization Associated with Pharmacy F Tags

Key elements for “Scope” determination:
- **Isolated**: One or limited residents; one or limited staff
- **Pattern**: Very limited residents; very limited staff
- **Widespread**: Pervasive among residents and staff.

Levels of severity:
- **Level 4**: Immediate jeopardy (serious injury, harm, impairment or death) to resident health or safety;
- **Level 3**: Actual harm that is not immediate jeopardy;
- **Level 2**: No actual harm with potential for more than minimal harm that is not immediate jeopardy;
- **No actual harm** with potential for minimal harm.
Survey and Enforcement Process for SNFs

- Enforcement Remedies, based upon scope and severity
  - Termination of provider agreement with CMS
  - Denial of payment for new admissions
  - Civil money penalties
  - Corrective actions
The CMS State Operations Manual

Questions