

Updates to the State Operations Manual (SOM) and Implications for Medication Management in Nursing Homes

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DRUG THERAPY AND AGING

To what facilities do these new Federal guidelines apply?

- CMS-certified Skilled Nursing Facilities (SNFs) and Nursing Facilities, as defined by CMS
- NOT...
 - ICF-MR/DD
 - Assisted Living Facilities (including Board and Care, Group Homes, Adult Care, etc)
 - Regulated by individual states

What exactly has changed?

- State Operations Manual
 - Appendix P: Survey Protocol for LTC
 - Task 5 revised - especially 5E, which now evaluates not only the Medication Pass, but ALSO Pharmacy Services (F425), including Storage/Labeling/Controlled Medications (F431)

What exactly has changed?

- State Operations Manual
 - Appendix PP: Interpretive Guidelines for LTC
 - Regulations (HAVEN'T CHANGED) - Categorized by F-Tags
 - Interpretive Guidelines
 - Investigative Protocol
 - New combined investigative protocol for Unnecessary Medications (F329) and Medication Regimen Review (F428) found in F329
 - Severity Guidance/Deficiency Categorization

Tags Combined

- Unnecessary Medications
 - New Tag F329 = Old Tags F329, F330, F331
 - Unnecessary Medications
- Pharmaceutical Services
 - New Tag F425 = Old Tags F425, F426, and F427 (b) (1)
 - Pharmaceutical Services and Procedures
 - New Tag F428 = Old Tags F428, F429, F430
 - DRR/MRR
 - New Tag F431 = Old Tags F427 (b) (2) and (3), F431, F432
 - Labeling and Storage, including Controlled Medications

Unnecessary Medications

Guidance Training
42 CFR § 483.25(l)(1),(2)
F329

F329 - Unnecessary Meds Regulations

- Each resident's medication regimen must be free from unnecessary medications. An unnecessary medication is any medication when used:
 - In excessive doses (including duplicate therapy); or
 - For excessive duration; or
 - Without adequate monitoring; or
 - Without adequate indications for its use; or
 - In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
 - Any combinations of the reasons above

F329 - Unnecessary Meds Regulations

- Antipsychotics - Based on a comprehensive assessment of a resident, the facility must ensure that:
 - Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and
 - Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs

F329 - Unnecessary Medications Care Process

- Medication management is based in the care process and includes:
 - Recognition or identification of the problem/need
 - Assessment
 - Diagnosis/cause identification
 - Management/treatment
 - Monitoring
 - Revising interventions

F329 - Unnecessary Meds Six Medication Management Considerations

- Indications for use
- Monitoring for efficacy and adverse consequences
- Dose
- Duration
- Tapering/Gradual dose reduction
- Prevention, identification, and response to adverse consequences

F329 - Unnecessary Meds Tapering/GDR

- Tapering of any medication may be indicated when, for example:
 - the resident's clinical condition has improved/stabilized
 - the underlying causes have resolved
 - non-pharmacological interventions have been effective

F329 - Unnecessary Meds Tapering/GDR

- Opportunities for evaluation of medication, in regards to duration/dose:
 - CP's MRR
 - MD's visit or signing of orders
 - During quarterly MDS review
- What to evaluate:
 - Resident's target symptoms and the effect of the medication on symptoms (e.g., severity, frequency)
 - Changes in resident's function during previous quarter (e.g., MDS)
 - Whether resident experienced any medication-related adverse consequences during previous quarter

Pharmaceutical Services

Guidance Training
CFR § 483.60, 483.60(a)(b)(1)
F425

F425 - Pharmaceutical Services Regulations

- The facility must:
 - Provide routine and emergency medications and biologicals to its residents, or obtain them under an agreement
 - Provide pharmaceutical services including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all medications and biologicals to meet the needs of each resident
 - Employ or obtain the services of a licensed pharmacist who provides consultation on all aspects of the provision of pharmacy services in the facility
- The facility may:
 - Permit unlicensed personnel to administer medications if state law permits, but only under the general supervision of a licensed nurse.

New F425 - Overview

- Provision of Medications
 - Timeliness/Availability to meets needs of each resident
- Services of a Pharmacist
 - “The facility is responsible for employing or contracting for the services of a pharmacist to provide consultation on all aspects of pharmaceutical services.”
- Pharmaceutical Services Procedures
 - Acquiring
 - Receiving
 - Dispensing
 - Authorized personnel
 - Administering
 - Disposal
 - Labeling/Storage

F425 - Pharmaceutical Services Provision of Meds

- Factors that may help determine timeliness and guide procedures for acquisition include:
 - Availability of meds to enable continuity of care for anticipated admission or transfer
 - Condition of resident (e.g., severity/instability of condition, current S+S, potential impact of a delay)
 - Category of medication (e.g., antibiotic, pain)
 - Availability of medications in emergency supply
 - Ordered start time

F425 - Pharmaceutical Services Pharmacist Services

- Consultant pharmacist's responsibilities, in collaboration with the facility, MAY include:
 - Coordinate pharmaceutical services if and when multiple service providers are utilized, for example:
 - Multiple pharmacies
 - Infusion provider
 - Hospice
 - Prescription Drug Plan (PDP)

F425 - Pharmaceutical Services Pharmacist Services

- P+Ps - “Develop, implement, evaluate, and revise (as necessary)”
- IV therapy procedures
- E-Kits
- Develop mechanisms for communicating, addressing, resolving issues related to pharmacy services
- “Strive to assure” meds requested, received and administered in timely manner
- Med pass review/feedback
- ID team, QA+A Committee

F425 - Pharmaceutical Services Pharmacist Services

- MRR procedures (more on MRR in F428, but this is P+Ps)
 - Conducting MRR for each resident
 - Addressing expected time frames for conducting and reporting
 - Addressing irregularities
 - Documenting and reporting results
 - Addressing MRRs for residents:
 - anticipated to stay less than 30 days
 - who experience an acute change in condition as identified by facility staff

F425 - Pharmaceutical Services Pharmacist Services

- NOTE (in document):
 - “Facility procedures should address...
 - how and when the need for a consultation will be communicated,
 - how the medication review will be handled in the pharmacist is off-site,
 - how the results or report of their findings will be communicated to the physician
 - expectations for the physician’s response and follow-up, and
 - how and where this information will be documented.”

F425 - Pharmaceutical Services Pharmacist Services

- Procedures/guidance regarding contacting prescriber about medication issue (e.g., info to gather)
- Process for receiving, transcribing, recapitulating med orders
- Medication packaging
- Automated dispensing machines/delivery devices/cabinets
- Medication references/resources
- Staff education

Storage, Labeling, Controlled Medications

Guidance Training
CFR § 483.60(b)(2)(3)(d)(e)
F431

F431- Storage, Labeling, Controlled Meds Regulations

- The facility must employ or obtain the services of a licensed pharmacist who:
 - Establishes a system of records of receipt and disposition of all controlled medications in sufficient detail to enable an accurate reconciliation
 - Determines that medication records are in order and that an account of all controlled medications is maintained and periodically reconciled

F431- Storage, Labeling, Controlled Meds Regulations

- Labeling...
 - Medications and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions and expiration date when applicable
- Storage...
 - In accordance with state and federal laws/requirements, the facility must store all medications and biologicals in locked compartments under proper temperature controls and permit only authorized personnel to have access.

F431- Storage, Labeling, Controlled Meds Regulations

- Controlled Meds...
 - The facility must provide separately locked, permanently affixed compartments for storage of controlled medications listed in Schedule II...and other medications subject to abuse, except when the facility uses single unit package medication distribution systems in which the quantity stored is minimal and a missing dose can be readily detected

F431 - Labeling New Key Points

- Facility ensures labeling in response to order changes is accurate and consistent with state requirements (i.e., nurse cannot re-label or alter label)
- For meds designed for multiple administrations - “Multi-Dose” (e.g., inhalers, eye drops, etc), label is affixed in manner to promote administration to resident for whom it was prescribed

Labeling in Long-Term Care

- Per the Maryland Board of Pharmacy, the director or the director's pharmacist designee shall ensure that all medications dispensed by the pharmacy and intended for use within the facility are dispensed in appropriate containers and labeled with the
 - name and address of the pharmacy
 - date of dispensing
 - prescription number assigned by the pharmacy
 - name of the resident
 - name, quantity and strength of the drug
 - name of the prescriber
 - expiration date of the drug when required by law
 - required precautionary information regarding controlled substances
 - further cautionary information as may be required or desirable for proper use of the medication

COMAR 10.34.23.90 Labeling of Patient Medications

F431 - Access and Storage New Key Points

- Access can be controlled by keys, security codes or cards, or other technology (e.g., fingerprints)
- Med pass...
 - During a med pass, medications must be under the direct observation (*vs. control*) of the person administering the medications or locked in the med storage area/cart
- Self-administration...
 - Important that the facility have procedures for the control and safe storage of medications for those residents who can self-administer

F431 - Access and Storage New Key Points

- Temperature, light, humidity...
 - Important that facility implement procedures that address and monitor the safe storage and handling of medications in accordance with manufacturer specifications, state requirements, and standards of practice (e.g., USP)

Survey Protocol for Medication Pass and Pharmacy Services

- Revised survey protocol in Appendix P, Task 5 to partially serve as evaluation tool for F425 and F431
- Observation of medication pass now includes evaluation of pharmacy services - including compliance with storage, labeling, and controlled medication guidelines

Medication Regimen Review

Guidance Training
CFR § 483.60(c)(1)(2)
F428

F428 - MRR Regulations

- The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist
- The pharmacist must report any irregularities to the attending physician and the director of nursing
- And, these reports must be acted upon

F428 - MRR

- What is MRR?
 - “Thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medications; The review includes preventing, identifying, reporting, and resolving medication-related problems (MRPs), medication errors, or other irregularities and collaborating with others members of the interdisciplinary team.”

F428 - MRR

- Given this definition, it’s important to note that the document also states:
 - “This guidance is not intended to imply that all adverse consequences related to medications are preventable, but rather to specify that a SYSTEM exists to assure that medication usage is evaluated on an ongoing basis...”

F428 - MRR Frequency of Review

- Monthly or more frequently, depending on:
 - the resident's condition, and
 - the risks for adverse consequences related to current medications
- This sounds alarming, but it is virtually the same as current survey guidelines
- Remember, there is additional guidance related to this in F425

F428 - MRR Where to Conduct the Review

- Generally within facility because important info may be attainable only by talking to staff, reviewing "paper" chart, observing/speaking with resident
- BUT new technology (electronic health records) may permit the PHARMACIST to conduct some components of the review outside of the facility

F428 - MRR Notification of Findings

- Pharmacist is expected to document either that no irregularity was identified or the nature of the irregularity(ies), if any were identified
 - If none, pharmacist would include a signed and dated statement to that effect

F428 - MRR Notification of Findings

- Timeliness of notification depends on potential for or presence of serious adverse consequences
 - Examples include:
 - Bleeding resident on anticoagulants
 - Possible allergic reactions to antibiotic
- Collaborate with facility to identify the most effective means of notification/documentation
- Notification/documentation may be done electronically

F428 - MRR

Notification of Findings

- Pharmacist's findings are part of clinical record
 - If not maintained within active clinical record, it must still be maintained within facility and readily available
- Guidelines strive to find balance between:
 - Encouraging/facilitating other HC professionals to utilize
 - Allowing facilities flexibility in determining a consistent location that suits their needs

F428 - MRR

Response to Findings

- Physician either:
 - Accepts recommendation and acts, OR
 - Rejects the recommendation and provides a brief explanation, such as in a dated progress note
- “It is not acceptable for a physician to document only that he/she disagrees with the report without providing some basis for disagreeing.”
- For those direct care issues that do not require physician intervention, DON or designated nurse can address and document action taken

SOM: Key Messages

- Regulations themselves have not changed - same as they are now
- These new guidelines take a holistic approach to medication management, stressing the importance of the care process as a whole
- Changes in the SOM are increasing awareness to the impact of medications on the resident.

SOM - Key Messages

- Medication review needs to be incorporated into the resident centered care process
- Updating and utilization of policies and procedures is critical to improving pharmaceutical care.

Where we are?

Medical Error Statistics

- Within hospitals and skilled nursing facilities, one out of five medications are administered in error
- More people die in a given year as a result of medical errors than from motor vehicle accidents, breast cancer or AIDS.
- For every dollar spent on drugs in nursing facilities
 - \$1.33 is consumed in treatment of drug related morbidity and mortality
 - amounting to 7.6 billion dollars for the nation as a whole
 - of which 3.6 billion is estimated to be avoidable

Barker KN, et al. Medication errors observed in 36 health care facilities. Arch Intern Med 2002;162(16):1897-903.

Institute of Medicine. To err is human: building a safer health system. Washington, DC: National Academies Press; 2000.

Staff Education

- LTC medication errors tend to be due to
 - knowledge deficits
 - drug information
 - patient information
 - performance deficits
 - fatigue
 - interruptions
 - failure to follow the 5 rights

Pelletier PL. Medication errors: A lesson from long-term care. *Nursing Management*. 2001;32(11):49-50.

Where we are going?

National Patient Safety Goal 8

- Accurately and completely reconcile medications across the continuum of care
- Requires a process for comparing the patient's current medications with those ordered for the patient while under the care of the organization
- Requires a complete list of the patient's medications to be communicated to the next provider of service when a patient is referred or transferred to another setting, service, practitioner or level of care within or outside the organization. The complete list of medications is also provided to the patient on discharge from the organization.

2007 National Patient Safety Goals- www.jointcommission.org- accessed February 2007.

Clinical Impact...

- Hopefully we will see a:
 - Decrease in Medication administration errors
 - Decrease in Unnecessary Medications and improvement in Appropriate Medication which can only....

Improve Medication Management in Nursing Homes.

Medication Reconciliation Resources

- Institute of Healthcare Improvement
 - www.ihl.org
 - one of 6 initiatives in their 100,000 lives campaign to encourage hospitals to be proactive in preventing avoidable deaths
- Massachusetts Coalition for Prevention of Medical Errors, Reconciling Medications: A Medication Safety Collaborative
 - www.macoalition.org
 - free materials on medication reconciliation including forms, sample policy, staff education, implementation guides and safe practice resources

Online SOM Resources

- CMS website with SOM:
http://www.cms.hhs.gov/manuals/downloads/som107_Appendicestoc.pdf
- CMS website with Survey and Certification (S&C) Memos to States/Regions
<http://www.cms.hhs.gov/SurveyCertificationGeneralInfo/PMSR/list.asp#TopOfPage>
- Nursing Facility Survey and Regulations Briefing Room on ASCP website:
www.ascp.com/public/pr/nfsurvey or
www.ascp.com/som

QUESTIONS???