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CMS Revised Pharmacy Regulations: Lessons Learned from Phase 1, Guidance for Phase 2

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OBJECTIVES

- Identify three areas of increased regulatory risk related to phase 1 regulations.
- Describe two approaches to reduce the risk associated with the implementation of phase 1 regulations
- Discuss the effect that the expanded definition of "psychotropic drug" will have on medication management in nursing facilities.
- Describe how person-centered care planning impacts medication management.

HOW WE GOT HERE

1935: Social Security Act
- Private nursing homes

1965: Medicare & Medicaid
- Nursing home utilization dramatically increased, government largest payer for LTC

1967: Amendment to SSA → state licensure of nursing homes

1968: Moss amendments → Withhold funds for poor care

1974: Final nursing home regulations passed including enforcement

1986: Institute of Medicine: *Improving the Quality of Care in Nursing Homes*
- "what is needed is not more regulation, but better regulation"

1987: OBRA-87

1994: OBRA-87 final rule passed

2005: Quality Indicator Survey demonstration project

2016: **Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities**

MEDICARE AND MEDICAID PROGRAMS: REFORM OF REQUIREMENTS FOR LONG-TERM CARE FACILITIES

Effective Date: November 28, 2016

Implementation Dates:

- Phase 1: November 28,2016
- Phase 2: November 28. 2017
- Phase 3: November 28, 2018

PHASE 1 : STARTED 11/28/2016

The Pharmacist must report irregularities to:	Response to Pharmacist Reports:	P&P for Drug Regimen Review	Updated Definition of "Irregularity"
Attending Physician	Attending Physician must document in the **medical record**:	Facility must develop and maintain **Policies and Procedures** for the monthly Drug Regimen Review	**Irregularity** = Includes but not limited to Unnecessary Drug F329
Director of Nursing	1) What irregularity has been reviewed 2) What **action** has been taken to address 3) If no changes, document the **rationale** in the medical record	Policy must identify **timeframes** for different steps in the process	**Unnecessary Drug** = Any drug when used in: 1) Excessive dose (including duplicate therapy) 2) For excessive duration 3) Without adequate monitoring 4) Without adequate indications for its use 5) In the presence of adverse consequences 6) Any combinations of the reasons
Medical Director		Identify steps the Pharmacist must take when an irregularity is identified that requires **urgent action**	
Report **must include** resident's name, relevant drug, and irregularity			

IRREGULARITY

Existing definition:

" … any event that is inconsistent with usual, proper, accepted, or right approaches to providing pharmaceutical services (see definition in F425), or that impedes or interferes with achieving the intended outcomes of those services."

- Guidance to surveyors F 428

PHARMACEUTICAL SERVICES

The process (including **documentation**, as applicable) of receiving and interpreting prescriber's orders; acquiring, receiving, storing, controlling, reconciling, compounding (e.g., intravenous antibiotics), dispensing, packaging, labeling, distributing, **administering**, **monitoring** responses to, using and/or disposing of all medications, biologicals, chemicals (e.g., povidone iodine, hydrogen peroxide);

o The provision of medication-related information to health care professionals and residents;

o The process of identifying, evaluating and addressing **medication-related issues** including the prevention and reporting of **medication errors**; and

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

- Guidance to surveyors F 425

IRREGULARITY

Revised definition:

" … include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug."

- Regulation F 428

(d) = F 329:

- Excessive dose
- Excessive duration
- Inadequate monitoring
- Inadequate indication
- Adverse consequences

IRREGULARITY: LOW THRESHOLD

THE PHARMACIST DOCUMENTS THE FOLLOWING IRREGULARITIES. WHICH MUST BE REPORTED TO THE ATTENDING PHYSICIAN?

- Resident is administered Digoxin daily with an order to hold the drug for a pulse < 60 bpm. Nursing staff failed to document a pulse prior to administering the drug 4 out of 28 days in February of 2017.
- Resident is administered Coumadin daily. Nursing staff noted new onset dark, tarry stools 2 days ago.
- Resident has a documented allergy to "iron pills" and currently receive a daily multivitamin containing iron. Nursing staff reports no adverse consequences since starting the drug three weeks ago.
- Resident is administered Synthroid daily and is ordered a TSH to be obtained once a year. The most recent TSH contained in the medical record is normal but is 13 months old.
- Resident, receiving multiple chronic medications, returned from 3 day LOA to Colorado where he admits using recreational marijuana. Resident is currently stable.

F428: §483.45(C) DRUG REGIMEN REVIEW.

- "The pharmacist must report <u>any</u> irregularities to the attending physician …"
- "<u>Any</u> irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician …"

➢ Guidance pending

IRREGULARITIES → MEDICAL DIRECTOR

F 501:

The medical director is responsible for—

(i) Implementation of resident care policies; and

(ii) The coordination of medical care in the facility.

Guidance:

The medical director helps the facility identify, evaluate, and address/resolve medical and clinical concerns and issues that:

o Affect resident care, medical care or quality of life; or

o Are related to the provision of services by physicians and other licensed health care practitioners.

IRREGULARITIES → MEDICAL DIRECTOR

Notification: process/documentation

- 'If I sign these, I'm responsible"

Focus:

- Clinical care
- Policy implementation
  - High risk drugs
- Practitioners
- QAPI (data: trends/patterns)
  - Antipsychotics
  - Antibiotics
  - Opioids

IRREGULARITIES → NOTIFICATION

How soon is soon enough?

- Pharmacology
- Resident condition
- Policy

Urgent:

- Resolution before next dose?
- Impact act: midnight the next day

Routine:

- Triage
- No later than next visit

IRREGULARITIES → RESPONSE

Must come from the attending physician

- What about deferring to consultants?

Must be part of the medical record

- "Lets put in an administrative file"

Accept

- Plan to implement

Reject

- Rationale
  - Evidence based
  - Benefit versus risk
  - Best interest of the resident

PHASE 1 POTENTIAL PITFALLS

Deviation from policy

- " … develop and maintain policies and procedures for the monthly drug regimen review …" (F 428)

Resistance to change → monitor

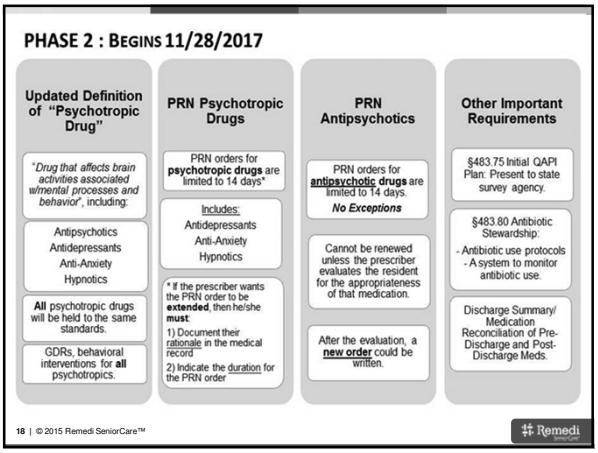
EHR vulnerabilities

Communication (DON@facility.com)

Volume → resources

Interim medication regimen review?

- Policy
- Guidance



PSYCHOTROPIC DRUG

" … any drug that affects brain activities associated with mental processes and behavior … include but not limited to:"

- Anti-psychotic - F 428
- Anti-depressant
- Anti-anxiety
- Hypnotic

*Opioids were included in draft regs

Note: Definition remains broad!

Survey strategy → top 20 drugs, ADRs

PSYCHOTROPIC DRUG – IMPACT

F 329: New reg language

PRN administration (Psychotropics):

- specific condition diagnosed and documented in the clinical record
- 14 day limit unless rationale in medical record / expected duration

PRN administration (Antipsychotics):

- 14 limit
- Renewal requires attending or prescriber evaluation (in person?)

PSYCHOTROPIC DRUG – IMPACT

F 329: Existing reg language

Antipsychotic →Psychotropic

- specific condition diagnosed and documented in the clinical record
- Gradual dose reduction
- Behavioral interventions

➢ pharmacy recommendations, care planning, activities, behavioral flow sheets, etc.

PSYCHOTROPIC DRUG PRN PITFALLS

Professional standards of practice

Person-centered care plan

Resident goals/preferences

Benefit / Risk

Non-pharmacological interventions

Effectiveness

Patterns of administration

Chemical restraint

GUIDANCE TO SURVEYORS

"surveyors must base all cited deficiencies on a violation of statutory and/or regulatory requirements, rather than sections of the interpretive guidelines. The deficiency citation must be written to explain how the entity fails to comply with the regulatory requirements, not how the facility fails to comply with the guidelines for the interpretation of those requirements."

- CMS S&C-08-10, Jan.18, 2008

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCletter08-10.pdf

F 441: ANTIBIOTIC STEWARDSHIP

Protocols

- Don't reinvent the wheel (CDC, APIC,IDSA, etc.)

Monitoring

- Pharmacy
- Lab

⇨ Data ⇨ QAPI

Action items:

- Antibiogram
- Education

DRUG SAFETY ALERT!

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Drug Safety Alert: Fluoroquinolone Antibiotics

(ciprofloxacin, levofloxacin, moxifloxacin, ofloxiain, etc.)

FDA advises restricting fluoroquinolone antibiotic use for certain uncomplicated infections

5/13/16: The U.S. Food and Drug Administration is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with the following conditions who have other treatment options:

- Sinusitis
- Bronchitis
- Uncomplicated urinary tract infections
- For patients with these conditions, fluoroquinolone should be reserved for those who do not have alternative treatment options

An FDA safety review has shown that fluoroquinolones are associated with disabling and potentially permanent serious side effects that can occur together, involving:

- Tendon, joint, or muscle pain
- Neuropathy or 'pins and needles'
- Central nervous system effects, e.g., confusion, hallucinations

RECOMMENDATIONS:

- **Health care professionals should stop systemic fluoroquinolone treatment immediately if a patient reports serious side effects, and switch to a non-fluoroquinolone antibacterial drug to complete the patient's treatment course**
- **Careful consideration should be given to any use of fluoroquinolones for sinusitis, bronchitis, or uncomplicated UTI**

Additional information: http://www.fda.gov/Drugs/DrugSafety/ucm500143.htm

DEFICIENCY DATA*

*https://data.medicare.gov/data/nursing-home-compare

F 283: DISCHARGE SUMMARY

"Reconciliation of all pre-discharge medications with the resident's post-discharge medications (both prescribed and over-the-counter)"

Who will own this process?

Caution: chronic meds in acute rehab

"Discharge planning begins at the time of admission"

THANK YOU

PERSON-CENTERED CARE

" … to focus on the resident as the locus of control and support the resident in making their own choices and having control over their daily lives." (F 150)

Consent (F 154 – new language)

- Informed in advance
- Benefits / Risks
- Alternatives
- Right to accept or refuse

Medication pass