CMS Final Rule Pharmacy Services Update: What You Need to Know!

Presented by:

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Overview:
“Final Rule”

"Medicare and Medicaid Reform of Requirements

for Long Term Facilities"

- Proposed by CMS: July 16, 2015 – 103 pages of Rules *(CMS-3260-P)* affecting 42 CFR 483

- Final Rule Issued: October 4, 2016 – 185 pages of revisions and comments. *(CMS-3260-F)*

- **First Major Overhaul since 1991**
  - **Implementation in 3 phases: November 28, 2016; 2017; and 2018**

Overview:
Sections Revised Include:

Resident rights (§ 483.10)

Facility responsibilities (§ 483.11)

Freedom from abuse, neglect, and exploitation (§ 483.12)
Transitions of care (§ 483.15)
Resident assessments (§ 483.20)
Comprehensive resident-centered care plans (§ 483.21)
Quality of care and quality of life (§ 483.25)
Physician services (§ 483.30)

Nursing services (§ 483.35)
Behavioral health services (§ 483.40)

Overview:
Sections Revised Include:

Pharmacy services (§ 483.45)
Laboratory, radiology, and other diagnostic services (§ 483.50)
Dental services (§ 483.55)
Food and nutrition services (§ 483.60)

Specialized rehabilitative services (§ 483.65)
Outpatient Rehabilitative Services (§ 483.67)
Administration (§ 483.70)
Quality assurance and performance improvement (§ 483.75)
Infection control (§ 483.80)
Compliance and ethics program (§ 483.85)
Physical environment (§ 483.90)

Training requirements (§ 483.95)

Overview:
"Final Rule"

Why is CMS overhauling the Rules?

"This proposed rule would revise the requirements that Long-Term Care facilities must meet to participate in the Medicare and Medicaid programs.

These proposed changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety."

Overview:
"Final Rule"

"These proposals are also an integral part of our efforts to achieve broad-based improvements both in the quality of health care furnished through federal programs, and in patient safety, while at the same time reducing procedural burdens on providers."

Overview:
"Final Rule"

"We estimate the total projected cost of this rule would be $729,495,614 in the first year. This results in an estimated first-year cost of approximately $46,491 per facility and a subsequent-year cost of $40,685 per facility on 15,691 LTC facilities."

Overview:
“Final Rule”

Implementation

Three Phases….

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

Overview:
Final Rule

However…..

The State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities *(AKA – the Red Book with the F-Tags)*, as published by CMS, has not been updated since Revision #157, June 10, 2016.*

Therefore….

We can make some direct changes based on the actual language of the law, but we may, and *likely will need to make additional changes* when CMS releases the updated SOM.

*As of January 27, 2017

42 CFR §483.45
Pharmacy Services

§483.45 is a "New" Section

- Created by relocating parts of the old §483.25 (Quality of Care) and all of the old §483.60 (Pharmacy Services), *then adding new regulatory language*.

- Sections relocated to "New" §483.45 include:
  - §483.25(l) Unnecessary Drugs (F329)
  - §483.25(m) Medication Errors (F332/F333)
  - §483.60 Pharmacy Services
    - §483.60(a) Procedures (F425)
    - §483.60(b) Service Consultation (F425)
    - §483.60(c) Drug Regimen Review (F428)
    - §483.60(d) Labeling of Drugs and Biologicals (F425)
    - §483.60(e) Storage of Drugs and Biologicals (F425)

§ 483.45 *Pharmacy Services*

Net (expected) result?

When the "State Operations Manual Appendix PP - Guidance to Surveyors" is finally updated:

- F332/333 Medication Errors,
- F329 Unnecessary Drug,
- F425 Pharmacy Services, and
- F428 Medication Regimen Review

will all likely appear as one (very large) F425 Pharmacy Services tag.

§ 483.45 *Pharmacy Services*

To view *(a stitched together version of)* § 483.45 in it's entirety at www.GuardianConsulting.com

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§ 483.45 *Pharmacy Services*

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§483.45 Pharmacy Services *(formerly §483.60)*
(Effective November 28, 2016, except (c)(2) and (e), effective November 28, 2017)
Legend: Regular Font Text = Existing regulations; *Italics = Existing regulations relocated to this section*; **Bold Text = New regulations**

We will keep our focus on the "New Regulations".

§ 483.45 *Pharmacy Services* New Sections

Formal expansion of the DRR requirement to include a full chart review:

(c) Drug regimen review.

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

(2) This review must include a review of the resident's medical chart.

§ 483.45 *Pharmacy Services* New Sections

Redefines "Antipsychotic" to "Psychotropic":

(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:

(i) Anti-psychotic;
(ii) Anti-depressant;
(iii) Anti-anxiety; and
(iv) Hypnotic.

Important! This sets the stage for CMS to go after "Class Shifting"!

Class Shifting: *The Next Target*

From CMS-3260-F, October 4, 2016 (Final Rule):

"..However, we are concerned that as the use of antipsychotics has decreased, the use of other psychotropic medications has increased."

Expectation: Use of Trazadone for sleep will be handled as if it were Ambien; use of Depakote, Xanax or even Hydroxyzine for behaviors/agitation will be handled as if it were Risperdal.

Recommendation: Get ahead of the curve on this!

§ 483.45 *Pharmacy Services* New Sections

Slight rewrite on the definition of an "Irregularity":

(4) The pharmacist must report any irregularities to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon.
(i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug.

- **"paragraph (d)"** referenced above contains the "classic" definition of an Unnecessary Drug: Too high a dose, duration, without adequate indication, etc..
- Note the language: "but are not limited to" – gives CMS wide latitude when crafting the new "Guidance to Surveyors"

§ 483.45 *Pharmacy Services*
New Sections

Paragraph (d) – *remains unchanged*

(d) Unnecessary drugs—General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—
(1) In excessive dose (including duplicate drug therapy); or
(2) For excessive duration; or
(3) Without adequate monitoring; or
(4) Without adequate indications for its use; or
(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued

§ 483.45 *Pharmacy Services* New Sections

Tightening of requirements on reporting of "Irregularities":

(ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified.

- CMS's goal? Make sure Medical Director and DNS are 'in the loop".
- "Separate, written report" to DNS and Medical Director requirement is a little ambiguous. Two easy ways to handle
  - Make a extra copy of DRR
  - Produce a separate "Executive Summary" report of all DRR's each month

§ 483.45 *Pharmacy Services*

Documentation of DRR REPSONSE on Medical Record

(iii) The 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.

Compliance Options:

1. Pharmacist writes DRR directly into Medical Record, physician responds directly *(Issue: Difficult to audit)*
2. Pharmacist writes DRR on separate form, physician writes response on form, then writes a separate note on Medical Record *(Issue: requires double documentation by physician)*
3. Pharmacist writes DRR on separate form, physician responds on form – copy maintained on file in Nursing Office, original to chart. ***(Our preferred, recommended method.)***

§ 483.45 *Pharmacy Services*

Timeframes for DRR REPSONSE

(5) The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

What step is CMS concerned with? ***Prescriber RESPONSE.***

Policy Options for Response ***(Unless/Until SOM is updated!)*****:**

1. "prior to Pharmacist's next monthly review"
2. "within 30 days, more promptly if possible"
3. "within 7-14 days, more promptly if possible"
4. "within 1-7 days"

Reality:

- DRR's should always be responded to as soon as possible
- We have no idea yet what CMS/Surveyors will deem acceptable

§ 483.45 *Pharmacy Services*

To view a *recommended draft P&P for Drug Regimen Review*, go to www.GuardianConsulting.com

then click on "Public Documents"

§ 483.45 *Pharmacy Services* New Sections

PHASE 2: Psychotropic PRN Orders – 14 days

(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in § 483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.

Important: *This is meds OTHER THAN antipsychotics!*

- Includes ANY OTHER med used as psychotropics!
  - Benzodiazepines (such as Xanax and Ativan)
  - Trazadone, Hydroxyzine (when used for agitation), others

§ 483.45 *Pharmacy Services* New Sections

PHASE 2: ANTIPSYCHOTIC PRN Orders – 14 days

(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

This is simply a stricter version of the "psychotropic PRN" rule, *but less strict than original proposed rule which called for max 72 hours, but…*

- Q: Should we be using ANY PRN's at all ? A: Rarely. PRN's psychotropics and antipsychotics remain a major survey risk for an Unnecessary Drug deficiency!

Recommendation: Get ahead of this requirement. WAY ahead. (If you haven't already – eliminate PRN use to the greatest extent possible.

§ 483.80 *Infection Control*
Antibiotic Stewardship

Not much detail in the section:

(a) *Infection prevention and control program.* The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:

(3) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.

Wait for the State Operations Manual update for guidance?
Recommendation: Get ahead of the requirement!

- *"It has been estimated that between 25 and 75 percent of antibiotic prescriptions in nursing homes may be inappropriate."*

§ 483.80 *Infection Control*
Antibiotic Stewardship

Multiple Agencies and players (besides CMS) all promoting Antibiotic Stewardship in LTC – *LOTS of resources available!*

- Centers for Disease Control
  - https://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html

- Agency for Healthcare Research and Quality (AHRQ)
  - https://www.ahrq.gov/nhguide/index.html

- National Nursing Home Quality Improvement Campaign

- Individual State DOH/DPH's

As for the Final Rule:

- Antibiotic Stewardship is *in Phase 2!*

§ 483.80 *Infection Control*
Antibiotic Stewardship

What can the Pharmacy and Consultant Pharmacist do in terms of Antibiotic Stewardship?

- Review use as part of Drug Regimen Review
  - Concurrent and Retrospective reviews with recommendations
- Assist in evaluation of Antibiograms
  - Prescriber education on empiric drug selection
- Staff Education on appropriate antibiotic utilization
- Provide Utilization Reports to QA Committee

§ 483.80 *Infection Control*

Antibiotic Stewardship

Example of an Antibiogram

Gram (-)	# of patients	Aminoglycosides			B-Lactams			Cephalosporins				Quinolones	Others	
		Amikacin	Gentamicin	Tobramycin	Ampicillin	Impipnem	Pipercillinp Tazobactam	Cefzolin	Cefoxitin	Ceftriaxone	Ceftazidime	Ciprofloxacin	Nitrofurantion	TMP/SMX
Echerichia coli	4	100	100	100		100	100				100	75		
Klebsiella sp	13	100	84.6	92.3	38.5	100	92.3	84.6	100	100	100	38.5	92.3	38.5
Proteus sp	7	71.4	57.1	71.4		85.7	85.7			57.1	57.1		28.6	71.4
Pseudomonas aeruginosa	13	100	83.3	92.3	91.7		100		81.8	100	100	30.8		69.2

Gram (-)	# of patients	Penicillins				Cephalosporins		Quinolones		Others						
		Penicillins	Ampicillin	Oxacillin	Nafcillin	Cephalothin	Ceftriaxone	Ciprofloxacin	Moxifloxacin	Gentamacin	Linezoid	Rifampin	Tetracycline	TMP/SMX	Vancomycin	Nitrofurantion
Staph aureus (all)	8	0		0	0			0	0	87.5	100	100	100	100	100	100
Methicillin Resistant (MRSA)	8	0		0	0				0	87.5	100	100	100	100	100	100
Methicillin Susceptible (MRSA)	0															
Enterococcus sp	4	100	100					50		75			25		100	100

§ 483.80 *Infection Control*
Antibiotic Stewardship

From the "National Nursing Home Quality Improvement Campaign" checklist

SECTION 3. MONITORING PRACTICES				
		YES	NO	N/A
Q1	Does the pharmacy service provide a monthly report of antibiotic use (e.g., new orders, number of days of antibiotic treatment) for the nursing home?			
Q2	Does your nursing home have a process to perform a follow-up assessment 3 days after a new antibiotic start to determine whether the antibiotic is still indicated and appropriate?			
Q3	Does your nursing home provide feedback on antibiotic prescribing practices to medical personnel?			
Q4	Does the laboratory provide your nursing home with a report of antibiotic resistance in bacteria identified from cultures sent from your nursing home (e.g., antibiogram)?			

https://www.nhqualitycampaign.org/files/AntibioticStewardship_Assessment.pdf

§ 483.80 *Infection Control*

To view a *recommended draft P&P for Antibiotic Stewardship AND (a stitched together) 483.80* , go to www.GuardianConsulting.com

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Thank you for listening!

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