THE GATEWAY
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CMS Mega Rule:
Implications for Pharmacists and Pharmacies

Curt Wood, RPh, BCGP, FASCP
Curt Wood declares no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings and honoraria.
Pharmacist Objectives

At the conclusion of this program, the pharmacist will be able to:

1. Describe the implications of the ‘Mega’ Rule on long-term care facilities.
2. Summarize the implications of the ‘Mega Rule on pharmacies/pharmacists.
3. Identify the Phases of the ‘Mega’ Rule and effective dates of each Phase.
4. Identify the additional responsibilities of the consultant pharmacist on Antibiotic Stewardship and Unnecessary Medications.
Technician Objectives

At the conclusion of this program, the technician will be able to:

1. Describe the implications of the ‘Mega’ Rule on long-term care facilities.
2. Summarize the implications of the ‘Mega’ Rule on pharmacists/pharmacies.
3. Identify the Phases of the ‘Mega’ Rule and effective dates of each Phase.
4. Identify the additional responsibilities of pharmacists/pharmacies in order to develop processes to support them in providing the additional services required by the ‘Mega’ Rule.
Pre-Test Questions

1. T or F: Implementation of the ‘Mega’ Rule was completed on 11/28/2016.

2. The ‘Mega’ Rule is expected to cost each facility (in the first year) an average of:
   A. $22,900
   B. $42,900
   C. $62,900
   D. $82,900
Pre-Test Questions

3. Which of the following methods is acceptable for the attending physician to document response to Drug Regimen Review (DRR)?
   A. Pharmacist writes DRR into Medical Record and Physician responds directly into medical record.
   B. Pharmacist writes DRR on separate form, physician writes response on form, then writes a separate note into medical record.
   C. Pharmacist writes DRR on separate form, physician responds on form and form is placed in medical record.
   D. All are acceptable.

4. T or F: PRN orders for Alprazolam, Lorazepam, Trazodone or Hydroxyzine (used for anxiety/behaviors) must be limited to 14 days, unless the physician documents the rationale for a longer time frame, *and* indicates the duration for the PRN order.
CMS Mega Rule: Implications for Pharmacists and Pharmacies
CMS has stated that they:

“…reviewed regulations in an effort to improve the quality of life, care, and services in LTC facilities, optimize resident safety, reflect current professional standards, and improve the logical flow of the regulations.”

“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 reduction procedural burdens on providers.”
CMS first published requirements for long term care (LTC) facilities in the Federal Register on February 2, 1989. Last comprehensive update occurred September 26, 1991. CMS believes that since the last update (1991), “…significant innovations in resident care and quality assessment practices have emerged. In addition, the population of LTC facilities has changed, and has become more diverse and more clinically complex. CMS further states that extensive, evidence-based research has been conducted and has enhanced knowledge about resident safety, health outcomes, individual choice, and quality assurance and performance improvement.
Then Comes the ‘Mega’ Rule!

- ‘Mega’ Rule proposed on July 16, 2015
  - CMS offered an extended comment period for review of proposed rule by industry leaders and experts, facilities, those working in the industry, and the public.
- Final ‘Mega’ Rule published on September 26, 2016.
  - Rewrites all LTC regulations required for participation in Medicare/Medicaid.
  - Totals 185 pages in the Federal Register.
Then Comes the ‘Mega’ Rule!

• 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)
Then Comes the ‘Mega’ Rule!

• Sections Revised continued:
  – 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)
Phase-In of Regulations

• CMS stated “Given the comprehensive nature of the regulatory revisions, it agreed that a longer period of time is necessary to implement the challenges outlined in this final rule.”

• The also stated, “In addition, we anticipate that additional time will be needed to develop revised interpretive guidance and survey process, conduct surveyor training on the changes and implement the software changes in the Quality Indicator Survey (QIS) system.”
Phase-In of Regulations

• Phase 1 went into effect on November 28, 2016.

• Phase 2 takes effect on November 28, 2017.

• Phase 3 takes effect on November 28, 2019.
Better Quality? At What Cost?

- Federal government estimates initial federal startup costs between $15-20 million and also $15-20 million annually in additional survey costs.

- CMS expects that complying with the ‘Mega’ Rule will cost facilities $831 million in the first year. That is an average of $62,900 per facility!

- Projected costs after the first year are estimated at $736 million or $55,000 per facility!
These projected costs are likely to be extremely conservative! – especially in rural areas where attracting and keeping qualified staff is exceedingly difficult.

In addition, failure to comply with the ‘Mega’ Rule will result in compliance issues, penalties, and fines!
Phase 1 – Focus on Pharmacy

• Medications Errors: F332 and F333 moved to Pharmacy Services CFR 483.45. Still requires less than 5% med errors and residents are free from any significant medication errors.

• Influenza and Pneumococcal Immunization: F334 moved to Pharmacy Services CFR 483.45.
Phase 1 – Focus on Pharmacy

• Drug Regimen Review (DRR): F428 moved to Pharmacy Services CFR 483.45.
  – Facility must have policy and procedure for monthly DRR that includes time frames for different steps in the process and steps the PHARMACIST must take when identifying an irregularity that requires *urgent* action to protect the resident.
  
    – The facility Medical Director must also receive/review any irregularities identified by the PHARMACIST. Irregularities are defined as, *but not limited to*, any drug that meets the criteria for an unnecessary medication.
Phase 1 – Focus on Pharmacy

• **RECOMMENDATION:**
  
  – Make an extra copy of reports for Medical Director – make sure it is documented that he/she has received and reviewed them!

  • Use a separate sheet that states something like **“RECEIPT OF CONSULTANT PHARMACIST’S REPORTS.”** As Medical Director of this facility, I have received and reviewed the reports from the Consultant Pharmacist for the following months.”

  • Produce a separate “Executive Summary” report of all DRR’s each month.

  • Some software programs now provide a signature for the Medical Director for documentation of receipt and review.
Drug Regimen Review (DRR) continued:

- 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 not a change in the medication, the attending physician should document his or her rationale in the resident’s medical record.
Phase 1 – Focus on Pharmacy

• RECOMMENDATION:
  – Pharmacist writes DRR on separate form, physician responds on form
    • Original to be placed in chart or scanned into medical record.
    • Copy to be maintained in Nursing Office.
Phase 1 – Focus on Pharmacy

• Drug Regimen Review (DRR) continued:
  
  – The facility must develop and maintain policies and procedures for the monthly drug regimen review that includes, 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.

• EXPECTATION: CMS is concerned with prescriber response to DRR. It is unclear at this time what CMS Surveyors will deem acceptable.
Phase 1 – Focus on Pharmacy

• **RECOMMENDATION:**
  
  – Policy might state something like “Physician response to DRR will occur within 30 days, or more promptly, if possible.”
Phase 1 – Just How Did It Go?

- CMS considered most new rule implementation to be ‘minor’.
- In addition, CMS did NOT provide any Interpretive Guidance for specific F-tags.
- Among industry discussions, the biggest change appears to be in the new prohibition on pre-dispute arbitration agreements.
Phase 1 – Just How Did It Go?

- Industry reports indicate that there have been citations issued regarding requirements for discharge summary for each discharged resident and a grievance policy being developed and implemented in each facility.

- Unfortunately, CMS has not released data regarding the ability of facilities to meet the demands of the modified and new requirements in Phase 1.
Phase 2 – Focus on Pharmacy

• DRR and Medical Chart Review: F428 moves to Pharmacy Services CFR 483.45.
  – DRR must include a review of the entire medical record – NOT just the physician orders.

• Infection Control: F441 moves to CFR 483.80.
  – The facility must develop an Infection Prevention and Control Program (IPCP) that includes an Antibiotic Stewardship Program.
Phase 2 – Focus on Pharmacy

• Unnecessary Drugs: F329 moves to Pharmacy Services CFR 483.45.
  – Continues to state that each resident’s drug regimen is free from unnecessary medications.
  – The term ‘psychotropic’ has been redefined as “any drug that affects brain activities associated with a mental process and behavior.”
    • This includes antipsychotics, antidepressants, anxiolytics, and hypnotics.
Phase 2 – Focus on Pharmacy
Antibiotic Stewardship

CMS estimates “that between 25%-75% of antibiotic prescriptions in nursing homes may be inappropriate.”
Phase 2 – Focus on Pharmacy
Antibiotic Stewardship

• CDC Guidelines Include:
  – Core Elements of Antibiotic Stewardship for Nursing Homes
  – CHECKLIST: Core Elements of Antibiotic Stewardship for Nursing Homes
  – APPENDIX A: Policy and Practice Actions to Improve Antibiotic Use
  – APPENDIX B: Measures of Antibiotic Prescribing, Use and Outcomes

• Loeb Criteria for Initiation of Antibiotics in Long-Term Care Residents
Phase 2 – Focus on Pharmacy
Antibiotic Stewardship

• Antibiotic Stewardship

  – Facilities must have written policies and procedures for infection control and a system of surveillance.

  – Designation one or more individuals as an “infection preventionist” responsible for the infection control program has been pushed off until Phase 3.
Phase 2 – Focus on Pharmacy Antibiotic Stewardship

• RECOMMENDATION:
  
  – Review antibiotic use as part of monthly DRR.
  – Assist in evaluation of Antibiograms including prescriber education on empiric drug selection.
  – Staff education on appropriate antibiotic utilization.
  – Provide Utilization Reports to QA Committee.
Phase 2 – Focus on Pharmacy
Antibiotic Stewardship

• RECOMMENDATION continued:

  – Sample Policy and Procedure *might include*:
    • Antibiotic orders should include:
      – Stop date or duration of therapy.
      – An appropriate diagnosis – use of a symptom (nasal congestion, rhinorrhea, sore throat, cough, etc.) is NOT a diagnosis.
      – A culture, when possible/appropriate PRIOR to beginning antibiotics.
    • Quinolone antibiotics should be avoided in *uncomplicated* infections.
    • Culture reports should be reviewed to insure the organism is sensitive to the antibiotic; if resistant, the antibiotic must be discontinued/changed to another agent.
Phase 2 – Focus on Pharmacy
Antibiotic Stewardship

• RECOMMENDATION continued:
  – Sample Policy and Procedure *might include*:
    • If culture is negative, the antibiotic must be discontinued immediately.
    • Monthly review of infections and antibiotics used by medical director and consultant pharmacist for appropriate diagnostic testing, antibiotic dose and duration, and whether antibiotic was changed or discontinued based on culture report.
    • Facility shall obtain an antibiogram (at least annually) and distribute to medical director, physicians, and consultant pharmacist.
Phase 2 – Focus on Pharmacy
Unnecessary Drugs

• Unnecessary Drugs: F329 moves to Pharmacy Services CFR 483.45.
  – Continues to state that each resident’s drug regimen is free from unnecessary medications.
  – The term ‘psychotropic’ has been redefined as “any drug that affects brain activities associated with a mental processes and behavior”. This includes antipsychotics, antidepressants, anxiolytics, and hypnotics.
Phase 2 – Focus on Pharmacy
Unnecessary Drugs

- **Unacceptable indications for use:**
  - Wandering, restlessness, mild anxiety, fidgeting, nervousness, uncooperativeness
  - Poor self-care
  - Impaired memory
  - Insomnia
  - Sadness or crying that is not related to depression or psychiatric disorders

- Excessive doses (including duplicate therapy)
- Meds without adequate monitoring
- Adverse consequences which indicate the dose be reduced or discontinued?
Phase 2 – Focus on Pharmacy
Unnecessary Drugs

- Monitoring must include:
  - Narcotics – assess pain, implement bowel program
  - Anticoagulants – bleeding/bruising, PT/INRs, interactions
  - Diuretics – edema, K+ level, signs of electrolyte imbalance
  - All psychoactive medications
    - Hypnotics – causes for insomnia, hours of sleep
    - Antidepressants – duplicative therapies and effectiveness
Phase 2 – Focus on Pharmacy
Unnecessary Drugs

• EXPECTATION
  – Physician **must** provide clinical rationale for continuing a med that may be causing an adverse consequence, including risks vs. benefits.
  – Pharmacist should identify and report any med irregularities.
  – Physician or DON must act upon any reported irregularities.
  – Facility must care plan for interventions for meds that pose a high risk of adverse consequences.
  – Non-pharmacologic interventions may be used when/if appropriate (invited to activity? physical needs met? etc.).
  – Must identify specific mood/disorder for any psychoactive med.
Phase 2 – Focus on Pharmacy
Unnecessary Drugs

• EXPECTATION
  – Resident or representative must be provided risks vs. benefits of current medication therapy.
  – Staff must be able to identify non-pharmacologic interventions.
  – Staff must know clinical indication for high-risk med.
  – Staff must know behavior is being monitored for antipsychotics and anxiolytics.
  – Facility must know last GDR attempt and the results.
  – Physician must provide risk vs. benefits statement describing the contra-indications if GDR was denied.
Phase 2 – Focus on Pharmacy
Unnecessary Drugs

• A closer look at psychotropics (antipsychotics, anxiolytics, antidepressants, and hypnotics)
  – Residents who have not used psychotropic medications are NOT started on a psychotropic unless the medication is necessary to treat a specific condition diagnosed and documented in the medical record.
  – Residents who use psychotropic medications receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these medications.
  – Residents DO NOT receive psychotropic medications pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition documented in the clinical record.
  – PRN orders for psychotropic medications are limited to 14 days, unless the prescriber believes the it is appropriate for the PRN order to be extended beyond 14 days. If so, the prescriber must document the rationale in the resident’s medical record and indicate the duration for the PRN order.
  – PRN orders for antipsychotics are limited to 14 days and CANNOT be renewed unless the attending physician or prescriber evaluates the resident for appropriateness of that medication; AND, writes a new order to extend the timeframe of use.
Phase 2 – Focus on Pharmacy
Unnecessary Drugs

• Implications of redefining ‘psychotropic’ meds
  – Class shifting
    CMS states, “…However, we are concerned that as the use of antipsychotics has decreased, the use of other psychotropic medications has increased.”

• EXPECTATION:
  – Use of Trazodone for sleep will be handled as if it were Ambien.
  – What about Melatonin?
  – Use of Depakote, Xanax, Hydroxyzine, etc. for behaviors or agitation will be handled as if it were Risperdal (antipsychotic).
Phase 2 – Focus on Pharmacy
Unnecessary Drugs

• RECOMMENDATION:

Get ahead of the curve!!!!!
Phase 2 – Focus on Pharmacy
Unnecessary Drugs

- 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.

- EXPECTATION:
  - PRN psychotropics should be \textit{rarely} used.
  - PRN psychotropics remain a \textit{major} survey risk for an Unnecessary Drug deficiency.
Phase 2 – Focus on Pharmacy Unnecessary Drugs

• RECOMMENDATION:
  
  – If you haven’t already, eliminate PRN use to the greatest extent possible.
  
  – Stress importance of complete nursing documentation of situation, behavior, and non-pharmacologic interventions attempted prior to administering PRN psychotropics!!!!!
Phase 2 – Focus on Pharmacy

Miscellaneous

- How is the MRR conducted and how often?
- Under what circumstances is the MRR conducted more often than monthly?
- How is the MRR conducted for short-stay residents?
- Pharmacist must identify actual or potential adverse consequences which may result from medications
- Surveyor may ask consultant pharmacist:
  - What do you review during your MRR?
  - Did you identify and report any irregularities to DON and attending physician?
  - What do you think of a specific issue?
  - Is this something you should have identified during the monthly MRR?
Phase 2 – Focus on Pharmacy

Miscellaneous

• Pharmacist review must consider whether:
  – The physician and staff have documented objective findings, diagnoses, symptoms, and/or resident goals and preferences.
  – Potential side effects and interactions have been identified and acted upon.
  – Dose, frequency, route, and duration are consistent with resident’s condition and standards of practice.
  – The physician and staff have documented progress towards, decline from, or maintenance of resident’s goals.
  – A GDR has been attempted or any non-pharmacologic approaches been added.
  – Medication errors exist or are likely to occur.
Phase 3 – Focus on Pharmacy

• Pharmacist involved in QAPI Plan/Process

• Pharmacist involved in Infection Control and Infection Control Training

• Designation of Infection Preventionist - must have professional training in nursing, medical technology, microbiology, epidemiology, or related field; and, may be qualified by education, training, experience, or certification.
CMS ‘Mega’ Rule Conclusion

• New regulatory requirements are significant and challenging!
• ‘Mega’ Rule is phased-in over 3 phases.
  – Phase 1 went into effect November 28, 2016
  – Phase 2 goes into effect November 28, 2017
  – Phase 3 goes into effect November 28, 2019
• New requirements are very costly to facilities!
• Places more responsibility and expectation on pharmacies and the consultant pharmacist!
  – In particular, antibiotic stewardship and the use of unnecessary medications (especially psychotropic medications)
References

• 80 Fed Reg 42168, Proposed Rule, July 16, 2015
• [Link](http://www.ltcp pharmacynews.com/docs/PDF%20Docs/LTC%20Requirements%20Update.pdf)
• [Link](https://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html)
T or F: Implementation of the ‘Mega’ Rule was completed on 11/28/2016.
T or F: Implementation of the ‘Mega’ Rule was completed on 11/28/2016.

ANSWER: False. The ‘Mega’ is being implemented over a three year period. Phase 1 was implemented on 11/28/2016. Phase 2 will be implemented on 11/28/2017. Phase 3 will be implemented on 11/28/2019.
The ‘Mega’ Rule is expected to cost each facility (in the first year) an average of:

A: $22,900
B: $42,900
C: $62,900
D: $82,900
The ‘Mega’ Rule is expected to cost each facility an average of:

A: $22,900
B: $42,900
C: $62,900
D: $82,900

ANSWER: C. However, it is likely that these projected costs are conservative. CMS acknowledges that LTC facilities in certain parts of the country may have difficulty hiring and retaining qualified staff required by the ‘Mega’ Rule.
Which of the following methods is acceptable for the attending physician to document response to DRR?

A: Pharmacist writes DRR into Medical Record and the Physician may respond directly into medical record.
B: Pharmacist writes DRR on separate form and the Physician writes response on form, then writes a separate note into medical record.
C: Pharmacist writes DRR on separate form and the Physician responds on form with the form to be placed in medical record.
D: All are acceptable.
Which of the following methods is acceptable for the attending physician to document response to DRR?

A: Pharmacist writes DRR into Medical Record and the Physician may respond directly into medical record.

B: Pharmacist writes DRR on separate form and the Physician writes response on form, then writes a separate note into medical record.

C: Pharmacist writes DRR on separate form and the Physician responds on form with the form to be placed in medical record.

D: All are acceptable.

ANSWER: D. All are acceptable. The facility just must be able to provide documentation of physician response.
T or F: PRN orders for Alprazolam, Lorazepam, Trazodone, Hydroxyzine, etc. must be limited to 14 days, unless the physician documents the rationale for a longer time frame; and he or she must indicate the duration of the PRN order.
T or F: PRN orders for Alprazolam, Lorazepam, Trazodone, Hydroxyzine, etc. must be limited to 14 days, unless the physician documents the rationale for a longer time frame; and he or she must indicate the duration of the PRN order.

ANSWER: TRUE. Get ahead of the curve on this! Limit PRN use of psychotropics. All PRN psychotropics must be limited to 14 days unless the physician documents rationale and includes the duration for the order.
Speaker Contact Information

ELDER CARE PHARMACY CONSULTANTS, LLC

CURT WOOD, RPH, FASCP
Certified Geriatric Pharmacist

573-795-6351
Fax: 573-985-3076
17566 Doe Run Rd.
New London, MO
63459

curt@eldecarerxconsultants.com

Senior Care Committee Chairman
Missouri Pharmacist Assn.