Mega Rule: How a Massive Pharmacy Regulation is Shaping Healthcare

The Mega Rule deconstructed. Find out the key issues for long-term care facilities and how PharMerica consultant pharmacists can aid in compliance.

When the so-called "Mega Rule" was unveiled in early 2016, it was instantly referred to as the most comprehensive revision of Medicare and Medicaid rules of participation requirements for long-term care facilities in 25 years. So massive was the 700-page regulation, its implementation needed more than four years to achieve.

Portions of the mega-rule affecting medication management have been viewed by many as necessary as they are onerous. Few can argue the noble and welcome efforts to better control the use of powerful psychotic drugs on frail elderly, or curb long-standing antibiotic dispensing practices that have given rise to more powerful mutated versions of the very pathogens they were meant to curtail. But many of the mandates designed to achieve those ends have exacted considerable burdens – both bureaucratic and financial – on nursing homes.

And yet, no one disputes the important role the Mega Rule will play reducing medication errors and re-hospitalizations and. In so doing, they have significantly shed light on the important role consultant pharmacists now play.

"With the newly established CMS Requirements of Participation, the enhanced focus on polypharmacy, unnecessary medications and medication related adverse events in the elderly have resulted in expansion of medication management processes across multiple care transition points," said Frank Grosso, RPh, former executive director and CEO of the American Society of Consultant Pharmacists.

Here's a look at the key issues of the rule:

Reconciliation

Observers have noted that issues around transitions – that critical time between hospital discharge and nursing home admittance – prompted CMS to refine and emphasize the practice of reconciliation, the process

of identifying the most accurate list of all medications a patient is taking, including name, dosage, frequency, and route, by comparing the medications that was prescribed prior to being discharged from the facility with those prescribed when leaving the facility.

The rule requires facilities to include all prescribed (during and after a hospital stay) and over-the-counter medications in the resident's discharge summary.

The importance of the rule is simple: More than 40% of all medication errors are the result of inadequate reconciliation of medications in hand-off's during admission, transfer and discharge of patients.

Monthly drug regimen (DRRs)

DRRs also are designed to reduce re-hospitalizations and curtail adverse drug events (ADEs).

Accountability seems to fall squarely on the shoulders of medical directors, which the rule designates as the primary gatekeepers of DRRs.

Under the rule, consultant pharmacists' DRRs must be provided to attending physicians, the medical and nursing directors within 72 hours of completion, and be included in the resident's permanent health record. The DRRs must be updated monthly, and nurses and attending physicians must immediately be notified of any urgent medication irregularities.

Psychotropic drugs

Loosely defined, these are medications that affect and in some cases, alter the chemical processes of the brain. For years leading up to the Mega Rule, debate raged in clinical circles about the harmful effects such medications have on already fragile minds in the elderly. Many believed the medications helped caregivers more than the residents themselves.

Key provisions in the rule: 14-day limits on PRN orders with longer periods permitted with proper documentation.

Many observers rightfully defended the industry's self-management of the problem, and believe the new rules do more to punish than resolve the core problem. The intent of the Mega Rule provisions, meanwhile, is seen as positive step toward ensuring these powerful drugs are appropriately prescribed and monitored. The pharmacy community is generally credited with succeeding in broadening interpretation of the rules. Meanwhile, the industry is moving toward finding alternative therapies for controlling the kinds of behaviors psychotropics were designed to curb.

Antimicrobial stewardship and infection preventionists

Combined with new provisions around infection prevention, antimicrobial stewardship rules are seen as the most expensive part of the Mega Rule to implement.

The rule requires all nursing facilities to establish an antimicrobial stewardship and infection prevention and control program.

The rule requires facilities to monitor antimicrobial use and establish protocols and designate either a full- or part-time staff infection preventionist (IP) to identify, investigate, report, prevent, and control infections and communicable diseases. The rule also includes various requirements on pneumococcal and influenza vaccines.

The Mega Rule addresses a vast number of issues around the manner in which drugs are dosed, administered and managed. Implementing these rules has created significant challenges for skilled nursing facilities.

For one, the mandates around infection preventionists and antimicrobial stewardship have imposed thorny conundrums around prescribing, administering and monitoring, says Marti Wdowicki, PharmD., director of clinical operations for PharMerica.

Technology barriers

“Antibiotic stewardship is designed to develop guidelines for making the best clinical decisions for the most common types of suspected infections in nursing homes -- urinary tract, respiratory, skin or soft tissue and gastrointestinal infections,” says Wdowicki. “In the frail elderly, these can be very serious infections with a high risk of complications and/or mortality or they can be uncomplicated colonization.

Wdowicki believes tracking and trending data that provides accountability and feedback on the success of antibiotic stewardship is still elusive to many long term care facilities. “One of the problems with having a really good program like this has to do with prescribers and their ability to make quick decisions,” she says. “Most nursing homes don’t have on-premises STAT labs, which significantly curtails the ability to manage infections and antibiotics within the parameters of the rule. Many facilities don’t have the benefit of having that information from a prescriber perspective in front of them and to be able to say whether this patient needs an antibiotic. Compounding matters is most of the targets of these therapies are frail seniors with multiple comorbidities.”

At a PharMerica meeting to help customers understand the new mandates, Wdowicki echoed the words of one attendee, who told her, “In the real world, no prescriber wants to be that person who prescribes an antibiotic that results in a life threatening C. Diff infection or multi-drug resistant organism that can’t be treated resulting in a terrible outcome. But you also don’t want to be the one who doesn’t prescribe and then the patient decompensates or worse, dies.”

“That’s a rock and a hard place,” Wdowicki notes. “That’s real. How do we get STAT labs in long-term care? How do we improve that aspect? That’s a very identifiable weakness or deficiency in the system that should promote better care. I don’t have an answer for that. Not sure there even is an answer. Technology is the other weakness.”

Workforce challenges

All the technology in the world helps little without an adequately staffed facility with trained caregivers. The rules around stewardship and infection prevention are deeply impacted by workforce issue that plague so many facilities today.

“CMS wants to drive non-pharmacological interventions. That’s what we all want. When nursing homes use psychotropics, there’s an additional financial burden that accompanies that. It’s very difficult when you have high staff turnover to implement non-pharmacological interventions and sustain them and have them be meaningful.”

Challenges happen with untrained or new staff as well. For example, new staff may not identify significant signs and symptoms of infection or be familiar with facility antibiotic stewardship guidelines when communicating with clinicians. Implementing and sustaining additional programs requires additional staff hours – which may not be available, she adds.

“One of the biggest roadblocks to operators in skilled nursing facilities is staff turnover,” says Wdowicki. “It’s widely known how staff turnover relates to quality of care, but when you try to implement programs and make sure that you can stand up to the documentation in a survey process that supports that implementation, it’s very challenging. Anyone can create something and roll it out and say they have an antibiotic stewardship program or an infection control program and am compliant with the psychotropic standards and here’s why. But when surveyors go to interview staff who may have only been there a week it’s just very difficult.”

Pharmacists’ role in drug regimen reviews

Consultant pharmacists are no stranger to drug regimen reviews. But complying with the new DRR requirements in the Mega Rule isn’t with challenges.

“Most of them are dealing with it in the best way they know how and can,” Wdowicki says. “For obvious reasons, the best person to evaluate DRRs has always been a pharmacist. The need for the pharmacist to perform a comprehensive review can’t be overstated. Does those reviews requires having the resident’s history, the diagnoses, the nurses notes, the multidisciplinary interventions. When you do a DRR and you are truly trying to impact the transition of care and ensure everything is thorough and there are no gaps as far as medications, you need to look at the entire patient record. And it’s not that accessible at this point in time.”

PharMerica’s role in assisting Mega Rule compliance

Having a qualified pharmacy services provider is a generally seen as a Godsend for cash- and staff-strapped skilled nursing facilities. The value and role of consultant pharmacists in Mega Rule compliance cannot be overstated.

“I want to give our senior leadership credit,” Wdowicki adds. “As far as antibiotic stewardship goes, that was answering the bell. That was a facility requirement. We have systems that don’t have the resources to create that kind of program or if they do, that’s not the best use of those resources spent developing complicated

programs like the Mega Rule requires. We came back internally and created solutions to address the Mega Rule. This took an enormous amount of man hours on our part and engaged both internal and external resources. An infectious disease specialist created our protocols and reviews them on an annual basis. Senior leadership said to all of us, 'go forth and make that happen.'"

Advice for providers

Having a vendor partner that's invested in helping facilities comply makes a big difference. "One of the biggest things we need to understand from a consultant pharmacist's viewpoint is that education can't be a one and done," she adds. "It's difficult for a SNF to have the necessary staff to do the repetitive kind of education that needs to happen when you want to have a sustainable and effective program in almost any aspect."

Wdowicki also suggests facilities identify and engage staff champions and multi-disciplinary partners, develop checklists and employ consistent monitoring and auditing throughout the year.

Other pharmacy executives advise SNFs to taps into the resources of the Institute for Safe Medication Practices, adopt clinical practice guidelines around high-risk drugs and residents, employ closed loop electronic medication systems, implement quality assurance and performance improvement teams and allow open discussion about medication errors at staff meetings.

Other recommendations include adopting best practices, providing ample yet specific geriatric-related resources for doctors, nurses and pharmacists, EHR and clinical decision support tools, consistent labeling systems and automated dispensing machines, which can help track medications and provide an additional point of verification.

To learn more about our solutions to address the Mega Rule, contact us at info@PharMerica.com or 855-637-1755.