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PHARMACY ROADMAP

PROVIDERS GET GLIMPSE AT WHAT THE NEXT THREE YEARS WILL MEAN FOR MEDICATION SERVICES UNDER THE NEW MEGA-RULE

It is a regulation as significant as it is voluminous, even by government standards. The "mega-rule," aptly named for the 700-plus pages it occupies, no doubt left some of the hundreds who attended a late January *McKnight's* webinar recalling that famous line from Robert Frost's poem, "Stopping by Woods on a Snowy Evening."

"I have promises to keep,
And miles to go before I sleep,
And miles to go before I sleep."

Indeed, long-term care providers and operators have miles to go before they rest from the broad changes the mega-rule is making not only to participation rules in Medicare and Medicaid, but also to the manner how drugs are dosed and managed.

Rolled out last year by the Centers for Medicare & Medicaid Services, the rules will be enacted in three phases, all beginning November 28 — in 2016, 2017 and 2019. The mega-rule is the most comprehensive revision of Medicare and Medicaid requirements for long-term care facilities since 1991.

The components affecting pharmacy already have administrators hustling.

Some of the looming changes are downright evolutionary. They were explained in detail by Todd King, Pharm.D., CGP, FASCP, director of clinical services for Omnicare, a CVS Health company during a *McKnight's* Jan. 31 webinar, titled "The mega-rule's clout: How changes in pharmacy-related services will impact you."

Four months into the first phase of the initiative, providers are grappling with some of the headiest parts of the massive regulation, including medication regimen review (MRR) processes designed to stem adverse drug events and rehospitalizations. King urged participants to waste no time engaging medical directors as the new gatekeepers of MRRs, while ensuring attending physicians are aware of the changes. But the one component

A SUPPLEMENT TO McKnight's LONG-TERM CARE NEWS

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of the mega-rule that promises the most heartburn is the mandate that all facilities establish an Infection Prevention and Control Program by Nov. 28, 2017, and have an antimicrobial stewardship program in place.

"From a clinical standpoint, antimicrobial stewardship and the infection control requirements around it are going to be a huge part of this going forward," he said.

CMS recognizes this will be a costly aspect of the mega-rule for facilities, he said. But it's a great opportunity to focus on "reducing hospitalizations, appropriate antimicrobial use and providing care to our residents," he added.

Already underway

Phase 1 of the mega-rule became effective Nov. 28, 2016. One of the five key tenets it asks for is for medication reconciliation processes to be defined and broadened.

What that means is CMS has formally defined reconciliation as 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 were prescribed prior to discharge from the facility with those prescribed when leaving the facility.

Facilities also are now required to produce a discharge summary that includes reconciliation of prescribed and over-the-counter pre- and post-discharge drugs.

King stressed that while there currently is some "subjectivity" around the format for a discharge summary, "I think CMS is wanting us to move in this direction because we all know a lot of the issues that happen in transitions of care are medication-related."

For more information

The original webcast is available at www.mcknights.com

Psychotropic drugs also have formally been defined. CMS now says they are any drug that affects brain activities associated with mental processes and behavior and include antipsychotics and antidepressants.

The good news is the long-term care industry has made big strides in managing antipsychotics, King said. He expects CMS and state surveyors will now begin looking into other drug categories, "specifically, the anti-anxiety and sedative hypnotic drugs, to ensure residents are taking the most appropriate dose ... and when the drug is no longer needed, making sure it's appropriately reviewed and discontinued, if possible."

Success with CMS

He added that the long-term care review community was successful at convincing CMS to modify an earlier draft that included certain drugs that have central nervous side effects, such as opioid analgesics and Parkinson's disease therapies.

"It does give clinicians a little subjectivity in terms of interpretation," he said. "Most of us are anxiously awaiting interpretive guidelines around these specific medications."

A third key point in Phase 1 issued clarifications concerning "irregularities" and "unnecessary" drugs.

Any irregularities noted by the pharmacist during the 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. It must list, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified. The attending physician must document in the resident's medical record his or her rationale for not changing a medication, or that an identified irregularity has been reviewed, and what, if any, action has been taken.

King praised the requirement, saying it will provide medical directors with "an opportunity to identify any trends or issues, that are repeatedly addressed, and have an impactful peer-to-peer conversation."

The consultant pharmacist's monthly drug regimen reviews must now be part of the resident's permanent health record. Complete reports (MRRs and summary admissions) must be provided to the facility in a timely manner. Facility staff provide the MRR reports to attending physicians, the medical director and DON per facility policy.

COMING TO TERMS

Monthly drug regimen reviews are something providers must make a high priority and vigilantly execute, experts say.

Photo: Moments Captured by Vanessa @ Courtney Manor

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Facilities also must develop and maintain policies for monthly MRRs that minimally include defined timeframes around the MRR process and steps the pharmacist must take when an irregularity requires urgent action to protect the resident.

When the consultant pharmacist identifies an urgent medication irregularity during MRR that requires immediate action, the facility policy shall dictate the notification of the prescriber.

"We deal with very sick patients who are on a lot of different medications and have multiple diagnoses from different physicians," King said. "There are times when critical issues happen around medications, and CMS is wanting facilities to have procedures for those issues so they can be addressed in a timely manner."

Controlling infections

One of the biggest points of emphasis is operators must develop an Infection Prevention and Control Program (IPCP).

Facilities must start and run an IPCP for identifying, investigating, reporting, preventing and controlling infections, and communicable diseases for staff, residents, families and the public.

"CMS is going to require facilities to establish these infection control committees," King stressed, "and over the next two phases of the implementation, there will be significant areas where facilities will have to ramp up their monitoring of antimicrobial use."

Also notable are the requirement that facilities develop and record a detailed care plan for each resident within 48 hours of admission, and new guidance on the duration restrictions and documentation requirements for "as needed" (PRN) psychotropics.

In addition, PRN orders for antipsychotics must be limited to 14 days, and can be renewed only with prescriber evaluation.

King believes the new PRN rule likely will further reduce the use of antipsychotics.

"This is a great opportunity for you to start talking to your physicians about the potential of this rule because the doctors are the ones who are going to be responsible for writing those orders and providing the associated documentation," King said.

He told providers to monitor any PRN drugs linked to "routine" medications in light of the new restrictions.

Facilities also must develop and implement a facility antibiotic stewardship program.

It must include:

- Antibiotic use protocols
- Systems to monitor antibiotic use
- Designation of one or more facility-based infection preventionists (IPs)
- Ongoing influenza and pneumococcal vaccine requirements

King said interpretive guidelines likely will specify issues such as whether IPs can serve part-time, and whether certifications will be required.

"Those with certifications would likely carry a lot of weight when you have a survey or monitoring and review of your programs," he added.

Marking the final and third phase of the mega-rule, which becomes fully effective in November 2019, facilities will be required to develop and implement a data-driven Quality Assurance and Performance Improvement Program.

Providers will be mandated to track medical errors and adverse events and analyze their causes — and perform regular analyses from medication regimen reviews.

By 2019, performance improvement activities will evolve to focus heavily on errors and adverse-related drug events, King said.

OVERALL SUMMARY OF MEGA-RULE

Phase 1

Effective date: Nov. 28, 2016

- Facility discharge summary must include medication reconciliation.
- Medical director must receive all consultant pharmacist irregularity reports.
- Drug regimen review (DRR) responses must be documented in resident's medical record.
- Facility must develop and maintain policies for monthly DRR process.
- Facility must establish and maintain an infection prevention and control program that includes defined elements.

Phase 2

Effective date: Nov. 28, 2017

- Each resident must have a baseline care plan within 48 hours of admission.
- A monthly drug regimen review must be performed with medical chart.
- PRN psychotropics have new duration restrictions and documentation requirements.
- Facilities must have an antibiotic stewardship program.

Phase 3

Effective date: Nov. 28, 2019

- Each long-term care facility must develop, implement, and maintain an effective, comprehensive, data-driven Quality Assurance and Performance Improvement (QAPI) program.

Source: Todd King, Omnicare, A CVS Health Company

Keeping things in perspective

Avoid procrastination, he emphasized. Also, expect ongoing interpretive guidelines around various topics that may seem fuzzy around the edges, like antimicrobial stewardship and drug regimen reviews.

Start by designating someone the unenviable task of reading the *Federal Register* notice containing the mega-rule.

The document can be accessed at *https://tinyurl.com/jgsp9ou*.

To put everything into perspective, King points to goals that everyone along the continuum agrees with: reducing re-hospitalizations and medication errors.

"Overall ... these are great opportunities for consultant pharmacists to interact with their facilities," King said.

Success will be found by ensuring there are drug and medication regimen review processes in place, following up on recommendations in a timely manner and ensuring documentation is going into the permanent medical record.

"Let's be honest," King said, "the stuff we're dealing with now is basically just very low hanging fruit.

"If we can all comply, we all should do well in future." ■

Editor's note

This McKnight's *Webinar Plus supplement is based on a similarly named webinar presented on January 31. The event was sponsored by Omnicare. The full presentation is available at* www.mcknights.com/January31webinar.