Medicare Adds New Long-Term-Care Pharmacy Rules
Agency Passes Again on Pharmacist Independence Requirements

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The Medicare and Medicaid programs have added some pharmacy requirements for long-term-care (LTC) facilities that put more responsibility on pharmacists. The final rule from the Centers for Medicare and Medicaid Services (CMS) issued at the end of September1 keeps the requirement for a monthly drug-regimen review (DRR) but adds a requirement for a simultaneous review of a resident’s medical chart and puts both requirements in a new pharmacy services section of the nursing home rules, in part to emphasize the importance of prescription drug oversight by the pharmacist. The new pharmacy services section also adds restrictions on the use of psychotropic medications, which have been widely described as overused in nursing homes to keep unruly patients quiet.

“The new regulation expands pharmacist services, and in many cases will increase the costs to provide these services,” said Khristy McClelland, President of Guardian Pharmacy in Jacksonville, Florida. Consultant pharmacists routinely review several sources of medical information during DRRs, including medical charts and medical administration records. “In some instances, barriers are present and may prevent pharmacists from accessing all of the medical records,” McClelland added. “In order to maintain compliance with the new regulations, facilities will have to ensure that pharmacists have access to these records.” In addition, facilities must have reporting procedures for pharmacists, which include a response timeline from prescribers when immediate action is required based on a DRR.

The new rule, which adds numerous provisions beyond the pharmacy section, seeks to reduce avoidable hospital readmissions and speed quality improvement throughout facilities.

The American Health Care Association (AHCA), which represents the nursing home industry, tried to convince the CMS to soften the pharmacist requirements. It argued that mandating a pharmacist’s review of a resident’s medical record will increase the time pharmacists spend in a facility, thus increasing facilities’ costs. “The increased costs to pharmacies will likely also be incorporated into the medication costs that are frequently reimbursed by Medicaid or Medicare Part D. As such, we believe that this proposed change represents an unfunded mandate to state Medicaid programs and Medicare Part D, which were not included in the CMS estimates of cost implications of the proposed rule,” the AHCA argued.

The AHCA also opposed a provision requiring pharmacists to alert the attending physician in writing of any “unnecessary medications” a resident may be taking. The AHCA complained that while the pharmacist’s monthly DRR may have a legitimate and clinically acceptable rationale, repeated notification of physicians and repeated documenting of the rationale related to the pharmacist’s findings is not a productive use of anyone’s time and may lead to inadvertent changes in medication regimens that could be harmful. According to Mark Parkinson, President and Chief Executive Officer of the AHCA:

While the agency took some steps forward in helping individuals in our centers, there were several provisions that harm our efforts to continue the tremendous strides we’ve made in quality and care delivery. Further, even CMS admits this new wave of regulations will bring with it hundreds of millions in additional costs without any new funding streams. We will spend the coming days and weeks determining what overall impact those mandates will have on our members.

CMS Punts on Pharmacist “Independence”

The final rule arrived weeks before the U.S. Justice Department announced that nursing home pharmacy service provider Omnicare had agreed to pay $28.1 million to settle charges it demanded kickbacks from Abbott Laboratories to increase use of its epilepsy drug Depakote.2 Depakote (divalprox sodium) is used to control behavioral disturbances in dementia patients, but the Food and Drug Administration has not approved that use. CVS Health purchased Omnicare in 2015; the Justice Department acknowledged that CVS halted the alleged misconduct. In May 2012, Abbott entered its own settlement with federal and state officials over the kickback scheme, paying $1.5 billion to resolve its liability under the False Claims Act. The scheme also involved the pharmacy company PharMerica, which paid $9 million in 2015 for accepting kickbacks. Omnicare and PharMerica, the two biggest players in the nursing home pharmacy market, serve approximately half of nursing facilities. The rest are served by roughly 1,200 independent LTC pharmacies, approximately 800 of which belong to the group purchasing organization Managed Healthcare Associates.

As the Justice Department was pursuing those cases, the CMS, starting in 2011, was considering imposing independence and conflict-of-interest rules on nursing home pharmacy service providers as part of a larger Medicare rule overhaul. The AHCA and the American Society of Consultant Pharmacists (ASCP) opposed such rules, and the CMS dropped the idea. But when the CMS undertook this latest rulemaking in 2015—specifically aimed at LTC facilities—groups such as the California Advocates for Nursing Home Reform (CANHR) pushed for pharmacy independence provisions, arguing that any improvements on DRRs would be “greatly compromised” by CMS’s failure to address widespread conflicts of interest involving consultant pharmacists. Despite its legwork in 2012...
and the subsequent Justice Department actions, the CMS omitted any provisions on independence from the 2015 proposed rule and therefore declined to address conflict-of-interest restrictions in the final rule. However, the agency added it would consider the issue in any future related rulemaking.¹

The CMS’s refusal to pursue this issue seems a bit surprising. In October 2011, as part of broader Medicare rulemaking, the CMS said various arrangements involving LTC facilities, LTC pharmacies, LTC consultants, and pharmaceutical manufacturers and/or distributors raised concerns about the quality of consultant pharmacists’ reviews and the potential impact on resident health and safety. “We believe these concerns may be addressed by changes we are considering that would require LTC consultant pharmacists be independent of the LTC facility pharmacy, pharmaceutical manufacturers or distributors, or any affiliate of these entities,” the CMS said then.² That proposed rule stated: “We are considering requiring that long-term-care facilities employ or directly or indirectly contract the services of a licensed pharmacist who is independent. We also are considering including a definition of the term ‘independence’ to mean that the licensed pharmacist must not be employed, under contract, or otherwise affiliated with the facility’s pharmacy, a pharmaceutical manufacturer or distributor, or any affiliate of these entities. Our changes would also prohibit nursing homes from contracting for the provision of consultant pharmacy services with entities (such as a subsidiary of an LTC pharmacy) that have been created for the purpose of providing reorganized consultant pharmacist services.”

In February 2012, after receiving comments on the proposed rule, the CMS said a significant number of commenters who identified themselves as current or former consultant pharmacists either acknowledged that they had experienced a conflict of interest or confirmed that such conflicts were an ongoing problem.³ “The reports of conflict of interest are sufficient to indicate it continues to exist, and our concerns regarding its impact on the quality of care in LTC facilities are well-founded. We believe that this demonstrates that change is necessary to ensure that all LTC consultant pharmacists are free from conflicts of interest, are able to base their professional medication recommendations on the best interest and clinical needs of LTC facility residents, and are able to advocate for the Medicare beneficiary,” the CMS said.

Despite arguing that change was necessary in 2012, the agency decided then not to pursue it, saying that “since a requirement for independent consultant pharmacists will not solve the entire problem, but would be significantly disruptive for much of the LTC industry, we are not finalizing this provision at this time. Instead, we are soliciting additional comments to help us determine a more comprehensive approach to eliminate overprescribing and the use of chemical restraints in LTC.”

The ASCP’s position has been that the industry is taking voluntary steps to avoid conflicts of interest—for instance, by transitioning to service agreement models for LTC facility clients that include separate contracts for consultant pharmacist services and pharmacy dispensing services. However, the ASCP wanted in 2012 that more work was needed to demonstrate independence and to ensure transparency across the LTC industry. It cited tools it had developed to assist consultant pharmacists and LTC pharmacies with demonstrating independence, including sample disclosure statements.

“It is highly disturbing that CMS pointed to its own failure to address this known problem in the July 2015 proposal as the reason it could not establish an independence requirement in the final regulations,” CANHR advocate Mike Connors said. “By continuing to punt the need to require independence until another day, CMS is exposing hundreds of thousands of nursing home residents to dangerous drugging practices.”

Provisions That May Indirectly Affect Pharmacists

While pharmacists and nursing homes will not have to contend with new independence rules, they will face additional requirements beyond those in the new pharmacy services section. For example, all LTC facilities will have to:

- Develop, implement, and maintain an effective, comprehensive, data-driven quality assurance and performance improvement program that focuses on systems of care, outcomes of care, and quality of life.
- Develop an infection prevention and control program that includes an antibiotic stewardship program.
- Develop and implement a baseline care plan for each resident, within 48 hours of his or her admission, that includes the instructions needed to provide effective, person-centered care that meets professional standards of quality care.

In some cases pharmacy groups had hoped that these new sections would have a more direct impact. One example is the requirement that a facility put together an interdisciplinary team (IDT) to prepare the baseline plan cited above within 48 hours. The rules specifically add a nurse’s aide and a member of the food and nutrition services staff to the required IDT membership. That IDT would also be involved in discharge planning. The decision to exclude pharmacists is perhaps understandable given that they are not considered providers under the Social Security Act, while nurse’s aides and food and nutrition staffers are. Legislation is pending in Congress to grant pharmacists that status, but it has never had a hearing or vote in a House or Senate committee.

The ASCP wanted the CMS to add a pharmacist to the IDT. Moreover, it suggested that a pharmacist ought to provide a comprehensive medication review (CMR) both when a resident arrives and when a resident leaves, either to go to a hospital, to his or her home, or to a relative’s home. In the final rule, the CMS said it considered requiring a pharmacist to participate on the IDT and “determined that it would be overly burdensome.” While pharmacist inclusion on the IDT is not required, neither is it prohibited. The LTC can make the call. Nor did the CMS opt to include the pharmacist in the discharge process, much less require a CMR. The baseline plan that is required upon admission falls short of a full medical review as well as a CMR, which is a systematic process that includes collecting patient information, identifying and prioritizing medication-related problems, and creating a plan to resolve medication-related problems with the patient, caregiver, and/or prescriber.

Pharmacists are also not included in the list of “clinically qualified” personnel whom the attending physician can designate as service providers. That delegation does not include pharmacists being able to deliver medication, which they can do in 40 states subject to collaboration agreements with physicians. However, pharmacists will definitely be involved in new

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¹See 763 P&T 595, 601 (July 2015) (Petition for Reconsideration).

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infection control programs. The ASCP believes consultant pharmacists will be called on to “train the trainers” on safe and prudent antibiotic use. The association is developing products and programs designed to give senior care pharmacotherapy specialists the tools they will need to assist facilities.

**New Pharmacy Services Section**

While there were disappointments for pharmacists hoping to gain additional statutory roles, there was also reason for satisfaction. At the proposal stage, the requirement for a medical records review was limited to three situations: when the resident is new to the facility; when a prior resident returns or is transferred from a hospital or other facility; and during each monthly DRR when the resident has been prescribed or is taking a psychotropic drug, an antibiotic, or any drug that the quality assessment and assurance committee has asked to be included in the pharmacist’s monthly drug review. The final rule dictates a review of the medical chart each month for every resident.

The purpose of a DRR and the associated medical record review is to identify any unnecessary medications a resident may be taking. It is up to the individual facility to determine how narrow or how broad this DRR is. But the elements must include time frames for the different steps in the process and actions the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

“Unnecessary” is defined as 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. “Irregularities” would be any unnecessary drugs the pharmacist believes the resident is taking. The pharmacist must report any irregularities to the attending physician and the facility’s medical director and director of nursing; these reports must be acted upon. 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.

What happens, though, if the physician declines to change a resident’s medication upon being notified by the pharmacist of irregularities? Does the pharmacist have recourse to appeal? Some argued the pharmacist should be able to report the irregularities to some entity outside the purview of the LTC and the physician. Not only did the CMS decline to provide that outside appeal, it also declined to require a pharmacist’s finding of irregularities to be reported to the resident or his or her representative. “The irregularity identified by the pharmacist may require no action, updating or modifying documentation, or some other action that does not affect the quality of care for the resident,” the agency said. “Unnecessary notifications could lead to confusion and anxiety for the resident.”

**New Requirements for Psychotropic Drugs**

One of the more controversial aspects of this rewrite of Medicare LTC rules is the expansion of drugs of particular concern. Congressional hearings and sundry reports have focused on the improper use of drugs to pacify unruly nursing home residents. Formerly the CMS nursing-home rules paid enforced attention only to antipsychotics. The new rule expands that to psychotropic drugs. This raised all sorts of concerns at the proposal stage, both because of the particular drugs likely to be included, especially opioids, and rules around PRN (pro re nata or as needed) orders and gradual dose reduction (GDR).

The new rules say that based on a comprehensive assessment of a resident, the facility must ensure that residents who have not used psychotropic drugs are not given them unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record. Residents who use psychotropic drugs, either when entering the facility or when having them prescribed after entering, must receive GDR and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs. PRN orders for psychotropic drugs are limited to 14 days unless the attending physician or prescribing practitioner documents the rationale in the resident’s medical record.

The CMS backed off a bit in the final rule on which drugs are considered psychotropic. The proposed definition cited any drug that affects brain activities associated with mental processes and behavior. Specific categories listed were antipsychotics, antidepressants, antianxiety drugs, hypnotics, opioid analgesics, and any other drug that results in effects similar to the drugs listed in the categories mentioned. That last phrase prompted a lot of opposition, as did the inclusion of opioids.

In the final rule, the CMS admitted that the proposed definition of psychotropic drugs might include many medications for which the additional requirements “would be superfluous and unnecessary.” So it removed the clause “any other drug that results in effects similar ...” from the definition. The agency also dropped opioids. In doing so, it stated: “We are particularly concerned about the possibility that including opioid analgesics in the definition could result in negative consequences for pain management, especially since they are usually given PRN and there could be interruptions in the prescriptions due to the proposed limitation on PRN prescriptions.”

Although pharmacists will not have to tip toe around opioid prescriptions, they will have to be vigilant about the other categories. To the extent that makes them whistleblowers of a sort, they may sometimes be in an uncomfortable position of second-guessing physicians treating patients with dementia and other psychiatric afflictions. Guardian’s McClelland says, “There is concern that the new psychotropic regulations may have the potential to impede, rather than improve, patient health and safety.”

**REFERENCES**


