Pharmacies Cannot Directly Bill Medicare For Compounded Drugs Sent to Physicians

Stephen Barlas

Mr. Barlas is a freelance writer in Washington, D.C., who covers issues inside the Beltway. Send ideas for topics and your comments to sbarlas@verizon.net.

The FDA isn’t the only federal agency under fire for its policies on compounding pharmacies. A little-discussed final rule, issued in November by the Centers for Medicare and Medicaid Services (CMS), concerns policies for physician payments starting January 1, 2013. The rule prohibits pharmacies from billing Medicare directly for compounded drugs that they supply to physicians’ offices for administration to patients via implantable intrathecal pumps. Almost all of these drugs are compounded Schedule II controlled substances (e.g., morphine, hydromorphone, fentanyl, bupivacaine, clonidine, and baclofen).

Some Medicare contractors have been paying pharmacies for compounded drugs that they supply to physicians, and some have not. Both the pharmacies that have been billing Medicare directly and the physicians who have been handling them claim that the CMS decision will force physicians to stop administering compounded cancer and pain medications because they don’t have the financial resources to carry the costs of the drugs.

Andrew Holt, DPh, Executive Director of the Tennessee Board of Pharmacy, says that the CMS policy, as outlined in the final rule, is not allowable under Tennessee law and, in fact, might create a conflict with federal laws regarding controlled substances. He said individualized, compounded drugs cannot be sold to a physician, only to a patient or the patient’s agent.

Logan E. Davis, PharmD, Director of Franchise Development at Vital Care, Inc., says that the Medicare decision will make the fungal meningitis outbreak stemming from the New England Compounding Center in Framingham, Mass., even worse. Vital Care grants franchises to independently owned and operated independent pharmacies in 19 states. Some of these pharmacies do compound medications. The Vital Care pharmacies that have so far been able to bill Medicare directly for drugs that they supply to physicians must be accredited in order to receive payment from Medicare. Accrediting agencies include The Joint Commission and the Accreditation Commission for Health Care. Logan Davis explains:

“These accreditation bodies enforce sterile compounding standards. It is shocking that this final rule says, in effect, that if you sell to a doctor’s office and the doctor bills Medicare, you, the pharmacy, no longer have to worry about accreditation.

Under Part B, Medicare reimburses for drugs when a physician buys a drug and administers it to a patient in the office (the primary way) and when the drug is necessary for the effective use of durable medical equipment. In the latter case, pharmacies can bill Medicare directly for drugs used with nebulizers or external pumps when multiple doses are dispensed and delivered to a patient over a given time period. This policy is not changing.

Medicare had long maintained that it could not be directly billed by compounding pharmacies for drugs supplied to physicians’ offices. However, Medicare contractors Cahaba GBA, Trailblazer Health Enterprises, WPS Medicare, and First Coast Service Options had been reimbursing pharmacies. Collectively, these contractors serve as the local carriers for 13 states plus Puerto Rico and Indian Health Services. Instead of stepping in and telling those contractors to cease and desist, Medicare dilly-dallied over the past couple of years with “change requests” that were meant to set the record straight and kept delaying the effective date of those policy statements.

The confusion helped some compounding pharmacies and hurt others. In states where Medicare contractors (who approve Part B payments) allowed pharmacies to bill directly for compounded opiates used in physician offices, the pharmacies marketed that fact to a fare-thee-well. In its final rule issued on November 4, 2012, the CMS said, “Inconsistent application of the policy has given a distinct economic advantage to some pharmacies relative to others that we do not believe is equitable.”

The rule added that although Medicare might have been a little slow to correct contractors that reimburse pharmacies, that is clearly an unapproved process and it should stop.

Here is where things get tricky. A sizable portion of the compounded drugs used in implantable pumps consists of opiates. That brings the Drug Enforcement Administration (DEA) into the picture. Pharmacies can register with the DEA as a manufacturer/distributor. It is a criminal violation of the law when a DEA-registered pharmacy knowingly and intentionally delivers opiates to any person other than the patient or a member of the patient’s household. However, a DEA-registered manufacturer/distributor may distribute controlled substances to providers under conditions outlined by the DEA. For pharmacies that register as a distributor, a “5 percent rule” specifies that they can supply no more than 5% of their dosage units to physicians’ offices. This does not apply if a drug must be compounded from bulk chemicals.

Logan Davis says:

Generally, if pharmacies dispensing these preparations were to distribute the preparations to physicians, their distribution would exceed 5% of all of the controlled substances they dispense in a calendar year. Since these preparations are unique, high-risk sterile compounds, rather than a bottle of pills, a registration with the DEA as a distributor would not suffice. To distribute these controlled substances, a pharmacy would have to register with the DEA as a manufacturer, and this registration would have implications related to pharmacy registration with the FDA and most state Boards of Pharmacy.