Blue Cross and Blue Shield of New Mexico

Medicare Part D pharmacy updates: Pharmacy compounding

Compounding is an ancient practice in which pharmacists combine, mix, or alter ingredients to create unique medications that meet specific needs of individual patients. Compounding continues to attract the scrutiny of the U.S Food and Drug Administration (FDA) mainly because of instances where compounded drugs have endangered public health.

The FDA considers virtually all compounded drugs as unapproved new drugs for which safety and efficacy have not been demonstrated with the type of data the FDA requires to approve a new drug. However, the FDA also considers "traditional" compounding to be a valuable service and does not take enforcement action against these practices. The FDA defines traditional compounding as customizing a drug for someone who is allergic to a dye or preservative in an FDA-approved medicine, or compounding a liquid dosage form specifically for a younger patient. Compounding generally does not include mixing or reconstituting commercial products in accordance with the manufacturer's instructions or the product's approved labeling.

Red flags and FDA enforcement activities

The FDA is concerned about the emergence over the past 10 to 15 years of firms with pharmacy licenses making and distributing unapproved new drugs in a way that is clearly outside the bounds of traditional pharmacy practice. FDA enforcement has been directed to those pharmacies whose activities raise the kinds of concerns normally associated with a drug manufacturer and whose compounding practices result in significant violations of the new drug, adulteration, or misbranding provisions of the federal Food, Drug, and Cosmetic Act (FDCA).

In addition, unlike commercial drug manufacturers, pharmacies are not required to report adverse events associated with compounded drugs. In 2007, the FDA reported knowledge of more than 200 adverse events involving 71 compounded products since 1990. Examples of some of these adverse events included three deaths due to contaminated compounded intravenous solutions, blinding of two patients, and damaged eyesight to others from a bacterially contaminated compounded product used in cataract surgery. In a 2001 FDA survey of compounded drug products, the agency found 34 percent of the products tested failed standard quality tests, as opposed to a less than 2 percent failure rate for commercially produced drug samples.

As a consequence, the FDA has issued warning letters to pharmacies that specialize in female hormone products (e.g., bioidentical hormone replacement therapies), anti-infective inhalation products, sustained-release/delayed-release/extended-release products, and local anesthetic pain products. FDA warning letters have also been sent in cases where the FDA believes pharmacy communications (advertisements or website information) contain false and misleading claims about product safety, effectiveness, and superiority to FDA-approved and commercially available products.

When contemplating further action against compounding pharmacies, the FDA considers whether the pharmacy engages in the following acts:

- Compounding drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions.
- Compounding drugs that were withdrawn or removed from the market for safety reasons.
- Compounding finished drugs from bulk active ingredients that are not components of FDA-approved drugs (e.g., estriol) without an FDA-sanctioned investigational new drug application.
- Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility.
- Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.
- Using commercial scale manufacturing or testing equipment for compounded drug products.
- Compounding drugs for third parties who resell to individual patients, or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.
- Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved, commercially available drug. In these circumstances, FDA will consider whether there is documentation that a patient needs a particular compound.
- Failing to operate in compliance with applicable state law regulating the practice of pharmacy.

What is BCBSNM experiencing?

Prime Therapeutics®, the pharmacy benefits manager (PBM) for BCBSNM, has identified the billing practices of non-traditional compounding pharmacies as one of the most common reasons network pharmacies are placed on Corrective Action Plans (CAPs) or other related actions. Prime has identified a number of pharmacies with questionable compounding practices. Examples of inappropriate practices include:

- Submitting pharmacy claims with incorrect or invalid NDCs according to the compounding log
- Claims for compounds that contain medications not covered by Medicare Part D based on their intended route of administration
- Marketing of compounded drugs utilizing a non-FDA-approved aerosolizing device
- Compounding copies or near-copies of FDA-approved commercially available drugs

What do the CMS regulations say?
Chapter Six of the *Medicare Prescription Drug Benefit Manual* provides the following guidance on the coverage of "Extemporaneous Compounds":

- Compounded prescription drug products can contain **all**, **some**, or **no** Part D drug product components.
- Only costs associated with those components that satisfy the definition of a Part D drug are allowable costs under Part D because the compounded products as a whole do not satisfy the definition of a Part D drug. As a consequence, claims for compounded prescriptions can consist only of National Drug Codes (NDC) for FDA-approved prescription drug products. Traditional compounding powders are typically not FDA-approved drug products.
- The labor costs associated with mixing a compounded product that contains at least one Part D drug component can be included in the dispensing fee.

What should providers do?
Providers should discuss with their patients whether the use of compounded medications in lieu of FDA-approved and clinically tested products is the best option for their specific medical needs. Patients or practitioners who encounter problems (e.g., adverse drug events) with compounded products are asked to file a MedWatch report in one of the following ways:

- By phone: **800-332-1088**
- By fax: **800-FDA-0178**
- By mail: MedWatch, 5600 Fishers Lane, Rockville, MD, 20852-9787
- Online: www.fda.gov/medwatch