Compounding Pharmacies and Compounded Drugs: Information for Prescribers

Compounding pharmacies provide customized medication for patients who require a medication that is not commercially available or need a specific dosage form or strength. Compounded drugs are not approved by the FDA and are not subject to the same regulations as commercially available drugs.

Rules and regulations that govern compounding pharmacies

Compounding pharmacies are subject to oversight by both federal and state authorities. They are overseen by state boards of pharmacy and must comply with regulations and standards set forth by the United States Pharmacopeia (USP) and other professional organizations. Compounding pharmacies are required to adhere to the regulations set forth in Section 503A of the Federal Food, Drug, and Cosmetic Act, and in California, they must also comply with Title 16 of the California Code of Regulations (CCR). Inspections may be conducted by state boards of pharmacy or other regulatory bodies to ensure compliance. The Accreditation Council for Health Care (ACHC) offers Pharmacy Compounding Accreditation to assess the nonsterile and sterile pharmacy compounding process according to specific standards.

What compounding pharmacies can do

Compounding pharmacies can customize the strength or dosage of the medication, flavor it, reformulate it to exclude unwanted nonessential ingredients, and change the form of the medication. However, they are not allowed to compound medications in bulk, for resale, make copies of commercially available drugs, or compound biological products. Compounding pharmacies must comply with strict safety and sterility requirements to prevent contamination and ensure patient safety.

Risks and other concerns

Compounded medications may pose risks to patients, including contamination, inconsistent dosing, and ineffective treatment. Compounded drugs are not reviewed by the FDA for safety, effectiveness, or quality before being given to patients, and there have been many cases of serious patient injury linked to poor quality compounded drugs. Congress passed the Drug Quality and Security Act (DQSA) in 2013 in response to these incidents, which made updates to the Federal Food, Drug, and Cosmetic Act (FD&C Act) regarding human drug compounding. The DQSA established a new category of compounders known as outsourcing facilities, which are subject to current good manufacturing practice (CGMP) requirements and FDA inspections. Compounding practices lack standardization, which can lead to variability in potency, stability, and dosing accuracy. The potential for contamination or adulteration of compounded drugs can pose serious health risks to patients. Patients may also be at risk for drug interactions or other adverse events if they are taking multiple compounded medications or combining them with other drugs.

The FDA has issued warnings and recalls for several compounded medications that were found to be unsafe or ineffective. In addition, there have been cases of compounding pharmacies engaging in unethical practices, such as selling unapproved drugs. Patients should be informed of the risks and benefits of compounded medications and should only use them under the direction of a licensed prescriber. Prescribers should carefully consider the risks and benefits of compounded medications and ensure that the compounding pharmacy is reputable and compliant with regulations and guidelines. They should also be aware that insurance coverage may be limited or non-existent for compounded medications.

Recommendations

- Rare situations when using a compounding pharmacy maybe justified are in clients with swallowing difficulties, or when micro-dosing is needed for tolerability.
- First check the attached list of available psychotropics available in oral solution and disintegrating formulations. Preferring commercially available products before compounded products.
- If compounding is needed, obtain approval from Medical Chief, Deputy Medical Director, or Medical Director prior to writing the prescription
- Submit Prior Authorization (PA) to client's insurance plan.
- Involve BHRS pharmacy team for compounding pharmacy referral, assistance with PA, and billing.

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