Compounding for Prescriber “Office Use”

The International Academy of Compounding Pharmacists (IACP) supports the ability of pharmacists to compound and dispense medications to an authorized prescriber for the purposes of “office use” in the prescriber's in-office care of patients.

IACP encourages pharmacists to consider the following when dispensing a compounded preparation to an authorized prescriber for “office use”:

1) In the judgment of the dispensing pharmacist, the quantity being compounded and dispensed for “office use” is consistent with accepted practice.
2) All compounds dispensed on an “office use” prescription or medication order should be labeled “For Institutional or Office Use Only – Not for Resale” or as otherwise required by state pharmacy practice acts.
3) The pharmacist should provide to the authorized prescriber on each dispensing of an “office use” compounded preparation the name and strength of the preparation or a list of active ingredients and strengths, the pharmacy’s lot number, a beyond-use expiration date as determined by the pharmacist using appropriate documented criteria, and any necessary and appropriate ancillary instructions or cautionary statements.
4) The pharmacy should have written procedures for notifying each authorized prescriber or facility to which the “office use” compounded preparation was dispensed in the event of a recall.

IACP encourages pharmacists to advise prescribers that the resale or redispensing of any “office use” compounded product may lead to violations of practice acts or other state regulations involving labeling and recordkeeping.

IACP encourages pharmacists to carefully consider federal and state laws when dispensing an “office use” compounded preparation to an authorized prescriber if the pharmacist has reason to believe that the preparation will be subsequently redispensed or resold by the prescriber.

IACP opposes legislative or regulatory actions that would prevent authorized prescribers from obtaining compounded medications for “office use.”

IACP opposes legislative or regulatory actions that would require the pharmacist to be responsible and accountable for how the authorized prescriber and/or the prescriber’s staff document, record or use the compounded prescription in their practice.
Background

Compounding medication for office use has historically been recognized as an important part of the practice of pharmacy. When deciding whether to fill a prescription for a compounded medication for office use, pharmacists should first ensure that there are no state laws or regulations that specifically prohibit compounding for office use. Pharmacists must then turn to federal law for further guidance on compounding for office use.

In discussions leading up to the passage of the Food and Drug Modernization Act of 1997 (FDAMA) and the subsequent reaffirmation of FDAMA Section 503A in the Drug Quality and Security Act of 2013, the FDA and legislators recognized the importance of the practice of compounding for office use and that it should not be banned. FDA recognized that certain dermatological applications must be administered in the prescriber’s offices. Further, a prescriber’s expertise may be needed to administer a “first dose” of a certain medication in the office and send the remaining portion of the medication home for the patient to administer him/herself. Pharmacists should always document who is receiving the compounded medication even if the compounded medication is dispensed to a physician for office use.

FDCA 503A does not explicitly recognize the compounding for office use. FDAMA exempts pharmacies from complying with certain FDA requirements if the drug product is compounded for an individual patient. While the risk of FDA enforcing action based on the compounding for office use is probably very low provided that the compounded medication is provided to a physician’s office pursuant to a physician’s order for use in the office for a valid medical reason and provided that the pharmacist complies with the other provisions of the federal law and any applicable state requirements. FDA may issue regulations in the future regarding compounding for office use to further implement 503A.

Pharmacies who dispense compounded medications to physicians who are in turn reselling the medications, are no longer selling at retail. Such pharmacies may be viewed as manufacturers and/or wholesalers and come under registration requirements. Section 510 of the Food Drug & Cosmetic Act imposes FDA registration requirements (see 21 U.S.C. § 360(b)) and there are also individual state requirements for registration as a manufacturer and/or wholesale distributor. However, pharmacists are exempt from such requirements provided that they do not “manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business or dispensing or selling drugs or devices at retail” (see 21 U.S.C. § 360 (g)(1) and 21 U.S.C. § 704(a)(2)(A)).

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