The Truth About Pharmacy Compounding

A briefing for physicians and other prescribers

A highly regulated profession

Pharmacy compounding is not a new phenomenon. It goes back a thousand years or more, to the very beginnings of pharmacy practice. In an ancient world in which standardized, mass-produced drugs were not yet dreamed of, compounding *was* pharmacy — mixing ingredients to create a treatment for a specific person or animal.

Pharmacy practice has come a long way since then, and so has pharmacy compounding. What has remained consistent is the role of compounding in healthcare. These days, upon an order from a prescriber, traditional compounding pharmacies use pure ingredients to create customized medications for a specific human or animal patient.

Pharmacy compounding for human patients, then, is a legacy therapy that existed well before the establishment of mass-produced drugs and government regulation of those drugs. But being a legacy does not mean it's obsolete or unimportant; in fact, the American healthcare system depends on pharmacy compounding. Compounding is an appropriate and essential therapy option when, in the judgement of a prescriber, an FDA-approved, mass-produced drug is not suited to a specific human patient's need. This is why it is enshrined in the U. S. Food, Drug & Cosmetic Act and permitted so long as certain criteria are met.

Courtesy of:

From the simple addition of grape flavoring for a child's medication to the compounding of critical medications in shortage, compounding pharmacies are highly regulated, adhering to high standards of quality and compliance. Just as with pharmaceutical manufacturers, the active pharmaceutical ingredients — API — that compounding pharmacies use must come from FDA-registered facilities and manufacturers. Compounding labs and the equipment in them are subject to exacting regulation and are inspected by state boards of pharmacy and by the FDA. In addition, pharmacy compounders must adhere to state laws and regulations governing compounding as well as standards promulgated by the United States Pharmacopoeia, the internationally recognized standards-setting organization. In fact, many (if not all) states have expressly adopted some or all USP standards directly into their laws.

The lives and health of millions of Americans are enriched daily by compounded medications ordered by a physician or other prescriber.

Alliance for Pharmacy Compounding

Pharmacy Compounding Foundation

What can be compounded?

Under federal law, to be eligible for use in a compounded product, an active ingredient must meet one of the following criteria:

1. Be component of an FDA-approved drug product.
2. Have a USP or National Formulary monograph.
3. Appear on the 503A Bulks List published by the FDA.

At the same time, the law also prohibits traditional pharmacies from compounding a drug that is "essentially a copy" of an FDA-approved commercially available manufactured drug. A pharmacist can't just create a compounded version of Estrace, for instance — because that drug is commercially available.

FDA has set out criteria to be used in evaluating whether a compounded drug is not "essentially a copy" of an approved drug. A compounded drug isn't "essentially a copy" of an approved drug when:

1. The manufactured drug product has been withdrawn from the market for reasons other than safety or lack of effectiveness.
2. The compounded drug product uses a different route of administration than the commercial version.
3. The compounded drug product's ingredients and/or strength are not easily substituted with the commercial version.
4. The compounded drug product has been changed, and that change produces a significant difference for the patient or patient population (for example, removing an ingredient for patients who are allergic).
5. The manufactured drug appears on the FDA's Drug Shortage List.

A significant exception to the three-point criteria for APIs and rules prohibiting "essential copies" is #5 above — when a drug appears on the FDA's Drug Shortage List. Then, a pharmacist may be able to compound essential copies of FDA-approved drugs.

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The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers.

In traditional compounding, pharmacists create a customized medication, most often from pure ingredients, for an individual patient pursuant to a prescription. Pharmacists' ability to compound medications from pure ingredients is authorized in federal law and for good reason: Manufactured drugs don't come in strengths and dosage forms that are right for everyone, and prescribers need to be able to prescribe customized medications when, in their judgment, a manufactured drug is not the best course of therapy for a human or animal patient.

Every day, APC members play a critical role in patients' lives, preparing essential, custom medications for a range of health conditions, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, animal health, and others.

Learn more at **A4PC.org** and **compounding.com**