

Why Custom Compounding?

Source: International Academy of Compounding Pharmacists (www.iacprx.org or www.compoundingfacts.org)

Compounding medications is an integral part of the practice of pharmacy; an estimated 30 million to 40 million prescriptions are compounded each year. Yet many people may not even be aware of its role. Compounded medications are prescriptions that are written by physicians, veterinarians and other legally authorized prescribers and prepared for an individual patient by a specially trained pharmacist.

A growing number of people have unique health needs that off-the-shelf prescription medicines cannot meet. For them, customized, compounded medications -- prescribed or ordered by licensed physicians or veterinarians and mixed safely by trained, licensed compounding pharmacists -- are the only way to better health. Compounding is in even greater demand for treating animals because of the relatively narrow selection of medicines that are manufactured by pharmaceutical companies.

Pharmacists are the only health care professionals that have studied chemical compatibilities and can prepare alternate dosage forms. In fact, each state requires that pharmacy schools must, as part of their core curriculum, instruct students on the compounding of pharmaceutical ingredients. Many pharmacies practice a small degree of compounding, while others specialize in the centuries-old practice. Compounding pharmacies are licensed and regulated in the 50 states and the District of Columbia by their respective state boards of pharmacy.

Because every patient is different and has different needs, customized, compounded medications are a vital part of quality medical care.

Why do healthcare practitioners prescribe compounded medications?

The basis of the profession of pharmacy has always been the "triad," the patient-physician-pharmacist relationship. Through this relationship, patient needs are determined by a physician, who chooses a treatment regimen that may include a compounded medication. Physicians often prescribe compounded medications for reasons that include (but are not limited to) the following situations:

- When needed medications are discontinued by or generally unavailable from pharmaceutical companies, often because the medications are no longer profitable to manufacture;
- When the patient is allergic to certain preservatives, dyes or binders in available off-the-shelf medications;
- When treatment requires tailored dosage strengths for patients with unique needs (for example, an infant);
- When a pharmacist can combine several medications the patient is taking to increase compliance;
- When the patient cannot ingest the medication in its commercially available form and a pharmacist can prepare the medication in cream, liquid or other form that the patient can easily take; and
- When medications require flavor additives to make them more palatable for some patients, most often children;
- When standard treatments have failed and an alternative is needed;
- When the dosage forms available may be unusable by some patients. (For example, a product that is only available as a tablet may need to be formulated so that it can be absorbed through the skin or taken as a suppository for a patient who cannot swallow.)

Commonly compounded medicines include hormone-replacement therapy; pain medication for hospice patients and pedi-



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atric formulations of a variety of drugs. Also, compounding is extremely important to the veterinary community, which often requires more flavors, dosages forms and dosage strengths than commercially available medications supply. There are no perfect medications. The medicine or dosage form that works well on one patient for one particular condition may not work well for another patient or a different condition. This is why your physician, dentist or other prescriber, needs options. With each patient and each treatment, the doctor must consider and assess the risks and benefits among all alternatives – including the choice of doing nothing.

How are compounded medications different from manufactured medications?

They are not commercially available; rather, they are prescribed by a physician, dentist, veterinarian or other legally authorized prescriber and prepared by a pharmacist to meet an individual's unique needs. Compounded prescriptions may differ from manufactured medications in several ways:

- They are customized, meaning they are prescribed to meet the needs of a particular patient, whereas manufactured
 medications are formulated to meet the needs of a large "average" population. A compounded medication does not exist
 until it is ordered for a particular patient.
- In the one case, the medication is matched to the patient, whereas in the other, the patient is matched to the medication that is available.
- Manufactured medications are manufactured under federal law, and thus are subject to FDA regulations. In contrast, the
 practice of pharmacy (as with the practice of all healthcare professions) is controlled by individual states.

Do most pharmacies provide compounded medications, or do only specialized pharmacies do this?

Many pharmacies will provide some compounding. Most will perform basic compounding – for example, combining two ointments into one preparation. The more complicated and time-consuming the procedure, the more likely it is to be performed only in specialized pharmacies. Often, the equipment needed for complicated or sensitive compounding is expensive. For example, if the resulting compounded preparation must be sterile, a special air-filtering system will probably be required. In the case of higher-level sterile products, an entire room designed to meet special requirements as a "clean room" will be necessary.

Compounding Information Resources

International Academy of Compounding Pharmacists: www.iacprx.org or www.compoundingfacts.org

American Pharmacists Association: www.aphanet.org

Patients and Professionals for Customized Care: www.savemymedicine.org

United States Pharmacopeia: www.usp.org