



DC FEDERAL LEGISLATIVE INITIATIVE

AMERICAN ASSOCIATION OF NATUROPATHIC PHYSICIANS

Glossary for Protecting Patient Access to Compounded Medications

Compounding Pharmacy: Pharmacy compounding is the act of preparing personalized medications for patients. Compounded medications are made based on a practitioner's prescription in which individual ingredients are mixed together in the exact strength and dosage form needed by the patient. NDs rely on compounding medications to treat patients with GI issues who don't digest drugs well, with allergies or food sensitivities, or to offer an herbal or natural option that has fewer side effects than the drug.

Inactive Ingredients (also called "Excipients"): These are ingredients, often derived from foodstuff, that are added to pharmaceuticals to enhance flavor, appearance or aid the manufacturing process, to enhance stability, or to make the drug more bioavailable for the patient. Because these ingredients are made from foodstuffs such as derivatives from eggs, milk, soy, fish, and connective tissue from cows and pigs, though considered inactive in the pharmaceutical, they could induce allergic reactions in patients.

Examples of compounding needs:

- Stevia instead of Corn Syrup for a patient who is allergic to corn or diabetic
- Methylcellulose filler instead of lactose, which is common in many commercial drugs and causes stomach issues for lactose sensitive patients
- Dye-free capsules for patients who cannot tolerate color dyes found in many commercial tablets and capsules

Active Ingredients: These are the ingredients that have a therapeutic effect. While therapeutic, these can still affect patients negatively, especially those who have an allergy (ex: acetaminophen is the active ingredient in Tylenol and in most pain medications, but many people are allergic to this ingredient.)

Monograph: a statement that specifies the kinds and amounts of ingredients a drug or class of drugs may contain, the directions for the drug's use, the conditions in which it may be used, and the contraindications to its use. FDA has determined that Dietary Ingredient Monographs, which set forth the standards of identity for natural ingredients, are not sufficient to provide a basis for compounding.

Office-Use: The practice of compounding medicinal formulas for individual patients for either for immediate use in the provider's office or to dispense to the patient for immediate use at home. FDA has determined office-use compounding is no longer acceptable and that practitioners must write individual prescriptions for each patient. Without office-use, access to medications for the patient is delayed as they must send in the order to a compounding pharmacy, wait for delivery, and potentially make a second office visit to the doctor for the compounded medication to be administered. This also increases cost for duplicate office visits, and not being able to take advantage of bulk prices.

Examples of office-use compounded formulas NDs might use include:

- Baclofen suppositories for Pelvic Floor pain (no commercial products available for this condition)
- Ketoprofen/ Baclofen cream - for pain and muscle spasms
- Turmeric/Curcumin cream - an anti-inflammatory for pain
- Azelaic Acid cream - for rosacea and acne
- Niacinamide cream - for hyperpigmentation or acne