

PFA Tips

Compounding Pharmacy

Customized Medications, Nutritional Formulations & Nutritional Products

Compounding pharmacy is the art and science of preparing personalized medications for patients. Compounded medications have experienced resurgence due to the demand for customized medications to meet specific patient needs that are not being met through mass produced pharmaceuticals.

What is compounding?

Compounded medications are made based on a practitioner's prescription in which individual ingredients are mixed together in the exact strength and dosage form required for the patient. This method allows the compounding pharmacist to work with the patient and the prescriber to customize a medication to meet the patient's specific needs. At one time, nearly all prescriptions were compounded. With the advent of mass drug manufacturing in the 1950s and '60s, compounding rapidly declined. The pharmacist's role as a preparer of medications quickly changed to that of a dispenser of manufactured dosage forms, and most pharmacists no longer were trained to compound medications. However, the "one-size-fits-all" nature of many mass-produced medications meant that some patients' needs were not being met.

What is nutrition compounding?

Similar to the preparation of personalized medications, compounding can prepare customized nutritional formulas that include vitamin, mineral, nutritional and herbal ingredients. This aspect of compounding allows practitioners to address specific nutritional deficiencies that a mass produced vitamin/mineral product may not. In addition, some compounding pharmacies may also work with herbal and botanical remedies that can be customized for specific patient needs.

How are medications and nutritional products customized?

Compounding pharmacy can also be described as a "problem solving" process.

Compounding pharmacists can literally make a medication "from scratch", thus the ability to find an answer to a medication challenge is improved. Here are some specific examples of customized preparations for children with Autism Spectrum Disorder:

- **Elimination of Problem-Causing Excipients** – Medications and nutritional formulations can be customized to eliminate gluten, casein, dyes, sugar, lactose, alcohol, nuts, stearates, unwanted flavorings and preservatives.
- **Flavoring** – Pleasantly flavored suspensions, solutions, concentrates, freezer pops, gummy bears or lozenges, in a pleasing color, can entice a child to take medications or supplements. A palatable formulation is more likely to improve compliance and minimize waste.
- **Change in Route of Administration** – Some preparations are commercially available only as injections or oral dosage forms that must be swallowed. A child may be unable to swallow a tablet, capsule, or liquid, or refuse food that is used to improve palatability. Compounding can provide additional therapeutic options by compounding alternate dosage forms such as medicated chocolates, lollipops, gummy bears, or transdermal gels.
- **Change in Dosage Form** – If a child is unable to take, has not responded to, or experienced adverse effects from commercially available medications, numerous options exist. Compounding the needed drug(s) into different dosage forms,



such as transdermal creams that can be massaged into the skin, lozenges, lollipops, gummy bears or freezer pops.

- **Combination Preparations** – Compounding can combine compatible drugs, medicinal herbs, or vitamin/mineral supplements into a single dosage form to simplify a medication administration schedule, and improve compliance. Also, a synergistic effect can be achieved when certain agents are used in combination.
- **Unavailable Medications** – When a medication is temporarily unavailable or discontinued due to manufacturing concerns, compounding pharmacists can usually obtain the needed drug as a pharmaceutical grade chemical and compound a similar preparation.
- **Individualized Dosing** – Compounding pharmacists can compound a dosage form that contains the optimal dose (based on age, weight, and disease state) to provide needed benefits but minimize the risk of adverse effects. Also, single doses can be packaged for school or travel.

continued on page 2

Compounding Pharmacy – cont.



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• Prescriber-Specific Formulations

– Physicians often develop specific formulations to meet the unique needs of their patient population. Compounding pharmacists commonly prepare these customized therapies.

Compounding Pharmacy Licensure and Regulation

Compounding pharmacies are licensed and inspected by the state board of pharmacy. License renewal and on-site inspections occur annually. Compounding pharmacists obtain pharmacy degrees from schools of pharmacy and may choose to specialize in compounding pharmacy beyond their standard pharmacy certification and licensure. Compounding pharmacies may also be a member of the Professional Compounding Centers of America (PCCARx.com), a professional association that provides training, continuing education and supplies for member compounding pharmacists.

Quality Assurance & Safety

- Drug chemicals are United States Food & Drug Administration (USFDA) approved
- United States Pharmacopeia/National Formulary (USP/NF) standardized monographs on chemicals and ingredients
- Each chemical has a Certificate of Origin which tracks it from manufacturer through distributor
- Uniquely identified by lot number and expiration
- Compounded preparations are documented with compounding sheet logging; time preparation, chemical lot number, expiration date, compounding pharmacist, unique formulation number
- Internal pharmacy and procedures include policy regarding how to recall and notify patients if errors or discrepancies occur, or manufacturer recall of chemicals
- Regular inspections by the state board of pharmacy
- Pharmacists must obtain state mandated continuing education hours for license renewal

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