



A Snapshot of Pharmacy Compounding in America

2023 - 2024

Pharmacy compounding is an ancient science. The root of modern pharmacy practice is in compounding, and compounding pharmacies have provided essential therapies to Americans for generations.

In fall 2023, the Alliance for Pharmacy Compounding — with support from Fagron, Medisca, and PCCA — commissioned the University of Utah College of Pharmacy to conduct a demographic survey of more than 11,400 pharmacy compounders across America. The survey received 699 responses, representing 529 unique 503A compounding pharmacies or 503B outsourcing facilities.

Based in part on those responses, we have created this snapshot of the profession. Unless otherwise indicated, reported numbers and percentages represent pharmacies for whom pharmacy compounding is more than 20 percent of their business.

What is pharmacy compounding?

In traditional compounding, a pharmacist creates a customized medication, most often from an active pharmaceutical ingredient, for an individual patient based on a prescription from a licensed provider. Pharmacists' ability to compound medications from pure ingredients is authorized in federal law and FDA guidance in two circumstances:

APPROPRIATENESS: Manufactured drugs don't come in strengths and dosage forms that are appropriate for everyone, and providers must be able to prescribe a customized medication when a commercially available FDA-approved drug does not come in a dosage form, strength, or combination the provider judges right for a particular patient.

AVAILABILITY: To assure continuity of patient care during a drug shortage, providers may prescribe a compounded copy of an FDA-approved drug when the FDA-approved drug appears on the FDA Drug Shortage list.

Compounded medications are also prepared by entities known as **outsourcing facilities**. Unlike traditional pharmacies, outsourcing facilities must adhere to manufacturing standards, called Current Good Manufacturing Practices, which are much like those to which manufacturers of FDA-approved drugs must adhere. As a result, federal law allows outsourcing facilities to prepare much larger batches of compounded drugs and **distribute** them to hospitals and clinics for administration by a physician or other provider without a patient-specific prescription.

That's an important distinction: Traditional compounding pharmacies **dispense** compounded drugs pursuant to a prescription. Outsourcing facilities **distribute** compounded drugs to healthcare facilities without need for a patient-specific prescription. Given the prevalence of drug shortages today, many American hospitals and clinics rely on compounded drugs prepared by outsourcing facilities to preserve the lives of patients they serve.

For generations, pharmacy compounders have filled a critical need in America's health care system — and played a critical role in patients' lives — by preparing essential, bespoke medications for a range of health conditions. Those include, but aren't limited to, autism, autoimmune disorders, dermatology, oncology, ophthalmology, podiatry, pediatrics, women's and men's health, and animal health.

Rough estimates are that compounded medications account for **1% to 3%** of all prescriptions written in the U.S. There's a good chance you know someone who has benefited — or whose pet has benefited — from a compounded drug.

A rigorous regulatory framework

Traditional compounded drugs are not “knock-offs,” “duplicates,” or “counterfeits.” Rather, they are legitimate therapies created from FDA-regulated bulk ingredients by pharmacies that adhere to the rigorous compounding standards of the US Pharmacopeia, are licensed by state boards of pharmacy, and are inspected by those state boards and often by FDA as well.

Compounding pharmacies can prepare both non-sterile and sterile compounded prescriptions.



Non-sterile dosage forms include topical creams, oral tablets and capsules, and suppositories — essentially, medications that are used in or on parts of the body where sterility is not necessary for patient safety.



Sterile preparations have much stricter compounding standards and requirements to ensure that no microorganisms or other potential contaminants are present. Sterile compounds include ophthalmic solutions, injectables, or parenteral nutrition.

Traditional Compounding Pharmacies (503A)

Section 503A of the U.S. Food, Drug & Cosmetic Act authorizes state-licensed pharmacies to compound drugs using active pharmaceutical ingredient(s), or API, acquired from an FDA-registered manufacturer or wholesale distributor. To be eligible for compounding under Section 503A, an API must be a component of an FDA-approved drug product; or have an applicable USP or National Formulary monograph; or appear on FDA’s 503A Bulks List.

When a compounded medication is dispensed by a traditional pharmacy, it’s because a prescriber – physician, nurse practitioner, physician associate, or veterinarian – wrote the prescription for that compounded medication. The compounded drug is not a substitution for an FDA-approved drug; rather, the prescriber has intentionally prescribed a compounded drug in a specific dosage strength or form or combination of medications that they believe is right for their patient. It’s the prescriber, not the pharmacist or the patient, who decides a compounded drug is warranted.

Compounding-only versus hybrid pharmacies

13%

Only 13% of compounding pharmacies are compounding-only – meaning they only dispense compounded preparations. The rest are hybrid pharmacies, providing traditional retail dispensing of FDA-approved drugs as well as compounded medications.

30%

In the median hybrid pharmacy, 30% of all prescriptions are for compounded medications – meaning compounded prescriptions dispensed is higher than 30% of volume for half of the respondents and is lower than 30% for the other half of respondents.

44%

44% of compounding pharmacies dispense fewer than 100 compounded prescriptions a week.

30%

30% of compounding pharmacies dispense more than 250 compounded prescriptions a week.

Prescribers served

58% of compounding pharmacies fill compounded prescriptions for fewer than 50 prescribers.

58%



22% of compounding pharmacies fill compounded prescriptions for more than 200 different prescribers.

22%



61%

61% of compounding pharmacies employ 12 individuals or fewer.

15%

About 15% of compounding pharmacies employ more than 50 employees.

Locations

88% of pharmacies that compound drugs have only one location.



57% of compounding pharmacies are cash-only, not accepting any form of insurance. Possibly because very few insurers cover compounded preparations at all.

Cash vs insurance

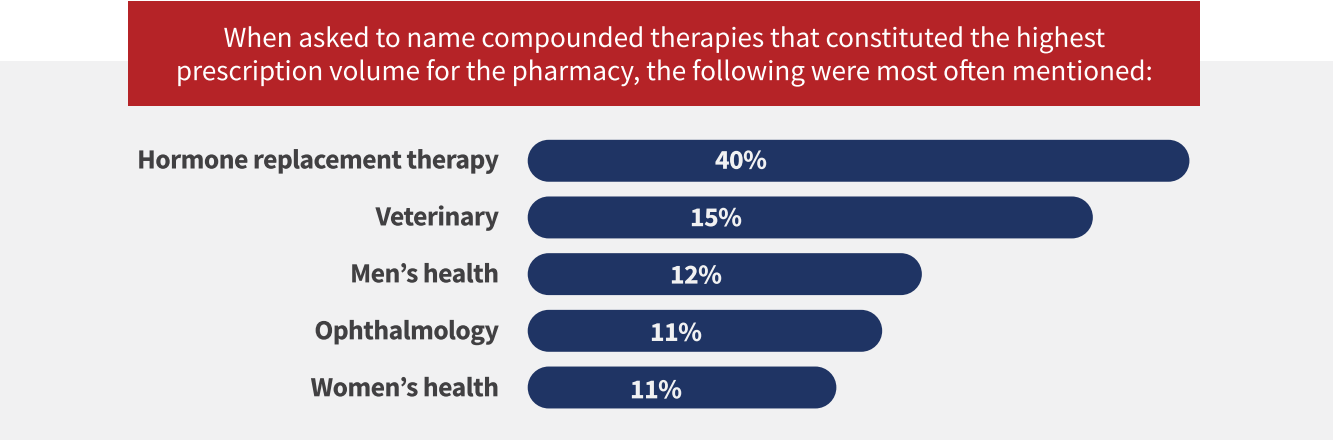
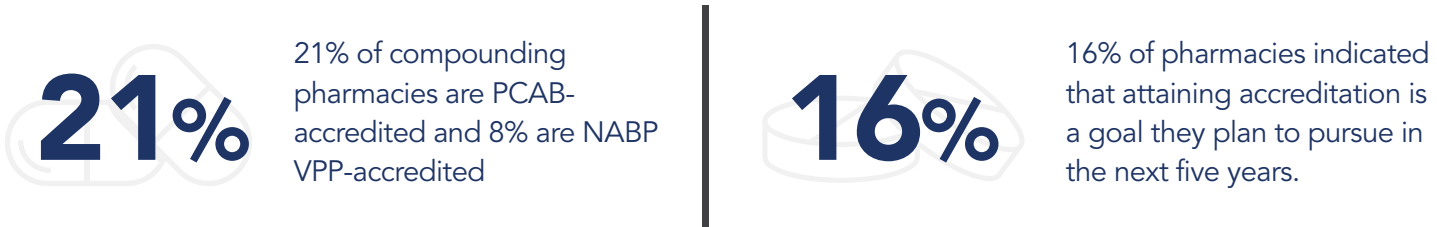
40%

40% of compounding pharmacies are licensed in multiple states.

73%

73% of compounding pharmacies ship less than 5% of their compounded preparations out of state.

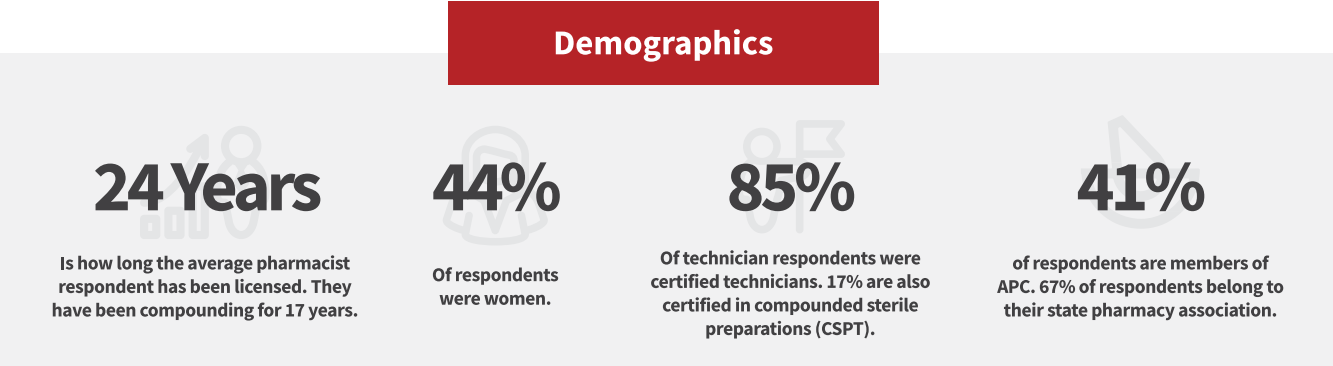
Accreditation shows that a pharmacy is committed to exceeding the minimum standards for ensuring the compounded medications they make are of highest quality. There are a few different accrediting bodies for compounding pharmacies, but the two most common are PCAB and NABP VPP.



Yes, but how many compounding pharmacies are there?

The answer is: It's hard to say. Arriving at a number depends on how you define "compounding pharmacy." Most independent pharmacies and some larger chains do some volume of rudimentary compounding – for instance, creating a suspension for a child who cannot swallow the FDA-approved tablet, or combining two creams into one preparation. Let's say that pharmacy fills only three such compounded prescriptions a week. Should it be considered a compounding pharmacy when compared to a pharmacy for which compounded drugs account for more than, say, 20% of its prescription volume?

The American Pharmacists Association has estimated that there are about 7,500 pharmacies that provide compounding services in America. **What we do know, though, is that most compounding pharmacies are small businesses, based locally, helping provide for patients in their communities.**



Compounding Drugs in Shortage

Federal law prohibits the compounding of a medication that is a copy of an FDA-approved drug but provides for a few important exceptions, including drug shortages. This exception is essential for continuation of patient care when a drug is in shortage – as, amid continuing post-COVID supply chain issues, many are from time to time.



Owners
Percentages reference ownership or interest in compounding pharmacies or outsourcing facilities.

61%

Were sole owners

39%

Were co-owners

ABOUT APC

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, students, researchers, and suppliers.

Compounding exists for patients and animals who are not served by traditional pharmaceutical manufacturers. Every day, APC members play a critical, often life-or-death role in patients' lives, creating essential medications unavailable elsewhere for a range of health conditions, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, animal health, and others.

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