

Pharmaceutical Compounding

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Physicians of all specialty types are concerned about the FDA and whether compounding is legal. Of course it is; it's a fundamental right of every pharmacist. More importantly, physicians have the right to treat their patients based on their best judgment whether medications are used off-label or compounded by a specialty pharmacist.

The Right and Responsibility of Pharmacists to Compound

Among all healthcare professionals, only pharmacists have studied chemical compatibilities and can prepare dosage forms. Even when modern scientific technologies have produced new chemical entities, it remains the domain of the pharmacist to combine one or more chemicals into a new preparation or to process the existing dosage form into one that is better suited to a patient's needs. Compounding of medications by pharmacists is a long-standing and traditional part of pharmacy. The right – if not the obligation – to compound exists under the pharmacy laws of each of the 50 states and is pervasively regulated by each state. States require that pharmacy schools must, as part of their core curriculum, instruct students on the compounding of pharmaceuticals.

The risk that the FDA might take enforcement action for drug compounding for office use is probably very low, provided that the compounded medication is provided to a physician's office pursuant to a physician's order for use in the office for a valid medical reason, and provided that the pharmacist complies with the other provisions of the federal law and any applicable state requirements. FDA may issue regulations in the future regarding compounding for office use.

Further, if pharmacies dispense compounded medications to physicians who in turn resell the medications, they are no longer selling at retail. Such pharmacies may be viewed as manufacturers and/or wholesalers and would come under registration requirements. Section 510 of the Food, Drug and Cosmetic Act imposes FDA registration requirements (see 21 U.S.C. § 360(b)). However, pharmacists are exempt from such requirements

provided that they do not “manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business or dispensing or selling drugs or devices at retail” (see 21 U.S.C. § 360 (g)(1) and 21 U.S.C. § 704(a)(2)(A)). Manufacturers must comply with Good Manufacturing Practices, FDA's New Drug Approval process, and other requirements.

Legal medications are defined as follows: The drug is an FDA-approved medication, the drug comes from an FDA-approved facility, and the drug has an NDC number for importation. NOTE: Pharmacies cannot dispense outside of their actual physical pharmacy location, for example, exhibitors are prohibited from selling prescribed medications at trade shows.

The Code of Ethics of the International Academy of Compounding Pharmacists establishes minimum standards of conduct, which may change to address ethical problems that arise due to advancing knowledge, technology, and legal and regulatory changes.

Choose a pharmacy based on trust and your finely honed gut instincts. Remember, your patients come first. **Price should never be the primary concern or issue.** Stick with one pharmacy for your needs, unless you require something that they cannot prepare. This way, there will be fewer compatibility and stability problems with injections, especially with mesotherapy formulations.

Compounding pharmacies must have state-of the art technology, which allows them to compound any preparation for your patients and clinics. They must be qualified and have the education and experience to prepare the medications you need. Make sure they follow the code of ethics. A great compounding pharmacy does not compound just for the sake of compounding. Their patients and physicians come first. They are committed to bringing you quality prescription medications you need when you need them. When a drug is not readily available it's not just an inconvenience, it's a problem that can make a clinical difference in outcomes.

The Responsibilities of Pharmacists to the Profession, Patients, and Colleagues

1. Operate in conformance with applicable state law regulating the practice of pharmacy.
2. Ensure that your professional conduct is above reproach.
3. Practice the art and skill of compounding pharmacy to the best of your ability.
4. Know the limits of your expertise and refer to colleagues on issues beyond your knowledge and skill.
5. Continue self-education to improve your standard of compounding practice.
6. When possible, accept responsibility to advance the profession of pharmacy and the practice of compounding by participating in properly developed programs, research projects, seminars, teaching opportunities, lectures, and publications.
7. When possible, accept responsibility to advance the profession of pharmacy and practice of compounding by taking leadership positions with the state association, licensing authority, college of pharmacy, national pharmacy organization, or other organizations that have as their objective the betterment of the profession of pharmacy.
8. Willingly accept responsibility to advance the profession of pharmacy and the practice of compounding by representing to lawmakers at the state and national level the policies and agendas that have as

their objective the betterment of the profession of pharmacy.

9. Ensure that marketing practices, fee structures, and overall promotion of your practice are implemented in the best interest of the profession and the treatment of patients.
10. Share ideas and information with colleagues and assist them in their professional development.
11. Give credit to the contributions of your colleagues.
12. Be responsible when placing an appropriate value on your services, and consider the time, skill, experience, and any special circumstances involved in the performance of that service when determining any fee.
13. Do not deny services on the basis of race, religion, gender, disability, age, or national origin.
14. Do not dispense medications to a third entity for resale.
15. Uphold the triad relationship of patient, physician, and pharmacist as the basis for pharmacy practice.
16. Know the details of and adhere to the National Association of Boards of Pharmacy Good Compounding Practices Applicable to State-Licensed Pharmacies or other international standards.
17. Do not engage in marketing or promotional practices that:
 - a. Utilize manufacturers' names or the names of patented products
 - b. Create misinformation with claims of therapeutic equivalence
 - c. Create misinformation by perception that compounded products are generic products
 - d. Base such promotion and advertising solely on price

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Mr Karolchyk co-owns Pharmacy Creations, a premier compounding pharmacy in Randolph, New Jersey. He taught pharmaceuticals at the University of Iowa College of Pharmacy for 10 years as a graduate student and then as adjunct professor, and he is currently an adjunct professor and preceptor for the College of Pharmacy at Rutgers University, New Jersey. He has several patents on novel compounded medications and is involved in several clinical studies evaluating transdermal medications for orofacial pain at UMDNJ. His specialties include drug formulations, sterile admixtures, transdermal technology, and pain management. He enjoys modified custom motorcycles and sports cars in his leisure time.