

Q. I have heard that there is a federal law governing compounding. Is that true?

A. Yes. In November 2013, Congress passed and the President signed into law, the Drug Quality and Security Act (“DQSA”). DQSA regulates compounding by pharmacies as part of the federal Food, Drug, and Cosmetic Act.

Q. Does DQSA prohibit me from compounding?

A. No. DQSA allows a pharmacy to compound medications so long as the pharmacy meets certain conditions when doing so.

Q. Does DQSA place limitations on my ability to compound?

A. Yes. In particular, DQSA makes clear that a pharmacy may only compound prescription drugs pursuant to an individual patient prescription. A pharmacy may also prepare compounds in advance based on a history of receiving individual patient prescriptions from a prescriber. But, while advance preparation is allowed, the pharmacy may not dispense the compound unless and until it receives an individual patient prescription.

Q. Can I compound for “office use”?

A. No. As discussed above, the DQSA makes clear that a pharmacy may only compound prescription drugs pursuant to an individual patient prescription.

Q. But the Board of Pharmacy’s rules allow office use compounding, so why can’t I?

A. Board of Pharmacy Rule .2801(c) says “A pharmacy may supply compounded drug products to practitioners authorized by law to prescribe drugs for those practitioners’ patients. Such compounding for office use shall comply with applicable federal law.” As discussed above, federal law does not permit a pharmacy to compound, except pursuant to individual patient prescriptions.

Q. Can anybody compound for office use?

A. Yes. DQSA allows an “outsourcing facility” to compound drug products without an individual patient prescription. An outsourcing facility must be registered with the FDA and must, among other things, comply with cGMPs. More information about outsourcing facilities may be found here:

<http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm393571.htm>

Q. DQSA says that outsourcing facilities compound sterile products. Does this mean that I can compound non-sterile products for office use?

A. No. It is correct that the definition of an outsourcing facility refers to sterile products. But, as noted above, a pharmacy may only compound pursuant to an individual patient prescription, whether the compound is a sterile product or a non-sterile product.

Q. DQSA says that registration as an “outsourcing facility” is “voluntary”. So, if I don’t volunteer to become an outsourcing facility, can I compound for “office use”?

A. No. It is true DQSA does not “force” anyone to become an outsourcing facility. But DQSA makes clear that only outsourcing facilities may compound products without an individual patient prescription. Think of it this way: North Carolina doesn’t “force” anyone to get a driver’s license. But if you want to drive legally in North Carolina, you have to get one.

Q. May I provide a compounded product to a practitioner’s office if the practitioner agrees to supply me with the names of patients who received the product after he/she administers the compound?

A. No. Even before the DQSA became law, FDA had already stated, via a January 2013 letter to Pharmedium, that “post hoc” name matching to office use did not comply with federal law:

<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/pharmacocompounding/ucm338614.pdf>

The DQSA completely closes that option.

Q. May I compound veterinary products for “office use”?

A. Yes. The DQSA places limitations on office use compounding for human use. Compounding drugs for a veterinarian to administer to a patient at the veterinarian’s office must comport with FDA guidelines, which are found here:

http://www.fda.gov/animalveterinary/resourcesforyou/ucm268128.htm#Compounding_of_Animal_Drugs

Note that both federal and North Carolina law prohibit the compounding of prescription drugs, human or animal, for resale.

Q. Are there other conditions that DQSA places on pharmacy compounding?

A. Yes. A pharmacy that compounds must:

- Compound with approved substances.
- Follow United States Pharmacopeia chapters <795> and <797> (also required by Board rule).
- Not compound medications that have been “withdrawn or removed from the market” due to being found to be “unsafe” or “not effective”.
- Not compound drugs that are “essentially a copy of a commercially available drug product”.
- Not compound products that FDA has determined pose demonstrable difficulties for compounding. FDA is required to produce a list of such products, but has not done so at the time of this writing. Board staff will update as developments warrant.

Q. How do I know whether a compound is “essentially a copy of a commercially available drug product”?

A. If a change is made to a medication for an “identified individual patient” that the prescriber determines for that individual will provide a “significant difference” between the compounded product and a commercially available product, then the compound is not “essentially a copy of a commercially available drug product”. Board staff urges caution here. Board staff becomes aware from time to time that a pharmacy is, in fact, engaged in the practice of essentially copying commercially available products, primarily to game reimbursement rates. Such practices are neither legal nor safe.

Q. What happens if my compounding practices violate DQSA?

A. If a pharmacy does not comply with DQSA, then every compounded product produced would be adulterated and misbranded under the federal Food, Drug, and Cosmetic Act. Such products would not be exempt from federal cGMP requirements, manufacturer labeling requirements, and the requirement to prove that the product is safe and effective for its indicated use through the New Drug Application process. Such compounding would also violate North Carolina law. Moreover, DQSA obligates state boards of pharmacy to report suspected violations of the statute to the FDA.

Q. Does DQSA limit the amount of compounded product that I can ship to patients in other states?

A. Yes, but some context is necessary. DQSA says that pharmacies in states that do not enter into a Memorandum of Understanding (“MOU”) with the FDA on the regulation of interstate shipment of compounded products will be limited to shipping no more than 5% of their compounded products to other states. However, FDA has stated that it will not enforce the “5% limitation” until an MOU has been developed and states have had an opportunity to decide whether to agree to its terms. On February 13, 2015, the FDA published a draft MOU for commentary. It is found here: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm434270.htm> The comment period runs through June 12, 2015.

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