

**Barriers to compounding in physician offices: The future is now**



*To the Editor:* Two recent articles in the *Journal of the American Academy of Dermatology*<sup>1,2</sup> suggest compounding lidocaine hydrochloride 1% with epinephrine (1:100,000) with 8.4% sodium bicarbonate to produce buffered lidocaine for local anesthetic that is less painful or compounding lidocaine hydrochloride 1% with epinephrine (1:100,000) with plain lidocaine to stretch the limited supply of lidocaine with epinephrine during a period of shortage. The safety of in-office compounding has been proven by generations of dermatologists who have used in-office compounding for decades and the literature.<sup>1,3-5</sup>

We, as well as the executives of the Ohio Dermatological Association and our lobbyists, are astounded by the intrusiveness of the pharmacy board and have been actively fighting against their over reach, since new rules effecting the practice of medicine were promulgated in 2016. In Ohio, preparing tumescent anesthesia, buffering lidocaine with epinephrine or bicarbonate, and diluting steroid with lidocaine or saline is compounding. Mixing any prescription drug into another vehicle, such as a liquid, gel, or ointment, for topical use is compounding. When you are compounding a prescription, you are compounding a dangerous drug.<sup>5</sup>

All of these common and safe office practices now require a Terminal Distributor of Dangerous Drug License, which requires completing a 17-page form, an annual \$160.00 fee, and an agreement to have your office inspected (and disrupted) at any time without notice.

Dermatologists offices that have been inspected have had numerous violations cited including not keeping a separate log of each time a medication is diluted or mixed, not recording the lot number of each sample dispensed, and not disposing of their botulinum toxin in  $\leq 6$  hours. Violations after the initial warning will result in fines per incident.

State legislatures, state boards of pharmacy, and medical boards continue to create policies in response to the 2012 New England Compounding Center meningitis outbreak. Food and Drug Administration implementation of federal compounding law and information provided to states have caused confusion among state boards and have adversely affected patient and physician access to vital medications.

The US Pharmacopeia (USP) is reviewing and potentially revising chapter 797 governing sterile compounding (Pharmaceutical Compounding – Sterile Preparations). More than 8000 comments, some of which oppose the burdensome requirements, were submitted. USP has released a new draft for stakeholder input. The USP Compounding Expert Committee stated that it will be proposing the 1-hour exemption (time between preparation and administration) but would consider evidence submitted to USP. Many state pharmacy boards have adopted or are considering adopting USP 797, so it is critical that dermatologists advocate against such a proposal.

The American Academy of Dermatology Association is advocating for an in-office compounding exemption for physicians nationwide to maintain continued access to medications for patients and avoid onerous burdensome regulation. Ohio is the test case for the board of pharmacy rules being proposed across the country, so all medical practitioners, but in particular dermatologists, should be concerned.

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**OHIO REVISED CODE**

729.541 A(3) and B 4729.541 Persons not requiring terminal distributor license; pain management clinics. (A)(1) Except as provided in divisions (A)(2) and (3) of this section, a business entity described in division (B)(1)(j) or (k) of section 4729.51 of the Revised Code may possess, have custody or control of, and distribute the dangerous drugs in category I, category II, and category III, as defined in section 4729.54 of the Revised Code, without holding a terminal distributor of dangerous drugs license issued under that section. (2) If a business entity described in division (B)(1)(j) or (k) of section 4729.51 of the Revised Code is a pain management clinic or is operating a pain management clinic, the entity shall hold a license as a terminal distributor of dangerous drugs with a pain management clinic classification issued under section 4729.552 of the Revised Code. (3) A business entity described in division (B)(1)(j) or (k) of section

4729.51 of the Revised Code shall hold a license as a terminal distributor of dangerous drugs in order to possess, have custody or control of, and distribute either of the following: (a) Dangerous drugs that are compounded or used for the purpose of compounding; (b) Controlled substances containing buprenorphine that are used for the purpose of treating drug dependence or addiction. (B) A licensed health professional authorized to prescribe drugs who does not practice in the form of a business entity described in division (B)(1)(j) or (k) of section 4729.51 of the Revised Code shall hold a license as a terminal distributor of dangerous drugs in order to possess, have custody or control of, and distribute, including personally furnish, either of the following: (1) Dangerous drugs that are compounded or used for the purpose of compounding; (2) Controlled substances containing buprenorphine that are used for the purpose of treating drug dependence or addiction.