Cold Iron Truth

The compounding struggle continues

BY BRETT M. COLDIRON, MD

Six years ago, there was an outbreak of fungal meningitis from improperly manufactured intrathecal steroid by a criminal pharmacist and pharmacy owner. Physicians, who had nothing to do with the pharmacy, are still struggling with the fallout from this.

In particular, 2 years ago, Ohio became the test state for outrageous restrictions on physician's use of medications in their offices by a state pharmacy board (see "Beware the state pharmacy board," Dermatology News, June 3, 2016). These rules degrade patient care by making medications inaccessible and much more expensive, and by eliminating office treatment options – and make the practice of medicine much more difficult.

However, since the original promulgation of these rules in Ohio, organized medicine at the state and national level has resisted and has made some progress.

In its recently published draft guidance for industry, the Food and Drug Administration excluded physician offices from enforcement in its compounding rules. While this is a great victory, the guidance also mentioned that physicians may be subject to rules promulgated by the U.S. Pharmacopeia (USP) and state pharmacy boards, who have adopted USP guidelines to physician offices in the past. Thus, our focus shifts to the USP.

The USP is a private, nongovernmental organization of mostly pharmacists and national medical society representatives, organized to create a reference of uniform preparations for the most commonly used drugs – with tests to ensure their quality, potency, and purity. This has been a very good thing for American medicine, but the compounding chapter is written by pharmacists, to apply to compounding pharmacies. That is fine. The problem arises when you redefine a physician's office as a compounding pharmacy. This is what took place in Ohio, and what pharmacy boards want to do nationwide.

Do not be naive. This is a national scope-of-practice issue that could determine how physicians can use medications in their offices. In Ohio, they were particularly devious in my opinion. The state legislature (in an omnibus spending bill) explicitly expanded the Ohio Board of Pharmacy's mandate to supervise the "compounding of hazardous medications." I think the legislature, the state medical society, and everyone else assumed this meant drugs manufactured and sold by compounding pharmacies, such as intrathecal steroids.

The pharmacy board readily recognized an opening here and went on to define hazardous drugs as any prescription drug, and compounding as mixture or even sterile dilution of any prescription drug. The board then proposed a $112 dollar annual licensing fee (since reduced to $55) that would affect doctors, dentists, and even veterinarians.

When the rules were first published, there was outrage. The board was even going to require a compounding license to reconstitute vaccines. This requirement was quickly withdrawn when it was pointed out that vaccines were advertised for sale at pharmacies, an obvious restraint of trade issue.

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So, what's the big deal with paying $55 a year for a compounding license from the pharmacy board? It involves a 17-page form, and you must agree to unannounced inspections of your office. A northern Ohio physician who obtained his terminal distribution of drugs and compounding license had an almost immediate unannounced inspection, where he was cited for an unlocked sample closet door, for expired samples, and for not recording all the lot numbers of each sample dispensed. He also was cited for not having a separate clean drawing room in which he mixed his syringes and for not discarding any reconstitutions or mixtures not used. Think botulinum toxin here. He was required to draft a remediation plan, which includes recording all medications compounded (anything mixed in a syringe!) in separate log books (conventional medical records are not adequate) and recording lot numbers of all samples dispensed. Consider a log entry each time you dilute Kenalog for injection or buffer lidocaine.

Do not think you will fly under the radar here. I expect state pharmacy boards to requisition botulinum toxin and bicarbonate purchase records from supply houses and to investigate purchasers. They can cite you for $3,000 per violation and can also instruct suppliers to no longer sell product to you.

USP rules

The revised USP rules are a difficult fit for physicians' offices. Because they have granted a 1-hour exemption, you will have to use buffered lidocaine and reconstituted botulinum toxin in 1 hour or less, then discard it under these rules. This means you cannot draw up all your buffered lidocaine for the day in the morning and use it throughout the day; never mind that there are good data showing redrawn syringes of buffered lidocaine and botulinum toxin are stable for several weeks in a refrigerator (J Clin Neurol. 2013 Jul;9[3]:157-64).

I think these rules eventually will be settled by a restraint-of-trade lawsuit. After all, none can be shown to improve patient care; in fact, they degrade it and increase the costs to patients and physicians. We may end up being grateful that the U.S. Supreme Court emasculated state professional boards in the famous 2015 North Carolina tooth-whitening ruling.

The USP is accepting comments about the rules until Nov. 30. The American Academy of Dermatology has a sample letter to the USP Compounding Expert Committee on its website, which suggests that you ask for at least a 12-hour exemption.

I strongly suggest you write and explain why pharmacy board regulations that interfere with a physician's ability to administer individualized, customized medication will hurt your patients and will cost more. Physicians have been treating their patients with individualized, customized medications for more than 2,000 years. It seems unreasonable to hand this skillful and essential part of medicine over to pharmacists in the absence of any compelling evidence. ■

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