



AMERICAN SOCIETY OF
PLASTIC SURGEONS®



THE PLASTIC SURGERY
FOUNDATION®

Executive Office

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May 24, 2016

State of Ohio Board of Pharmacy
Kilee S. Yarosh, B.S., R.Ph, President
Steven W. Schierholt, Esq., Executive Director
77th South High Street, 17th Floor
Columbus, OH 43215

RE: **Ohio Admin. Code 4729-16-04, Drugs Compounded by a Prescriber**

Dear President Yarosh, Executive Director Schierholt and the Members of the State of Ohio Board of Pharmacy:

On behalf of the American Society of Plastic Surgeons (ASPS), I am writing to you today to urge you to preserve the ability of physician practices to reconstitute medication for in-office patient administration. The proposed changes to Ohio Admin. Code 4729-16-04, if implemented, will require all prescribers who order and store compounded drugs or compound drugs to obtain licensure as a terminal distributor of dangerous drugs (TDDD).

ASPS is the world's largest association of plastic surgeons, with over 7,000 members representing 94 percent of Board-Certified Plastic Surgeons in the United States. ASPS promotes not only the highest quality in patient care, but also in professional and ethical standards. Our members are highly skilled surgeons who improve both the functional capacity and quality of life for patients, including treatment of congenital deformities, burn injuries, traumatic injuries, hand conditions and cancer reconstruction.

As you know, in 2012, a national crisis was sparked by an outbreak of fungal meningitis that was linked to contaminated compound drugs sourced from the New England Compounding Center. These tragic events triggered a national response to ensure that patient safety was better protected in the manufacturing and distribution of compound drugs. The adulterated drugs entering the supply chain were indeed not caused by practitioners but by a drug compounding facility. ASPS agrees that it is of the utmost importance that patients receive the safest and most effective drugs. However, requiring a practitioner's office to register as a TDDD to merely store compounded drugs and reconstitute drugs for patient administration is an example of over-regulating that will unnecessarily increase the cost of and reduce access to care.

Many new drugs are initially marketed in powdered form, which helps maintain stability and potency over time. Historically, patients treated in a private physician office setting looked to their physician, not a pharmacy, to reconstitute and deliver medications via sterile techniques. While accreditation requirements

have addressed many facility design issues, not all private-practice physician offices are equipped with the requirements to obtain licensure as a TDDD. Physician's offices that reconstitute sterile drugs currently follow the US Pharmacopeia Chapter 797 standards. Requiring that these small businesses also register as a TDDD is both unnecessary and will deal a crushing blow to solo and small practice physicians in Ohio.

Additionally, I respectfully remind the Board of Pharmacy, that every day, patients and family members reconstitute medications in the home setting. It is important to ensure that future regulations developed do not restrict ease of administration, limit access, or increase costs of care for patients who currently manage chronic diseases in their home. It is also unnecessary and ill advised to impose harsher restrictions on physicians than it is on patients administering their own medications.

I do not believe it is the intent of the State of Ohio Board of Pharmacy to restrict patient care and increase the cost of medicine, and respectfully ask for reconsideration of the proposed policies to ensure reasonable standards for private practice physicians.

Thank you for your consideration of ASPS's comments regarding pharmaceutical compounding standards. Please do not hesitate to contact Patrick Hermes, Senior Manager of Advocacy and Government Affairs, with any questions at Phermes@plasticsurgery.org or (847) 228-3331.

Regards,



David Song, MD, MBA
President, American Society of Plastic Surgeons



Michael Johnson, MD
President, Ohio Valley Society of Plastic Surgeons



Anne Taylor, MD, MPH
Board Vice President, Health Policy and Advocacy
American Society of Plastic Surgeons

Cc: All Members of the State of Ohio Board of Pharmacy