



AMERICAN SOCIETY OF
PLASTIC SURGEONS®



THE PLASTIC SURGERY
FOUNDATION®

Executive Office

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August 5, 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 4729-16-13, Revisions to 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) and the Ohio Valley Society of Plastic Surgeons (OVSPS), we are writing to thank you for proposing Section 4729-16-13. The revisions to the physician-in-office compounding standards are a welcome relief to small and solo practice physicians who would be heavily burdened by complying with 4729-16-04. The new section does not require physicians to comply with ISO Class 5 air quality standards and contains more achievable physical facility requirements in certain circumstances.

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 and OVSPS promote 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.

The revisions to the pharmacy code come as a welcome relief for physicians who now have to be licensed as terminal distributors of dangerous drugs and comply with standards outlined by the pharmacy board. However, ASPS continues to assert that reconstitution should not be considered compounding. 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 look to their physician, not a pharmacy, to reconstitute and deliver medications via sterile techniques. Physicians' offices that reconstitute sterile drugs currently follow the US Pharmacopeia Chapter 797 standards.

Additionally, as stated in our previously submitted comments, we 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 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 counterintuitive to impose harsher restrictions on physicians in an office setting than on patients administering their own

medications in the home. Kaiser Health News reported last month that government spending on compounded drugs has skyrocketed over the last year. Medicare Part D spending on compounded drugs rose 56%. Federal investigators are beginning to target drug compounding for fraud and over-billing concerns. While patient safety is the greatest concern in the regulation of drug compounding, over-regulation of this practice can severely increase the costs of drugs and, in turn, the cost of healthcare delivery.

We 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 while we are grateful for the additions in 4729-16-13, we ask that the Board reconsider treating reconstitution as drug compounding.

Thank you for your consideration of ASPS's and OVSPS'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
Immediate Past 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