AMERICAN SOCIETY OF PLASTIC SURGEONS ®
THE PLASTIC SURGERY FOUNDATION ®

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May 22, 2018

Oregon Board of Pharmacy
c/o Mo Klein
800 NE Oregon St., Suite 150
Portland, OR 97232

RE: Proposed Changes to OAR Chapter 855

Dear Members of the Oregon Board of Pharmacy:

I am writing on behalf of the American Society of Plastic Surgeons (ASPS) regarding the proposed changes to Oregon Administrative Rules (OAR) Chapter 855. ASPS is the largest association of plastic surgeons in the world, representing more than 94 percent of all board-certified plastic surgeons in the United States – including 83 board-certified plastic surgeons in Oregon. Our mission is to advance quality care for plastic surgery patients and promote public policy that protects patient safety.

We appreciate the Oregon Board of Pharmacy's (Board) effort to take a formal position on physician compounding. However, it is important to note that the legislative and regulatory backlash against in-office compounding began not as a result of physicians mishandling compounded medications, but rather as the result of the contamination of compounded products made by a compounding pharmacy. Therefore, we have outlined several sections of the proposed changes that we believe should either be amended or removed to better reflect the position of physicians on this issue.

855-045-055 would require all compounders to adhere to guidelines of the current edition of the United States Pharmacopeia (USP) Chapters 795 and 797, as well as all applicable chapters of USP and USP-NF related to the compounding practices at any location. Many pharmacy boards rely on United States Pharmacopeia (USP) policies to dictate physician compounding, but the Food and Drug Administration (FDA) has acknowledged the need to revise draft USP guidance documents related to compounding. Furthermore, in order to justify the adverse impact to physicians that onerous compounding rules may have, state pharmacy boards have cited a 2012 Centers for Disease Control and Prevention (CDC) study[1] that examines the use of single-use vials. This is misleading, as physician in-office compounding is typically performed by using multiple-dose vials, which are designed for multiple uses and include preservatives and manufacturer-specific expiration dates to ensure safety. ASPS recommends that the Board postpone the adoption of 855-045-055 until the updated guidance documents are written in order to reduce creating an undue burden on physicians who routinely compound drugs and medicine in a safe and sanitary manner that minimizes patient risk.

855-045-0530(5)(b) includes language that allows the compounding of a commercially-available drug product if it is not reasonably available in the market in time to meet the patient's needs. Further restricting physicians' ability to mix a drug such as lidocaine – which is listed as currently in shortage by the FDA – would limit treatment options for patients who are in need of these compounds. Therefore, we thank the Board for recognizing the difficulties that physicians face when dealing with drugs that are not commercially-available. Examples of mixtures that our physicians prepare – for which there are no commercially-available alternatives – on a frequent (often daily) basis are: sterile local anesthetics with sterile sodium bicarbonate to alleviate injection pain; sterile lidocaine with sterile bupivacaine for injection for longer-acting anesthesia; and lidocaine with triamcinolone when injecting hypertrophic/keloid scars to alleviate injection pain.

[1] https://www.cdc.gov/injectionsafety/PDF/CDC-SDC-Position05022012.pdf

855-045-0570 creates various recordkeeping requirements of compounders in Oregon. While ASPS appreciates the reasoning behind 855-045-0570, this rule places an unnecessary administrative burden on physician offices. Therefore, we respectfully request that the Board lessens this requirement by requiring physicians to keep a log of medications that were compounded in the patient's medical record. This would provide physicians with easily-accessible information if they would need to contact affected patients due to a recall.

Rules 855-045-0600 through 855-045-0630 cover the practice of sterile compounding. ASPS understands the Board's need to cover this practice for pharmacists and pharmacy personnel; however – as our physicians do not perform sterile compounding – we respectfully request that you exempt physicians from these requirements.

For the reasons outlined above, we urge you to amend the proposed changes to OAR Chapter 855. Thank you for your consideration of our position on this important issue. Please do not hesitate to contact Patrick Hermes, Director of Advocacy and Government Relations, at phermes@plasticsurgery.org or (847) 228-3331 with any questions.

Sincerely,

Lynn Jeffers, MD
Board Vice President of Advocacy & Health Policy
American Society of Plastic Surgeons