AMERICAN SOCIETY OF PLASTIC SURGEONS ®
THE PLASTIC SURGERY FOUNDATION ®

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January 25, 2018

Claudette E. Dalton, MD, *Chair*
Committee on Ethics and Professionalism
Federation of State Medical Boards
400 Fuller Wiser Road
Euless, TX 76039

RE: Position Statement on Compounding of Medications by Physicians

Dear Chair Dalton:

I am writing on behalf of the American Society of Plastic Surgeons (ASPS) regarding the draft Position of the Federation of State Medical Boards (FSMB): Compounding of Medications by Physicians. 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. Our mission is to advance quality care for plastic surgery patients and promote public policy that protects patient safety.

We appreciate the FSMB's 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 clauses from the position statement that we believe should either be amended or removed to better reflect the position of physicians on this issue.

PDF at lines 52-54

In instances where patients require medications in forms that are different from those commercially available, physicians are encouraged to establish relationships with pharmacies or other entities that have registered as outsourcing facilities with the FDA.

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
- IV tumescent fluid for liposuction (and other cases) with lidocaine, epinephrine, and sodium bicarbonate
- Antibiotics for triple antibiotic irrigation for breast implant cases
- Lidocaine with triamcinolone when injecting hypertrophic/keloid scares to alleviate injection pain
- Local anesthetic with sterile saline to reduce its concentration:

    - i.e., 0.25% lidocaine with epinephrine for breast surgery: 30 ml of 1% lidocaine with 1:100,000 epinephrine, mixed with 90 ml normal saline
- Antibiotics to a saline bag not just for irrigation, but for pre-operational prophylaxis, or mixing tumescent liposuction solution

These are only a small sampling of the number of medications that physicians prepare that are not commercially-available. Encouraging physicians to establish relationships with pharmacies or other entities is unnecessary when these preparations have been done in office settings without the occurrence of any adverse events for decades.

PDF at lines 61-62

If physicians choose to compound medications themselves, they are encouraged, where possible, to limit compounding activity to non-sterile preparations.

The previous examples regarding commercially-available medications pertain to this clause, as many are identified as sterile. To reiterate, our members have compounded sterile medications without incident for decades.

PDF at lines 65-67

While state laws on compounding vary across the U.S., physicians should comply with the standards set out in the United States Pharmacopeia National Formulary (USP-NF), particularly Chapters 795, 797, and 800.

We encourage the FSMB to advise state medical boards to work with the USP-NF to avoid conflicting federal and state requirements. Especially due to the fact that states are given wide deference in how they regulate medicine and pharmacies, collaboration prior to final rulemaking would help eliminate confusion and allow every party involved in the regulatory environment – from regulators to practitioners – to operate within clearer parameters.

We would be remiss to not also point out that the FDA has recently acknowledged a need to revise draft USP-NF guidance documents describing insanitary compounding. They have also recognized the need for a balanced approach to regulation. Any attempts by the FSMB or state agencies to set new policy prior to publication of these updated guidance documents may create an undue burden for physicians who routinely combine drugs and medicine in a manner that creates negligible patient risk.

PDF at lines 78-80

While in-office compounding may occur in some states in the absence of regulatory oversight, it is unlikely that state medical boards have the resources or established protocols to provide this function.

The overlapping nature of this issue necessitates a two-pronged approach by experts in the medical and pharmaceutical fields. Regardless of the availability of resources or existence of established protocols to be the sole regulators of in-office compounding, the FSMB should urge state medical

boards to work in tandem with state pharmacy boards to regulate compounding in outsourcing facilities or by pharmacy compounders.

We urge you to revise the draft position statement to better reflect the position of physicians 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 or concerns.

Sincerely,

Jeffrey E. Janis, MD, FACS
President, American Society of Plastic Surgeons

cc: Members, Federation of State Medical Boards Committee on Ethics and Professionalism