April 19, 2016

Reference Committee B
Federation of State Medical Boards (FSMB)
400 Fuller Wiser Road
Euless, TX 76039

Re: Draft Position Statement 4 – Compounding of Medications by Physicians

Dear Members of Reference Committee B,

On behalf of the 13,500 U.S.-based members of the American Academy of Dermatology Association (Academy), I am writing to provide input to this reference committee on the Federation of State Medical Board (FSMB) draft position statement on the Compounding of Medications by Physicians. The Academy is committed to excellence in medical and surgical treatment of skin disease; advocating high standards in clinical practice, education, and research in dermatology and dermatopathology; and supporting and enhancing patient care to reduce the burden of disease. We appreciate the opportunity to provide input to this FSMB reference committee and hope that the Academy’s input and opposition to this draft position statement will be considered when evaluating this position statement.

This FSMB position statement encourages physicians who compound medications in their offices to limit compounding activity to non-sterile preparations because of safety concerns. In order to obtain sterile medications, it encourages physicians to establish relationship with pharmacies and outsourcing facilities. The Academy is concerned that if state medical boards adopt this position and ban sterile compounding by physicians, this restriction on scope of practice would impede access to care and interfere with the patient-physician relationship.

We support FSMB’s efforts to ensure the safety of sterile compounded medications. What the Academy aims to preserve is the common practice of dermatologists treating their own patients using medications compounded in their individual practice settings. The compounding in which dermatologists engage frequently involves very low risk practices such as compounding diluted solutions for intralesional injections.

Steroids are often diluted with sterile saline or lidocaine and used for treatment of many dermatological conditions, including, but not limited to, acne cysts, keloids, alopecia areata, hypertrophic scars, and psoriasis. The dermatologist determines the appropriate dilution during the patient visit. It is not possible to order the correct solution for intralesional injections prior to the visit.1 If required to obtain the sterile

medication from pharmacies and outsourcing facilities, the patient must wait for delivery and then return to the physician for administration. During this waiting period, the presenting dermatological condition(s) may worsen.

It is also common for physicians to buffer or dilute lidocaine, using sodium bicarbonate, epinephrine, and/or saline. This practice is proven to significantly reduce the pain associated with the use of this local anesthetic.\textsuperscript{2,3,4,5}

The compounds used in the practice of dermatology do not involve the risks associated with intravenous, intrathecal, or intramuscular injections. The preparation of the compounds used by dermatologists must follow aseptic technique, and procedures must be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids.

Additionally, the position statement encourages physicians to familiarize themselves with United States Pharmacopeia-National Formulary (USP-NP), including Section 797 on sterile preparations. The Academy wrote USP on this chapter in January, expressing disagreement with the USP position that any other reconstitution or dilution of a conventionally manufactured sterile product must be performed in accordance with this chapter (i.e., requiring dermatologists to adhere to the same standards as large compounding facilities).

The Academy appreciates the opportunity to provide input on this FSMB position statement. We respectfully request that the FSMB does not adopt this position statement and offer our assistance in providing further information and feedback that may help guide future policy development. Please contact Natasha Pattanshetti, JD, MPH, Manager of Regulatory Policy at npattanshetti@aad.org or (202) 712-2618 if you require clarification on any of the points or would like more information.

Sincerely,

Abel Torres, MD, JD
President, American Academy of Dermatology Association

CC: Elaine Weiss, JD, Executive Director
    Barbara Greenan, Senior Director, Advocacy and Policy
    Leslie Stein Lloyd, JD, Director, Regulatory and Payment Policy