AMA
AMERICAN MEDICAL ASSOCIATION

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Claudette Dalton, MD
Chair
Ethics and Professionalism Committee
Federation of State Medical Boards
400 Fuller Wiser Road, Suite 300
Euless, TX 76039

Dear Dr. Dalton:

On behalf of the physician and medical student members of the American Medical Association (AMA), I want to thank you for your efforts to create sound guidance for state medical boards on issues related to drug compounding. The AMA appreciates the opportunity to provide input on the Federation of State Medical Boards (FSMB) recent draft position statement on Compounding of Medication by Physicians. The AMA remains committed to ensuring the safety of the compounded drug supply and maintaining access to critical treatments for our patients. While we strongly support portions of this statement, such as calls for clear guidelines and appropriate training of physician and staff participating in sterile preparations, we have some concerns with the statement in its current form, which are outlined below.

In-Office Preparation of Sterile Drug Products is Critical to the Treatment of Patients Across Specialties

As you know, physicians across a number of medical specialties frequently prepare sterile drug products in their offices for administration to patients as a routine part of clinical practice. Preparation of sterile drug products for patients can include activities such as, drawing up a steroid joint injection with a local anesthetic, preparing botulinum toxin for administration, preparing allergy/immunotherapy injections for individual patients, buffering lidocaine, and a number of others. In the majority of cases, these activities are routine practices that physicians have been engaging in for years. In many cases, they represent the standard of care for a particular condition. Physicians across specialties have a long history of preparing sterile drug products that provide safe and effective treatments to patients. There is no compelling body of evidence showing these activities, when performed in physician offices, pose any increased risk to patients of infection or other adverse events.

The physician community maintains that the preparation of sterile drug products at the point of care for administration to patients is not a traditional drug compounding activity. It is, in many cases, a routine part of clinical practice and accepted component of the practice of medicine. As such, we recommend that FSMB strike language in lines 61-62 suggesting that physicians limit preparation to non-sterile compounding when possible. We also urge FSMB against considering any additional changes that would serve to further limit the ability of physicians to prepare necessarily sterile drug products for administration to patients in treatment settings. These revisions are necessary to prevent likely disruptions in care that would be created by the imposition of new guidance.

FSMB Should Not Defer Oversight of Physician Activity to State Boards of Pharmacy

Lines 74-82 discuss the relationship of state boards of medicine and state boards of pharmacy as related to oversight of physician "compounding" activities. These lines raise a certain level of concern for the physician community. As discussed above, the physician community maintains that the preparation of drug products for the administration to patients at the point of care is not a traditional drug compounding activity. Where these activities represent part of routine clinical practice, these activities should continue to be regulated by state boards of medicine. We believe that state medical boards remain the best positioned to determine what is appropriate and safe medical practice by a physician in a clinical setting, and we recommend against any deferral of this oversight authority to state boards of pharmacy. While we understand that FSMB remains concerned about potential resource constraints, we urge FSMB to consider that physician preparation of drug products for administration to patients is not a new activity, and given the lack of any significant evidence of increased risk to patients, this would not actually require much, if any, additional medical board resources. Moreover, we do not believe these routine practices warrant additional oversight, as additional oversight could ultimately result in restricted access for patients while doing little to increase the safety profile of the drug products in question. However, where physicians do engage in activities outside the norm and that could be considered to carry a level of risk inappropriate for office settings without tighter controls, we encourage state boards of medicine to work collaboratively with federal and state regulators and state boards of pharmacy to determine the most appropriate way to proceed.

FSMB Policy in this Area May be Premature

Given the significant work currently being undertaken by the U.S. Food and Drug Administration (FDA) and United States Pharmacopeia (USP) in this area, the AMA is concerned that FSMB policy in this area may be somewhat premature and result in confusion for physicians and regulators at the state level. While we understand the desire of state boards of medicine to have clarity in this area, the AMA urges FSMB to consider delaying the creation of new policy at this time and instead suggests ensuring that any new policy is harmonized with the finalized work of both FDA and USP.

The AMA applauds FSMB's efforts to ensure the safety of the sterile and non-sterile preparations received by patients and greatly appreciates the opportunity to provide input as policy is developed. We look forward to continuing to work with FSMB on this important topic. Should you have any questions or wish to discuss this further, please do not hesitate to contact Shannon Curtis, Assistant Director of Federal Affairs, at shannon.curtis@ama-assn.org or 202-789-8510.

Sincerely,

James L. Madara, MD