AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

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Gigi Davidson, BSPh, DICVP
Chair, Expert Committee on Compounding
United States Pharmacopoeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Dear Dr. Davidson:

On behalf of our physician and medical student members, the American Medical Association (AMA), appreciates the opportunity to comment on the United States Pharmacopoeia (USP) revised draft Chapter 797 guidelines for sterile compounding. Many AMA member physicians provide sterile drug preparations to patients as part of their regular practice. As such, we have been closely monitoring the work of USP and the Expert Committee on Compounding to see how revisions to Chapter 797 may impact the ability of physicians to provide critical sterile preparations to their patients. The AMA's first and foremost concern has been and continues to be providing safe and effective treatments to our patients. However, we are also concerned about the ability of our patients to access essential treatments in their physicians' offices. While we are pleased to see changes in the most recent draft Chapter 797 that would help physicians maintain access to these important in-office treatments, we have continued concerns that the current proposal may limit access to critical products for physicians in some 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 sterile injectables with a local anesthetic, 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 long-held standard of care and preferred practice 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 statistically significant evidence showing these activities, when performed in a physician's offices, pose any increased risk to patients of infection or other adverse events.

The AMA was pleased to see changes to the revised draft Chapter 797 that would provide some accommodation to physicians engaged in these essential activities. By providing an exception for activities deemed "administration" under the proposed Chapter, a number of physician specialties that engage in in-office preparation of treatments for their patients would be able to continue those practices without facing significantly increased regulatory, financial, and possibly construction burdens that would come with being subject to the full requirements of Chapter 797. New provisions governing the preparation of allergy and immunotherapy products also appear workable for our allergy colleagues. However, the limited one-hour time frame included in the definition of administration in the proposed Chapter is still unworkable for some physician specialties and their patients, particularly our dermatology colleagues.

Dermatologists and others engaged in in-office procedures requiring buffered lidocaine as a local anesthetic cannot reasonably work within the one-hour time frame included in the definition of administration in the proposed Chapter. Typically, lidocaine is buffered by physicians and/or their staff in the office in advance of that day's patients. As buffered lidocaine is used frequently for procedures such as skin biopsies and skin cancer removal, it is not feasible for practices to prepare this product within a one-hour time frame for each patient without encountering significant burdens on busy practices. Further, some procedures, such as Moh's surgeries, frequently last longer than one hour and require re-administration of local anesthetic throughout the duration of the procedure. In those instances, physicians need to have a supply of buffered lidocaine that will last the entire duration of the procedure, as stopping to prepare additional drug product lengthens the time of the procedure and adds an increased risk of infection to the patient. For further information and discussion on the use of buffered lidocaine, please refer to the comment letters submitted by our dermatology colleagues.

For those specialties requiring a time frame for preparation longer than one-hour, the AMA strongly urges USP and the Expert Committee to consider extending the time frame for administration under the chapter, or to consider other alternatives or exemptions to the chapter requirements that will ensure physicians and patients have continued access to these products. In many cases, compounding pharmacies do not represent a viable alternative source of drug products. In these instances, the products in question are not available from pharmacies or do not remain sufficiently stable over the time periods needed for shipping/transport. Given the lack of evidence showing increased risk of harm for many of the products in question and given the increased risks to patients if access to these treatments is limited or eliminated, it is critical that USP and the Expert Committee work to ensure that physicians can continue to offer these treatments in office settings without the increased burden of meeting the full requirements of Chapter 797.

The AMA appreciates the opportunity to have worked with USP on this important issue. We are especially appreciative of the Expert Committee's inclusion of physician representatives as consultants to the committee's work in recent months. We cannot stress enough how important the physician voice is and continues to be in this effort, as the provisions of Chapter 797 have the potential to greatly impact access to essential treatments provided in physician offices. It is our hope that the USP and the Expert Committee will continue to work closely with the physician community as they move towards finalization of Chapter 797 and that an acceptable resolution to outstanding concerns can be found. Please do not hesitate to contact Shannon Curtis, Assistant Director, Federal Affairs at Shannon.Curtis@ama-assn.org or 202-789-8510 with any questions.

Sincerely,

James L. Madara, MD