AMA
AMERICAN MEDICAL ASSOCIATION

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Carrie C. Phillips, MS, PharmD
Executive Officer
Board of Pharmacy
Vermont Office of Professional Regulation
Office of Professional Regulation
89 Main Street, 3rd Floor
Montpelier, VT 05620-3402

Dear Dr. Phillips:

On behalf of the American Medical Association (AMA) and our medical student and physician members, I am writing to provide the AMA's perspective on physician compounding to the Interdisciplinary Task Force. As you likely are aware, a significant number of physicians across a number of different specialties prepare sterile products in office settings for administration to their patients. In many cases, in-office preparation and administration of these products represents the long-held standard of care for a certain condition or disease state within a certain specialty. In almost all cases, the in-office preparation of these products has been a preferred pattern of practice for years. Further, preparation of these products generally presents an extremely low risk to patient safety and there has been little evidence of increased sterility issues associated with the act of preparation in the physician office.

Patients of many specialists rely on the ability of their physicians to prepare these drugs in-office to avoid: (1) certain increased risks; (2) follow-up appointments for treatment; and (3) receiving treatment in higher-cost care settings. For example:

- Allergy and immunotherapy patients receive patient-specific treatments prepared by their physician in that physician's office, where treatment dilutions can be carefully controlled to avoid potential life-threatening complications, i.e., serious allergic reactions.
- Dermatology and plastic surgery patients rely on in-office preparation of buffered lidocaine for use during outpatient procedures.
- Other specialists provide treatments, such as joint injections, to help patients deal with pain. These treatments are drawn up with a local anesthetic immediately prior to administration.

In the majority of cases, acquiring these products in a ready-to-use form from a compounding pharmacy is not a viable option, either due to stability issues with the drug, an increase in potential risks to patients, a delay in treatment or a significant increase in cost of treatment. Our patients rely on the ability of our members to prepare critical sterile treatments in the office setting for administration to their patients.

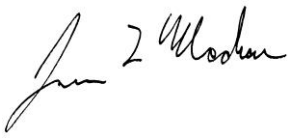
Restricting the ability of our members to offer these necessary services would likely result in a significant increase in access issues and costs and overall worse health outcomes for our patients. Physicians are simply unable to retrofit practice facilities with new equipment/clean rooms or undergo other structural facility changes to meet safety and sterile requirements akin to those in compounding pharmacy facilities.

In addition, as mentioned above, there is a significant lack of evidence showing risks to patients that warrants further change or restrictions on practice.

The health and safety of our patients is, and has always been, the first priority of our members. We share your goals of ensuring patient safety while simultaneously supporting efforts to provide access to necessary treatments in a physician's office. To that end, we urge you to work closely with the physician community to determine the most appropriate path forward that both ensures sterility of drug products prepared in office settings and maintains access to critical treatments for patients.

Representatives of the physician community welcome further discussion with the Interdisciplinary Task Force to accomplish our shared goals. If you have any questions, please contact Daniel Blaney-Koen, JD, Senior Legislative Attorney, AMA Advocacy Resource Center, at daniel.blaney-koen@ama-assn.org or (312) 464-4954. Thank you for your consideration.

Sincerely,



James L. Madara, MD

cc: Vermont Medical Society