

August 10, 2023

Joe Schnabel
Executive Director
Oregon Board of Pharmacy
800 NE Oregon St., Ste 150
Portland, OR 97232

Dear Board Members and Mr. Schnabel:

On behalf of the Alliance for Pharmacy Compounding (APC) and the National Community Pharmacists Association (NCPA), I write in response to the fiscal impact request posted by the Oregon Board of Pharmacy circulated on August 4, 2023.

The Alliance for Pharmacy Compounding ("APC") is the voice for pharmacy compounding, representing compounding pharmacists and technicians in both 503A and 503B settings, as well as educators, prescribers, researchers, and suppliers. Pharmacy compounding is authorized in federal and state law as an appropriate therapeutic option for patients and animals whose needs cannot be met by traditional pharmaceutical manufacturers.

Thank you for the opportunity to comment on the fiscal impact of the proposed rules for Division 183 pertaining to compounding. We wish to offer our support of Number 10 of the August 4, 2023, request.

10. Permitting a drug outlet to regularly compound or compound inordinate amounts of an approved drug if the outlet is unable to obtain an adequate supply to regularly meet patient need of the approved drug from a Wholesale Distributor Drug Outlet.

The ability of compounders to compound drugs that are on shortage has a positive economic impact. When medications are on shortage, a priority is allowing the continuation of care without interruption to treatment, often difficult when access to the medication or alternatives is severely hindered. Allowing compounders to supply these approved drugs while they are on shortage therefore can reduce the number of emergency room visits and hospitalizations caused by a patient's inability to access their medication. This was seen recently in the albuterol shortage, in which compounders were able to provide a lifesaving medication for asthma and COPD patients. According to the most recent data, the CDC estimates that there are 377,851 patients suffering from asthma and COPD in the state of Oregon, of which approximately 6%, or 22,671 are children aged 0-17 years old, the primary users of albuterol inhalant solution. According to Mira Healthcare, an average ER visit costs \$1437.00. If only 1% of those children had to be rushed to the emergency room because their inhalation therapy was not available, the cost to payors would have been \$325,782.00. Albuterol inhalant solution has been in shortage since October 2022. Fortunately, a number of compounding pharmacies and outsourcing facilities have stepped up their production of the medication, minimizing the therapeutic impact on the patient and the financial impact to the payor.

Furthermore, we appreciate that the Oregon Board has recognized unavailability from a Wholesale Distributor Drug Outlet as the trigger criteria for compounding inordinate amounts of an approved drug. FDA's Drug Shortage List has frequently been criticized for being slow or unresponsive to

shortage situations. Likewise, it fails to consider regional shortages, something that the Oregon Board of Pharmacy has addressed in its proposed rules.

We very much appreciate the opportunity to comment on the Proposed Rules and we appreciate the Oregon Board of Pharmacy decision to promulgate constructive regulations for compounded medications.

Thank you for this opportunity to comment on the proposed regulation changes. Please direct any questions to APC's Savannah Cunningham at savannah@a4pc.org.

Best,

A handwritten signature in black ink, appearing to read 'S. Brunner', with a stylized, cursive script.

Scott Brunner, CAE
Chief Executive Officer