

August 26, 2021

The Honorable Henry Cuellar
United States House of Representatives
Washington, DC 20515

The Honorable Morgan Griffith
United States House of Representatives
Washington, DC 20515

Dear Congressman Cuellar and Congressman Griffith:

The undersigned organizations represent thousands of compounding pharmacy professionals. We write today in strong support of HR 3662, *the Patient Access to Urgent-Use Pharmacy Compounding Act of 2021*. As the recent pandemic has shown, there are patient access gaps in our health care system that occur when critical drugs go into shortage, including those needed for administration to patients in hospitals and other clinical settings. We thank you for introducing this important legislation that will help address those gaps and improve patient care.

FDA has interpreted Section 503A of the Food, Drug and Cosmetic Act (FDAC) to require pharmacies to obtain a patient specific prescription for each drug they compound before the drug leaves the pharmacy. This requirement for a patient-specific prescription for an urgent patient need is hampering patient care. For instance, certain patients may need anti-bacterial, anti-fungal, and anti-viral compounded medications to treat eye-infections in immediate if not emergency circumstances. These drugs are often unavailable commercially or from a 503B outsourcing facility that can compound without a patient-specific prescription.

Because a delay in providing the medication can result in patient harm, in limited circumstances it is appropriate and necessary for 503A pharmacies to compound the medications without having a patient-specific prescription – and ensure that the patient information is relayed to the compounding pharmacy within seven days. The patient information will then be married up in the pharmacy's records. When the FDA published a temporary COVID-related guidance document titled *Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency*, the FDA acknowledged that urgent patient need should outweigh prescription requirements for 503A compounding, provided that other safeguards are in place. This bill strikes that critical balance.

During the COVID pandemic, the FDA also utilized enforcement discretion for compounding identified drugs with respect to certain "essentially a copy" requirements. For example, if an identified drug was in shortage, 503A pharmacies and 503B Outsourcing Facilities could produce the drug in shortage, and the FDA would not enforce statutory requirements that compounded drugs cannot be "essentially a copy" of a commercially available product. This bill would codify that flexibility, while also providing safeguards to protect patients from further drug shortages by expanding the shortage definition to include the FDA's list of drug shortages and shortages identified by the American Society of Health-System Pharmacists (ASHP), given that ASHP's list encompasses local and regional (not just national) shortages.

Again, we thank you for your leadership on this important legislation that will improve patient access to the critical medications needed in urgent-use medical situations and when those drugs are in shortage.

If you have questions, please contact Scott Brunner at the Alliance for Pharmacy Compounding:
scott@a4pc.org or 404.844.8607

Sincerely,

Alliance for Pharmacy Compounding
Alabama Pharmacy Association
American Pharmacists Association
Arizona Pharmacy Association
Arkansas Pharmacists Association
California Pharmacists Association
Colorado Pharmacists Society
Connecticut Pharmacists Association
Delaware Pharmacists Society
Florida Pharmacy Association
Georgia Pharmacy Association
Illinois Pharmacists Association
Indiana Pharmacists Association
Louisiana Pharmacists Association
Maine Pharmacy Association
Maryland Pharmacists Association
Massachusetts Pharmacists Association
Michigan Pharmacists Association
Minnesota Pharmacists Association
Mississippi Pharmacists Association
Missouri Pharmacy Association
National Alliance of State Pharmacy Associations
National Community Pharmacists Association
Nebraska Pharmacists Association
Nevada Pharmacy Alliance
New Jersey Pharmacists Association
North Carolina Association of Pharmacists
North Dakota Pharmacists Association
Ohio Pharmacists Association
Oklahoma Pharmacists Association
Oregon State Pharmacy Association
Pennsylvania Pharmacists Association
Pharmacists Society of the State of New York
Rhode Island Pharmacists Association
South Dakota Pharmacists Association
Tennessee Pharmacists Association
Texas Pharmacy Association
Utah Pharmacy Association
Virginia Pharmacists Association
Washington DC Pharmacy Association