NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Alliance for Pharmacy Compounding
Compounding the Joy of Living®

April 22, 2024

Gail Bormel, JD, RPh
Director, Office of Compounding Quality and Compliance
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Bormel:

On behalf of the Alliance for Pharmacy Compounding and The National Community Pharmacists Association, we write regarding implementation and enforcement of recent changes to USP Chapter <797>, particularly the requirement that sterile compounding pharmacies have completed stability studies for Compounded Sterile Preparations (CSPs) in Category 3. As the trade associations representing compounding pharmacists, we recognize the importance of ensuring CSPs are stable and free from microbial contamination through the expected beyond-use date of the product. We fully support the FDA's efforts to uphold rigorous standards in pharmaceutical compounding.

A complication we've been made aware of – and about which we wish to inform you – is a current and significant delay in obtaining stability test results from the analytical labs. Testing laboratories are experiencing considerably longer turnaround times, largely due to the increased volume of testing requests that the new <797> standard has prompted.

While we acknowledge the importance of ensuring the stability and microbial safety of Compounded Sterile Preparations, we wish to bring your attention to the practical implications of the current testing backlog. Sterile compounders are diligently working toward completing stability studies; however, the extended turnaround times for test results are, in some cases, hindering their ability to comply with the regulatory requirement within the expected timeframe.

Therefore, we urge the FDA to consider the testing backlogs and the impact as FDA is reviewing pharmacies' ability meet the requirements. We are concerned that these delays could impact continuity of care for patients, whose prescriptions for compounded sterile medications may have shorter beyond-use dates during this period.

Additionally, given the diversity in state-level regulations, it is possible that some states may have different requirements or are currently exercising enforcement discretion for pharmacies moving toward full compliance with updated compounding standards.

We're writing simply as a courtesy to make you aware of this situation. We want to ensure that all relevant stakeholders are informed, both about the potential variations in regulatory practices across different jurisdictions and about potential implications for patients.

Thank you for your consideration of this matter. If you have questions, please contact Scott Brunner, CAE at scott@a4pc.org.

Sincerely,

ALLIANCE FOR PHARMACY COMPOUNDING
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION