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Alliance for Pharmacy Compounding

Compounding the Joy of Living

April 12, 2023

Lucy Shell, PharmD
Executive Director
Tennessee Board of Pharmacy
710 James Robertson Parkway
Nashville, Tennessee 37243

Dear Dr. Shell:

I am writing on behalf of the Alliance for Pharmacy Compounding in response to the recently proposed amendments to Chapter 1140 in your state.

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers.

We support the Tennessee Board of Pharmacy and its mission to protect patients by maintaining the highest quality and standards for the pharmacy compounding profession. We also believe the agency has an obligation to demonstrate how its regulatory proposals keep patients safer and that there is a clear and enunciated scientific basis and benefit to new regulation. Without such justification or evidence, additional regulation simply imposes a burden without benefit.

In that regard, we wish to comment on several items of concern in your proposal:

- Rule 1140-07-.06: This update requires "*At the time of labeling the final compounded drug product, the dispensing container must bear a label which contains the following information: (d) Identification of all personnel who compounded the product*." Generally speaking, we ask the board to enunciate evidence that patient safety is enhanced by such a requirement. More practically, we would note that the space on a label simply isn't sufficient to encompass all that information. Moreover, as required in Rule 1140-07-.02 (4)(g), the identities of all personnel who were involved in compounding a product will be included on the compounding record for reference should it be necessary. We urge the board to reject this proposal.
- Rule 1140-01-.08: This update requires "*an out-of-state pharmacy practice site engaged in compounding must provide an inspection performed within the previous twelve (12) months.*" The board has not enunciated a rationale for this change in frequency – a change we assert is unnecessary. To our knowledge, most other states accept an inspection within the previous 24 months, and NABP requires an inspection every 18 months. Under this proposal, many compounders would be forced to undergo an NABP inspection every 12 months, which would be onerous, costly, and – absent any compelling rationale from the board – unnecessary.

Thank you for this opportunity to comment on the proposed regulation changes. Please direct any questions to me at scott@a4pc.org.

Best,

Scott Brunner, CAE
Chief Executive Officer