

January 21, 2015

Senator Kathy Campbell, Chair
Health and Human Services Committee
P.O. Box 94604
Lincoln, NE 68509-4604

RE: LB 37

Dear Senator Campbell and members of the Health and Human Services Committee:

LB 37 creates the Prescription Drug Safety Act which combines statutes relating to prescription drugs into one Act that pertains to all practitioners who have authority to prescribe, administer, or dispense. The Department of Health and Human Services, Division of Public Health, has reviewed LB 37 and has the following technical concerns which we have shared with the Nebraska Pharmacists Association. All of the concerns with the exception of the concern related to Section 44 have been resolved, but are included for your reference:

- In Section 27 and Section 56, language should be added to allow a pharmacy technician to receive refill authorizations which is something pharmacy technicians are currently allowed to do.
- In Section 35, the changes may prevent pharmacist interns from participating in pharmaceutical care agreements.
- Section 36 removes the minimum number of hours a PIC is required to work in a pharmacy. This change raises concern that a PIC may not spend a substantial amount of time in the pharmacy overseeing the practice of pharmacy which may impact public health and safety.
- Section 40 removes physician assistants from being authorized to hold a dispensing practitioner pharmacy license.
- Section 44 will require that any person who compounds drugs must comply with United States Pharmacopeia (USP) 795/797 Standards; however, this section also allows compounding for office use. This is a potential conflict with the federal Drug Quality and Security Act which has been interpreted by the federal Food and Drug Administration as prohibiting compounding for office use. Although Section 44 is requiring compliance with USP Standards, it allows authorized persons to reconstitute drug products in accordance with manufacturer's directions. This is also a potential conflict with federal law as the USP has interpreted reconstitution to be considered as compounding.

Thank you for your consideration of the Department's technical concerns.

Sincerely,

A handwritten signature in blue ink, appearing to read "Joe M. Acierno". The signature is fluid and cursive, with a long horizontal line extending to the right.

Joseph M. Acierno, M.D., J.D.
Chief Medical Officer
Director, Division of Public Health

Cc: Senator Krist