



Testimony concerning HB 2055
Senate Committee on Public Health and Welfare
Presented by Alexandra Blasi, Executive Secretary
On behalf of
The Kansas State Board of Pharmacy
March 7, 2017

Madam Chair and Members of the Committee:

The Kansas State Board of Pharmacy is pleased to testify as a proponent for HB 2055. These amendments include vital updates to the Pharmacy Practice Act to comply with federal law, emerging industry standards and trends, and improve our agency's function and protection of the public.

Federal Law Requirements

The Federal Drug Supply Chain Security Act (DSCSA), 21 U.S.C. 351 *et seq.*, falls under the Drug Quality and Supply Act, which is part of the Federal Food, Drug, and Cosmetic Act. Though primarily designed to regulate and monitor the manufacturing of compounded drugs, it was amended in 2014. These changes outlined a 10-year process for updating requirements for those in the drug manufacture and distribution chain, as well as creating an electronic, interoperable system to identify and trace prescription drugs all the way from the manufacturer through distribution, to the consumer. HB 2055 is the first step toward Kansas compliance with these new federal rules, including definitions and requirements for third-party logistics providers, outsourcing facilities, and repackagers. In addition, specifics were outlined regarding wholesale distributors, products, and co-licensed partners. For example, we currently register outsourcing facilities as pharmacies, manufacturers or distributors, but this is not how they are classified by the Federal Food and Drug Administration (FDA). Similarly, third-party logistics providers are now recognized as entities independent of manufacturers and wholesale distributors and must be appropriately classified, licensed, and inspected. Kansas law must now be updated to reflect and mandate compliance with these federal changes, as well as those requirements of the pharmaceutical industry. Any new fees are identical to current registration and permit fees and should have a null effect on revenue and expense, merely shifting from one licensure category to another. Certain definitions are also updated to be consistent with other federal standards, including durable medical equipment and labeling.

Adequate Regulation for Compounding and Automation

The Board's recommended updates include greater authority for the Board to properly and adequately regulate the sterile and nonsterile compounding, as well as the inclusion of automation in long term care and other pharmaceutical settings. Recently, the Board attempted to set forth such regulations and was made aware of current statutory limitations which preclude adopting appropriate professional safeguards. As compounding and automation become more commonplace in the healthcare setting, establishing criteria for compliance and evaluation are critical to the protection of the public.

Compounding means combining drug components into a compounded preparation. This may require a sterile environment and certain precautions to protect against contamination, as many compounded products are injected under the skin. For both sterile and nonsterile compounds, the Board needs to be able to set forth standards for physical facilities and procedures. Ventilation, hand-washing sinks, and sterile garments (i.e., face masks, gowns, booties, etc.) may be critical. In addition, requirements for proper documentation and procedural steps for sterile preparations, like the glove fingertip test, are vital to the compounding process. The need for such regulations are compounded by the fact that Kansas exists in a community of other state pharmacy regulatory boards that rely on our state to properly regulate and inspect Kansas compounding facilities shipping out of state, just as we rely on those states to regulate and inspect those non-resident compounding facilities shipping into our state.

Automation is an emerging trend in pharmacy, no doubt a result of enhancements in technology and security features. The Board currently has minimal statutory vehicles to allow automated systems in pharmacy, and is attempting to expand current standards to allow automated dispensing systems which have been adequately tested and approved in a variety of national and state pharmaceutical environments. It is time for Kansas to join this movement, while continuing to provide appropriate protections and requirements for proper administration and use of these systems. Regulations have recently been adopted to allow automation in long-term care facilities, pharmacies, and other licensed facilities, as long as certain criteria are met and appropriate safeguards put in place to ensure the protection of the public. As an additional level of assurance, amendments to the practice act specifically indicate that automated dispensing systems shall be under the supervision of a licensed pharmacist who shall be responsible for recordkeeping and storage of all drugs and verifying and documenting each prescription drug prepared or dispensed by such system. In addition, a structure is created to identify and track what systems are being used where, and to protect public safety.

Utilization of automated systems cuts down on time and costs associated with filling prescriptions and minimizes human error, further protecting the public. As more facilities automate with new technology, employing the necessary evaluation and inspection criteria is a crucial component of implementation. It is important that Kansas allow and adequately regulate this technology to avoid falling behind and losing our pharmacies and pharmaceutical business to other states and companies.

Pharmacy Technician Qualifications, Education and Training

Several years ago, the Board of Pharmacy convened a task force for reviewing the qualifications, education and training necessary for registration as a pharmacy technician. The proposed amendments to K.S.A. 65-1663 and subsequent regulations will serve as another step in that process. HB 2055 would require pharmacy technician applicants to possess a high school diploma or GED, or be currently enrolled and in good standing in a high school education program. In addition, new applicants may be required to pass a certification exam (approved by the Board) within a certain period of time after becoming registered. Two national exams are currently available, but the Board plans to set criteria that will allow other business, regional or local exams to be approved. Until the pharmacy technician has successfully passed the exam, the Board will implement certain restrictions on the duties he/she may perform.

Most states now require technicians to pass a certification exam and complete continuing education requirements to continue in the profession. As a comparison, 38 states mandate pharmacy technician training programs, 30 states require passage of a certification exam or continuing education, and 17 states require an exam and continuing education. The Board has engaged with licensees, stakeholders, and other interested groups, and believes these requirements would be consistent with fellow state

Boards and would take the necessary steps to adequately train technicians and protect the public. Currently, the Board requires 20 hours of continuing education to renew a pharmacy technician registration for a two-year period.

Licensure and Enforcement for Protection of the Public

The Board has also included several updates to support its overall mission of protecting the public. Such requirements are fairly standardized across licensing agencies and consistent with the operation of regulatory agencies in Kansas.

Throughout HB 2055, the Board has unified language requiring pharmacists, pharmacy students/interns, and pharmacy technicians to update the Board office with their current residence, name, contact information, and employment information. This will ensure that the Board is able to contact and regularly communicate with licensees, as well as properly inspect licensed facilities and investigate complaints. Currently, the Board is looking for new ways to stay in regular contact with licensees, but is limited because of outdated mailing and email addresses. The Board finds no reason to require different license types to provide different types of information updates and thus proposes this change.

Consistency is also the driver behind nametag requirements for those in the pharmacy setting. The statutes are being updated to require pharmacists, pharmacy students/interns, and pharmacy technicians to wear nametags at all times while on duty, with certain minimum information contained thereon.

The Board also seeks permission to take disciplinary action against individuals who have obtained, renewed, or reinstated, or attempted to obtain, renew, or reinstate any license or registration by false or fraudulent means, including misrepresentation of a material fact. Such attempts often come in the form of a partial report of an applicant's criminal history or substantial mischaracterization of a disciplinary case. Furthermore, the Board wishes to expand the types of offenses it may review and consider in making a licensing determination to include misdemeanors involving moral turpitude or gross immorality. While most infractions are felonies and may currently be considered, a few misdemeanor convictions slip through the cracks and those applicants may pose significant danger to the public in the healthcare setting. These changes merely allow the Board to consider these factors in determining an applicant's fitness and qualifications for licensure or renewal; they do not preclude rehabilitation or future licensure.

Other Clean-up

As a side note, there is a significant clean-up to K.S.A. 65-1637 and 65-1637b. In a previous legislative session, two separate bills were passed amending the original statute, thus resulting in two statutes with inconsistent language. While the intent of the language is the same, the Board has worked with the Office of the Revisor to consolidate the changes. Since K.S.A. 65-1637 has been cited to implement certain regulations adopted by the Board, the decision was made to repeal K.S.A. 65-1637b and update the full language of K.S.A. 65-1637. Changes to the language are immaterial, thus no substantive alterations are made to the current law.

The Board appreciates your support in providing these necessary updates to our practice act.