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Testimony concerning HB 2280
Senate Committee on Public Health and Welfare
Presented by Alexandra Blasi, Executive Secretary
On behalf of
The Kansas State Board of Pharmacy
March 25, 2021

Chairman Hilderbrand and Members of the Committee:

The Kansas State Board of Pharmacy is pleased to testify in support of HB 2280 concerning updates to the Kansas Pharmacy Practice Act. These amendments have been carefully crafted by the Board and vetted with the pharmacy stakeholder community. While many of these changes were proposed during last year's session, there are some additions this year resulting from the pandemic. The Board's last comprehensive updates to the Act occurred in 2017.

Below is a list of the substantive changes being made in the order they appear in HB 2280:

- Making investigations and related documents confidential
- Allowing the Board to charge registered facilities the actual costs of additional inspections as a condition of probation or other disciplinary action
- Allowing the Board to charge the costs of inspections requested by resident and non-resident facilities applying for registration or registered with the Board
- Creating a framework for telepharmacy in Kansas and requiring the Board to adopt rules and regulations detailing requirements for operation
- Clarifying the requirements for registration as a manufacturer
- Updating limitations of non-pharmacy use of the terms drugstore, pharmacy, Rx, apothecary, etc.
- Correcting the definition of manufacturing, wholesale distribution, and other transfer of prescription-only and over-the-counter items to include drugs or devices, previously inadvertently stricken from the Act
- Updating the definition of direct supervision and allowing the Board to adopt rules and regulations for any direct supervision not in-person
- Adding definitions of virtual manufacturers and virtual wholesale distributors
- Updating the Board's disciplinary authority to be consistent across all license and registration types, and to include limitation, condition, or public/private censure
- Updating the Board's disciplinary authority to include compliance with federal requirements
- Allowing the Board to expunge minor violations of the Pharmacy Act from a license or registration record
- Setting a maximum number of attempts for the pharmacy practice and pharmacy law examinations for applications from pharmacists by exam or reciprocity
- Correcting the requirements to operate as a manufacturer in Kansas
- Allowing pharmacy technicians to receive orders for a continuation of therapy from a prescriber

- Allowing pharmacists to exercise prescription adaptation for non-controlled medications based on their professional judgement in limited circumstances
- Adding a non-resident facility application and renewal fee
- Increasing fee maximums (caps) for most original and renewal applications
- Allowing a pharmacy to forward an original, unfilled prescription to another pharmacy at the request of the patient consistent with federal requirements
- Updating the Board's authority to assess civil fines for violations of the Pharmacy Act and allowing the Board to retain all collected civil fines in the Board of Pharmacy fee fund for the benefit of K-TRACS (previously sent to SGF)

Telepharmacy – New Section 3

In 2018, the Board commenced a pilot project allowing for the operation of a telepharmacy in the state of Kansas. Telepharmacy allows a pharmacist to conduct their review, supervision, verification, and patient counseling responsibilities virtually, while a pharmacy technician staffs the brick-and-mortar pharmacy and conducts the in-person dispensing process. Among other things, the software enables remote prescription verification and live-video counseling with patients including audio and video. The Kansas pilot has been operational for three years, demonstrating success and no increased risk to the public. In conjunction with licensees, pharmacy stakeholders, and telepharmacy software companies, the Board has crafted a series of criteria that may be used to develop telepharmacy regulations in Kansas and has even started the process of crafting such regulations. The criteria will include the following:

- Structure, security, technology, and equipment
- Staffing, training, and electronic supervision
- Inventory, record keeping, storage, and labeling
- Use of automation behind the pharmacy counter
- Allowance of Board waivers in limited circumstances

The National Association of Boards of Pharmacy (NABP) added telepharmacy to the Model Act in 2006 and 25 states have adopted telepharmacy laws or regulations, including Nebraska, Colorado, Texas, Iowa, and the Dakotas. Aside from the pilot project, current law does not allow telepharmacy in Kansas. The Board asserts that 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. As telemedicine and telepharmacy become more commonplace in the healthcare setting, establishing criteria for safe operation, compliance, and evaluation are critical to the protection of the public and access to pharmacy services, especially in rural or underserved areas.

Pharmacist Licensure Examination – Section 8

The Board is proposing setting a limit on the number of attempts for the national pharmacy practice exam and the state pharmacy law exam. The Board proposes a maximum of five attempts for each examination which is consistent with the NABP standards. This is imperative not only for exam integrity but for the protection of the public. The Board has a long-standing, five-attempt rule for Kansas applicants. Fortunately, it has not been exercised during my time with the Board. However, the Board recently learned that some states have no such limit. One state authorized a pharmacist to take the exam thirteen times over twenty years before allowing that applicant to become a licensed pharmacist. Based on current law, that individual could reciprocate their pharmacist license to Kansas. Many states limit

the number of exam attempts and the Board believes this measure protects the public while providing ample opportunities for qualified pharmacists to become licensed. [page 25, line 39] [page 26, line 3]

Use of Pharmacy Terms – Section 5

In Kansas, the terms drugstore, pharmacy, Rx, and apothecary in a business name are limited to use by registered Kansas pharmacies. However, the Board has learned that many other Kansas businesses attempt to use these terms, some even within the healthcare industry. In pursuing action to enforce Kansas law and prevent the use of these terms, the Board believes statutory changes are necessary. Consumers are capable of understanding that a restaurant called The Pharm or a store called FurnitureRx is not staffed by a licensed pharmacist. There is little to no danger to the public. However, consumers may be confused by a business called CBD Pharmacy or Health Rx and believe that licensed pharmacists or other experts provide counseling or expertise at those businesses. Based on legal precedent, the Board proposes limiting use of these terms only in health-related businesses and requiring a public disclaimer sufficient to communicate to consumers that no pharmacist is employed by the facility. [page 6, line 18] [page 13, line 37]

Updates to Standards of Practice

Over the past few years, some standards of pharmacy practice have changed and state law needs to be responsive. The Board's recommendations are in alignment with surrounding states and do not pose a risk to the public. Language in the Act needs to be updated from simple words like "refill" to "continuation of therapy that contains no changes." [page 28, line 32]

The Board borrowed language from Washington and Arizona to enable Kansas pharmacists to use their professional judgment to exercise prescription adaptation for non-controlled medications. [page 29, line 41] More than half of the states allow pharmacists this flexibility, which benefits the patient by enabling prompt dispensing of medications and fewer delays. Of course, this is an allowance not a requirement, and if the pharmacist has any doubt they would be required to contact the prescriber for verification prior to the action. The proposed language also requires notification back to the prescriber and only allows prescription adaptation for the following limited circumstances:

- Change Quantity
    - The prescribed quantity or package size is not commercially available
    - Related to a change in dosage form
    - Extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program
- Change dosage form, strength, or directions for use if it is in the best interest of the patient and the change achieves the intent of the prescriber
- Complete missing information if there is evidence to support the change

Updates also clarify the process for transferring unfilled patient prescriptions, a topic which has caused patients and pharmacies significant difficultly in recent years due to the opioid epidemic and new DEA rules. New language allows a pharmacy to forward (not transfer) an original, unfilled prescription to another pharmacy at the request of the patient. Certain federal requirements exist for this process and prescriptions for controlled substances are required to be forwarded electronically. [page 39, line 11]

During the pandemic, the pharmacy world has adapted to remote work alongside the rest of the world. As a result, pharmacist supervision of other pharmacy personnel has evolved to include certain duties and tasks that may be performed without direct supervision being provided in person. The Board now seeks authority to adopt rules and regulations consistent with these limited circumstances where remote supervision of pharmacy personnel may be possible. [page 8, line 30]

Enforcement, Inspections, and Protection of the Public

While the aforementioned updates are important, the Board's mission is to protect the public. This happens through the Board's enforcement authority; its ability to deny, limit, censure, revoke, and discipline a license or registration. It also happens through inspections of registered facilities and investigations. On the advice of counsel, the Board recommends adding a section detailing the confidentiality of certain complaints and documents associated with investigations. The provisions allow access to named parties and other state and federal regulatory agencies, but otherwise maintain integrity and privacy. Such provisions are standardized and are consistent with the operation of regulatory agencies in Kansas. [New Section 1]

Also on advice of counsel, the Board recommends streamlining and standardizing Board enforcement authority for all facility registrants, including non-resident facilities shipping into Kansas. The Board supports inclusion of authority to take action against individuals and facilities for violations of federal requirements and for disciplinary actions taken by the federal government. It is unclear why this language has not previously been included in the Act, but it is vital to ensuring the protection of the public. These changes merely allow the Board to consider these factors and do not mandate action. [Section 7] [page 41, line 27]

The Board also seeks permission to take disciplinary action in the form of a public or private censure. Such action would not rise to the level of formal discipline reportable to other states and jurisdictions, but would allow the Board to note minor noncompliance issues and levy a small administrative fine. The Board has repeatedly heard from licensees that reporting to other states often causes a form of "domino discipline" that results in an endless cycle of disciplinary actions against individuals and facilities for no reason other than the Board action. While the Board does not participate in domino discipline and usually relies on resident states to hold their registrants accountable, the Board is aware of and sensitive to this problematic practice. [page 19, line 28] [page 22, line 13] [page 23, line 24] [page 41, line 28] [page 44, line 16] [page 45, line 36]

Many licensees have also requested the Board consider expunging minor disciplinary actions from their licensure record. No such authority exists in Kansas administrative law or the Pharmacy Act. Though only a handful of states have ventured into this area, the Board feels strongly that licensees should have a one-time opportunity to remove minor administrative actions from their record after five years. [page 24, line 32]

Fees and Funding for K-TRACS

The Board has received increasing numbers of requests for Board staff to inspect non-resident facilities. While Kansas inspects all resident pharmacies every 18 months and other facilities every 36 months, other states only inspect every 3-5 years (Nebraska). This leaves facilities without a valid inspection to

present to the Board for registration in Kansas. The Board has approved the NABP Verified Pharmacy Program but these inspections are extremely costly. Though the Board has authority to conduct inspections of non-resident facilities, it is cost prohibitive. Therefore, the Board seeks authority to charge facilities the actual costs of inspections conducted at the request of the facility. Again, this would not impose a fee for routine inspections for resident facilities which are paid through annual renewal application fees. [page 2, line 16]

As Board funding has become an issue in recent years, the Board has carefully reviewed resource expenditures. Compliance inspections and audits that result from disciplinary action or probation are some of the Board's most expensive operations. Expenses include inspector time and mileage to travel to the pharmacy, conduct the inspection, review issues and provide education, and obtain/retrieve documents. New Section 2 authorizes the Board to charge the actual costs of compliance inspections or audits as a condition of probation or disciplinary action. This would not impose a fee for routine inspections which are paid through annual renewal application fees. [page 2, line 6]

Another growing area of expense is the review of non-resident facility applications and renewals. The Board currently registers 2,312 non-resident facilities. Despite implementation of stringent requirements to ensure resident and non-resident facilities are held to the same standards, the Board has a large proportion of non-resident facility registrants. While Kansas wants to remain business friendly, the Board also wants to ensure the protection of the public, especially when it comes to pharmaceuticals and healthcare. Bad actors can easily create 10-15 layers of holding companies to protect the identify of an owner that has been denied registration or had a registration revoked in another state. Facilities with a history of poor compliance attempt to bury federal and state findings by submitting inspection reports for a different address or neglecting to submit negative reports to the Board. The result is that Board staff must conduct detailed application review and vetting to ensure owner integrity and facility compliance. The Board estimates these reviews take more than two times longer than resident applications. The most significant concerns are with wholesale drug distributors and compounding facilities (outsourcing). To avoid penalizing resident facilities, the Board is requesting authority to impose a special non-resident facility application and renewal fee in addition to the other fees set by the Board. [page 35, line 21]

Perhaps the most challenging funding issue at the Board is the Prescription Monitoring Program, known as K-TRACS. K-TRACS is a vital program and a potent tool used by healthcare professionals to enhance patient care and aid in the identification of patients with drug-seeking behaviors. Information on the program's success and current status can be found in the 2021 K-TRACS Legislative Report. Despite continued grant applications and successful awards, funding presents the largest obstacle to maintaining K-TRACS, but the Board continues to work with stakeholders to identify permanent funding. The Board's proposed budget for FY2022 and FY2023 presented to our relevant budget committees involves retaining 100% of administrative fine revenues. Currently, the Board only retains fine revenue equal to the Board's actual case costs and the remainder is credited to the state general fund. The maximum transfer to SGF in recent years has been $83,000. [page 42, line 41]
The K-TRACS funding plan also involves increasing Board fees, necessitating review of statutory fee maximums. Since the Board already planned updates to the Pharmacy Act, amendments to statutory fee maximums seemed timely and they are proposed for consideration. However, the Board remains committed to only increasing the actual regulatory fees if/when it is necessary to do so. Such regulations will require review before the Joint Committee on Administrative Rules and Regulations as well as

public meetings. The Board reiterates the public reach and benefit of the K-TRACS program and remains committed to seeking new opportunities for alternative funding sources. The table below outlines the proposed, maximum fee increases the Board has contemplated:

Type	Current Cap	New Cap	Current Fee	New Fee	2018 KBOP #s	2019 KBOP #s	2020 KBOP #s	Rev Increase
Pharmacist by Exam App	$ 350.00		$ 100.00	$ 125.00	219	216	213	$ 5,400.00
Pharmacist by Recip App	$ 250.00	$ 350.00	$ 125.00	$ 250.00	155	382	310	$ 35,291.67
Pharmacist Renewal	$ 200.00		$ 150.00	$ 175.00	2686	3187	3440	$ 77,608.33
Pharmacy App	$ 150.00	$ 250.00	$ 150.00	$ 175.00	495	53	34	$ 4,850.00
Pharmacy Renewal	$ 125.00	$ 250.00	$ 125.00	$ 150.00	1576	1544	1574	$ 39,116.67
NPD App	$ 50.00	$ 100.00	$ 50.00	$ 75.00	13	30	13	$ 466.67
NPD Renewal	$ 50.00	$ 100.00	$ 50.00	$ 75.00	111	94	80	$ 2,375.00
Inst Drug Room App	$ 40.00	$ 100.00	$ 25.00	$ 50.00	14	25	19	$ 483.33
Inst Drug Room Renewal	$ 35.00	$ 100.00	$ 20.00	$ 50.00	137	50	55	$ 2,420.00
Sample App	$ 50.00	$ 100.00	$ 30.00	$ 50.00	2	1	9	$ 80.00
Sample Renewal	$ 50.00	$ 100.00	$ 30.00	$ 50.00	30	24	21	$ 500.00
Intern App	$ 25.00	$ 50.00	$ 20.00	$ 35.00	275	242	260	$ 3,885.00
Retail Dealer App	$ 12.00	$ 50.00	$ 10.00	$ 35.00	258	99	130	$ 4,058.33
Retail Dealer Renewal	$ 12.00	$ 50.00	$ 10.00	$ 35.00	1476	1589	1590	$ 38,791.67
Technician App	$ 50.00		$ 20.00	$ 35.00	1571	1448	1341	$ 21,800.00
Technician Renewal	$ 25.00	$ 50.00	$ 20.00	$ 35.00	2477	1828	2278	$ 32,915.00
NPD 3PL App	$ 50.00	$ 100.00	$ 50.00	$ 75.00				
NPD 3PL Renewal	$ 50.00	$ 100.00	$ 50.00	$ 75.00			35	$ 2,625.00
Outsourcing App	$ 500.00		$ 350.00	$ 400.00				
Outsourcing Renewal	$ 400.00	$ 500.00	$ 350.00	$ 400.00			29	$ 11,600.00
Non-Resident App		$ 350.00		$ 100.00				
Non-Resident Renewal		$ 250.00		$ 50.00			2312	$ 115,600.00
					TOTAL			$ 399,866.67

Other Clean-up

As a side note, there is significant clean-up throughout the bill. Clean-up includes reinsertion of language regarding FDA-approved devices that was inadvertently stricken in previous legislative changes. The Board has continued to regulate the device industry but needs to correct this issue. Additionally, clarification is needed for "virtual" categories of manufacturers and wholesale distributors. Manufacturer requirements also required standardization, similar to other Board facility registration types completed in previous years. Many of these changes stem from the Federal Drug Supply Chain Security Act (DSCSA), 21 U.S.C. 351 *et seq*., which was amended in 2014 and created a 10-year process updating requirements for those in the drug manufacture and distribution chain. The Board updated all federal and industry references and has worked with the Office of the Revisor to make appropriate language adjustments, where required.

Respectfully submitted.