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Testimony concerning SB 10
Senate Committee on Commerce
Presented by Alexandra Blasi, Executive Secretary
On behalf of
The Kansas State Board of Pharmacy
January 27, 2021

Chairman Olson and Members of the Committee:

The Kansas State Board of Pharmacy respectfully submits this testimony opposing the language in Senate Bill 10. The Board licenses individuals and facilities in relation to the practice of pharmacy, with the mission of protecting the public health, safety, and welfare. The Board fulfills this mission by licensing individuals and facilities in accordance with the highest standards of ethics, accountability, efficiency, and transparency. In reviewing applications, the Board does not rely on subjective opinions or arbitrary factors, but instead looks to the Pharmacy Act and Kansas precedent to objectively and consistently review each application. In crafting and revising administrative regulations, the Board looks to national standards of practice, the authority granted to the Board by the legislature, and past bad actors in Kansas. Ultimately, the Board's mission is to protect Kansas citizens.

Concerns with Timeline

Section 2 of the bill requires that by July 1, 2022, the Board must review and report all administrative regulations and all occupational license types to the legislature to ensure they meet the requirements of the bill, articulate such reasons, analyze the effects of such regulations and license types, and compare such regulations and license types to other states. If the Board finds a regulation or license type does not meet the standard, the Board is required to repeal such regulation or license type within 90 days or report the need for statutory changes to the legislature. The Board also must provide a report to the legislature by October 1, 2022 regarding the Board's progress toward these objectives and any actions taken or planned, and must make continued annual reports to the legislature thereafter in February of each year.

The Board has no concerns with the reporting requirements, nor does it shy away from providing regular review and revision of its administrative regulations. In fact, the Board routinely seeks to do so promptly and efficiently as required and authorized by the legislature in the Pharmacy Act of the State of Kansas and other laws under the Board's jurisdiction. The Board consults with pharmacy associations and stakeholders to ensure that regulations are not overly burdensome and serve the public interest. However, this is a complex task that simply cannot be accomplished in 90 days. Between a review from the Division of Budget, Department of Administration, Attorney General's Office, minimum 60-day public comment period, and review by the Joint Committee on Administrative Rules and Regulations (in that order), the Kansas rulemaking process takes a minimum of six months and can take years depending on the feedback and revisions necessary. Furthermore, a review of our 182 pages of regulations would require substantial resources to accomplish in the timeframe outlined in the bill. The Board would simply ask for more time to accomplish these objectives. For reference, a copy of the 95-page Policy and Procedure Manual for the Kansas administrative regulation rulemaking process can be found here: https://admin.ks.gov/docs/default-source/chief-counsel/website-documents/reg-manual-june-2018.pdf?sfvrsn=4f2688c7_14.

Administrative regulations fulfill an important role. The Board utilizes them to provide guidance and details where the Pharmacy Act leaves off. They are never designed to circumvent the law, exceed the scope of the Board's authority, or excessively restrict the practice of pharmacy. Regulations provide detailed standards, guidance, and protections to ensure that individuals are not harmed in the healthcare setting, one in which significant harm and loss of life are legitimate risks when practitioners fail to follow the rules. This may be the reason states like Tennessee exempted the healthcare professions from its version of this legislation. Furthermore, it is often challenging to prompt changes to the Pharmacy Act consistent with the standards of practice in a timely manner. The Board sometimes waits several years for legislative updates to take effect. This may act as a deterrent for agencies to seek legislative change when they can adopt regulations in shorter timeframes.

Concerns with Standard of Review and Liability

Section 3 of the bill authorizes any individual to petition the Board to repeal or modify any administrative regulation. Within 90 days of receipt of such petition, the Board must repeal the regulation, modify the regulation, or report in writing that the Board concludes the regulation should not be modified because it is necessary to fulfill legitimate public health, safety and welfare objectives. This creates a substantial and ongoing burden on the agency. There is no indication that the Board can meet this requirement once for each regulation and subvert all future petitions. Nor does it allow for the Board to prevent such petitions from being filed by proactively concluding that the regulation(s) are necessary to fulfill legitimate public health, safety, and welfare objectives. The Board also notes the brief, 90-day response time for responding to petitions and completing necessary actions. As previously stated, this timeline is impossible to achieve given the timeline for the administrative rulemaking process set forth in Kansas law. The bill also opens the floodgates to endless petitions.

Senate Bill 10 requires the Board to limit all occupational licenses and administrative regulations to those necessary to fulfill legitimate public health, safety and welfare objectives. On its face, this may not seem a steep hurdle. Certainly, the Board contends that all its regulations already meet this requirement. However, Section 3 authorizes an individual to file a court action challenging any Board regulation under this standard. The individual shall prevail if a court finds by a preponderance of the evidence that the Board regulation burdens entry into the profession or occupation and the Board has either failed to prove its necessity or legitimate public health, safety and welfare objectives may be achieved using less restrictive or less burdensome means. Herein lies the Board's greatest concern: this standard of review will be virtually impossible for any agency to meet, even in the healthcare context.

The Board has no way of estimating the potential number of petitions or court actions that may be filed by individuals requesting agency repeal or modification of administrative regulations. Furthermore, the bill does not prohibit individuals from filing frivolous petitions or court actions, which the Board would be required to respond to and defend against at significant expense. This has the potential to create a never-ending and substantial increase in workload for the Board and could open the floodgates for frivolous litigation against the agency. Costs to the Board would be in the form of staff time and resources associated with responding and defending against these actions to ensure compliance with state law. The agency cannot make any attempt to estimate these costs, but attorneys would be required to manage all work related to such petitions. Furthermore, if the individual prevails, the court may enjoin enforcement of the Board regulation and award attorney fees to the individual at the expense of the Board. The Board (or State General Fund) would be required to pay all attorney fees and costs to prevailing petitioners without any way to budget or estimate these amounts and no revenue to offset these unpredictable expenditures.

Concerns with Fiscal Impact

A one-time or temporary increase in agency expenditures will be related to the mandatory adoption and/or revision of regulations to be compliant with this bill. The staff time involved in reviewing, drafting revisions, and pushing changes through the administrative review process will require additional agency resources not previously budgeted. In addition, Board meetings for review and public hearings would contribute to costs, as well as publication of necessary administrative regulations. Though the Board anticipates all occupational licenses would be deemed essential to the public health, safety, and welfare, and many if not all of the Board's administrative regulations would be deemed compliant with SB10, the work to review, analyze, and report to the legislature within the designated time periods set out in the bill would be significant for a small agency. If significant revisions are necessary, costs would increase but exponential factors. Additionally, some reporting requirements are ongoing.

Costs to the Board of Pharmacy would come from the pharmacy fee fund beginning in FY2021. Since revenue is not anticipated, the Board would have to increase fees to offset these costs. As a result, costs to the agency, including petitions, court actions, and attorney fees would be borne by the Board's licensees and registrants through their application and renewal fees.

Depending on the potential changes to the existing regulatory framework, agency forms, FAQs, and published information would need updates (including drafts, reviews, publication, and distribution) and staff would need to be re-trained based on updated requirements. Many of these Board resources are developed through our software vendor directly in our electronic and web-based licensing system with internal and external portals. These costs are difficult to estimate because the effects are yet unknown.

In addition, the Board would incur costs associated with publication of regulations, notices of hearing, and adoption in the Kansas Register, published by the Kansas Secretary of State, which range from $500-$1,500 per publication depending on the length of the regulation(s). Since regulations are also required to be reviewed, publicly heard, and adopted by the Board, including regulations for repeal, additional meetings and per diem reimbursements may be necessary to accommodate review of such a large volume of regulations in such a short time period. Additional Board meetings cost between $500 - $5,000 per meeting depending on the location and duration.

The Board finds these costs very difficult to estimate and anticipates that there will be unforeseen expenses and resource requirements.

Concerns with Method

Ultimately, the Board understands and supports the need for transparency, predictability, and fairness in laws and regulations. The broad-sweeping language of SB 10 goes beyond those objectives and effectively prevents the Board from carrying out its responsibility to protect the public safety, if for no other reason than it will be bogged down in constant litigation. The Board joins other agencies in supporting efforts to achieve more focused, efficient, practical, and updated professional regulations, and has begun voluntarily taking steps toward that goal over the past few years. It is difficult to understand why this bill attempts to mold all regulatory agencies with template language when the legislature has already crafted such unique statutory schemes for each regulatory agency and specifically outlined – even mandated in some cases – each agency's specific authority to adopt administrative regulations. If statutory or regulatory revisions are needed, let's work together to address the issues with specificity, where they are needed, and in a more efficient and streamlined process. The Board of Pharmacy welcomes that opportunity.
Respectfully submitted.