

STATE OF KANSAS



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Testimony concerning SB 421
Senate Committee on Federal and State Affairs
March 7, 2018

Chairman Estes and Members of the Committee:

The Kansas State Board of Pharmacy respectfully submits this testimony in opposition to SB 421. The Board of Pharmacy licenses a variety of facilities and individuals in relation to the practice of pharmacy, with the mission of ensuring that all persons and entities conducting business relating to the practice of pharmacy in this state are properly licensed and registered in order to protect the public's health, safety, and welfare. The proposed amendments to K.S.A. 74-120 would affect applicants for the licenses of pharmacist, pharmacy student/intern, and pharmacy technician, and are of concern to the Board for four key reasons:

1. The potential danger to the health and safety of the public associated with licensing individuals that would currently be denied a license or be issued a restricted license;
2. The brief timeline for accomplishing revisions to existing statutes and regulations and making preliminary determinations regarding disqualification from licensure;
3. The cost to the Board of Pharmacy of handling additional complaints, investigations, and disciplinary actions; and
4. The risks in applying a one-size-fits-all regulatory structure to distinct professional and occupational licenses.

The Board of Pharmacy aims to protect the public by licensing individuals in accordance with the highest standards of ethics, accountability, efficiency, and openness. In reviewing an applicant's offense or disciplinary history, the Board of Pharmacy does not rely on subjective opinions or arbitrary factors, but instead looks to the Pharmacy Practice Act and Kansas precedent to objectively and consistently review offense and disciplinary history. K.S.A. 65-1627 sets forth the grounds for denial of a pharmacist, pharmacy student/intern, and pharmacy technician license:

- conviction of a felony without demonstration of sufficient rehabilitation;
- unprofessional conduct or professional incompetency as defined by K.S.A. 65-1626(sss);
- an addiction to liquor or a drug habit to such a degree as to render the licensee unfit to practice the profession of pharmacy;
- a violation of the federal or state food, drug, and cosmetic act; the Kansas uniform controlled substances act; or any rule and regulation adopted under any such act;
- having a Board of Pharmacy license revoked, suspended, limited, censured, or disciplined in another state; and
- self-administering any controlled substance without a practitioner's prescription order or a mid-level practitioner's prescription order.

Furthermore, the Kansas Court of Appeals set forth a series of standards in *Vakas v. Kansas Board of Healing Arts* that the Board uses as a guide in reviewing an applicant's offense history. This factor-test

evaluates the applicant's: (1) present moral fitness; (2) demonstrated consciousness of the wrongful conduct; (3) rehabilitation; (4) nature and seriousness of the original misconduct; (5) conduct subsequent to discipline; (6) time elapsed; (7) character, maturity, and experience at the time of the original misconduct; and (8) present competence.

The Board of Pharmacy takes their licensing responsibility very seriously and gives applicants ample opportunity and leeway to provide statements, documents, and other evidence of their rehabilitation to support their application. In many cases, the Board of Pharmacy refers individuals to the impaired provider program to receive assistance or tables an application to allow an applicant additional time to demonstrate their rehabilitation. In fact, such actions were taken at the Board's quarterly meeting in November, which buttresses the Board of Pharmacy's strong commitment to transparency in how applications are reviewed, in the degree of consideration and latitude for demonstration of rehabilitation, and the level of public trust and responsibility placed in Kansas' pharmacy licensees.

While many offenses or the time elapsed since conviction may not impact an individual's profession or occupation, pharmacy is generally not one of those professions. The bill mentions only that criminal records directly related to the profession, less than five years old (except person felonies), and convictions may be considered. The Board of Pharmacy is concerned that "related" may be too narrowly construed. All drug or alcohol-related offenses may be precursors for a habit – a serious concern in the pharmaceutical industry. Theft and fraud offenses are concerning because of the access to drugs, provider information (i.e., DEA number, prescription pad templates, etc.), patient health information, insurance numbers and accounts, credit cards, and social security numbers. Violent or sexual offenses may be indicators of risk for other licensees or for patients in private, one-on-one healthcare settings where patients are often vulnerable. The assumption that criminal offenses more than five years old do not have a bearing on current qualification for licensure is short-sighted, as many of these offenses demonstrate a pattern and practice of behavior over time, and the bill fails to account for any post-conviction probation, parole, or other court-mandated requirements which may take years to complete. For example, individuals with any felony drug offense are prevented from working in a pharmacy pursuant to 21 C.F.R. 1301.76 and it would be inappropriate to license them regardless of the time since conviction. The bill also doesn't contemplate the severity of certain offenses which result in diversion, without any recorded plea or conviction. The Board of Pharmacy has reviewed and denied at least one application with more than three DUI or other drug-related diversion agreements with no additional criminal history. The bill would not allow the Board to consider these matters, despite the obvious danger this individual could pose in a pharmacy setting.

In short, a one-size-fits-all approach is ill-suited for the unique qualifications and character required of each type of Kansas license. Even within the Board of Pharmacy, the duty of care, responsibility, and access is different for a pharmacist than it is for a pharmacy technician. The Board of Pharmacy does its level best to thoroughly and competently review each applicant's qualification and offense history. However, just in case the Board does not get it right every time, each applicant that is denied a license, revoked, limited, or otherwise disciplined in any way is given an opportunity to be heard and to appeal in accordance with the Kansas Administrative Procedure Act.

This bill also raises questions about whether the Board of Pharmacy would be allowed to request background checks on individuals requesting a preliminary determination for licensure based on their criminal history, which is specifically authorized by statute only for applicants and licensees. The Board

currently conducts background checks on ALL applicants. In an ideal world, all individuals with criminal or disciplinary history would honestly self-report such information on their application or in a petition for a licensure determination. However, that is not the reality. Applicants often misrepresent their past offenses, “forget” to report certain offenses, or fail to report them altogether. Without the background check, the Board of Pharmacy would be unable to properly screen individuals which could easily provide an inaccurate preliminary determination based on an applicant’s false statement or misrepresentation. This lack of transparency could create significant barriers. If a mechanism for the background check were created for these preliminary determinations, a \$47 fee would also need to be assessed and collected to offset any additional cost to the Board.

The Board of Pharmacy would require a temporary increase in agency expenditures to review and revise statutory and regulatory requirements to comply with the bill. Staff time involved in reviewing, drafting revisions, and pushing changes through the appropriate administrative regulatory or legislative process will be substantial given the brief 120-day timeline. In addition, the need to hold at least two Board meetings for review and statutorily-mandated public comment would contribute to costs, as well as publication of regulations. 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 resources are developed through the Board of Pharmacy’s software vendor directly in our electronic and web-based licensing system with internal and external portals.

The Board of Pharmacy would also need to hire additional staff to meet the ongoing 30-day requirement for the preliminary determination regarding potential disqualification from licensure based on criminal history. Though the Board works hard to evaluate and license individuals in the shortest time possible, due to the volume and cyclical nature of applications received, a 30-day maximum would be particularly challenging. In excess of an added FTE, part-time seasonal staff may be necessary. In many cases, applications that note criminal history require significant follow-up, correspondence, in-depth analysis, collection of additional documents, or even an investigation. This process takes time and requires review by senior staff and a Board member. Unfortunately, the bill makes no exception to the 30-day time limit, even for incomplete requests or lengthy criminal histories.

If the Board of Pharmacy considers this issue purely from a financial and resource perspective, additional concerns are notable. The Board already receives a high volume of complaints and referrals for investigations related to alleged offenses. If the bill is implemented and many of these individuals who would otherwise be denied a license or limited in some way are allowed into the profession, the number of complaints and referrals is certain to increase. Responding to such increases would result in additional expenditures related to investigation and discipline related to impaired licensees, violations of the pharmacy practice act, drug theft/loss/diversion, and new criminal charges, which would detract from routine compliance inspections of pharmacies and other licensed facilities, which are necessary for the protection of the public.

The Board currently operates with the minimum staff required to timely and accurately complete our statutory duties, so there is no cushion to absorb this additional work. Necessary work stations, equipment, and system/Internet access would also be required. The Board is also at maximum capacity for our current office space – doubling staff in several offices – which would present a need for additional square footage and amendment to our current lease.

An increased need for staff and resources would result in a major financial shortage for the agency, which would result in the need for additional expenditure authority in the minimum amount of \$145,000 and a need for additional revenue. Therefore, a fee increase would be assessed on the remaining licensees, which include non-resident pharmacies, manufacturers, distributors, labs, retail dealers, and those individual licensees who do not have criminal history. In effect, the bill would burden certain licensees with the cost of other applicants. Since this bill does not contemplate the opportunity to charge a fee for the preliminary determination or even the opportunity to charge a fee to conduct a KBI/FBI background check, and these fees/costs would not fall into traditional licensure application fee categories, no revenue is anticipated to offset expenditures. Furthermore, statutory change of the Pharmacy Practice Act would be required to charge any fee to generate revenue from these petitions for preliminary determination. In order to increase revenues to offset increases in expenditures, the Board would be required to adjust regulations to increase other licensure fee categories or adjust statutes if fees are at statutory caps.

Regardless of the costs to the Board of Pharmacy, imagine the costs to the State and its citizens from a single bad actor admitted to the profession. Though there is no protection that can prevent all errors or malicious acts from occurring, this bill opens the professional door to countless individuals with heightened risk factors without the proper checks and balances. It is imperative that an applicant's record be properly screened and evaluated to protect the public. Certainly there is a monetary risk but, moreover, as in most areas of healthcare, people's lives are literally at stake. Diversion of drugs, malicious or accidental misfills, and other errors put Kansans' lives and wellbeing at risk. Does every individual with a criminal history pose a threat to the public? Perhaps not. Are there additional pharmacy protections in place? Certainly. That said, in a profession with significant access to drugs and a high duty of care to patients and their families, it is our responsibility to take the appropriate precautions to license qualified individuals that do not pose a significant danger to the public. Quite simply, this bill limits the Board's ability to do that.

Respectfully submitted.