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Sam Brownback, Governor

Testimony concerning HB 2055
House Committee on Health and Human Services
Presented by Alexandra Blasi, Executive Secretary
On behalf of
The Kansas State Board of Pharmacy
January 19, 2017

Chairman Hawkins 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.

HB 2055 and Agency Overview

JANUARY 19, 2017

ALEXANDRA BLASI, JD, MBA
EXECUTIVE SECRETARY

Agency Mission

Protect the Public

The mission of the Kansas Board of Pharmacy is to ensure that all persons and entities conducting business relating to the practice of pharmacy in this state, are properly licensed and registered. This will protect the public's health, safety and welfare as well as promote the education and understanding of pharmacy related practices.

Agency Mission

- Assurance of statutory compliance regarding compounding and dispensing of prescription drugs and maintenance of professional practice standards
- Assurance of statutory compliance regarding manufacture, distribution, and sale of prescription and non-prescription drugs and devices
- Protection of the public against the unprofessional, improper, unauthorized, and unqualified practice of pharmacy
- Assurance of the competency of licensed pharmacists by requiring passage of examinations and continuing education thereafter
- Prevention of drug diversion and drug abuse
- Education on pharmacy and prescribing trends

Protection – ensure the practice of pharmacy protects the health and welfare of Kansas citizens

- License competent and qualified individuals
  - Pharmacist and Intern/Student
  - Technician
- Facility Registration
  - Pharmacy, Retail Dealer, Manufacturer, Distributor, Lab, etc.
  - Pre-opening Inspections

Compliance – facilitate compliance with Kansas statutes, rules, and regulations regarding dispensing prescription items, and proper manufacturing, distribution, and sale of prescription and non-prescription drugs by entities doing business in Kansas

- Regulate the profession
- Inspect registered facilities (annually)
- Discipline for violations of Kansas law
- Refer matters to DEA, KBI, FDA and other regulatory agencies
- Audit CE records
- Monitor reporting to K-TRACS and NPLEx

Maintenance and Education – maintain professional pharmacy practice standards that promote clinical and best practice standards

- Pharmacist and Technician continuing education
- K-TRACS (Prescription Monitoring Program)
- Methamphetamin Prescursor Tracking System (NPLEx)
- Unused Medication Donation Program
- Medication Disposal Program
- Recommendations for Controlled Substance Act

Members

- John Worden, PharmD, Chair
- Michael Lonergan, RPh, Vice
- Chad Ullom, RPh
- Jim Garrelts, PharmD
- Robert Haneke, PharmD
- David Schoech, RPh
- Cheri Pugh, Public Member

Licensing and Registration

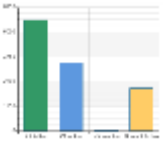
Statistics for Licensing and Registration

		FY08	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18*	FY19*
Individuals													
	Intern/Student	803	803	1,133	1,149	1,199	1,199	1,171	1,165	1,158	1,134	1,150	1,150
	Pharmacists	3,980	4,362	4,467	4,727	4,842	4,842	5,228	5,197	5,364	5,742	5,875	6,000
	Technicians	5,415	7,434	6,245	6,554	6,700	6,700	7,242	7,377	7,600	8,049	8,290	8,500
Facilities													
	Ambulance	141	156	126	148	150	150	174	161	173	176	175	175
	Analytical Lab	31	30	26	30	28	28	30	26	29	30	29	29
	County Health, Family Planning	89	89	106	117	110	110	113	103	105	101	98	98
	Distributor	802	1,504	875	1,021	976	976	1,074	1,043	1,100	1,151	1,125	1,125
	Durable Medical Equipment		325	434	434	435	435	475	421	438	441	427	427
	Institutional Drug Room	51	51	54	59	54	54	80	55	56	52	52	52
	Manufacturer	13	19	17	18	16	16	13	13	15	16	16	16
	Non-resident pharmacy	424	424	491	591	584	584	842	839	960	960	935	935
	NPD Distributor	74	74	78	88	73	73	106	107	110	101	97	97
	Pharmacy	836	836	864	891	893	893	907	901	924	920	920	920
	Research&Teaching	71	88	63	93	80	80	105	90	99	112	99	99
	Retail Dealer	1,904	1,997	1,655	1,577	1,529	1,529	1,514	1,528	1,515	1,542	1,519	1,519
	Sample Distributor	22	45	34	47	46	46	52	44	41	43	43	43
		*estimated registrations											

Statistics for Pharmacist Licensees

Age of Active Pharmacists

Number of Active Pharmacists



eLicensing

- Executed Contract with eSoftware Solutions in December 2015 to provide full-service, custom licensing software
- "Go Live" was May 24, 2016
- Web-enabled system
  - Real-time inspection reports
  - Electronic applications, renewals, updates, license verification, and license printing
  - Integration with NABP CPE Monitor and K-TRACS
  - Internal case management system
  - Internal document management/storage system
  - Staff activity audit feature
  - Online portal activity reports
  - Real-time dashboard

eSoftware Solutions

Staff Education and Training

- NABP
- Pharmacy Law Class
- Critical Point Compounding
- MALTAGON
- CLEAR
- Customer Service
- Leadership and Supervisory Skills
- KPhA Board Meetings and Annual Meeting
- NASCSA
- Appriss
- TALKOM

NASCSA

NABP

KU

Council on Licensure, Enforcement & Regulation
Promoting Regulatory Excellence

KPhA

Compliance with Federal Law

- Drug Supply Chain Security Act (2014)
  - part of the Drug Quality and Security Act
    - part of the Federal Food, Drug, and Cosmetic Act
- Regulate and monitor the manufacturing of compounded drugs
- Electronic, interoperable system to identify and trace prescription drugs from manufacturer, through distribution, to the end user
- Triggers certain requirements over a 10-year period
- Include definitions and requirements for third-party logistics providers, outsourcing facilities, and repackagers; adjust requirements for wholesale distributors, manufacturers.

- Creates new license/registration types; currently all under 1 or 2 types, now shifting to identify each individual
  - Need to be consistent federally and with other states to match
- Defines the facilities or carriers
- Requires those facilities/carries maintain compliance with DSCSA
- Matching graphic

Regulatory Authority

- Compounding - combining drug components into a compounded preparation
  - Sterile vs. Nonsterile
  - Ventilation
  - Sterile technique
  - Testing/Monitoring
- USP Standards

- Resident and Non-Resident Pharmacies
- Automated Dispensing – robotic or mechanical system for prescription drugs
  - Storage
  - Packaging
  - Labeling
  - Dispensing
  - Distribution
- Adopted new regulations in 2016
- Identify, track, and inspect for compliance

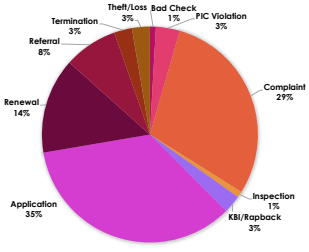
Pharmacy Techs

- 36 states register techs
- 38 states require training programs (OTJ or formal)
- 22 states require certification
- 22 require CE, 16 require 20 hrs/2 yrs

Miscellaneous

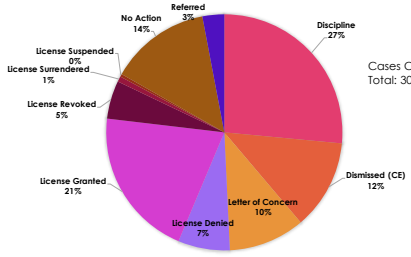
- Regular and timely updates to the Board for Pharmacists, Interns, & Techs
  - Employment
  - Contact Information
- Nametags in the Pharmacy setting
- Disciplinary Authority

Compliance – 2016 Disciplinary Statistics



Cases Opened in 2016
Total: 229

Compliance – 2016 Disciplinary Statistics



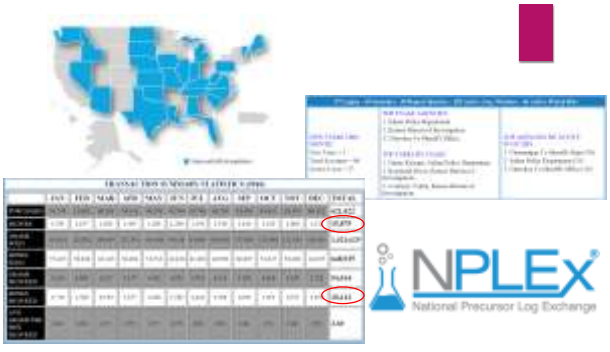
Cases Closed in 2016
Total: 301

Compliance – 2016 Disciplinary Statistics

- Average time open for cases closed in 2016 – 282 days
  - (some cases multiple years old)
- Average time open for cases open and closed in 2016 – 86 days

What is NPLEx?

- The National Precursor Log Exchange (NPLEx) is a real-time electronic logging system used by pharmacies and law enforcement to track sales of over-the-counter (OTC) cold and allergy medications containing precursors to the illegal drug, methamphetamine, such as Pseudophedrine.
- There are approximately 528 pharmacies that are actively using NPLEx in Kansas. Those pharmacies that do not sell ephedrine or pseudoephedrine items over the counter are exempt from reporting.



NPLEx
National Precursor Log Exchange

K-TRACS

KANSAS PRESCRIPTION MONITORING PROGRAM

What is K-TRACS

- The Prescription Monitoring Program (PMP) in Kansas.
  - Monitors Schedule II-IV controlled substance prescriptions, as well as drugs of concern dispensed within the state as reported by pharmacies and other dispensers
- Program administered by the Board of Pharmacy
- K-TRACS is a web-accessible database, available 24 hours, that provides tools to help address one of the largest threats to patient safety in the state of Kansas: the misuse, abuse, and diversion of controlled pharmaceutical substances

The Need for K-TRACS

- Education and Information. PMPs provide useful feedback to prescribers on their own prescribing trends as well as their patients' controlled substance histories. PMPs also provide useful information to prescribers when they suspect that a patient may be non-compliant in their controlled substance use.
- Public Health Initiatives. The public health community can use information from the PMP to monitor trends and address controlled substance prescribing or utilization problems.
- Drug Abuse and Diversion Prevention. Prescribers, dispensers, and consumers will be deterred from participating in illegal drug diversion schemes if they know a PMP is in place.
- Early Intervention. Identify patients for early assessment and treatment of potential controlled substance utilization problems.

Reporting and Data Collection

Who reports to PMP?

- Dispensers – practitioner or pharmacist who delivers to a Kansas end-user
- includes non-resident pharmacies dispensing to Kansas residents

Who doesn't report?

- Hospital pharmacy – distributes for the purpose of inpatient care
- Medical care facility – administers direct to patient
- Wholesale distributor
- Veterinarian
- Exempt Practitioner

Reporting and Data Collection

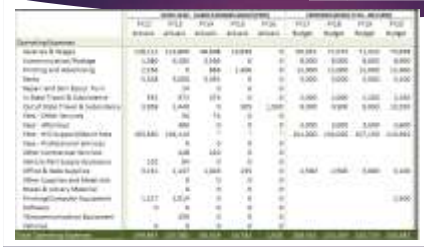
- Dispensers report to K-TRACS
  - Daily, including zero reporting
  - Electronically
  - Each prescription dispensed for Schedule II-IV controlled substances and "drugs of concern"
- Non-reportable
  - Emergency dispensing for a 48-hour supply or less does not have to be reported
  - Dispensing to inpatients
- Waivers available for paper submissions or in case of a force majeure event
- Reporting extensions available for electronic malfunction or circumstances beyond control

PMP in Other States

- 49 states currently have operating PMPs for at least one class of controlled substance
  - Missouri does not have a PMP program
  - Most states mandate reporting
  - Kansas does not require prescriber/dispenser use
    - 26 states require all prescribers and/or dispensers to register with their PMP
    - 30 states require prescribers and/or dispensers to access the PMP in certain circumstances
    - 35 total states require either registration or access

PMP Funding

	Number of Licensees	Funding FY18+FY19	Per Licensee
BOHA	12,128	$ 221,939.96	
Nursing	4,062	$ 74,333.78	
Dental	1,993	$ 36,471.50	
Pharmacy	5,633	$ 103,082.76	
	23,816	$ 435,828.00	$ 18.30



K-TRACS Quarterly Report

Number of Patient Queries

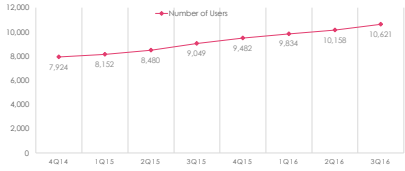
General PMP Update

- KTRACS Patient Queries (September 2016 Snap Shot):
  - Web (In-state) Requests: 1,631 per day (10%)
    - Compared to 1,692 per day in June 2016
  - Web + PMPi Requests: 16,305 per day (includes Via Christi/Gateway)
    - Compared to 16,917 per day in June 2016

2016

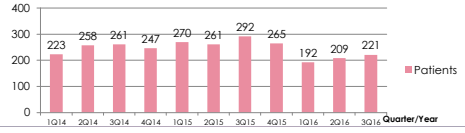
Number of Patient Queries

Total K-TRACS Users



PMP Threshold Patients

	4Q'13	1Q'14	2Q'14	3Q'14	4Q'14	1Q'15	2Q'15	3Q'15	4Q'15	1Q'16	2Q'16	3'Q16
Threshold Patients	276	223	258	261	247	270	261	292	265	192	209	221
Total Letters Sent	3,580	2,961	3,485	3,365	3,289	3,384	1,271	1,161	1,148	861	905	872
Total E-mails Sent							2,104	2,482	2,487	1,665	1,829	1,967
Total Notifications	3,580	2,961	3,485	3,365	3,289	3,384	3,375	3,643	3,635	2,526	2,739	2,839



PMP Threshold Patients

- 3Q16 Threshold report generated 221 individuals meeting 5/5/90.
- Top patient meeting threshold (5/5/90) visiting most **PHYSICIANS**:
  - 25 Physicians/ 5 Pharmacies/ 25 Prescriptions (Q3 2016)
  - 16 Physicians/ 7 Pharmacies/ 29 Prescriptions (Q2 2016)
  - 15 Physicians/ 5 Pharmacies/ 17 Prescriptions (Q1 2016)
  - 19 Physicians/ 9 Pharmacies/ 20 Prescriptions (Q4 2015)
  - 17 Physicians/ 11 Pharmacies/ 32 Prescriptions (Q3 2015)
- Top patient meeting threshold (5/5/90)visiting most **PHARMACIES**:
  - 15 Physicians/ 10 Pharmacies/22Prescriptions (Q3 2016)
  - 13 Physicians/ 9 Pharmacies/15 Prescriptions (Q2 2016)
  - 13 Physicians/ 13 Pharmacies/15 Prescriptions (Q1 2016)
  - 14 Physicians/ 13 Pharmacies/14 Prescriptions (Q4 2015)
  - 15 Physicians/ 12 Pharmacies/19 Prescriptions (Q3 2015)

Questions?

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