Disclaimers

• I speak for myself and do not intend to represent the thoughts or opinions of any others. Any opinions expressed in this presentation or on the following slide are solely those of the presenter and not those of the State of Kansas, its elected officials, or employees.
• The information provided herein is general information and should not be construed as legal advice of the Kansas State Board of Pharmacy, the State of Kansas, or any official, agency or employee thereof. Furthermore, the information on these slides may not necessarily reflect the most current legal developments.

Learning Objectives

• Identify Board of Pharmacy duties and responsibilities
• Develop and implement appropriate procedures and practices to respond to recent changes in Kansas law and regulation
• Anticipate coming changes in the Kansas Pharmacy Practice Act, Controlled Substance Act, and Prescription Monitoring Program Act
• Utilize K-TRACS as a resource and tool

Agency Mission

• 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.
  • 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

Functions

Licensing and Registration

• License competent and qualified individuals
• Pharmacist and Intern/Student
• Technician
• Facility Registration
• pharmacy, Retail Dealer, Manufacturer, Child Safety, Ltd., etc.

Compliance

• K-TRACS (Prescription Monitoring Program)
• EDI
• Medicare
• Medicaid
• K-TRACS and NPLEx

Administrative

• Day to day activities
• Budget
• Personnel
• Administrative
### Statistics and Active Licensees

| Year | NC | Non-Manufacturer | Manufacturer | 503 Distributor | 504 Distributor | Family Planning | NPD Distributor | Research & Teaching | Sample Distributor | Pharmacists | Pharamacy | Retail Dealer | Technicians | Admin Asst PT | Admin Specialist | Legal Asst PT | Licensed Pharmacy Inspector | Pharmacy Competency Inspector | Licensed Pharmacy Inspector |
|------|----|------------------|--------------|----------------|----------------|----------------|----------------|----------------|-------------------|-------------------|-------------|-----------|-------------|------------|---------------|----------------|-------------|-----------------------------|-----------------------------|-----------------------------|
| 2014 | 89 | 262              | 455          | 421            | 455            | 96             | 105            | 38              | 51                | 51                | 98          | 18        | 325         | 1,133       | 110           | 105            | 31          | 67              | 110                          |
| 2015 | 150 | 315              | 545          | 421            | 455            | 96             | 105            | 38              | 51                | 51                | 98          | 18        | 325         | 1,133       | 110           | 105            | 31          | 67              | 110                          |
| 2016 | 174 | 89               | 315          | 421            | 455            | 96             | 105            | 38              | 51                | 51                | 98          | 18        | 325         | 1,133       | 110           | 105            | 31          | 67              | 110                          |

### Complaints and Discipline

- 2014: 325 cases
  - 315 closed
  - 154 disciplined
- 2015: 262 cases
  - 211 closed
  - 106 disciplined
- 2016: 139 cases
  - 90 complaints
  - 47 criminal history inquiries
  - 66 already closed
  - 84 disciplined

### Kansas Controlled Substances Act Updates

- **Schedule I additions**
  - Acetyl fentanyl (1H-indole-3-carboxamide, 2,5-dimethoxy-3,4-methylenedioxy-N-benzyl fentanyl), and its optical, positional, and geometric isomers,
  - (1H-indole-3-carboxamide, 2,5-dimethoxy-3,4-methylenedioxy-N-benzyl fentanyl), and its optical, positional, and geometric isomers,
  - (1H-indole-3-carboxamide, 2,5-dimethoxy-3,4-methylenedioxy-N-benzyl fentanyl), and its optical, positional, and geometric isomers,

- **Schedule I amendment**
  - (13) Indazole-3-carboxamides
    - Any compound containing a 1H-indazole-3-carboxamide structure with substitution of the nitrogen of the carboxamide by a methyl, methoxy, hydroxy, or 1-amino-1-methoxycarbonyl-3-yl, or 1-methyl-1-carboxamido-2,4-dimethoxybutyl group, and addition at the 1 position of the pyridine ring by a benzyl, phenethyl, cycloalkylmethyl, or 2-furanyl substituting group, whether or not further substituted on the indazole ring to any extent and whether or not further substituted on the pyridine, pyrazine, pyrimidine, pyridazine, 1,4-dimethyl-1,2,3-triazol-4-yl, or benzyl groups to any extent.
Sen Sub HB2018 - Kansas Controlled Substances Act Updates

- Amending K.S.A. 65-4105(d) and K.S.A. 65-4127(e) and (d) to reflect Psilocin and Psilocyn as alternate spellings of the same substance, which is consistent with DEA.
- Schedule III amendment
  - Dronabinol contained in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved product
- Schedule IV addition
  - Eluxadoline: (S)-(2S,3S)-1-(2-amino-3-[4-aminocarbonyl]-2,6-dimethylphenyl)-3-{4-[2-(2-amino-3-[4-aminocarbonyl]-2,6-dimethylphenyl)]-2-methoxybenzoic acid) (including its optical isomers) and its salts, isomers, and salts of isomers

HB 2614 Pharmacy Act Amendments

- 1/25/16 - Introduced to House Health and Human Services Committee by Rep. Don Hill
- 2/4/16 - Bill number assigned and sent to HHS
- 2/16/16 - Hearing with no opponents
- 2/19/16 - HHS recommended amended bill be passed by House

2017 Pharmacy Act Amendments

- State alignment with federal requirements: DSCSA and DQSA
- Updated definitions
- Pharmacy Technician examination
- Disciplinary authority expansion
- Licensee and Registrant reporting requirements

Emergency Scheduling

- KSA 65-4102
  - KBOP shall initiate emergency scheduling of the controlled substance analog upon receipt of notice
  - Expires one year after adoption
  - Imminent hazard to the public safety
  - Analog of controlled substance scheduled in Kansas

Emergency Scheduling

- 2016 Special Session
  - SB2 adding U47700 to Schedule I of the Controlled Substance Act
  - Introduced into Senate Judiciary on June 23 and assigned bill number
  - No action due to session duration

- 2017
  - Schedule U47700 in Controlled Substances Act
  - Request expansion of authority to emergency scheduling:
    - allow analogs of federally scheduled substances; and/or
    - temporarily schedule any substance with approval from Joint Committee on Administrative Rules and Regs

Regulatory Update

- Collaboration
- CPE
- Collaborative Practice
Collaborative Practice Agreements (CPA) - KAR 68-7-22

- CPA - a signed agreement or protocol voluntarily entered into between one or more pharmacists and one or more physicians that provides for CDTM
- Although a physician shall remain responsible for the care of the patient, each pharmacist shall be responsible for all aspects of the CDTM performed by the pharmacist
- Appropriate to the training and experience of the pharmacist and physician
- Patient being treated by physician who has signed the pharmacist’s current CPA

- CPA must include:
  - Date and signature of each physician and pharmacist
  - General methods, procedures, and decision criteria for pharmacist
  - Procedures pharmacist should follow to document CDTM decisions and communicate to physician
  - Procedures for urgent situations involving patient health and alternate care provider
- Not for:
  - Immunizations
  - Current hospital or medical care facility procedures
  - Medication therapy management (MTM)

- Update at least once every two years
- Provide initial and all updated copies to Board within five business days of execution

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CDTM Committee

Automation

- 68-7-10 Long term care facilities
- 68-9-2 Pharmacies
- 68-9-3 Other
- Updates and additional regulation of automated drug delivery systems in long-term care facilities, pharmacies, medical facilities, institutional drug rooms, and certain nursing facilities
- A pilot project has been successful in Kansas and regulations expand programs with proper inspector and pharmacist oversight
- New language creates specific requirements for human intervention/oversight, maintenance, accountability and access, including duties, responsibilities and standards for the PIC and criteria for drugs which may be stored in an automated system

Continuing Education

- 68-1-1b Pharmacists 30 hrs per renewal period
- 68-5-18 Pharmacy Technicians 20 hrs per renewal period

- Rules are the same for both groups:
  - CE course will have to be submitted for approval at least 10 days in advance
  - CE course provider must provide certificate of completion to individual
  - Individual must submit CE certificate to the Board within 90 days
  - ACPE courses are automatically approved and reported to Board (exempt)
  - Cannot renew on active status until all CPE is completed
CPE - When does this start for Pharmacists?

- **2017 renewal group**
  - Required to have one of the following before completing online renewal:
    - Certificates submitted to Board office showing 30 hours of CE
    - NABP CPE Monitor showing 30 hours of CE
    - Combination of above with 30 total hours of CE
  - Hours must be earned between July 1, 2015 and June 30, 2017

- **2018 renewal group**
  - Required to have one of the following before completing online renewal:
    - Certificates submitted to Board office showing 30 hours of CE
    - NABP CPE Monitor showing 30 hours of CE
    - Combination of above with 30 total hours of CE
  - Hours must be earned between July 1, 2016 and June 30, 2018

CPE - When does this start for Technicians?

- **2016 renewal group** - No CE required

- **2017 renewal group** - 10 hours required (prorated)
  - Same proof as pharmacists
  - Hours must be earned between July 1, 2016 and June 30, 2017

- **2018 renewal group** - 20 hours required
  - Same proof as pharmacists
  - Hours must be earned between July 1, 2017 and June 30, 2018

  Note: 20 hours required after 2017

CE Audit Statistics

- **2014 - 184 Summary Orders issued**
  - 14 placed on inactive status (indefinite)
  - 8 dismissed for compliance
  - 3 requests for hearing
  - 85 effective orders

- **2015 - 104 Summary Orders issued**
  - 5 placed on inactive status (indefinite)
  - 48 dismissed for compliance
  - 1 request for hearing
  - 51 effective orders

Miscellaneous Regs

- **68-11-3 Fees**
  - Pharmacy Technicians
    - Application - $20
    - Renewal - $20
  - Pharmacy Interns (Students)
    - One-time application fee - $20
  - Does not include cost of background check ($40)

- **68-1-1f and 68-1-1g**
  - TOEFL exam scores for foreign graduates
  - Update to match the NABP requirements

Registration and Access

- **Other States**
  - Mandatory Registration - 23 states
  - Mandatory Access - 30 states
  - Both - 4 states

- **Kansas Law**
  - "Any prescriber [...] may obtain any program information relating to a patient under the prescriber's care"
  - "Any dispenser may obtain information..."

- **Proposed**
  - Mandatory registration for all prescribers and dispensers licensed in Kansas
  - MD, DO, DDS, RPM, PharmD, ARNP, DPM, PA, CRNA
Delegates

Other States
- 1 - Illinois
- 2 - Tennessee
- 3 - South Carolina, Colorado
- 4 - Idaho
- Unlimited - FL, GA, IN, VA - trend in 2016

Kansas Law
- "Any prescriber or health care practitioner authorized by a prescriber may obtain any program information relating to a patient under the prescriber’s care..."
- No legal limitation
- No definition

Proposed
- Define Delegates
- Pharm Tech, PT, PTA, OT, OTA, RA, LRT, RN, LPH, LAVT, CMA, EMR, EMT, Paramed
- Access K-TRACS on behalf of prescriber or dispenser
- Must be licensed or registered in KS
- Unlimited

Other States
- Massachusetts - Department shall work with licensing agencies annually to determine practitioner’s standing

Kansas Law
- PMP access given to "persons authorized to prescribe or dispense scheduled substances and drugs of concern, for the purpose of providing medical or pharmaceutical care for their patients"
- No notification requirement

Proposed
- Notify Board of Pharmacy within 30 days of any change in prescribing/dispensing authority
- Revoked
- Suspended/Probation
- Retired
- Expired/Canceled
- Inactive

Other States
- 2 - 7 years
- Indefinite
- Retain only de-identified or aggregate data

Kansas Law
- 5 years
- Indefinite for de-identified data for research or educational purposes

Proposed

Other States
- 2 - 7 years
- Indefinite
- Retain only de-identified or aggregate data

Kansas Law
- 5 years
- Indefinite for de-identified data for research or educational purposes

Proposed

PMP Advisory Committee

Other States
- KSA 65-1689
- Three-year terms
- Chair elected by Advisory Committee to serve one-year term
- Board can appoint (at its discretion) other persons authorized to prescribe or dispense scheduled substances and drugs of concern, recognized experts and representatives from law enforcement
- Upon the expiration of the term of office or in case of any vacancy, a successor shall be appointed by the board in accordance with the statute (fits qualifications of the chart)

Kansas Law

Proposed

Other States
- 2 - 7 years
- Indefinite
- Retain only de-identified or aggregate data

Kansas Law
- 5 years
- Indefinite for de-identified data for research or educational purposes

Proposed

Funding

Other States
- Fees
- Grants
- State Appropriation

Kansas Law
- "shall not impose any charge for the establishment or maintenance of the PMP on a registered wholesale distributor, pharmacist, dispenser or other person authorized to prescribe or dispense scheduled substances and drugs of concern"
- "shall not charge any fees for the transmission of data to the database"

Proposed
- Remove "shall not impose fee" language
- Allow Board of Pharmacy to establish a fee by rule and regulation for all prescribers and dispensers licensed in Kansas, not to exceed statutory cap
- Separate PMP Fee Fund
When to Report to the Clearinghouse

- Board Recommendation: Point of Sale

- Other: Prescription Fill
  - Must remove before reported to the Clearinghouse if prescription is not picked up by the patient by close of business
  - If reported to K-TRACS, cannot be removed if patient never picks up prescription

Our Email Addresses Changed

@pharmacy.ks.gov
@ks.gov

Meetings

- Board Meetings held quarterly under the Kansas Open Meetings Act (KOMA)

- Notice
  - All notices posted on Board website
  - Agenda posted one week prior to meeting
  - Minutes posted 7-10 days after approval by the Board

- Committees:
  - PMP Advisory Committee
  - Collaborative Drug Therapy Management Committee
  - CE Review Committee
Old Forms Out! New Forms In!

- [link](http://pharmacy.ks.gov/resources-consumer-info/forms)
- Brand new, updated, electronically fillable forms for your convenience... all in one central location! We even have a new Quick PIC Change Form. Each form has a "revised" date in the bottom right-hand corner. Make sure you're using the most up-to-date version!
- Beginning August 1, 2016, the Board will only accept current versions of Board of Pharmacy forms. Old forms will be returned (with payment) directly to the sender without processing.

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 and updates
  - Integration with NABP CPE monitor
  - Internal case management system

KsPRN - Impaired Pharmacists

- Administered by KPhA
- Mission: To assist any pharmacist or pharmacy intern whose health and/or professional effectiveness has been or is likely to be impaired by the disease of chemical dependency or other physical and/or mental health disorder.
- Most are referred by Board of Pharmacy

Special Requests and Reminders

- Bankruptcy Filings - please don’t send unless related to ownership change
- All correspondence is processed in the order it is received
- Emails are better than phone calls
- Please respectfully communicate directly with the staff member designated to assist you with your inquiry or issue

Post-Test Questions

1. Under what legal authority does the Board discipline its licensees and registrants?
   - [answer]
2. Is there a grace period for completing my CE?
   - [answer]
3. Does a CPA have to be submitted to the Board office? If so, when?
   - [answer]

Post-Test Questions

4. Do I have to use K-TRACS to look up patients?
   - a. Yes, I have to lookup each patient’s prescription in K-TRACS before dispensing
   - b. Yes, I have to lookup each patient’s controlled substance prescription in K-TRACS before dispensing
   - c. No, I never have to use K-TRACS
   - d. No, but I should use K-TRACS as a useful tool that has no legal liability attached
5. Board meetings are held in accordance with what Kansas law?
   - [answer]