


UPDATES

August 22, 2017
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 Executive Secretary



Disclaimer

- ▶ 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 slides 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.

- ▶ Identify Board of Pharmacy duties and responsibilities
- ▶ Explain recent changes to Board statutes, rules and regulations, and anticipated future changes, and develop and implement appropriate procedures and practices to respond to recent changes in Kansas law and regulation
- ▶ Provide resources for additional enrollment, function, and utilization of K-TRACS, including statewide integration opportunities
- ▶ Describe Board efforts (Pharmacy Tech / Rural Nurse Task Force) to increase participation, collaboration, and engagement across the health care professions in Kansas and eliminate duplication of roles, training, or requirements

LEARNING OBJECTIVES




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.


BOARD MEMBERS


- John Worden, PharmD, Chair
- Michael Lonergan, RPh, Vice
- Chad Ullom, RPh
- Robert Haneke, PharmD
- Jonathan Brunswig, PharmD
- William Walden, RPh
- Cheri Pugh, Public Member

Protection	ensure the practice of pharmacy protects the health and welfare of Kansas citizens
<ul style="list-style-type: none"> • License competent and qualified individuals <ul style="list-style-type: none"> • Pharmacist and Intern/Student • Technician • Facility Registration <ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • Pharmacist and Technician continuing education • K-TRACS (Prescription Drug Monitoring Program) • Methamphetamine Precursor Tracking System (NPLEX) • Unused Medication Donation Program • Medication Disposal Program • Recommendations for Controlled Substance Act 	

ELICENSING FEATURES

- ▶ Web-enabled system available 24/7
- ▶ Real-time inspection reports
- ▶ Licensee Portal
 - ▶ Original applications
 - ▶ Renewals
 - ▶ Electronic payment
 - ▶ Automatic renewal
 - ▶ Print your license/permit anytime, anywhere
 - ▶ Coming soon – licensee updates
- ▶ Integration with NABP CPE Monitor and K-TRACS
- ▶ License verification portal
- ▶ Internal case management system





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 Topeka, Kansas 66612-2244
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SAMPLE

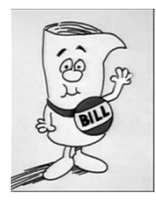
INSPECTION REPORT FOR: 2-09626	
STORMONT-VALE HEALTHCARE INC 1500 SW 107TH ST TOPEKA, KS 66604	Original Date: 5/3/2001 On Probation: No Discipline on File: No
INSPECTION REPORT	Inspection Date: 5/22/2017 Inspector: Jim Kunderknecht

This inspection report is not intended as an exhaustive listing of all pharmacy conditions. There may be deficiencies, non-compliance, or violation(s) of Kansas laws or regulations not detected, observed, or noted in this report.

General Information	
Licensee displayed State & DEA # (KA 65-1645a)	Y
DEA Number: 3-P-0302070	
PCI Name: also listed	
R.Ph. License posted - KA 65-1641	Y
Pharmacy	
Technician Registrations posted - KA 65-1603g	Y
Technicians	
Name tag - KAS 65-2-15	Y
Records	
Control of Record Keeping - KA 65-1642B(1)(2) & KA 65-20-10a	Y
Policy and Procedures (P&T) approved KAS 65-1-113b	Y
Quarterly checks KAS 65-7-11a	Y
Electronic signature KAS 65-20-11a(5)	Y
Is the facility accredited by a national accreditation organization	Y
File, by whom ACPSP	
MSB compliance	N/A

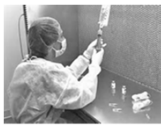
2017 LEGISLATIVE CHANGES

HB 2055, HB 2217, SB 51, HB 2030



HB 2055 Pharmacy Practice Act Amendments

- ▶ 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, registration categories, and requirements for third-party logistics providers, outsourcing facilities, and repackagers; adjusts requirements for wholesale distributors, manufacturers.



- ▶ 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 Technicians – certification
- ▶ Regular and timely updates to the Board for Pharmacists, Interns, & Techs
 - ▶ Employment
 - ▶ Contact Information
- ▶ Nametags in the Pharmacy setting
- ▶ Expansion of Disciplinary Authority
 - ▶ misdemeanors involving mortal turpitude or gross immorality
 - ▶ false or fraudulent attempts to obtain licensure/registration
 - ▶ failure to comply with Board order/directive
 - ▶ violation of any provision of the PDMP



MISCELLANEOUS

▶ Original Bill

- ▶ DSCSA Updates
- ▶ Expansion of Disciplinary Authority
- ▶ Pharmacy Technicians
- ▶ Compounding
- ▶ Automation

▶ Amended to Include

- ▶ HB 2107 – Biosimilars
- ▶ House Sub SB 52 – Nothing contained in the Ks Pharmacy Practice Act shall require an in-person exam or encounter between a person licensed to practice medicine and surgery and the patient prior to a pharmacist filling or refilling any prescription

SEN SUB FOR HB 2055

HOUSE SUB FOR SB 51

▶ CS Update

- ▶ Schedule I
 - ▶ AH-7921 and U-47700
 - ▶ Beta-hydroxythiofentanyl
 - ▶ Butyryl fentanyl, Furanyl fentanyl
 - ▶ O-desmethytramadol
 - ▶ Etizolam
- ▶ Schedule II - Thiafentanil
- ▶ Schedule IV
 - ▶ Cannabidiol, when comprising the sole active ingredient of a drug product approved by the FDA
- ▶ Schedule V - Brivaracetam

▶ Emergency Scheduling Authority

- ▶ Expires July 1 of the following calendar year
- ▶ KBOP shall initiate upon notice or its own finding of:
 - ▶ Imminent hazard to the public safety
 - ▶ Analog of controlled substance scheduled in Kansas

OTHER NEW 2017 LEGISLATION

▶ HB 2217



▶ Emergency Opioid Antagonists

- ▶ Statewide Protocol for Pharmacist Dispensing
- ▶ Access for LE, EMS, school nurses, and scientists
- ▶ Liability Waiver

▶ <http://pharmacy.ks.gov/resources/consumer-info/naloxone>

▶ HB 2030

- ▶ Expanded authority for immunizations by pharmacist or intern
- ▶ Influenza – anyone over age 6
- ▶ All others – anyone over age 12

▶ Update your protocol **first**



REGULATORY CHANGES

- Naloxone
- Licensing and Miscellaneous
- Collaborative Practice
- Compounding

**EMERGENCY OPIOID ANTAGONISTS
KAR 68-7-23**

- ▶ Temporary regulation adopted and effective July 1, 2017
- ▶ Permanent regulation adopted August 17, 2017
- ▶ Pharmacists may dispense emergency opioid antagonists to patients, bystanders, first responder agencies, and school nurses without a prescription in accordance with the Statewide Protocol
- ▶ Protocol
 - ▶ Download, sign, send copy to Board
 - ▶ Outlines decision tree for patient assessment and counseling/training
 - ▶ No counseling waiver permitted
 - ▶ Log dispensing pharmacist or protocol physician as "prescriber"
 - ▶ Maintain records

LICENSING AND MISCELLANEOUS

- ▶ KAR 68-1-3a – increasing required intern hours from 1,500 to 1,740 per NABP resolution
- ▶ KAR 68-2-20 – revisions consistent with language added to HB 2055 permitting fills on prescriptions resulting from telehealth encounters
- ▶ KAR 68-7-12a – new inspection and PIC licensing requirements for non-resident pharmacies
- ▶ KAR 68-7-15 – amending language to allow repackaging for prescribed Proteus sensor
- ▶ KAR 68-7-20 – requiring pharmacy, physician, physician assistant, or mid-level practitioner utilizing shared services to operate a pharmacy that is actively engaged in the practice of pharmacy
- ▶ KAR 68-11-2 – updating fees for new facility permit types (HB 2055)

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 CDIM
- ▶ Although a physician shall remain responsible for the care of the patient, each pharmacist shall be responsible for all aspects of the CDIM 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

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

COLLABORATIVE PRACTICE AGREEMENTS (CPA) – KAR 68-7-22

- ▶ 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 CDIM 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 (CMS)

COMPOUNDING



- ▶ New regulations consistent with USP <795> and <797>
- ▶ Approved by Dept of Admin
- ▶ Awaiting review by AG

- ▶ KAR 68-13-2 – definitions
- ▶ KAR 68-13-3 – nonsterile compounding
- ▶ KAR 68-13-4 – sterile compounding

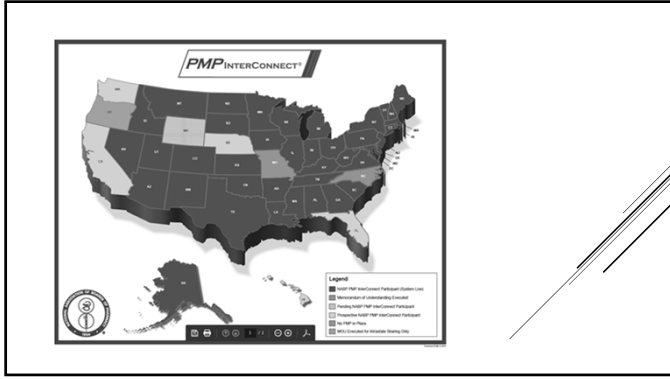


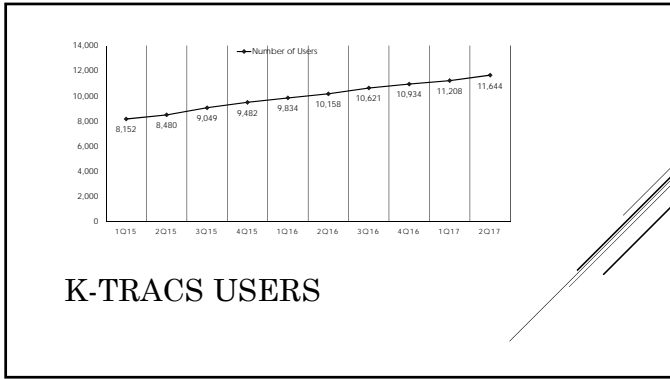
WHAT IS K-TRACS

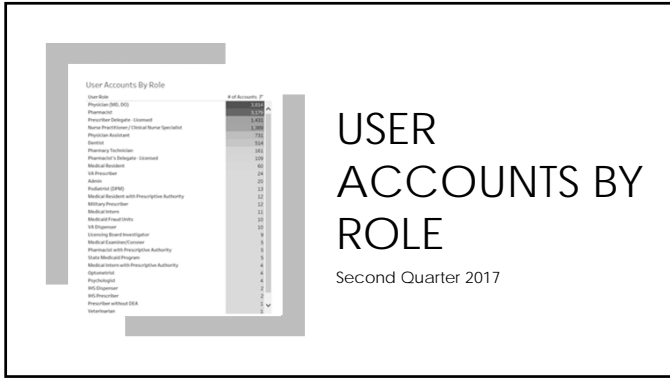
- ▶ The Prescription Drug Monitoring Program (PDMP) in Kansas.
 - ▶ Monitors Schedule II-IV controlled substance prescriptions, as well as drugs of concern dispensed within the state as reported by pharmacies and other dispensers
- ▶ Program administered by the Board of Pharmacy
- ▶ K-TRACS is a web-accessible 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

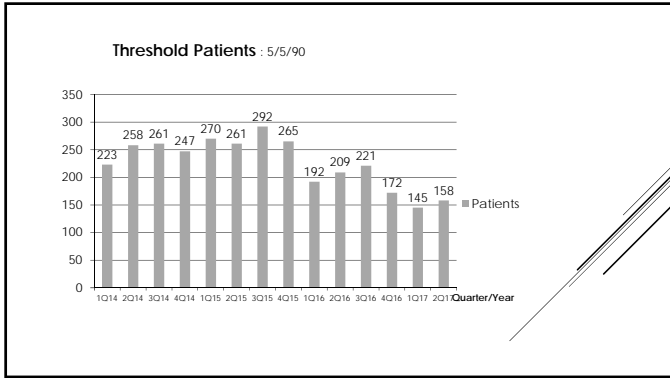
- ▶ KAR 68-21-7 – adding gabapentin to drugs of concern in Kansas
- ▶ Recommendations received from:
 - ▶ Various pharmacy stakeholders
 - ▶ PDMP Advisory Committee
- ▶ Consistent with national trend to track prescriptions as a result of increase in overdose deaths with gabapentin on toxicology screen

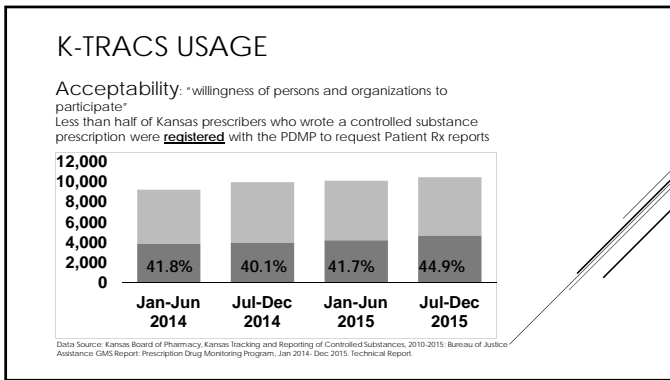
DRUGS OF CONCERN – KAR 68-21-7

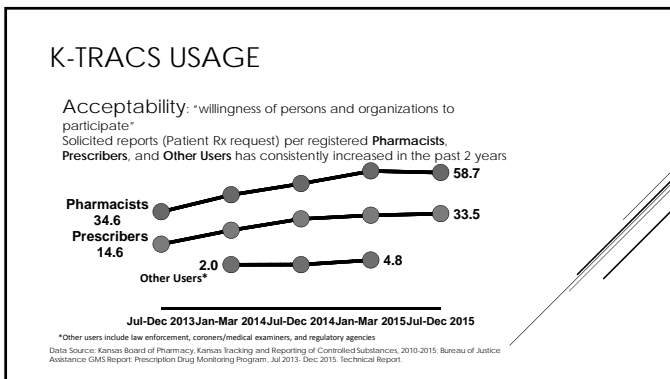


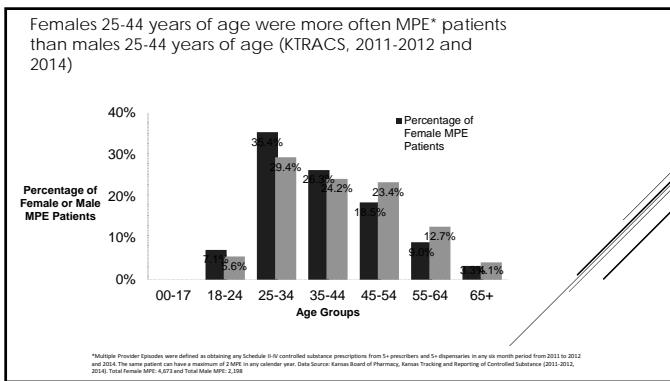


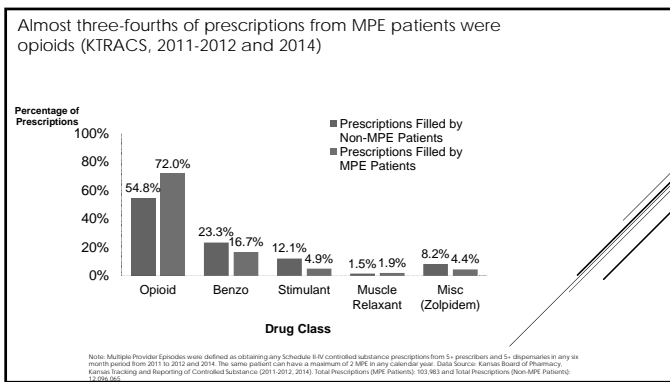


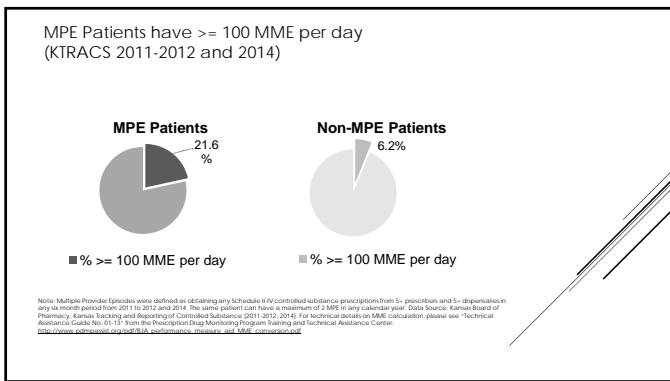


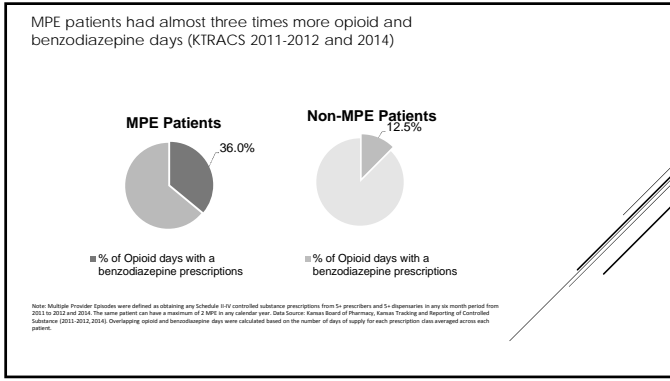












Patient Alert Enhancement

Patient Report Home Search
 Report Period: 08/17/2016 Date Range: 08/10/2015 - 08/10/2016

CAROL TESTPATIENT DOB: 01/01/1900 Gender: female 123 Somewhere St
CAROLINE TESTPATIENT DOB: 01/01/1900 Gender: female 123 Somewhere St

Linked Records

Name	DOB	ID	Gender	Address
CAROL TESTPATIENT	01/01/1900	1	FEMALE	123 Somewhere St

PATIENT ALERT

SUSPECTED PRESCRIBER/PHARMACY SHOPPER

Please note that this patient has received controlled substance prescriptions written by 6 prescribers and had them filled at 4 pharmacies during the past 3 months. This report is created the moment a prescription is dispensed and is generated on the day you log in to the system. It will be updated in real time as the number of prescriber and/or pharmacy shopping increases.

Caution: Report alert is sent, conditional alerting only. Please contact the board if you have any questions or need more information at: kspharmacy@ks.gov

PATIENT'S COUNTS	ALERT THRESHOLDS
Prescribers: 6	Prescribers: 5
Pharmacies: 5	Pharmacies: 3
	Months: 3 Months

Summary Prescriptions: 6 Prescribers: 6 Pharmacies: 5 Private Pay: 5 Active Morphine MME: 80

Prescriptions
Prescribers
Dispensers

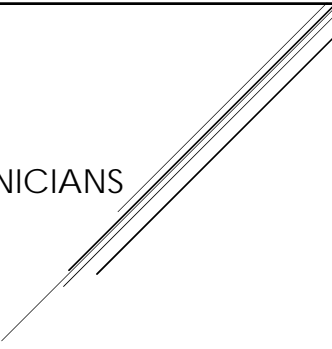
CDC GRANT FOR STATEWIDE K-TRACS INTEGRATION INTO EHR

<http://pharmacy.ks.gov/k-tracs/k-tracs-statewide-integration>

- ▶ Reduce barriers to registration and use of K-TRACS
- ▶ Increase number of prescribers and dispensers using K-TRACS
- ▶ Increase frequency and availability of unsolicited reports (quarterly prescriber report card)
- ▶ State will cover all PDMP Gateway® connection costs for each Kansas electronic health records and pharmacy management system approved for integration

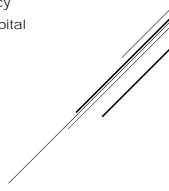
PHARMACY TECHNICIANS

Pharmacy Tech / Rural Nurse Task Force
Continuing Education
Certification Exam



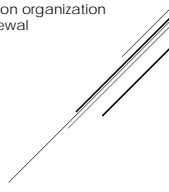
TASK FORCE REPS

- ▶ Kansas Board of Pharmacy
- ▶ Kansas Board of Nursing
- ▶ KU School of Pharmacy
- ▶ KPhA
- ▶ KPSC
- ▶ KCHP
- ▶ KACDS
- ▶ PBA Health
- ▶ Rooks Co Health Center
- ▶ Dillons
- ▶ CVS
- ▶ University of Kansas Health System
- ▶ OptumRx
- ▶ Salina Regional Medical Center
- ▶ Independence Pharmacy
- ▶ Lawrence Memorial Hospital
- ▶ Genoa
- ▶ Scott City Pharmacy



TASK FORCE DISCUSSION TOPICS

- ▶ Time to Certification
- ▶ Limitation of Licensure until Certification
- ▶ Approved Exams
- ▶ Ratio
- ▶ Rural Nurses – crossover from tech to nurse
- ▶ PIC Discretion
- ▶ Duties and Responsibilities
- ▶ OJT and competency evaluation
- ▶ Tech check Tech in the retail pharmacy setting (expansion)
- ▶ Role of technology moving forward – bar code technology, automation, and packaging (long term care, hospital, medication adherence)
- ▶ Order review in rural and medical sites
- ▶ Should CE for certification organization match CE for state renewal





▶ 68-5-18 Pharmacy Technicians 20 hrs per renewal period

- ▶ CE course must be submitted for approval at least 10 days in advance
- ▶ CE can be approved for pharmacists or technicians (or both)
- ▶ CE course provider must provide certificate of completion to individual
- ▶ Individual must submit CE certificate to the Board within 90 days
- ▶ ACPE, PTCB, and NHA courses are automatically approved
- ▶ CE approved by another state Board of Pharmacy automatically approved
- ▶ Cannot renew until all CE is completed


PHARMACY TECHNICIANS

- ▶ 2017 renewal group – 10 hours required (prorated)
 - ▶ Required to have one of the following before completing online renewal:
 - ▶ Certificates submitted to Board office showing 10 hours of CE
 - ▶ NABP CPE Monitor showing 10 hours of CE
 - ▶ Combination of above with 10 total hours of CE
 - ▶ Hours must be earned between September 1, 2015 and October 31, 2017
- ▶ 2018 renewal group – 20 hours required
 - ▶ Required to have one of the following before completing online renewal:
 - ▶ Certificates submitted to Board office showing 20 hours of CE
 - ▶ NABP CPE Monitor showing 20 hours of CE
 - ▶ Combination of above with 20 total hours of CE
 - ▶ Hours must be earned between September 1, 2016 and October 31, 2018

Note: 20 hours required after 2017

CERTIFICATION EXAM – KAR 68-5-17

- ▶ Applies to all technicians newly registered after July 1, 2017
- ▶ ExCPT or PTCB
- ▶ Must pass prior to first renewal (24 months)
- ▶ May request six month extension for good cause shown
- ▶ No requirement to remain certified
- ▶ No additional practice limitations prior to passing exam



QUESTIONS

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