



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)
- Methamphetamine Precursor 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

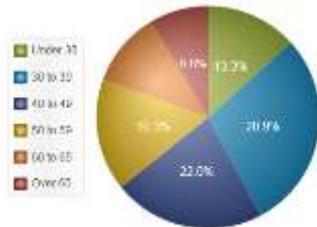
Statistics for Licensing and Registration

	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

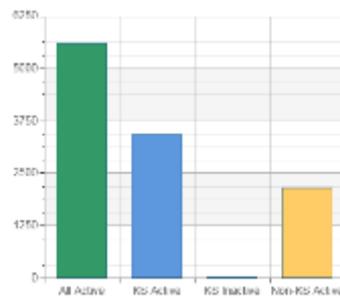
*estimated registrations

Statistics for Pharmacist Licensees

Age of Active Pharmacists



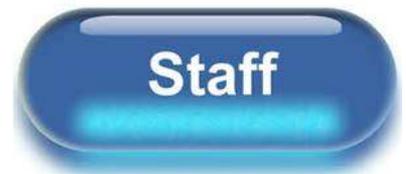
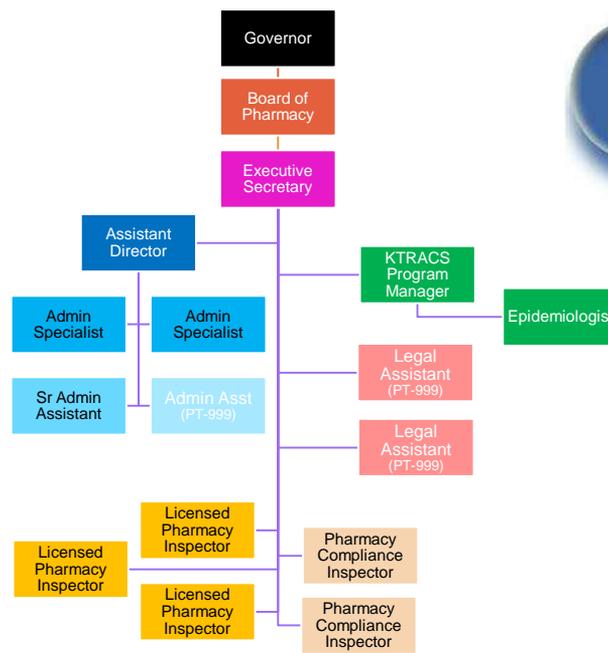
Number of Active Pharmacists



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

 **Software 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



**Council on Licensure,
Enforcement & Regulation**
Promoting Regulatory Excellence



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

DSCSA

Kansas

- ▶ Distributor

Federal / Other States

- ▶ Wholesale Distributor
- ▶ 3PL – 3rd Party Logistics Provider
- ▶ Reverse Distributor
- ▶ Outsourcing Facility
- ▶ Repackager

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

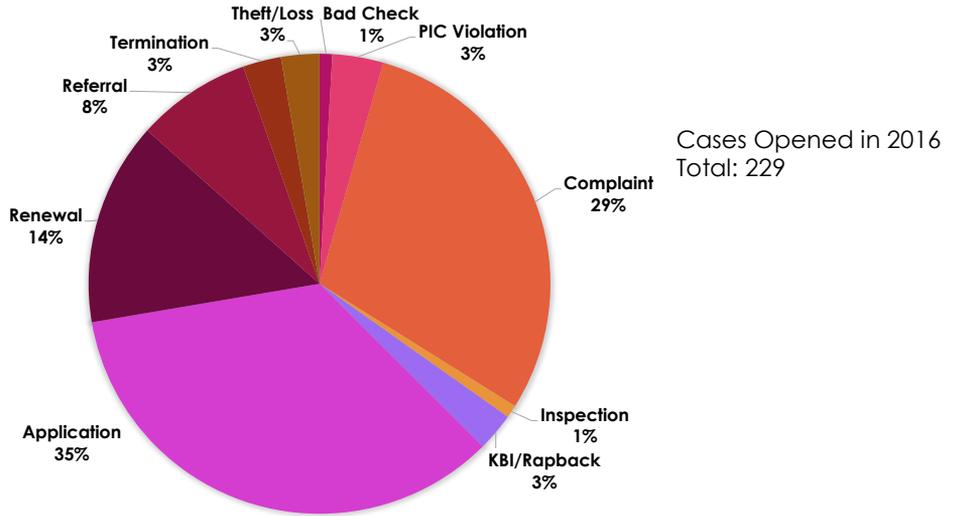
Pharmacy Techs

- ▶ 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

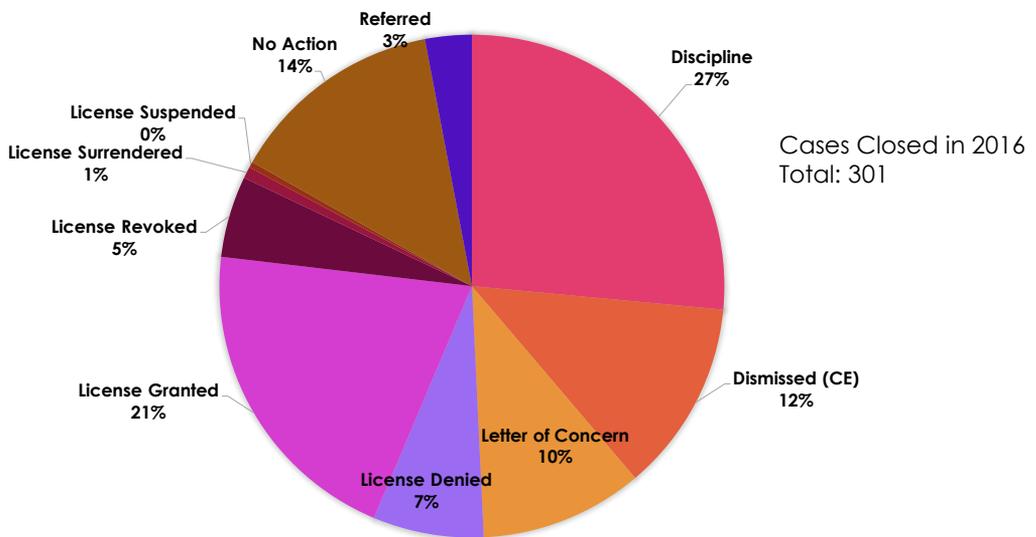
Miscellaneous

- ▶ 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



Compliance – 2016 Disciplinary Statistics



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 Pseudoephedrine.
 - ❖ 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.
-



27 Logins - 49 Searches - 30 Report Queries - 155 Active Avg. Watches - 40 Active Watch Lists

<p>NEW USERS THIS MONTH New Users = 1 Total Accounts = 90 Active Users = 27</p>	<p>TOP USAGE AGENCIES 1. Salina Police Department 2. Kansas Bureau of Investigation 3. Cherokee Co Sheriff's Office</p>	<p>TOP AGENCIES BY ACTIVE WATCHES 1. Chautauque Co Sheriff's Dept (50) 2. Salina Police Department (31) 3. Cherokee Co Sheriff's Office (16)</p>
<p>TOP USERS BY USAGE 1. Gtazy Kosegar, Salina Police Department 2. Raymond Drenn, Kansas Bureau of Investigation 3. Courtney Vaden, Kansas Bureau of Investigation</p>		

TRANSACTION SUMMARY STATISTICS (2016)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTAL
PURCHASES	84,748	85,808	89,501	94,136	89,789	91,296	89,746	86,770	96,498	80,617	90,361	80,132	621,022
BLOCKS	1,378	1,197	1,644	1,493	1,288	1,240	1,159	1,340	1,516	1,329	1,086	1,135	15,875
GRAMS SOLD	119,813	123,062	140,487	127,579	116,984	99,154	83,069	109,628	177,981	113,004	111,848	129,040	1,421,629
BOXES GOLD	57,425	58,618	63,123	58,404	51,515	45,638	41,628	48,350	60,887	51,847	52,669	62,825	648,935
GRAMS BLOCKED	4,529	4,098	5,427	5,157	4,432	4,233	3,781	4,515	5,708	4,469	3,545	3,722	54,014
BOXES BLOCKED	1,719	1,566	2,150	1,877	1,622	1,548	1,421	1,704	2,033	1,651	1,351	1,475	20,112
AVG GRAMS PER BOX BLOCKED	2.63	2.82	2.71	2.77	2.73	2.73	2.66	2.67	2.81	2.71	2.82	2.53	2.69



K-TRACS

KANSAS PRESCRIPTION MONITORING PROGRAM



What is



- ▶ 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?

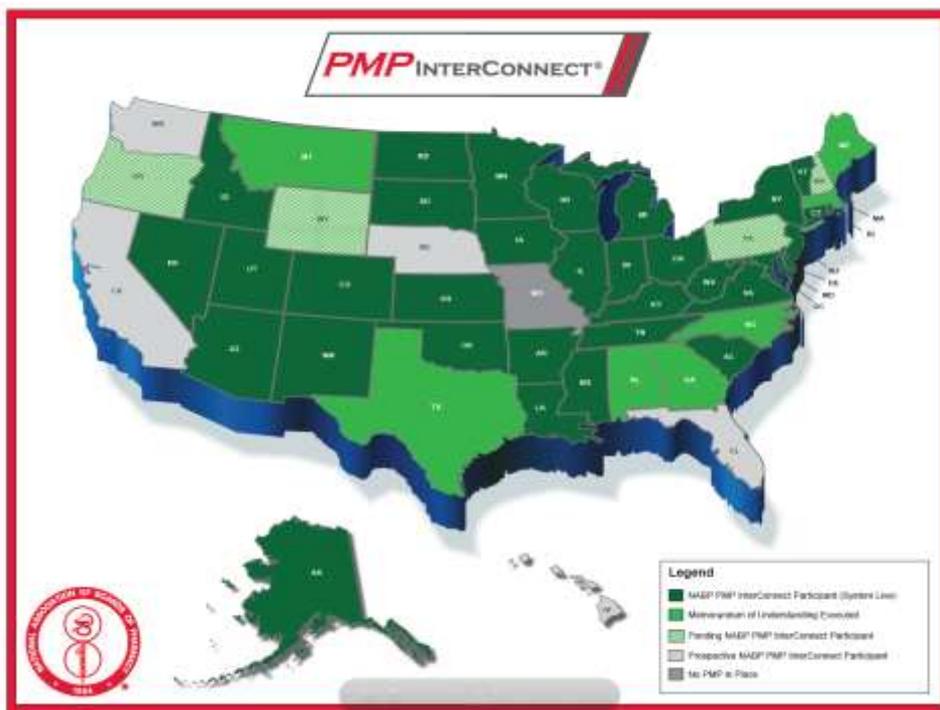
- ▶ Hospital pharmacy – distributes for the purpose of inpatient care
- ▶ Medical care facility – administers direct to patient
- ▶ Wholesale distributor
- ▶ Veterinarian
- ▶ Exempt Practitioner

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

	FUND 3188 - HAROLD ROGERS GRANT (PMP)					PROPOSED (FUND 2718 - FEE FUND)			
	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20
	Actuals	Actuals	Actuals	Actuals	Actuals	Budget	Budget	Budget	Budget
Operating Expenses									
Salaries & Wages	128,112	114,800	48,608	14,956	0	65,931	71,074	71,324	73,958
Communication/Postage	1,380	6,283	3,566	0	0	8,000	8,000	8,600	8,900
Printing and Advertising	2,256	0	866	1,406	0	12,000	12,000	12,000	12,360
Rents	5,528	5,000	5,591	0	0	5,000	3,000	3,000	3,100
Repair and Serv Equip Furn		24	0	0	0				
In State Travel & Subsistence	552	672	475	0	0	2,000	2,000	2,200	2,250
Out of State Travel & Subsistence	3,959	2,440	0	305	1,503	9,000	9,500	9,950	10,250
Fees - Other Services		50	74	0	0				
Fees - Attorneys		480	0	0	0	3,000	3,000	3,500	3,600
Fees - HID Support/Maint Fees	103,630	104,110	*	*	*	101,000	104,030	107,150	110,364
Fees - Professional Services		0	0	0	0				
Other Contractual Services		248	220	0	0				
Vehicle Part Supply Accessory	102	64	0	0	0				
Office & Data Supplies	3,131	1,137	1,026	135	0	2,500	2,500	3,000	3,100
Other Supplies and Materials		0	0	0	0				
Books & Library Material		0	0	0	0				
Printing/Computer Equipment	1,217	2,014	0	0	0				2,500
Software	0	0	0	0	0				
Telecommunication Equipment		259	0	0	0				
Vehicles	0	0	0	0	0				
Total Operating Expenses	249,867	237,582	60,424	16,782	1,503	208,431	215,104	220,724	230,382

K-TRACS Quarterly Report

Number of Patient Queries

General PMP Update

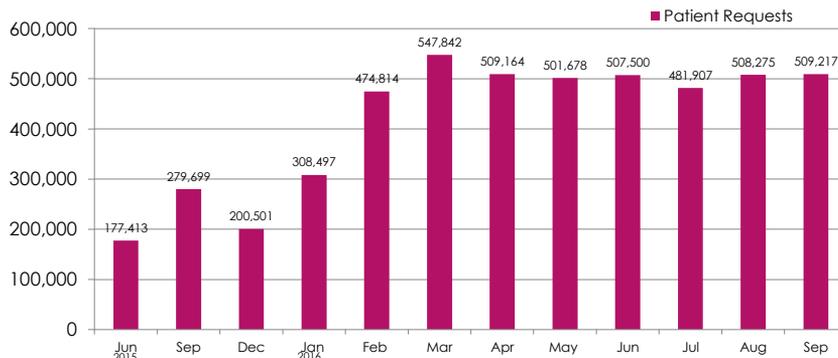
- ▶ KTRACS Patient Queries (September 2016 Snap Shot):
 - ▶ Web (In-state) Requests: **1,631** per day (10%)
 - ▶ Compared to 1,692 per day in June 2016
 - ▶ Web + PMPi Requests: **16,305** per day (includes Via Christi/Gateway)
 - ▶ Compared to 16,917 per day in June 2016

Top 3 Requesting States

1. Gateway
2. Via Christi Health
3. Oklahoma

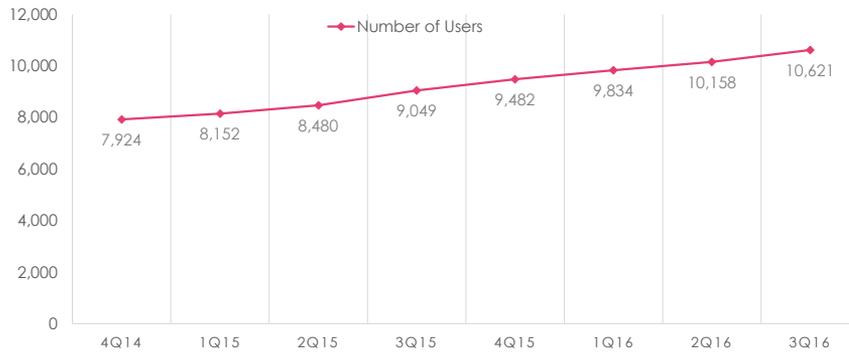
2016

Number of Patient Queries



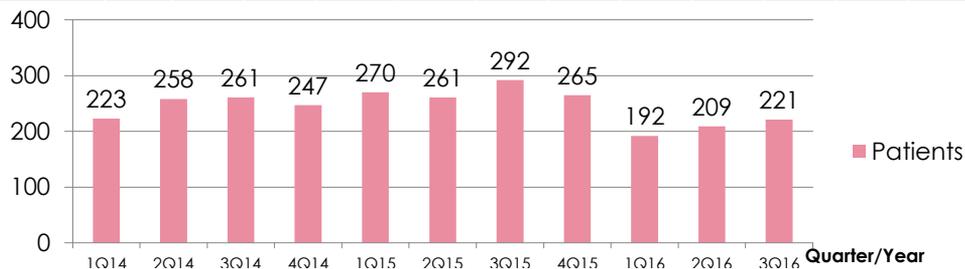
2016

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	3Q'16
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?

ALEXANDRA BLASI, JD, MBA
EXECUTIVE SECRETARY
KANSAS STATE BOARD OF
PHARMACY

ALEXANDRA.BLASI@KS.GOV

785-296-8419