

MISSOURI BOARD OF PHARMACY NEWSLETTER



FEBRUARY 2018

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FY17 ANNUAL REPORT

The Board's FY17 Annual Report is now available online. As reflected in the annual report, the Board had another successful fiscal year:

LICENSING:

- The Board's total licensee/registrant count increased a slight 1.99% from 36,189 licensees/registrants to 36,910 licensees/registrants in FY17.

LICENSING TOTALS	
Drug Distributors (licensed & temporary)	1,439
Drug Distributor Manufacturer Registrants	102
Intern Pharmacists	1,950
Pharmacists (active and inactive)	10,770
Pharmacists (temporary)	9
Pharmacies (instate, non-resident and temporary)	2,728
Pharmacy Technicians	19,912
TOTAL	36,910

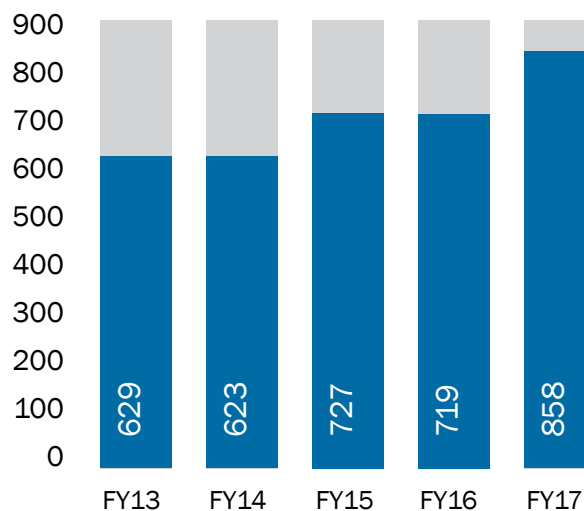
- Total licensed pharmacists decreased by 1.1% which is the first pharmacist decrease in more than 15 fiscal years.

- Approximately 55% of Missouri active pharmacists are male, 45% are female. 22% of Missouri pharmacists are over age 60.

COMPLAINTS:

- 858 new complaints were received/opened in FY 17 representing a 19% increase. Of the 858 complaints handled, 561 complaints were practice-related (65%) while 297 complaints were non-practice related tax compliance cases (approx. 35%).

Complaints Handled by FY



DISCIPLINE:

- 148 licensees/registrants were disciplined in FY 17 which included 116 technicians, 24 pharmacists, 7 pharmacies and 1 intern pharmacist.



- Pharmacy discipline decreased by 50%; Pharmacist discipline decreased by 11%.
- Technician discipline increased by 38%. A marked increase occurred in technicians disciplined for drug use likely attributable to expanded employer drug testing programs and mandatory employer reporting.
- The most common reasons for technician discipline were: (1) criminal history, (2) illegal drug usage/positive drug test and (3) drug diversion.

INSPECTIONS:

- 1,269 inspections and 247 investigations were conducted in FY 17. Investigations increased by 17% while inspections remained consistent.
- Approximately 70% of inspections resulted in violations noted or a compliance notice being issued, representing a 5% decrease.

FY17 INSPECTION RESULTS*

Approximately 70% of Board inspections resulted in violations noted or a compliance notice being issued, representing a 5% decrease from FY16. FY17 inspection results are summarized below:



Compliance notices issued after inspection decreased by 33.45%; No violation findings increased by 22%. Violations noted remained consistent.

* Includes inspection results for follow-up inspections and investigations.

A Complete copy of the FY17 Annual Report is available online at: <http://pr.mo.gov/pharmacists-annual-reports.asp>.



WHAT TAKES SO LONG?

The office is frequently asked how long it takes to issue a license or registration. Licensing times can depend on several factors, including, application volume, office staffing and criminal history information. Once an application is complete, the average pharmacy technician registration or pharmacist license is issued within 5-10 business days.

You can help speed up processing times by following these tips:

- Make sure the application is complete and signed. This includes checking all of the boxes and answering all questions.
- Make sure you sign your check or money order.
- Provide an explanation if you have prior criminal history or disciplinary actions. Remember, applicants are required to disclose criminal charges to the Board even if a Suspended Imposition of Sentence (SIS) was issued. Although SIS charges may not have to be disclosed to some private entities, SIS charges must be disclosed to the Board.

Applications with criminal charges or prior disciplinary actions may require additional review by the Executive Director or the full Board which will take additional time.

DID YOU KNOW?

Over the years, the Board has enacted/modified several rules that are intended to allow pharmacies and pharmacists to practice more efficiently and expand patient services. Examples include:

- 20 CSR 2220-2.013 (Prescription Delivery Requirements) expands prescription delivery options for all licensed pharmacies.
- 20 CSR 2220-2.900 (Automated Dispensing and Storage Systems) allows the use of offsite automated dispensing systems at long term care facilities and ambulatory care settings (practitioner clinics).
- 20 CSR 2220-2.950 (Automated Filling Systems) allows the use of automated systems to fill prescriptions and eliminates a final check by a pharmacist if the system meets designated requirements and auditing standards.
- 20 CSR 2220-2.650 (Standards of Operation for a Class J: Shared Services Pharmacy) allows pharmacies to collaborate in dispensing prescriptions. Examples include centralized filling and data entry/verification performed by other pharmacies.
- 20 CSR 2220-2.083 (Electronic Record-Keeping Systems) allows pharmacies to store electronic images of

prescription hard copies instead of maintaining a physical hard copy.

- 20 CSR 2220-6.050 (Non-Dispensing Activities) allows pharmacists to perform non-dispensing activities outside of a licensed pharmacy. Examples include offsite immunization clinics, remote order verification and drug utilization reviews.
- 20 CSR 2220-5.020 (Drug Distributor Licensing Requirements) allows a Missouri pharmacy to receive medication from an out-of-state pharmacy without the non-resident pharmacy having to hold a Missouri pharmacy license.

Pharmacists should review these regulations to learn the requirements that go along with these opportunities and contact their inspector if they have any questions. Pharmacists are also encouraged to reach out to professional associations, industry partners, and fellow colleagues to learn how these opportunities have been put to use in every day practice.

INSPECTION TIP

TIP # 1- Expiration Dating

Board inspectors frequently observe issues related to pharmacy expiration/beyond-use dating. Some reminders to help promote compliance:

- The expiration date of any repackaged product becomes the manufacturer's expiration date or twelve months, whichever is less. This also includes products placed into automatic dispensing/filling systems and bulk compounding ingredients that are repackaged.
- All repacked products must be labeled with an expiration date.
- Return to stock prescription expiration dates become the lesser of one year from the dispensing date on the label or the manufacturer's original expiration date, if known. Remind those checking inventory for outdated drugs when return to stock vials expire.
- If using MM/YY dating on repackaged products, be careful not to extend the date past 12 months. MM/YY dating implies the product expires on the last day of that month.
- Return to stock compounds need to be assigned and labeled with a beyond-use date if they were not already given one at the time of compounding. The beyond-use date must be entered on the compound log.
- The maximum expiration date on a multi-med pak is sixty days from the date of pak preparation.



- Pharmacist-in-Charge Tip: Routinely check your staff's work to ensure they are following procedures, retrain staff when needed.

Tip # 2- Compound Logs

Inspectors routinely find compound logs that pharmacists have signed off on containing inaccurate information. Some common issues are assigning a beyond-use date greater than an ingredient's expiration date or compounding with an ingredient listed as expired. Pharmacists should thoroughly review all documentation for accuracy and completeness before signing off on documents.

Extended BUD Example:

The section above must be completely filled out - DO NOT affix a prescription label in place of filling out the log.

Ingredient(s)	NDC	Manufacturer	Lot #	Expiration date	Quantity used
Nystatin oint	00472 016630	Actavis	L765053	5/19	30g
Cholestyminine	49884 046566	PAR	29274001	11/19	1 scoop
H ₂ O	—————→				12ml
Hydrocotril 0.5%	00168 001431	Fougere	GV 7168	8/18	29g
Auguaphor	72140063608	Beiersdorf	73050887	7/19	30g

Product Expiration Date (Beyond Use Date) **12-19-18** as defined by USP 795 Standards for non-sterile preparations



Expired Ingredients Example:

Compound ID: 92 Set Count: TotalQty: 44 Units: 44
Label: TRIAMCIN 0.025%/MUPIROC 2% Dec: Strn:

EXHIBIT 1d

Drug Code	IngrQty	Drug Name	Tx Qty: 44
TRIA025	22.000	TRIAMCINOLON 0.025% CRE FOUG	--> 22.000
MUPI	22.000	MUPIROCIN 2 % OINT**	--> 22.000
3			-->
4			-->
5			-->
6			-->

Disp Fee: [REDACTED]
Mixing Fee: [REDACTED]
Cmpd Time: 15
Cost Base: AWP
Price Code:
Comp:

Formula
WEIGH 22GM TRIAMCINOLONE Sched: 6 Rx: Y
AND MIX WITH 22GM MIPIROCIN Group:
MIX THOROUGHLY, 90 DAY EXP Added: 01/19/2016
LastUpd:
LastUse: 05/31/2016
Deactivate Date:

Lot	Manuf.	Exp.
1. U4440D	Fousera	02/12
2. 1N2A2	Periso	01/14

Compounded 5/31/2016

RULE UPDATES:

The Board recently amended its Class-J Shared Services Rule (20 CSR 2220-2.650). The new rule became effective on January 30, 2018 and includes the following major changes:

- 1) Class-J Shared Services pharmacies must share a common electronic database or allow access to each pharmacy's electronic prescription or medication records. Previously, only a common electronic file could be used. The allowed common database or electronically accessible record must provide real-time, online access to the patient's complete profile for the pharmacies involved.
- 2) Patients must be notified that their prescriptions or medication orders may be filled or compounded by another pharmacy if the pharmacies participating in the Class-J shared services arrangement are not under common ownership. Notification may be provided verbally, electronically or in writing.
- 3) Section 338.059, RSMo, requires that prescription labels include the "name and address of the pharmacy." For Class-J arrangements, the amended rule clarifies that the name and address of the pharmacy responsible for

offering patient counseling **or** the name and address of the pharmacy responsible for dispensing to the patient may be listed on the label as designated by the pharmacies by contract.

- 4) **Permit Exemption:** A Class-J Shared Services permit is no longer required if a completed and labeled prescription is delivered from one Missouri licensed pharmacy to another Missouri licensed pharmacy for administration by a pharmacist or other licensed health care professional on the same premises or physical location as the pharmacy. This exemption only applies if a completed and labeled prescription is delivered to the receiving pharmacy and the medication will be administered onsite. Significantly, participating pharmacies **are not** exempt from all Board licensure. A Missouri pharmacy permit in another classification is still required, however, **an additional** Class-J permit is not. (See the full rule for additional record-keeping and patient counseling requirements/exemptions).

This summary does not include all rule changes. Licensees should read the new rule in its entirety to ensure compliance with Missouri law.



MEET OUR NEW INSPECTOR!



Scott Spencer, RPh., has joined the Board as the new inspector in the Mid-Missouri area. Scott has been a licensed pharmacist for over 30 years and has an extensive background in retail and long-term care practice. We asked Scott a few questions:

What made you choose pharmacy?

My father was also a pharmacist. I remember being so curious in my youth, watching his career

path change from a Quality Control Director with a small drug manufacturer, then on to owning his own retail pharmacy and finally ending up in management with hospital pharmacy. I concluded this must be an excellent profession to study with so many different paths one could follow.

Where do you see pharmacy headed?

I believe that pharmacy is seeing a great deal of changes involving measures to assist patients with adherence to their medication regimens, education on proper use of medications, safety regarding compounded medications and emphasis on the ongoing battle against drug dependence. Pharmacy continues to adapt to these challenges, but a continued emphasis on new rules and regulations for pharmacies is a must to protect the public.

What have you learned since becoming an inspector?

As an inspector, I've learned that technicians and pharmacists are sometimes afraid to ask questions for a variety of reasons. I value being humble. Creating a working relationship where I am viewed as approachable, is as important as my willingness to remain humble in my efforts to work towards improved compliance in Missouri pharmacies.

Scott replaces Joe Dino who retired from the Board in 2016. We wish Joe the best in his retirement and thank him for his excellent service to the Board.

DISCIPLINARY ACTIONS:

PHARMACISTS:

Todd R. Campbell, #2007011415, Squires, MO. Public censure. Licensee diverted an antibiotic from the pharmacy's inventory. Section 338.055.2(5), (6), (13), and (15) RSMo.

Douglas E. Griggs, #040707, St. Louis, MO. License surrendered, and cannot reapply for three (3) years. Violation of discipline, tested positive for hydrocodone and opiates in a random drug screen. Failed to provide the Board copies of prescriptions within five days of receipt. Failed to notify employers of possible need for a BNDD and DEA waiver. Section 338.055.3 RSMo

Mohamed B. Hassen, #2001029694, St. Louis, MO. Public Censure. Dispensed prescription medication to an employee without a prescription and proper labeling. Section 338.055.2(5), (6), (13), and (15) RSMo.

Teresa A. Lowe, #2001018155, Blue Springs, MO. Additional one (1) year probation. Violation of discipline, administered vaccines without a valid protocol, prior to filing a notification of intent. Section 338.055.3 RSMo

Frank J. Nuber, #028056, Troy, MO. One (1) year probation. As pharmacist-in-charge, allowed a pharmacy technician to work while her registration was suspended. Section 338.055.2 (5), (6), (10), and (13), RSMo.

Laura A. Thomas, #2013035537, Joplin, MO. Public Censure. As Pharmacist-In-Charge, administered immunizations without a signed protocol and current CPR certification. Section 338.055.2(5), (6), (13), and (15) RSMo.

Kamlesh A. Trivedi, #040885, Shawnee, KS. Probation for five (5) years. Removed and consumed tramadol and diclofenac from the pharmacy without a valid prescription. Section 338.055.2 (13) and (17), RSMo.

Phillip K. Wilkins, #2009035951, Doniphan, MO. Probation for five (5) years. As pharmacist-in-charge, failed to timely dispense medication, failed to maintain accurate prescription and pharmacy records, improper partial fills of Schedule II controlled substance prescriptions. Section 338.055.2 (5), (6), (13), and (15), RSMo.

PHARMACIES:

Bruner's Pharmacy, #004952, Webb City, MO. Probation for three (3) years. Failed to maintain adequate security to deter theft of drugs and diversion of controlled substances. Section 338.055.2 (5),(6), (13), and (15), RSMo.

California Pharmacy and Compounding Center Inc., #2010002058, Newport Beach, CA. Voluntary Surrender. Prior discipline/legal action by the California Board of Pharmacy and Colorado Board of Pharmacy related to compounding and dispensing violations. Section 338.055.2 (8), (13), and (15)

GOLD CERTIFICATES



Congratulations to our newest "gold-certificate" pharmacists who have maintained a Missouri pharmacist license for 50 years:

Clinton W Claybaker

Armon R Crawford

Diana L McDaniel

Benny E Thomas