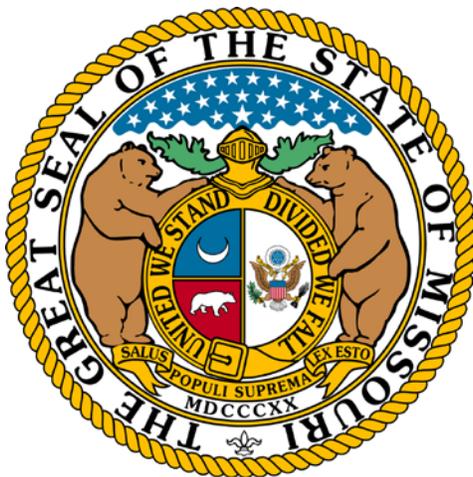


# MISSOURI BOARD OF PHARMACY



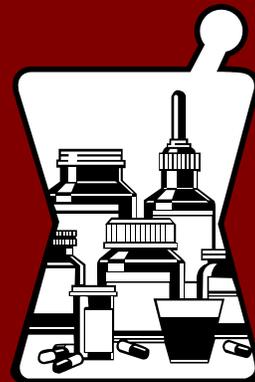
## ANNUAL REPORT

FY 2015

JEREMIAH W. "JAY" NIXON, GOVERNOR  
STATE OF MISSOURI

JOHN HUFF, DIRECTOR  
DEPT. OF INSURANCE, FINANCIAL INSTITUTIONS AND  
PROFESSIONAL REGISTRATION

KATHLEEN STEELE DANNER, DIRECTOR  
DIVISION OF PROFESSIONAL REGISTRATION





Jeremiah W. (Jay) Nixon  
Governor  
State of Missouri  
State of Missouri

Kathleen (Katie) Steele Danner, Division Director  
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance  
Financial Institutions  
and Professional Registration  
John M. Huff, Director

MISSOURI BOARD OF PHARMACY  
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Executive Director  
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email: [MissouriBOP@pr.mo.gov](mailto:MissouriBOP@pr.mo.gov)

To The Honorable Jeremiah W. "Jay" Nixon:

In compliance with § 338.140.3, RSMO, the Missouri Board of Pharmacy is pleased to submit its Annual Report. The Board of Pharmacy is pleased to report another successful year. This report contains the proceedings of the Board for the fiscal year ending June 30, 2015 ("FY 15").

Respectfully yours,

MISSOURI BOARD OF PHARMACY

By:

A handwritten signature in cursive script, appearing to read "K A Grinston".

---

Kimberly Grinston  
Executive Director

DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS  
AND PROFESSIONAL REGISTRATION

◆  
DIVISION OF PROFESSIONAL REGISTRATION  
◆

*Missouri Board of Pharmacy*

FY15

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**BOARD MEMBERS:**

JANINE M. BURKETT, R.PH., PRESIDENT  
PAMELA L. MARSHALL, R.PH., VICE-PRESIDENT  
BARBARA A. BILEK, PHARM.D., MEMBER  
CHRISTINA LINDSAY, PHARM.D., MEMBER  
CHRISTIAN TADRUS, PHARM.D., MEMBER  
ANITA K. PARRAN, PUBLIC MEMBER  
VACANT POSITIONS (1)



**Missouri Board of Pharmacy**

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**Kimberly A. Grinston, J.D., Executive Director**

# TABLE OF CONTENTS

|                                 |    |
|---------------------------------|----|
| EXECUTIVE SUMMARY.....          | 2  |
| ABOUT THE BOARD.....            | 4  |
| BOARD OPERATIONS.....           | 5  |
| FINANCIAL SUMMARY.....          | 7  |
| LICENSING.....                  | 9  |
| COMPLAINT HANDLING.....         | 19 |
| DISCIPLINARY ACTIONS.....       | 22 |
| INSPECTIONS/INVESTIGATIONS..... | 26 |
| COMPOUNDED DRUG TESTING.....    | 28 |
| RULEMAKING.....                 | 29 |
| BOARD INITIATIVES.....          | 30 |

## EXECUTIVE SUMMARY

This Annual Report covers the activities of the Missouri Board of Pharmacy from July 1, 2014 to June 30, 2015 (FY15). The Board is pleased to announce another successful regulatory year as reflected below:

### ***Board Operations***

---

- The Board held four (4) regular session meetings, eight (8) conference call meetings and seven (7) email ballot meetings during FY 15.
- The Board handled/processed approximately 37,307 licensing related applications and verification requests.
- The Board received/responded to 6,316 telephone calls representing a 5.4% increase in call volume.

### ***Financial Overview***

---

- The Board's total appropriation and authorized transfers for FY15 was \$2,532,295. Of the amount appropriated, the Board expended \$ 1,981,953.29. Board expenditures remained consistent with a minimal .12% decrease.
- In compliance with § 338.070, the Board lowered renewal fees in FY 15 for pharmacists, intern pharmacists, and pharmacy technicians. The fee decrease resulted in an anticipated 46% revenue decline.

### ***Licensing Summary***

---

- Total licensees/registrants increased from 34,673 licensees/registrants in FY14 to 35,174 licensees/registrants in FY15, representing a 1.44% increase.
- The number of licensed pharmacists increased 3.59% to 10,312 licensees. The number of inactive licensed pharmacists increased 106% from 261 inactive pharmacists in FY14 to 538 inactive pharmacists in FY15.
- Total registered pharmacy technicians remained consistent at 18,688, representing a minor .01% decrease.
- Total licensed pharmacies increased by 8.54% with a FY licensing total of 2,630 resident and non-resident pharmacies. The number of non-resident pharmacies increased approximately 18%.
- The total number of licensed drug distributors and drug distributor registrants increased by 3.85% to 1,561 licensees/registrants.

### ***Complaint Handling***

---

- The Board received/opened 727 new complaints in FY 15, representing a 13.3% increase in complaints handled.
- Complaints from the general public increased by 9%.
- Of the 727 complaints received/opened, 490 complaints were practice-related (approx. 67.5%) while 237 complaints were non-practice related Missouri Department of Revenue tax suspension cases (approx. 32.5%).

### ***Complaint Dispositions***

- The Board issued final dispositions on approximately 740 complaints, including, 237 Department of Revenue tax suspension complaints and 503 non-tax related complaints.

## EXECUTIVE SUMMARY

### ***Disciplinary Actions***

---

- The Board issued disciplinary action in approximately 389 cases, representing a 19% increase in disciplinary actions taken.
- One-hundred and fifty-two (152) of the disciplinary actions issued were practice related (39%). The remaining 237 cases involved non-practice related Department of Revenue tax suspensions (61%).
- Practice related disciplinary actions increased by 67% from FY14. Pharmacy technicians experienced the largest increase in practice-related disciplinary actions with a growth of 82.75%.

### ***Inspections***

---

- Board inspectors conducted a total of 1,224 inspections of pharmacies and drug distributors throughout the state, representing a 24% increase from FY14. Inspectors/staff also completed 228 investigations.
- Violations were observed or a Compliance Notice was issued in approximately 72% of inspections conducted.

### ***Compounded Drug Testing***

---

- In 2003, the Board initiated a program to test drug preparations compounded by pharmacies. 77.6% of products tested were satisfactory while 22.4% were unsatisfactory. All unsatisfactory results related to potency failures.

### ***Rulemaking***

---

- The Board promulgated the following rules in FY15:
  - 20 CSR 2220-4.020 (General Fees)
  - 20 CSR 2220-5.020 (Drug Distributor Licensing Requirements)
- Additionally, the Board substantively reviewed and opened the following rules for public comment:
  - 20 CSR 2220-2.090 (Pharmacist-In-Charge)
  - 20 CSR 2220-2.100 (Collection of Medication for Destruction)
  - 20 CSR 2220-2.200 (Sterile Compounding)

### ***Board Initiatives***

---

- The Board's public strategic planning meeting was held on July 16, 2014. The Board voted to pursue five (5) new legislative proposals related to pharmacy practice.
- The Board continued to promote its patient safety campaign and conducted a statewide Patient Survey of all Missouri licensees and registrants utilizing the Community Pharmacy Survey on Patient Safety Culture issued by the Agency for Healthcare Research and Quality. Survey results are currently under review.
- The Board co-sponsored Missouri's first Joint Regulatory Patient Safety Conference in conjunction with the Missouri Board of Nursing, the Missouri Board of Registration for the Healing Arts and the Missouri Dental Board. The free conference offered a forum for board members and healthcare providers to discuss effective patient safety tools and strategies.



## MISSION STATEMENT

*The Board's mission is to serve and protect the public by providing an accessible, responsible and accountable regulatory system that:*

- *Protects the public from incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty;*
- *Licenses only qualified and competent professionals, and;*
- *Ensures compliance with professional standards and federal and state pharmacy law.*

## ABOUT THE MISSOURI BOARD OF PHARMACY

The Missouri Board of Pharmacy was statutorily created in 1909 and has served the citizens of Missouri through the regulation of pharmacy practice for over 100 years. The Board of Pharmacy is an autonomous Board within the Division of Professional Registration, an agency of the Department of Insurance, Financial Institutions and Professional Registration.

## MEMBERSHIP

The Board consists of seven (7) members, including, six (6) licensed pharmacists actively engaged in the practice of pharmacy and one (1) public member. By statute, at least one member must provide pharmaceutical services to a hospital, skilled nursing facility or intermediate care facility on a full-time basis. Board members are appointed by the Governor and confirmed by the Missouri Senate. All members hold office for five (5) years from the date of their appointment or until their successors have been appointed and qualified. The Board annually elects a president and vice-president, each of whom serve one (1) year terms.

## FUNCTIONS

Pursuant to Chapter 338, RSMo, the Board has superintending control over the practice of pharmacy in the State of Missouri and its primary duties consist of:

- Ensuring compliance with Chapter 338, RSMo, and the rules of the Board;
- Licensing/registering pharmacists, pharmacy technicians, intern pharmacists, pharmacies and drug distributors;
- Investigating complaints within the Board's statutory jurisdiction;
- Disciplining licensees which may include, public censure, probation, suspension or revocation of a licensee/registrant;
- Inspection of pharmacies and drug distributors; and
- Approval of preceptors and intern training facilities.

**Board Operations**

During FY15, the Board held four (4) regular session meetings, eight (8) conference call meetings and seven (7) email ballot meetings. The following staff were employed by the Board in FY15:

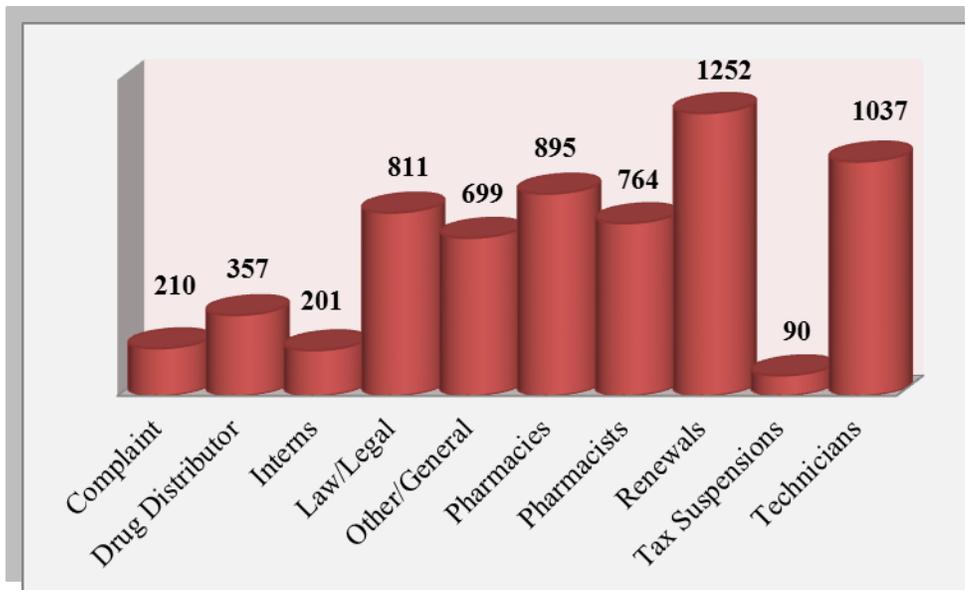
- **Kimberly Grinston, J.D., Executive Director**
- Tammy Siebert, Administrative Coordinator
- Jennifer Luebbert, Compliance Coordinator
- Laura Henke, Pharmacy/Drug Distributor Coordinator
- Sylvia Ferguson, Pharmacist Coordinator
- Kelly Bowers, Pharmacy Technician Coordinator

**Inspectors**

- **Tom Glenski, R.Ph., Chief Inspector**
- Bennie Dean, R.Ph.
- Joe Dino, R.Ph.
- Andrea “Andi” Miller, PharmD.
- Lisa Thompson, R.Ph.
- Daniel Vandersand, R.Ph.
- Frank VanFleet, R.Ph.
- Barbara Wood, R.Ph.

OFFICE ACTIVITIES

- The Board handled/processed approximately 37,307 licensing related applications and verification requests during FY15.
- The Board received/responded to 6,316 telephone calls during FY15 representing a 5.4% increase in call volume. Major topic areas are identified below:



## Education/Training

---

As part of its ongoing efforts to promote voluntary compliance, the Board hosted the following education and training programs in FY15 (*participants were awarded free continuing education credit*):

- 2014 Legislative/Rule and Review of Employment Listings/Waiver Requirements
- 2014 Joint Regulatory Patient Safety Conference
- 2014 Pharmacist Administration Regulation Review and Update
- 2015 Inspector Tips for Your Next Inspection
- 2015 DEA Update with Scott Collier

## Gold Certificates

---

The following individuals received Gold Certificates during 2015 representing fifty (50) years of active service as a Missouri licensed pharmacist:

- |                          |                          |
|--------------------------|--------------------------|
| ◆ Andes, Robert L        | ◆ Hagen, Donald L        |
| ◆ Beisner, Gerald H      | ◆ Hiner, William L       |
| ◆ Bilzing, Robert A      | ◆ Hively, Eules W        |
| ◆ Boone, William G       | ◆ Hodson, Larry E        |
| ◆ Brown, James T         | ◆ Kaye, Leonard E        |
| ◆ Caleca, Dominick R     | ◆ Lee, Mary K            |
| ◆ Carter, John M         | ◆ McDermott, Larry C     |
| ◆ Cohen, Sylvan H        | ◆ McMullin, John T       |
| ◆ Collins, Robert W      | ◆ Mikesic, Paula A       |
| ◆ Cordes, Raymond J, Jr. | ◆ Miller, Richard C, Jr  |
| ◆ Cradock, James C       | ◆ Milsark, Michael J, Jr |
| ◆ Cushman, Sam M         | ◆ Potter, Patrick T      |
| ◆ Eberhardt, Jon M       | ◆ Schachter, Willard     |
| ◆ Erdman, Diane A        | ◆ Sievers, William F, Jr |
| ◆ Fitzpatrick, William A | ◆ Sisson, Albert E, II   |
| ◆ Gaffney, William E     | ◆ Taylor, Melvin E, Jr   |
| ◆ Gershman, Jerome H     | ◆ Tishk, Harry N         |
| ◆ Greim, Larry E         | ◆ Underwood, George H    |



**Financial Overview**

The Missouri Board of Pharmacy's appropriation for fiscal year ending June 30, 2015, was as follows:

|                       |                   |
|-----------------------|-------------------|
| Personal Service      | \$ 954,923        |
| Expense and Equipment | \$ 666,448        |
| Criminal History Fund | \$ 5,000          |
| Licensure System      | \$ 73,900         |
| Transfers*            | <u>\$ 832,024</u> |
|                       | \$ 2,532,295      |

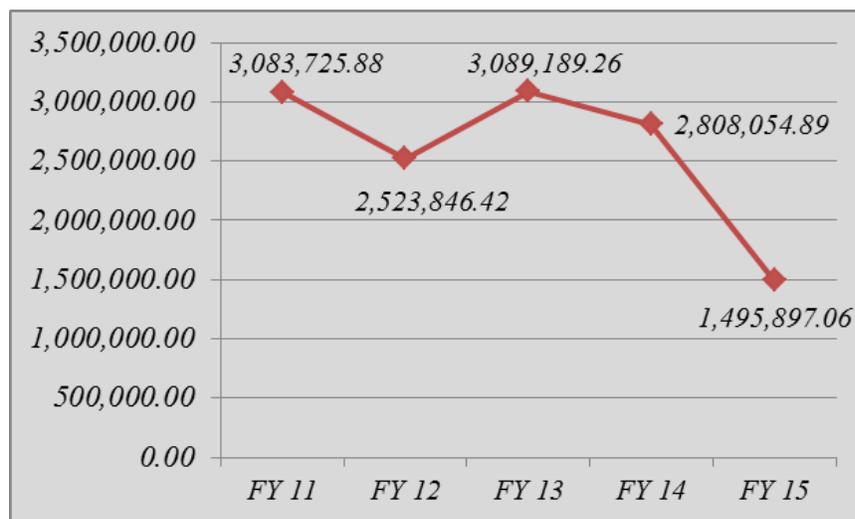
Of the amount appropriated, the Board expended \$ 1,981,953.29 in FY 15 as follows:

|                       |                        |
|-----------------------|------------------------|
| Personal Service      | \$ 904,956.81 (45.65%) |
| Expense and Equipment | \$ 355,457.50 (17.93%) |
| Transfers*            | \$ 721,538.98 (36.4%)  |

*\*Transfers include costs/transfers for rent, the Division of Professional Registration, IT transfers, licensee refunds, attorney general services, Administrative Hearing Commission, DIFP Allocated Expenses and OA Allocated Expenses.*

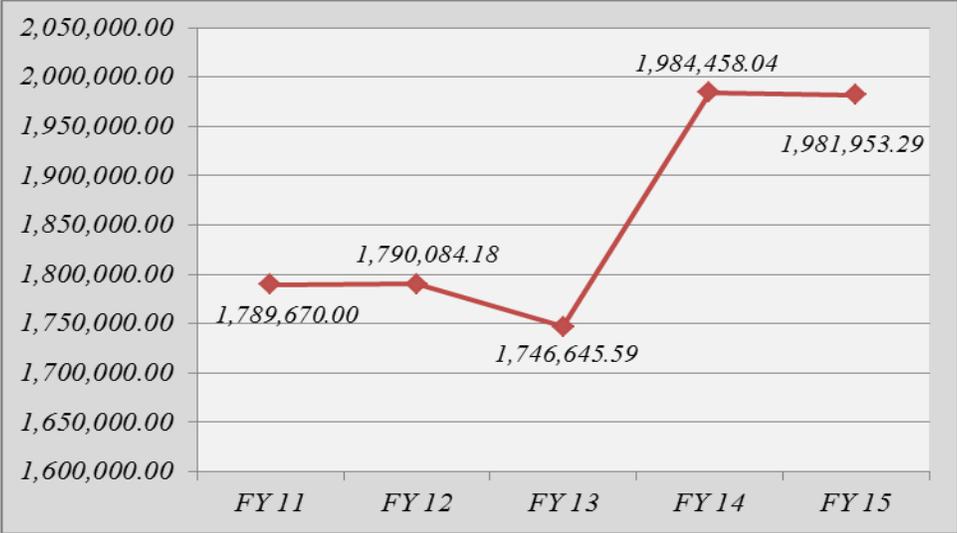
**Revenue Received:**

The Board of Pharmacy is statutorily obligated to establish fees as necessary to administer the provisions of Chapter 338, RSMo. Section 338.070, RSMo, provides fees must be appropriate so that the revenue produced does not substantially exceed the cost and expense of administering Chapter 338. In compliance with § 338.070, the Board lowered renewal fees in FY 15 for pharmacists, intern pharmacists, and pharmacy technicians to prevent an excessive fund balance. The fee decrease resulted in an anticipated 46% revenue decline in FY 15 as reflected below:



**Board Expenditures:**

- Board expenditures remained consistent in FY 15 with a slight .12% decrease as indicated below:



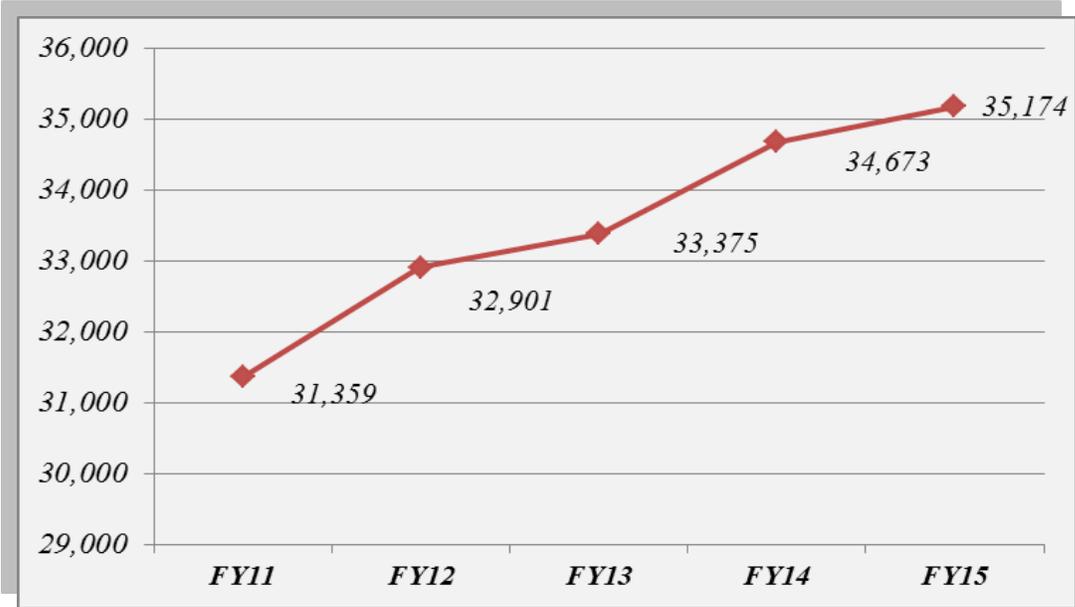
**Licensing Summary**

Pursuant to Chapter 338, the Board licenses and regulates pharmacists, intern pharmacists, pharmacy technicians, pharmacies and drug distributors.

- The Board’s total licensee/registrant count increased from 34,673 licensees/registrants in FY14 to 35,174 licensees/registrants in FY15.
- The Board’s licensing totals at the close of FY15 are provided by classification below:

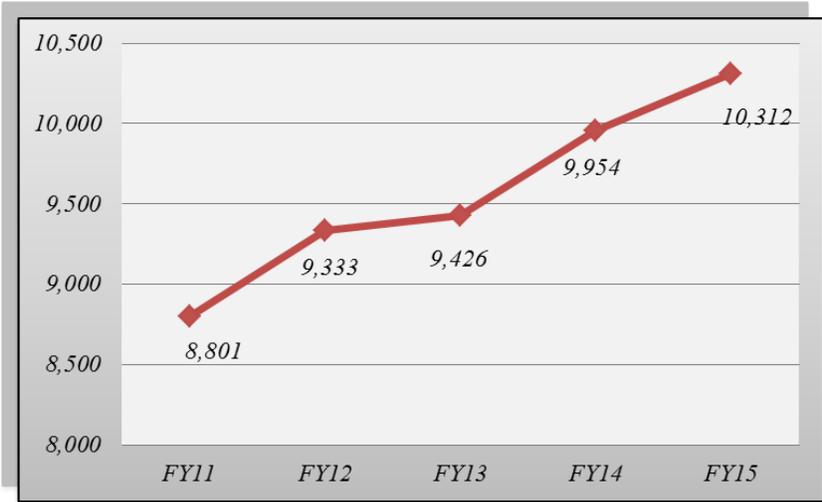
| <b>LICENSING TOTALS</b>                          |               |
|--|---------------|
| Drug Distributors (licensed & temporary)         | 1,445         |
| Drug Distributor Manufacturer Registrants        | 116           |
| Intern Pharmacists                               | 1,983         |
| Pharmacists (active and inactive)                | 10,312        |
| Pharmacies (instate, non-resident and temporary) | 2,630         |
| Pharmacy Technicians                             | 18,688        |
| <b>TOTAL</b>                                     | <b>35,174</b> |

Total Licensee/Registrant Totals By Fiscal Year



Pharmacists:

- The number of licensed pharmacists increased 3.59% to 10,312 in FY15 as reflected below:



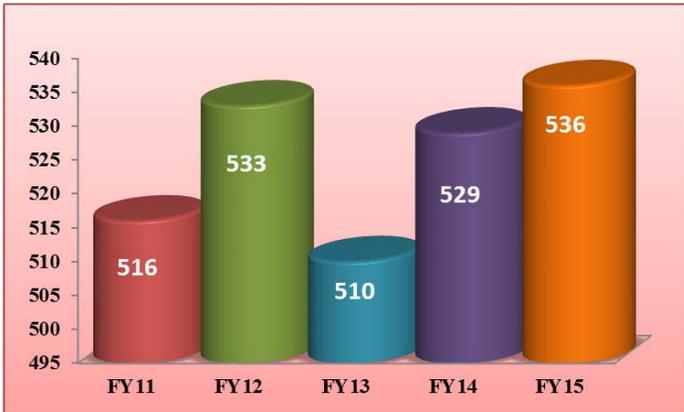
- Despite lower renewal fees, the total number of inactive licensed pharmacists increased 106% from 261 inactive pharmacists in FY14 to 538 inactive pharmacists in FY15. \*\* The total number of active vs. inactive Missouri pharmacists both resident and non-resident are reflected below:

|                                   |               |
|-----------------------------------|---------------|
| <b>Active Licensees</b>           | <b>9,774</b>  |
| Male                              | 4,537         |
| Female                            | 5,237         |
| <b>Inactive Licensees</b>         | <b>538</b>    |
| Male                              | 314           |
| Female                            | 224           |
| <b>TOTAL LICENSED PHARMACISTS</b> | <b>10,312</b> |

\*\* Inactive pharmacists are not authorized to practice in Missouri but remain licensed.

Number of New Pharmacist Licenses Issued

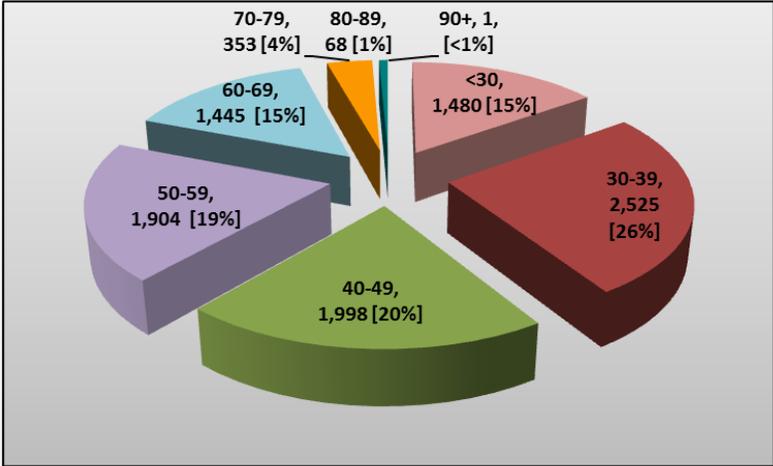
- The number of newly licensed pharmacists remained consistent in FY15 with a minor increase of approximately 1.3%.



Active Pharmacists By Age Group (Resident and Non-Resident) [#,%]

- No significant changes occurred in the number of licensed pharmacists categorized by age in FY15. Forty-two percent (42%) of licensed Missouri pharmacists are age 39 and under with the remaining fifty-eight percent (58%) at age 40 or above.

(Pharmacist Distribution by Age)



Pharmacists Residing in Missouri

- No significant changes occurred in licensed resident vs. non-resident pharmacists in FY15. Approximately 60% of pharmacists licensed by the Board reported a Missouri address (6,207 of the total 10,312 licensed pharmacists). The total number of resident pharmacists are reflected below:

|                     |       |
|---------------------|-------|
| Active Licensees    | 6,207 |
| Male                | 2,958 |
| Female              | 3,249 |
| Inactive Licensees* | 208   |
| Male                | 88    |
| Female              | 120   |

Administration & Immunizations:

Pursuant to § 338.010, RSMo, pharmacists are authorized to administer medication by prescription order and to administer influenza, shingles, meningitis and pneumonia vaccines pursuant to a protocol with a Missouri licensed physician, upon filing a *Notification of Intent* with the Board.

- The total number of pharmacists authorized to administer medication by prescription order increased 32% from 1,755 in FY14 to 2,327 in FY15.
- The total number of pharmacists authorized to immunize by protocol experienced a smaller 20% increase.
- The following Notifications of Intent were filed with the Board in FY15:

Administration by Medication Prescription Order.....2,327  
 Immunization by Protocol.....2,596

Medication Therapy Services:

Section 338.010, RSMo, also authorizes the Board to issue a Certificate of Medication Therapeutic Plan Authority (MT certificate) which allows pharmacists to provide medication therapy services.

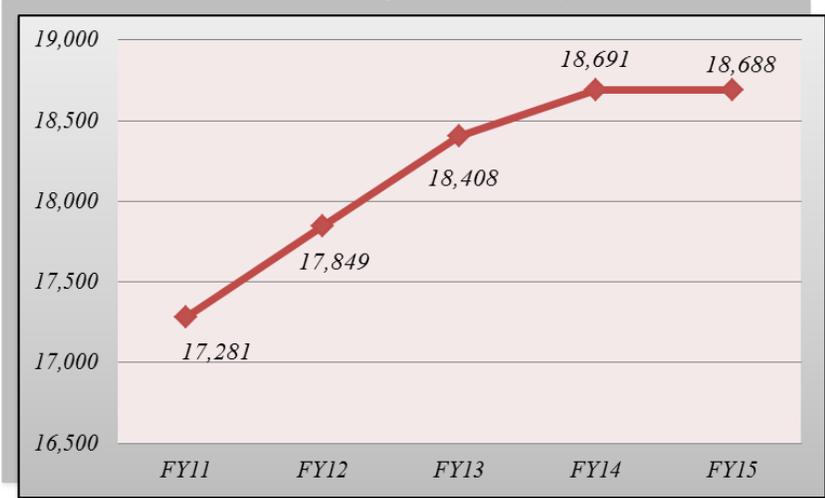
- The total number of pharmacists holding a MT certificate in FY15 increased by 77%. This represents a 411% increase in MT certificates issued since the Board began issuing certificates in 2013.
- The following reflects the total number of pharmacists holding a valid Certificate of Medication Therapeutic Plan Authority in the fiscal years identified:

|           |       |
|-----------|-------|
| FY13..... | 508   |
| FY14..... | 1,463 |
| FY15..... | 2,596 |

Pharmacy Technicians:

- The Board experienced a minor .01% decrease in total registered pharmacy technicians in FY15 as reflected below:

*(Total Technician Registrations by Fiscal Year)*



- The number of newly registered pharmacy technicians in FY15 decreased approximately 28%. The decrease likely resulted from vacancies in the Pharmacy Technician Coordinator position during FY15 and the transition to new staff.

New Pharmacy Technician Registrations Issued

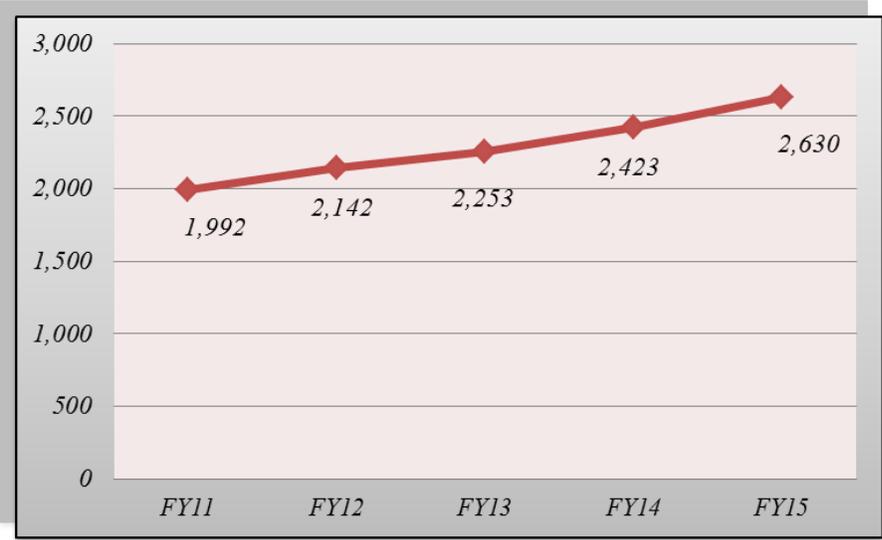


**Pharmacy Summary:**

- The Board experienced an 8.54% increase in total licensed pharmacies. Although instate pharmacies remained consistent, the number of non-resident pharmacies increased approximately 18%.

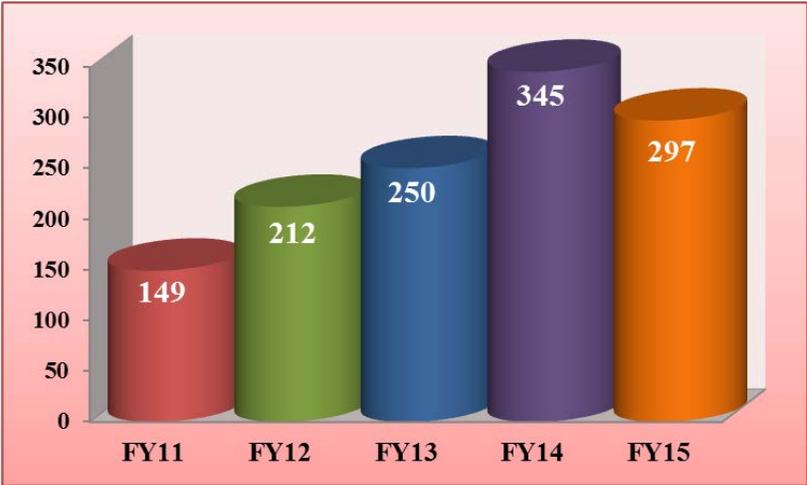
| PHARMACY PERMIT TOTALS  |              |
|-------------------------|--------------|
| Instate Pharmacies      | 1,524        |
| Non-Resident Pharmacies | 1,084        |
| Temporary Pharmacies    | 22           |
| <b>TOTAL</b>            | <b>2,630</b> |

**Pharmacy Permitholders By Fiscal Year**



**New Pharmacy Permits Issued**

- The Board experienced an approximate 14% decrease in new pharmacy permits issued as follows:

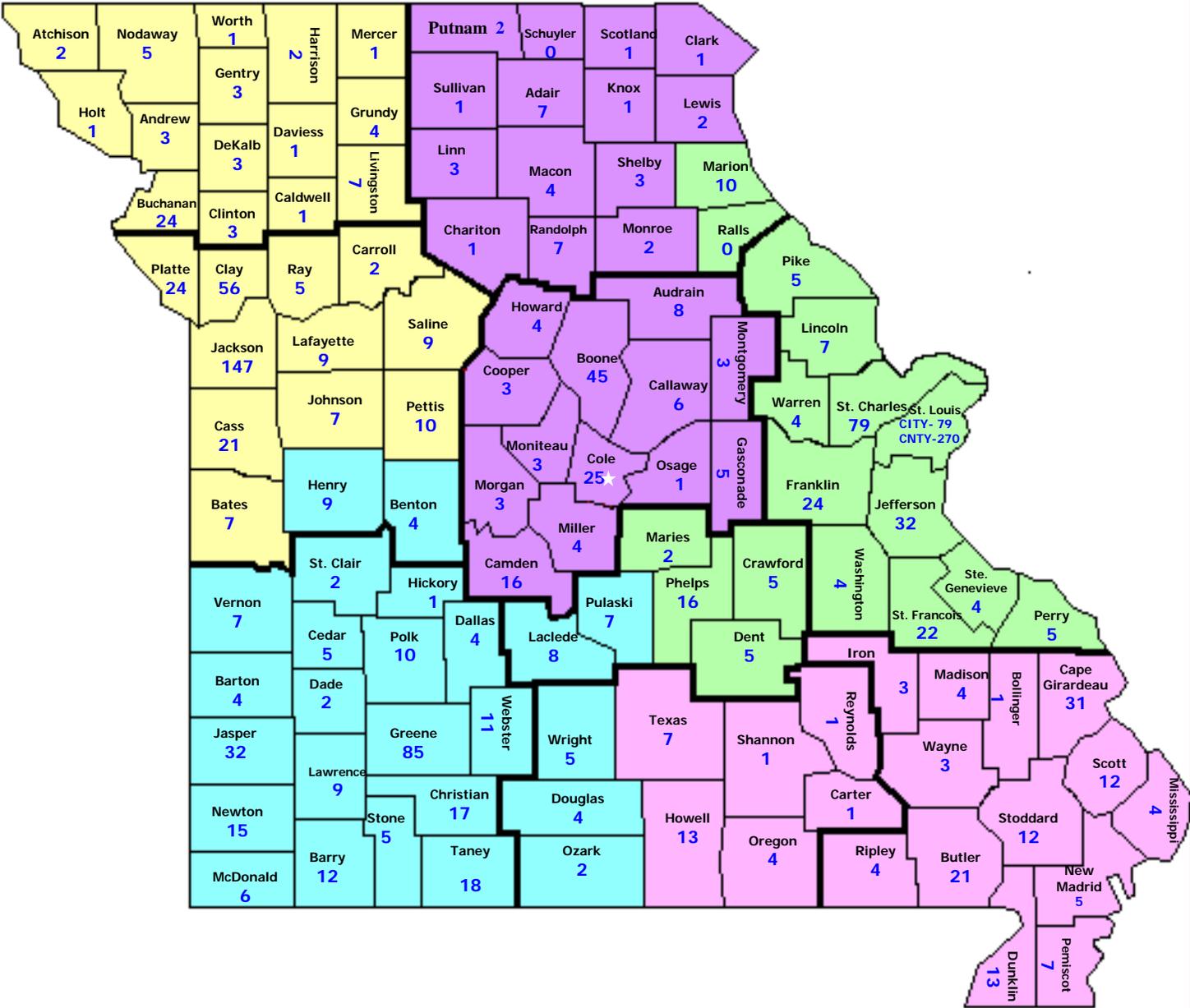


IN-STATE PHARMACIES BY CLASSIFICATION

|  |      |
|--|------|
| Class A - Community/Ambulatory           | 315  |
| Class B - Hospital Outpatient Pharmacies | 32   |
| Class C - LTC Pharmacies                 | 27   |
| Class D - Non-Sterile Compounding        | 32   |
| Class E - Radiopharmaceutical            | 14   |
| Class F - Renal Dialysis Pharmacies      | 6    |
| Class G - Medical Gas Pharmacies         | 0    |
| Class H - Sterile Products               | 21   |
| Class I - Consultant Pharmacy            | 7    |
| Class J - Shared Services Pharmacy       | 12   |
| Class K - Internet                       | 13   |
| Class L - Veterinary                     | 7    |
| Class M - Specialty (bleeding disorder)  | 0*   |
| Pharmacies with Multiple Classifications | 1038 |
| <b>TOTAL= 1,524</b>                      |      |

\* There were no pharmacies solely licensed as a Class-M pharmacy during FY15. However, several pharmacies held a Class-M permit in conjunction with other classifications and are included in the multiple classification category above.

# Missouri Pharmacies by County



Statistics to Note:

- ◆ Number of counties with 0 pharmacies: 2 (*Schuyler & Ralls County*)
- ◆ Number of counties with ≤ 10 pharmacies: 85
- ◆ Number of counties with 100+ pharmacies: 2 (*St. Louis & Jackson County*)

**Drug Distributor Summary:**

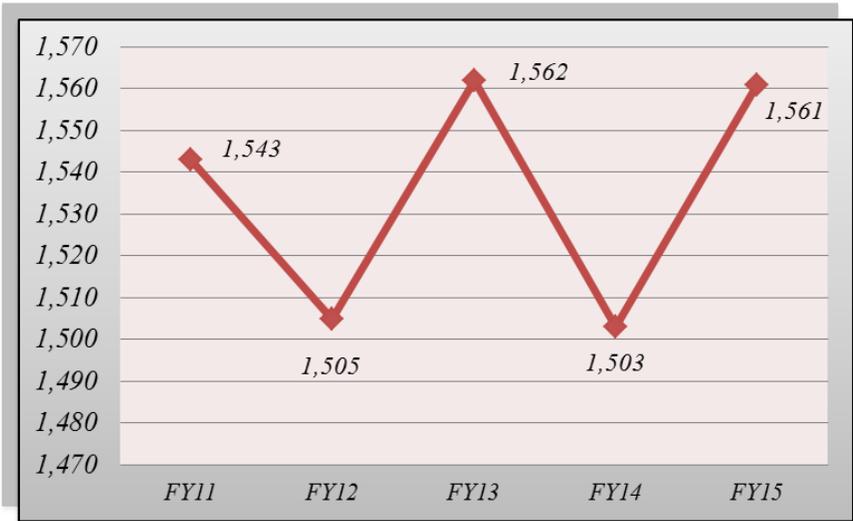
All in-state drug companies that ship/transfer legend pharmaceuticals are required to be licensed as a Missouri drug distributor. Additionally, any pharmacy that distributes legend drugs to an entity other than the consumer/patient (e.g., other pharmacies, physicians, etc.), must obtain a drug distributor’s license if the distribution exceeds 5% of the pharmacy’s total gross sales of legend products.

Out-of-state drug companies or manufacturers that ship/transfer legend drugs or devices into Missouri are also required to obtain an out-of-state Missouri drug distributor license. Upon application, out-of-state companies are issued a temporary license that is valid for one (1) year or until the application has been completely processed by this office, at which time, a permanent license is issued or the application is denied by the Board.

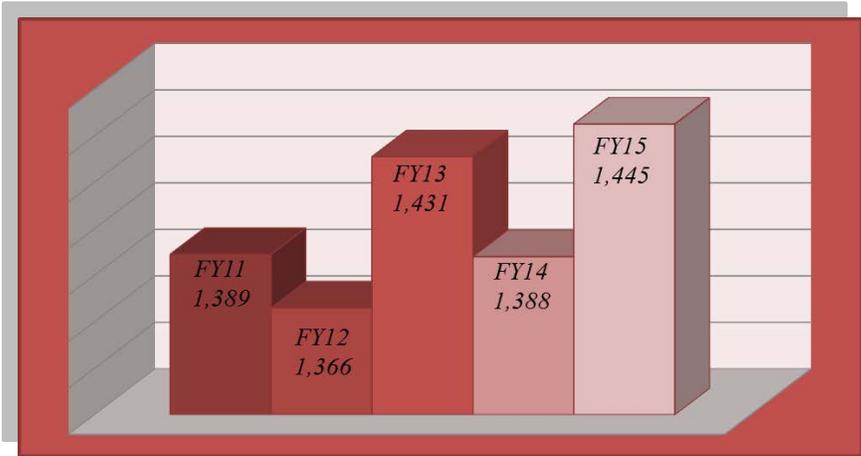
- The total number of licensed drug distributors and drug distributor registrants increased by 3.85% to 1,561 licensees/registrants. The number of drug distributors individually increased by 4.1% while the number of drug distributor registrants remained consistent reversing a historical decline.
- Although the Board experienced an overall increase in total drug distributors/registrants, the number of newly licensed drug distributors decreased by 25% while the number of new drug distributor registrants remained consistent.
- The Board continues to see an increase in drug distributor/registrants every two years which also corresponds with the fiscal year immediately following the biennial drug distributor renewal period.

| TOTAL DRUG DISTRIBUTORS/MANUFACTURERS (FY15) |              |
|--|--------------|
| Drug Distributors                            | 1,445        |
| Drug Distributor Manufacturer Registrants    | 116          |
| <b>TOTAL</b>                                 | <b>1,561</b> |

**TOTAL DRUG DISTRIBUTORS & DRUG DISTRIBUTOR REGISTRANTS BY FISCAL YEAR**



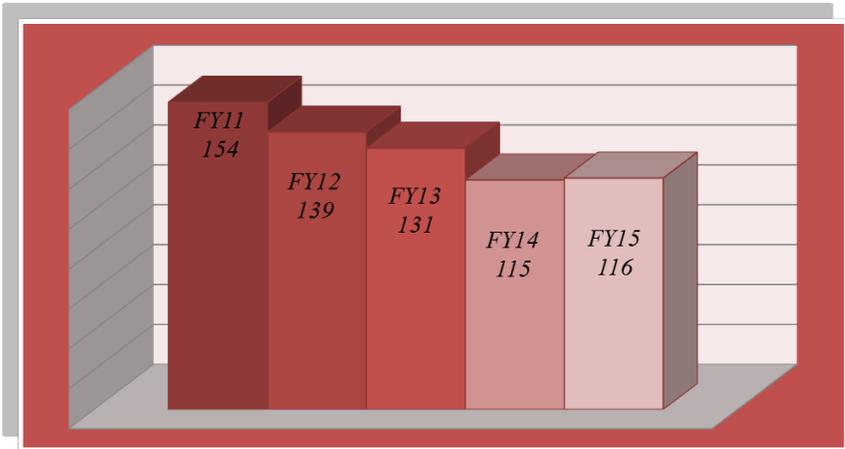
TOTAL DRUG DISTRIBUTORS BY FY



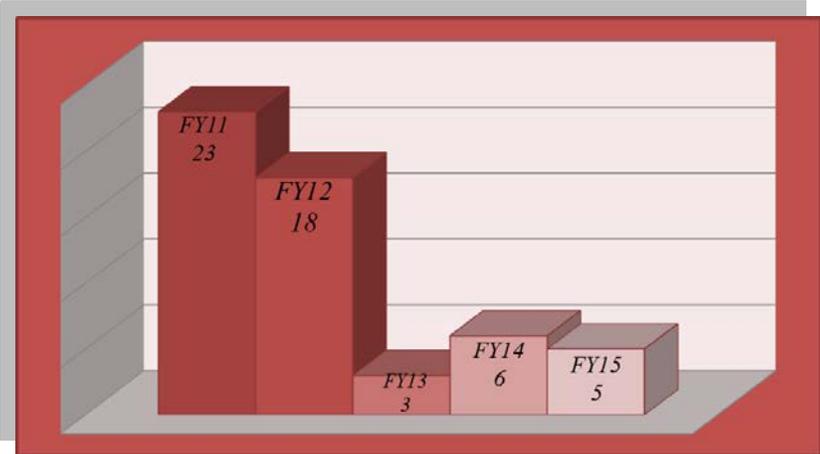
NEW DRUG DISTRIBUTORS LICENSED



TOTAL DRUG DISTRIBUTOR REGISTRANTS BY FY



NEW DRUG DISTRIBUTOR REGISTRANTS

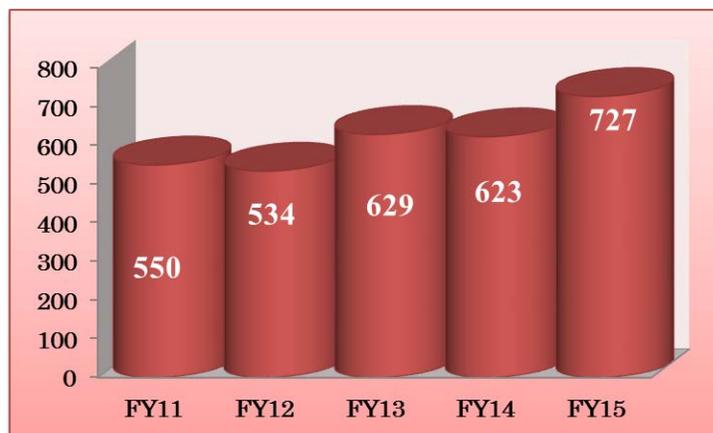


## Complaint Summary

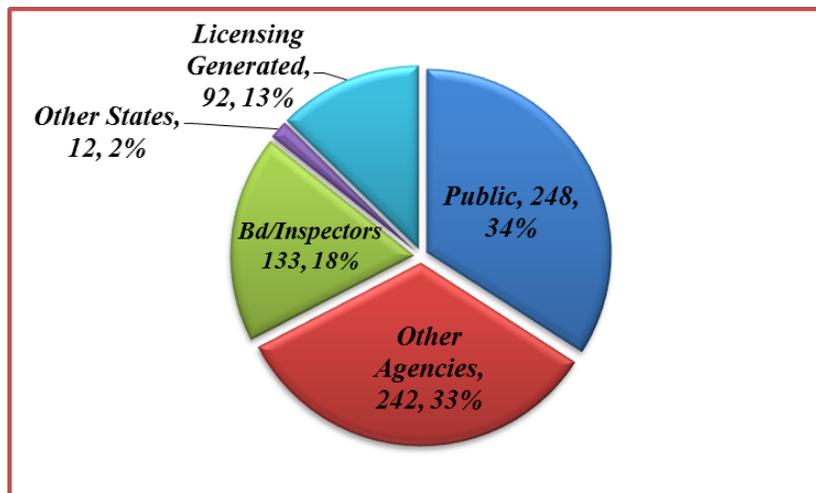
All matters investigated or officially reviewed by the Board are recorded as complaints and processed according to Board procedures. The Board received/opened 727 complaints in FY 15 representing a 13.3% increase in complaints handled.

- Of the 727 complaints handled, 490 complaints were practice-related complaints while 237 complaints were non-practice related Missouri Department of Revenue tax compliance cases.
- Of the 490 practice related complaints received:
  - 16.7% of the complaints involved dispensing errors [47] or improper dispensing [35]
  - 12% involved disciplinary action in another state [60]
  - 7% involved drug diversion [6], loss of drugs [6] or theft of drugs [24]
  - 6.9% involved immunization/administration [34]
  - 4% involved compounding [22]
- Complaints from the general public increased by 9% while complaints initiated by Board staff/ inspectors as the result of suspected/observed compliance violations increased 58%.

### Complaints Handled by FY



### Complaints by Source



## COMPLAINT HANDLING

### FY15 COMPLAINTS BY CATEGORY

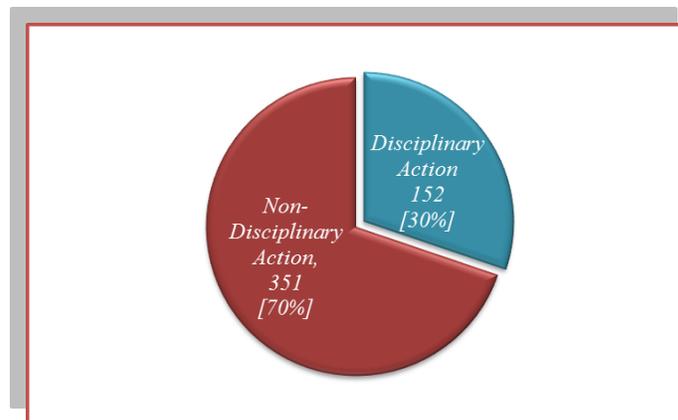
|  |            |
|--|------------|
| Adulterated Drugs                      | 2          |
| Advertising                            | 1          |
| Alcohol and Alcohol-Impaired Behavior  | 7          |
| Allowing Unlicensed Person to Practice | 4          |
| Audit Findings                         | 1          |
| Compounding                            | 22         |
| Confidentiality                        | 10         |
| Counseling                             | 1          |
| Criminal Convictions                   | 2          |
| Dispensing Error                       | 47         |
| Disciplinary Action in Another State   | 60         |
| Disciplinary Review Requests           | 2          |
| Diversion                              | 6          |
| Drug Distribution Violations           | 3          |
| Drugs                                  | 23         |
| Ethical                                | 2          |
| Expired Drugs in Inventory             | 1          |
| Felony                                 | 35         |
| Fraudulent Prescription                | 3          |
| Fraud-Unspecified                      | 1          |
| Immunization/Administration            | 34         |
| Improper Controls                      | 12         |
| Improper Dispensing                    | 34         |
| Insurance Fraud                        | 1          |
| Licensure Applicant                    | 45         |
| Loss of Drugs                          | 6          |
| Mental Reason                          | 1          |
| Misbranding                            | 1          |
| No Jurisdiction                        | 3          |
| Pharmacy Permit Violations             | 21         |
| Practicing Beyond Scope of License     | 1          |
| Practicing without a License           | 35         |
| Recordkeeping                          | 8          |
| Theft of Drugs                         | 24         |
| Theft of Money                         | 19         |
| Unauthorized Dispensing                | 8          |
| Unprofessional Conduct                 | 2          |
| Unsupervised Dispensing                | 1          |
| Violation of Disciplinary Order        | 1          |
| <b>TOTAL</b>                           | <b>490</b> |

## HISTORICAL COMPARISONS

|       | <i>Dispensing Errors</i> | <i>Improper Dispensing</i> | <i>Loss of Drugs</i> | <i>Pharmacy Permit Violations</i> | <i>Practicing w/o License</i> | <i>Diversion/Theft of Drugs</i> |
|-------|--------------------------|----------------------------|----------------------|-----------------------------------|-------------------------------|---------------------------------|
| FY 15 | 47                       | 34                         | 6                    | 21                                | 35                            | 30                              |
| FY 14 | 68                       | 15                         | 8                    | 16                                | 28                            | 26                              |
| FY 13 | 52                       | 27                         | 4                    | 20                                | 48                            | 35                              |
| FY 12 | 66                       | 41                         | 4                    | 13                                | 36                            | 31                              |
| FY 11 | 46                       | 41                         | 19                   | 6                                 | 27                            | 50                              |

## COMPLAINT DISPOSITIONS

The Board issued final dispositions on approximately 740 complaints in FY15 which included 237 Department of Revenue tax suspension complaints and 503 non-tax related complaints. \*\* The 503 non-tax related complaints were disposed of as follows:

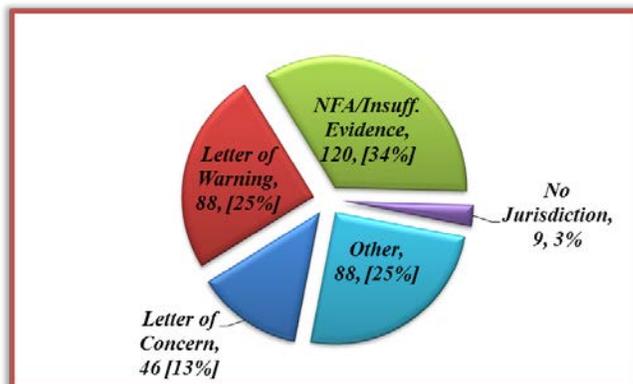


The ratio of non-disciplinary action vs. disciplinary action remained relatively consistent from FY14 when 73% of non-tax related complaints were closed without disciplinary action and 27% were closed with disciplinary action.

\* The 740 complaint dispositions includes complaints received in prior fiscal years but finally determined in FY15. As a result, the number of complaints disposed of will not equal the number of new complaints received.

## SUMMARY OF NON-DISCIPLINARY COMPLAINT RESOLUTIONS:

The following action was taken in the 351 non-tax related complaints closed without disciplinary action in FY15: (see *Disciplinary Action* section for complaints closed with disciplinary action)

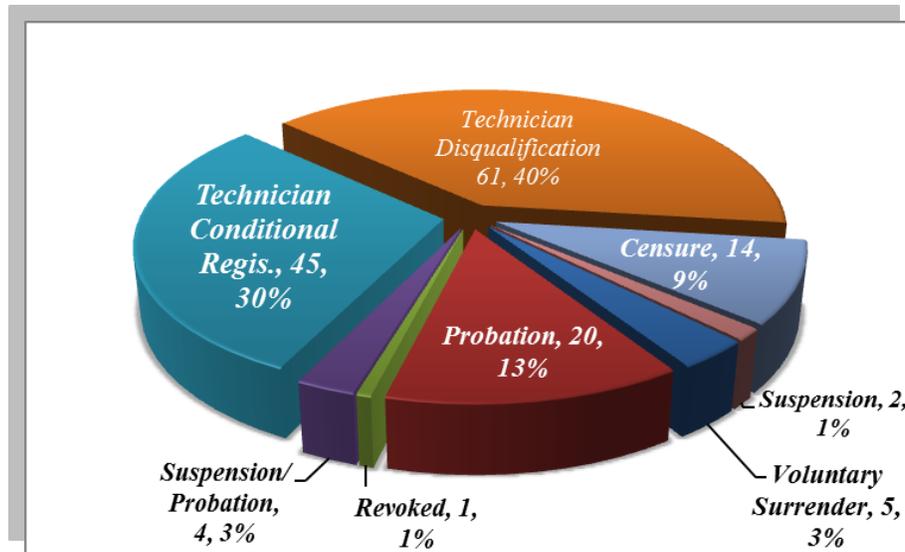


\* Other: Non-Administrative Letter [5], License Approved [52], Other [31]



***Summary of Disciplinary Action***

- The Board issued disciplinary action in approximately 389 cases in FY15, representing a 19% increase from FY14. One-hundred and fifty-two (152) of the disciplinary actions issued were practice related (39%). The remaining 237 cases involved non-practice related Department of Revenue tax suspensions (61%).
- One-hundred and six (106) pharmacy technicians, 17 pharmacists, 23 pharmacies and 3 drug distributors were disciplined for practice-related issues during FY15.
- The following action was taken in the 152 practice-related disciplinary actions issued:



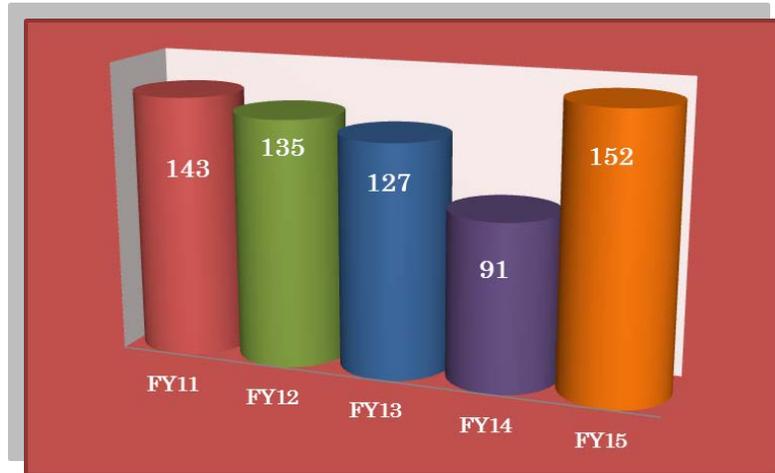
DISCIPLINARY ACTIONS BY CATEGORY

|   |            |
|---|------------|
| Pharmacists Suspended under § 324.010 (tax purposes)              | 5          |
| Interns Suspended under § 324.010 (tax purposes)                  | 1          |
| Technician Registrations Suspended under § 324.010 (tax purposes) | 231        |
| Technicians Disqualified  | 61         |
| Technicians Placed on Conditional Employment                      | 45         |
| Pharmacist Licenses Censured                                      | 5          |
| Pharmacist Licenses on Probation                                  | 5          |
| Pharmacist Licenses Suspended                                     | 2          |
| Pharmacist Licenses Suspended Followed by Probation               | 4          |
| Pharmacist Licenses Revoked                                       | 1          |
| Pharmacist Voluntary Surrender                                    | 5          |
| Pharmacy Permits Censured   | 9          |
| Pharmacy Permits on Probation                                     | 12         |
| Drug Distributor Licenses on Probation                            | 3          |
| <b>TOTAL</b>  | <b>389</b> |

## PRACTICE RELATED DISCIPLINARY ACTIONS \*

- Practice related disciplinary actions increased by 67% from FY14. Pharmacy technicians experienced the largest increase in practice-related disciplinary actions with a growth of 82.75%.

*(Total Practice-Related Disciplinary Actions by FY)*

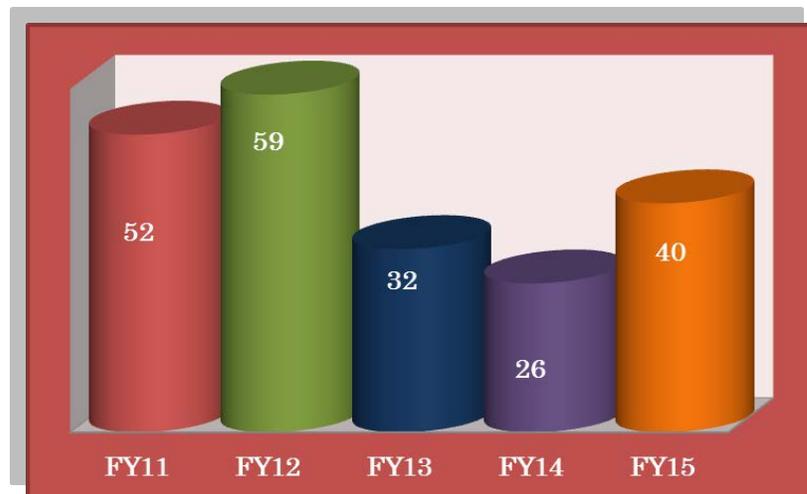


\* Does not include tax suspensions pursuant to § 324.010, RSMo.

## DISPOSITION BY SETTLEMENT AGREEMENT

- Twenty-six percent (26%) of practice related disciplinary actions were issued pursuant to a settlement agreement with the licensee, resulting in a 53.8% increase in disciplinary settlement agreements during FY15.

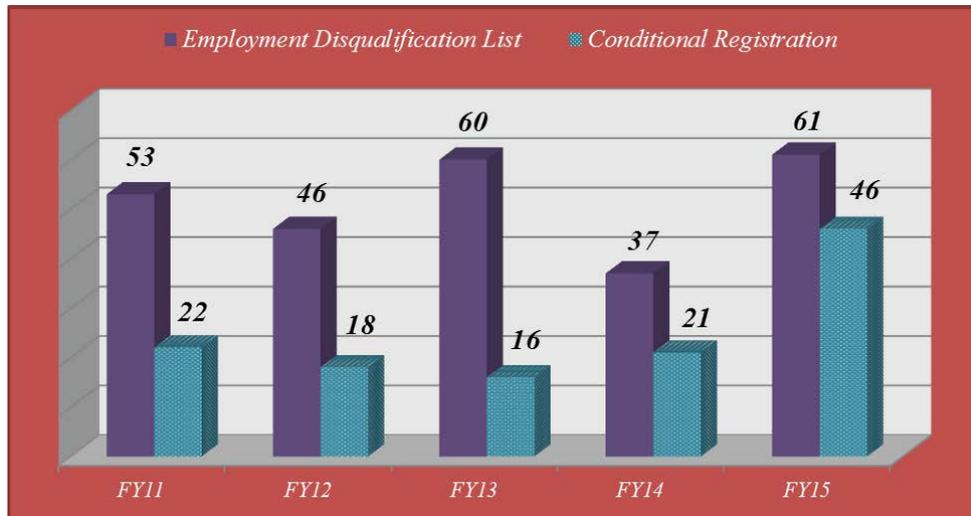
*(Disciplinary Settlement Agreements by FY)*



## PHARMACY TECHNICIAN DISCIPLINE

- Approximately 69.7% of practice related disciplinary actions in FY15 involved pharmacy technicians placed on the Employment Disqualification List or issued a conditional registration pursuant to § 338.013, RSMo.
- Practice-related disciplinary actions against pharmacy technicians experienced the largest disciplinary increase with a growth of 82.75%.

*(Practice Related Pharmacy Technician Discipline by FY)*



## EMPLOYMENT DISQUALIFICATIONS BY DISCIPLINARY GROUNDS *(Cause for EDL / # Disciplined)*

- Criminal History (26)
- Diversion (13)
- Illegal Drug Usage/Positive Drug Test (7)
- Theft (Non-Drug Related) (7)
- Misconduct/Unauthorized Dispensing (3)
- Misconduct/Fraudulent Prescriptions (2)
- False Application/Controlled Substance Violations (1)
- Illegal Drug Usage/Unauthorized Dispensing (1)
- Unlicensed activity (Working while suspended/expired) (1)

## CONDITIONAL REGISTRATIONS (CR) BY DISCIPLINARY GROUNDS *(Cause for CR/ # Disciplined)*

- Misconduct/Unauthorized Dispensing (22)
- Criminal History (13)
- Unlicensed activity (Working while suspended/expired) (1)
- Theft (Non-Drug Related) (7)
- HIPAA Violation (1)
- Prior admitted drug misuse (1)
- Misconduct/Improper drug use (1)

# DISCIPLINARY ACTIONS

## PHARMACIST DISCIPLINE BY FY

|                      | FY 11     | FY12      | FY13      | FY14      | FY15      |
|----------------------|-----------|-----------|-----------|-----------|-----------|
| Censure              | 9         | 8         | 11        | 7         | 5         |
| Probation            | 12        | 17        | 10        | 6         | 5         |
| Suspension           | 0         | 0         | 0         | 0         | 2         |
| Suspension/Probation | 14        | 9         | 5         | 2         | 4         |
| Revocation           | 1         | 2         | 2         | 2         | 1         |
| <b>TOTAL</b>         | <b>36</b> | <b>36</b> | <b>28</b> | <b>17</b> | <b>17</b> |

## PHARMACY DISCIPLINE BY FY

|                     | FY 11     | FY12      | FY13      | FY14      | FY15      |
|---------------------|-----------|-----------|-----------|-----------|-----------|
| Censure             | 8         | 3         | 4         | 2         | 9         |
| Probation           | 13        | 6         | 9         | 9         | 12        |
| Revocation          | 0         | 0         | 1         | 0         | 0         |
| Voluntary Surrender | 2         | 2         | 2         | 0         | 0         |
| <b>TOTAL</b>        | <b>23</b> | <b>11</b> | <b>16</b> | <b>11</b> | <b>21</b> |

## DRUG DISTRIBUTOR DISCIPLINE BY FY

|                     | FY 11     | FY12      | FY13     | FY14     | FY15     |
|---------------------|-----------|-----------|----------|----------|----------|
| Censure             | 3         | 7         | 0        | 0        | 0        |
| Probation           | 8         | 4         | 4        | 0        | 3        |
| Voluntary Surrender | 0         | 1         | 0        | 0        | 0        |
| <b>TOTAL</b>        | <b>11</b> | <b>12</b> | <b>4</b> | <b>0</b> | <b>3</b> |

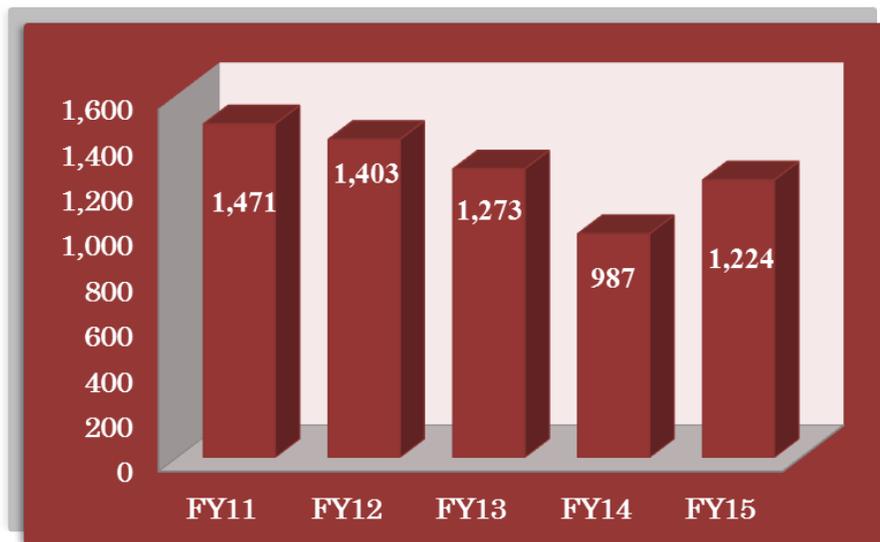


## *Inspection/Investigation Summary*

The Board conducts new and routine inspections of all Missouri located pharmacies and drug distributors. Board inspectors also conduct investigations as assigned.

- Board inspectors conducted 1,224 inspections of pharmacies and drug distributors throughout the state, representing a 24% increase from FY14.
- The Board continues to inspect all sterile compounding pharmacies annually.
- Board inspectors and staff completed a total of 228 investigations during FY15.

### Pharmacy/Drug Distributor Inspection Summary



### INSPECTION FINDINGS

At the conclusion of an inspection, the inspector may initiate one of the following resolutions:

- Observation Report: Issued if no compliance issues are identified at the time of inspection or if compliance violations are noted that can generally be corrected and do not require further review/documentation.
- Compliance Notice: Issued if compliance concerns are discovered that require official documentation of corrective measures or in instances of multiple or repeat compliance violations.
- Quality Assurance Report: Issued if there is a specific question regarding the dispensing/handling of a particular prescription and/or drug.
- Investigation: An investigation may be initiated during an inspection if additional factual information may be necessary to assess compliance.

## FY15 INSPECTION RESULT SUMMARY

- Violations were observed or a Compliance Notice was issued in approximately 72% of the Board's inspections as reflected below:



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



**Testing Summary**

In 2003, the Board initiated a program to test drug preparations compounded by pharmacies. All preparations are tested for potency and, if applicable, sterility and endotoxins. The tables listed below are for the fiscal year ending June 30, 2015:

| <i>Dosage Form</i>            | <i>Tests Performed</i> |
|-------------------------------|------------------------|
| <i>Aliquot powder</i>         | 1                      |
| <i>Capsule</i>                | 31                     |
| <i>I.V. solution</i>          | 4                      |
| <i>Implantable pellet</i>     | 1                      |
| <i>Injectable solution</i>    | 3                      |
| <i>Lollipop</i>               | 1                      |
| <i>Oral suspension</i>        | 6                      |
| <i>Suppository</i>            | 3                      |
| <i>Topical cream/ointment</i> | 6                      |
| <i>Troche</i>                 | 2                      |

| <i>Test Results</i>   | <i>Tests Performed</i> | <i>Percentage</i> |
|-----------------------|------------------------|-------------------|
| <i>Satisfactory</i>   | 45                     | 77.6%             |
| <i>Unsatisfactory</i> | 13                     | 22.4%             |
| <i>Total</i>          | 58                     | 100%              |

All unsatisfactory results were related to potency failures. An acceptable potency range is considered +/- 10% of the expected potency, unless a U.S.P. monograph states a different range for a specific preparation. Unsatisfactory potency results ranged from 13.36% to 258.0%. All unsatisfactory results were related to potency. Pharmacies are notified of unsatisfactory results and asked to complete a quality assurance review of their compounding practices and provide a corrective action plan.

| <i>Drugs With Unsatisfactory Results</i>                     |
|--|
| <i>Cyclobenzaprine/Gabapentin/Lidocaine/Prilocaine cream</i> |
| <i>Dantrolene oral suspension</i>                            |
| <i>Diethylstilbesterol capsule</i>                           |
| <i>Estradiol/Estriol/Estrone capsule</i>                     |
| <i>Estriol/Estradiol/Progesterone capsule</i>                |
| <i>Estradiol/Progesterone/Testosterone capsule</i>           |
| <i>Flecainide capsule</i>                                    |
| <i>Hydrocortisone/Neomycin suppository</i>                   |
| <i>Naltrexone capsule</i>                                    |
| <i>Nifedipine cream</i>                                      |
| <i>Quinacrine capsule</i>                                    |



**Rule Changes**

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The Board continued to review Missouri’s pharmacy rules to ensure appropriate and consistent regulation. The following rules were pending, approved and/or promulgated in FY15:

| <b>PROMULGATED RULES</b> |   |
|--------------------------|---|
| 20 CSR 2220-4.010        | General Fees                            |
| 20 CSR 2220-5.020        | Drug Distributor Licensing Requirements |

| <b>APPROVED RULES</b> <i>(Rules approved by the Board/Pending approval for filing)</i> |   |
|--|---|
| 20 CSR 2220-2.700  | Pharmacy Technician Registration        |
| 20 CSR 2220-6.080  | Medication Therapy Services by Protocol |

The Board also considered and received public comments on revisions to the following rules:

- 20 CSR 2220-2.090 (Pharmacist-In-Charge)
- 20 CSR 2220-2.100 (Collection of Medication for Destruction)
- 20 CSR 2220-2.200 (Sterile Compounding)

## Strategic Planning Initiatives

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As part of its regulatory mission, the Board holds an annual strategic planning meeting to assess Board operations and review Missouri's regulation of pharmacy practice. The Board's FY15 strategic planning meeting was held on July 16, 2014. As part of strategic planning, the Board voted to pursue the following legislative proposals during the 2014-2015 legislative session: \*\*

- Adverse Reactions: Would amend § 338.010, RSMo, to allow pharmacists to administer emergency medication to treat an adverse reaction after a vaccine or drug administered by a pharmacist.
- Implementation of the Drug Quality and Security Act: Would establish licensing requirements for third-party logistic providers as defined by the federal Drug Quality and Security Act.
- Disciplinary Authority: Would amend § 338.055, RSMo, to include additional grounds for discipline related to pharmacy practice.
- Mandatory Reporting: Would require Board licensees to report adverse licensing actions to the Board.
- Non-Resident Pharmacies & Drug Distributors: Would prohibit non-resident pharmacies and drug distributors from renewing their Missouri license/registration if the entity does not have a valid license in their home state.

\*\* All legislative proposals must be approved by the Governor prior to submission.

## Patient Safety

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The Board continued to promote its patient safety campaign designed to encourage and promote patient safety in pharmacy practice. As part of its ongoing efforts, the Board sponsored/hosted the following in FY15:

- In conjunction with the Center for Patient Safety, the Board conducted a statewide Patient Survey of all Missouri licensees and registrants utilizing the Community Pharmacy Survey on Patient Safety Culture issued by the Agency for Healthcare Research and Quality. Over 1,633 responded to the anonymous electronic survey. Responses were analyzed by the Center for Patient Safety and are under review by the Board's Patient Safety Advisory Group. The Patient Safety Advisory Group consists of a cross-section of pharmacy practice and representatives from consumer and industry advocacy groups.
- The Board co-sponsored Missouri's first Joint Regulatory Patient Safety Conference in conjunction with the Missouri Board of Nursing, the Missouri Board of Registration for the Healing Arts and the Missouri Dental Board. The free conference offered a forum for board members and healthcare providers to discuss effective patient safety tools and strategies. Presentations were given by patient safety leaders in Missouri and included sessions on the Second Victim Syndrome, Medication Reconciliation and a Regulatory Roundtable.