

Oregon Board of Pharmacy  
2015-17 Budget Presentation  
*(Governor's Budget)*



Joint Ways and Means  
Education Subcommittee  
February 16, 2015  
8:30 AM – Room H-170

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*“The mission of the Oregon State Board of Pharmacy is to promote, preserve and protect the public health, safety and welfare by ensuring high standards in the practice of pharmacy and by regulating the quality, manufacture, sale and distribution of drugs”.*

## **Executive Summary**

The Oregon Board of Pharmacy (OBOP), established in 1891 under ORS Chapter 689 regulates the practice of pharmacy and the commerce and quality of all prescription and non-prescription drugs within and into the State. The practice of pharmacy in the State of Oregon has been declared by the Oregon Legislature to be a professional practice affecting public health, safety and welfare and is subject to regulation and control in the interest of Oregon Citizens. The Legislature further declared it to be a matter of public interest and concern that the practice of pharmacy merit and receive the confidence of the citizens of Oregon and that only qualified persons be permitted to engage in the practice of pharmacy in the State.

The Board of Pharmacy consists of *seven* board members who are appointed by the Governor and subject to Senate confirmation, comprised of *two* public members and *five* pharmacists in active practice. The agency's staff currently consists of nineteen FTE. The [2015-17 proposed organizational chart](#) is located in the Appendix of this presentation on page 15. A detailed description of ongoing operational tasks can be found in the Governor's Balanced Budget binder.

## **Program Description**

The purpose of the Board of Pharmacy under ORS Chapter 689 is to promote, preserve, and protect the health, safety and welfare of Oregon citizens by control and regulation of the practice of pharmacy and the commerce and quality of drugs through outlets involved in the manufacture, production, sale and distribution of legend drugs (*prescription*), over-the-counter drugs (*non-prescription*), controlled substances (*drugs identified by the U.S. Drug Enforcement Administration (DEA) as having abuse or addiction potential*) and devices and other materials as may be used in the diagnosis, cure, mitigation, prevention and treatment of injury, illness and disease.

This is accomplished through:

**Examinations:** Any individual wishing to practice as a pharmacist in the State must take and pass an entry level competency exam, the North American Pharmacy Licensure Examination (NAPLEX). This exam has been standardized throughout all fifty states. Candidates for licensure in Oregon must also take and pass a pharmacy law exam, the Multistate Pharmacy Jurisprudence Examination (MPJE). These exams are administered by the National Association of Boards of Pharmacy (NABP). The exam questions are written and maintained and updated by OBOP staff and members through annual review of the exam question pool and psychometric analysis of the questions by NABP.

**Licensing:** Upon verifying that the exams have been taken and passed, the candidate is allowed to submit an application. The application and required documents are vetted through the NABP Disciplinary Clearinghouse and the OBOP completes an FBI criminal background check prior to issuing a license. Licenses are currently renewable annually, with the OBOP transitioning to biennial licensure for all "people" licenses over the next two years. The OBOP has established an electronic online renewal process for licensees. Pharmacy technicians must be licensed in the State and must become

nationally certified within one year of their initial Oregon license. Pharmacies, pharmaceutical manufacturers & wholesalers, non-prescription drug outlets, practitioner dispensing outlets and a variety of other drug outlets must also be licensed with the OBOP to do business in the State. Establishments seeking licensure undergo similar scrutiny and vetting of applications and documents for licensure.

Investigations: The OBOP investigates complaints and allegations of violations of the Oregon Pharmacy Act (ORS Chapter 689) and corresponding administrative rules (OAR Chapter 855). The OBOP also investigates allegations of drug diversion, illegal online drug distribution operations or unlicensed pharmacies and local prescription fraud activity.

Information and Education: All incoming phone calls are answered by a staff member and then routed to the appropriate person to respond. The OBOP staff receives questions from licensees, other healthcare professionals, the media and the public. OBOP staff also responds to many requests for appearances and presentations to pharmacy professional associations and pharmacy schools regarding pharmacy and drug law and licensing issues.

Agency costs are primarily reflected in staff payroll. Ongoing expenses for “services and supplies” are inherent and tend to not fluctuate significantly. Major cost drivers are described below.

Staffing is the largest single expenditure since what the agency does involves people working with people.

Instate travel is another cost. The OBOP’s authority is statewide; therefore, annual onsite inspections and investigations occur throughout the State. Board members also reside throughout the State, therefore, whenever meetings are held, some Board members are required to travel. Meetings are primarily held in Portland.

Administrative initiatives and projects such as budget preparation, document security, business continuity, workforce data, disaster planning, Program Funding Teams and cultural competence are some of the many activities that consume an increasing portion of staff time.

Legislative mandates utilize an increasing portion of staff time. Such Legislative mandates include revising rules for Naloxone dispensing and public health emergencies, bio similar and Health Professionals Service Program, among others.

Prescription drug abuse requires an increasing amount of staff time. Staff investigates illegal Internet drug distribution, local fraudulent prescription scams and diversion and theft of controlled substances from pharmacies. Many drug related issues such as these are also covered by the news media and requests for information, interviews and statements from Board members and staff are common.

Prescription drug overutilization in the form of opioid abuse and addiction continues to place significant pressure on state and local resources. Pharmacists are uniquely positioned to have a positive impact in reducing opioid abuse by utilizing the Oregon Prescription Drug Monitoring Program (PDMP) and communicating with health care

providers. The OBOP is currently working with the other health care boards to develop a strategy to increase PDMP utilization by all health care providers.

### **Major Changes in the Last 10 Years**

Longtime Executive Director Gary Schnabel retired in late 2013 and a new executive director, Marcus Watt was hired for the position in early 2014.

The agency is currently in the process of changing all of its “people” licenses from annual licensure to biennial licensure.

Federal regulations that influence the work of the OBOP and its licensees continue to force change. The DEA up-scheduling of Tramadol and Hydrocodone products, as well as FDA activities relating to pharmacy compounding have forced the Board to write rules and re-evaluate the ways that we regulate certain licensees.

Elimination of the Pharmacy Recovery Network in 2010. This program for impaired professionals was transitioned to the Health Professionals Service Program (HPSP) within the Oregon Health Authority; however not all at risk individuals are eligible for the HPSP program, so the Board continues to monitor these individuals through probation agreements.

The reinstatement of the Pharmacist Consultant position in 2013-2015 has had a significant effect on the Boards ability to work proactively to identify and address issues that impact it. Board staff is now able to react to evolving issues more quickly and develop strategies to address them more efficiently.

### **Process Changes for Efficiency**

Examples of changes the Board has implemented in the past few years to save resources and create efficiency include:

- In process of moving all “people” licenses to biennial licensure with a completion date of July 2016.
- Early adoption of the electronic fingerprint system developed at the direction of the Legislature.
- Revision of Board meeting dates to more efficiently utilize staff.
- Renewed focus on succession planning within the agency.
- Cross-training of some staff to allow for better resource allocation.
- Increased use of the Board’s website to provide self-inspection forms that were previously printed and mailed annually.
- Move to a flat-rate agreement with the Department of Justice
- Move to online banking.
- For more efficient orientation of new employees, complete and detailed desk manuals have been created for key positions.
- Continue to move towards paperless operations and record storage.
- Implemented more categories for online license renewals for interns and non-prescription drug outlets.
- The Board continues to primarily conduct the Board’s meetings in Portland, rather than in locations around the state in order to reduce travel expenses.

- The Board continues to utilize a facilitator for strategic planning only every other year, instead of every year, to control costs.
- Executive Director or designee meets monthly with other Health Professional Regulatory Boards to foster interagency communication, eliminate duplication and share resources.

### **2015-17 Program Priorities**

The Agency is budgeted as one Program Unit. For management efficiency, we have broken out the key areas of agency function, which include:

- Operations and Administration
- Licensing
- Compliance
- Board member activities
- Interagency activities

All areas are by their nature intricately connected and required to accomplish the statutory mission of the agency.

### **To Achieve the Agency's Mission and Deliver Services to Oregonians**

Agency staff engages in a variety of ongoing operational responsibilities to achieve the Agency's mission and deliver regulatory services to Oregonians. The 2015-17 Governor's Budget supports these activities adequately based on current projections. These operational responsibilities and services include:

- Efficient management of office and agency
- Efficient processing of examinations & licenses
- Perform regular pharmacy inspections
- Provide responsive research, information & assistance services
- Provide effective regulatory efforts
- Provide responsive consumer & other stakeholder services

Boards of pharmacy, unlike other health regulatory boards, are required to interface and interact with many other state and federal regulatory agencies including:

- U.S. Food and Drug Administration (FDA), with federal authority over prescription, and non-prescription drugs and devices
- U.S. Drug Enforcement Administration (DEA), with federal authority over controlled substances
- State health regulatory Boards for every discipline with the authority to prescribe, dispense, administer or possess drugs and devices.

Boards of pharmacy also uniquely differ from other health regulatory Boards in that they:

- regulate the licensed professional individual
- regulate the quality, distribution, and commerce of products and services and register the various types of drug outlets.

This dual role creates a variety of unique circumstances affecting pharmacy boards which are not shared by the other health regulatory Boards.

The Agency continues to work with NABP to promote and develop content for the AWARxE website <http://www.awarerx.org/> which provides information for consumers on counterfeit medications, prescription drug abuse and medication safety issues. This year, the Board also participated with NABP to link to a [Red Flag video](#) that helps pharmacists identify signs of drug seeking behavior, drug diversion and prescription forgeries. Pharmacists play a critical role in limiting inappropriate entry of controlled substances into the population. This video can also be accessed from our home page, [www.oregon.gov/pharmacy](http://www.oregon.gov/pharmacy).

### **Short Term Plan & Environmental Factors**

As previously mentioned, the Board of Pharmacy has an annual Strategic Planning Session during which the board members and staff review the priorities for the next two years. The Board's current strategic priorities include: Telemedicine, awareness of and rapid response to new technologies, medication reconciliation, a renewed customer service focus, technician duties, auto refills, prescription fraud, medication errors, non-pharmacy dispensing, and succession planning.

Current environmental factors include: Expanding automation and technology in drug distribution, Increasing prevalence of practitioner dispensing, increasing complexity and scope of investigations, changing pharmacist and pharmacy technician roles within Coordinated Care Organizations (CCO's), Accountable Care Organizations (ACO's) and challenges to drug supply security and integrity.

### **Legislation**

The following are 2015 proposed legislation that may impact the agency:

HB 2298 – Permits pharmacists to provide pharmacotherapy services to patients. Requires health insurers to provide payment or reimbursement for services provided by pharmacist under clinical pharmacy agreement. Defines “clinical pharmacy agreement.”

HB 2033 – Directs the Board to adopt rules to classify any synthetically manufactured cannabinoid as a controlled substance in Schedule 1.

HB 2558 – Directs the Board to adopt rules making nicotine a Schedule III controlled substance. Provides for phase-in of penalties by the Board.

SB 147 – Changes communications requirement for pharmacy or pharmacist that substitutes biological product. Requires pharmacy to provide notice of potential substitution.

SB 148 – Changes the State Board of Pharmacy membership to include one licensed pharmacy technician and remove one member of the public. Declares emergency, effective on passage.

SB 230 – Makes law requiring certain health care workers to submit demographic, education and other information to health care worker regulatory boards apply to all health care workers...upon renewal.

### **Program Justification and Link to 10-Year Outcome**

The Board of Pharmacy is linked to the Governor’s Safety outcome area.

Desired Program Outcomes:

1. The security and integrity of the drug supply in Oregon is maintained.
2. Oregon pharmacists are adequately trained, appropriately licensed and professionally competent.
3. Oregon citizens have convenient access to high quality professional pharmacy products and services.

Because of the efforts and diligence of the OBOP in administering the Oregon Pharmacy Act and the Oregon Controlled Substances Act, the safety of Oregon’s citizens is enhanced and protected. Active participation by Board members and staff with the DEA, the U.S. Food and Drug Administration, and NABP evokes national best practice standards on behalf of Oregonians.

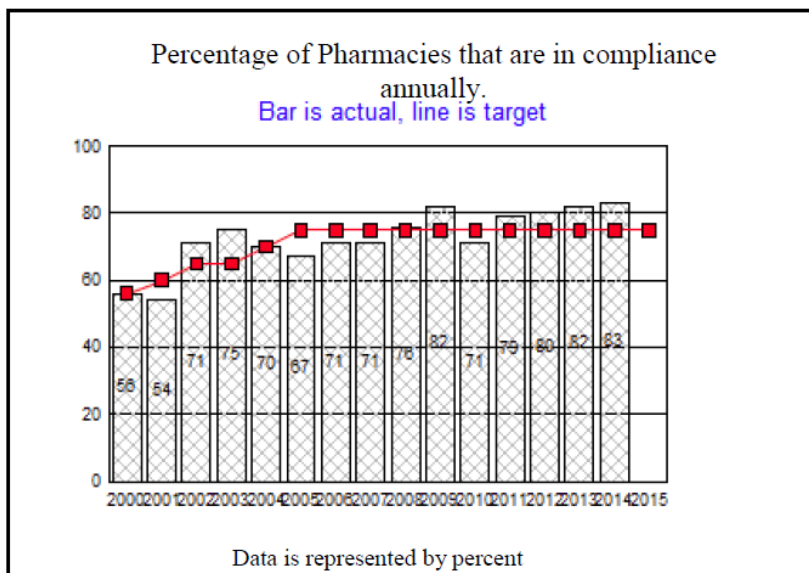
### **Agency Key Performance Measures**

#### Goals

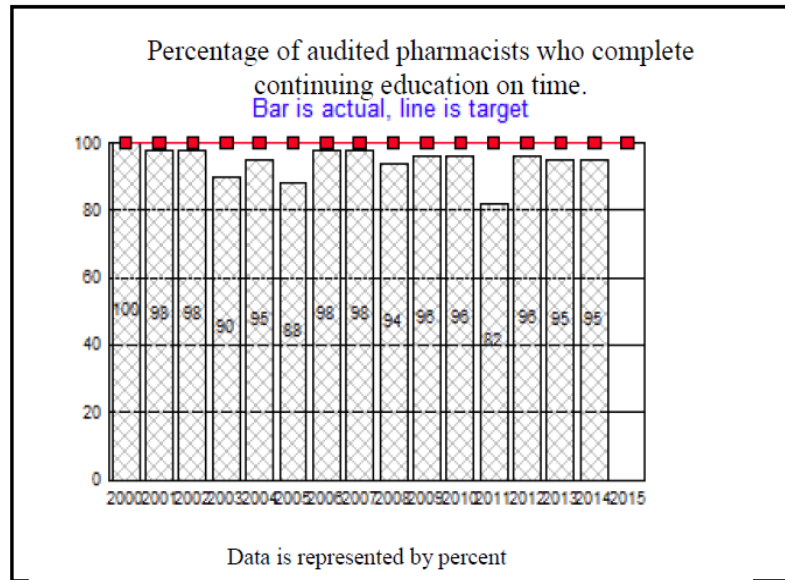
The Agency has identified three long-term strategic goals to align with Key Performance Measures (KPM) that are consistent with its mission statement and that will provide direction for ongoing activities and resource allocation. The goals and measures are:

1. Protect consumers by regulating the practice of pharmacy and the distribution of drugs;

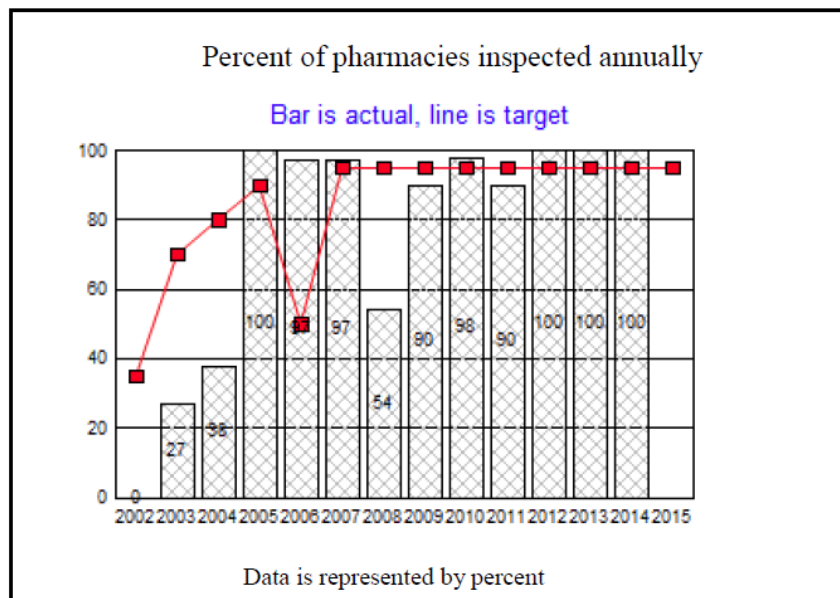
KPM #1 - Percent of annually inspected pharmacies that are in compliance with pharmacy laws & rules



KPM #2 - Percent of audited pharmacists who have completed their continuing education on time



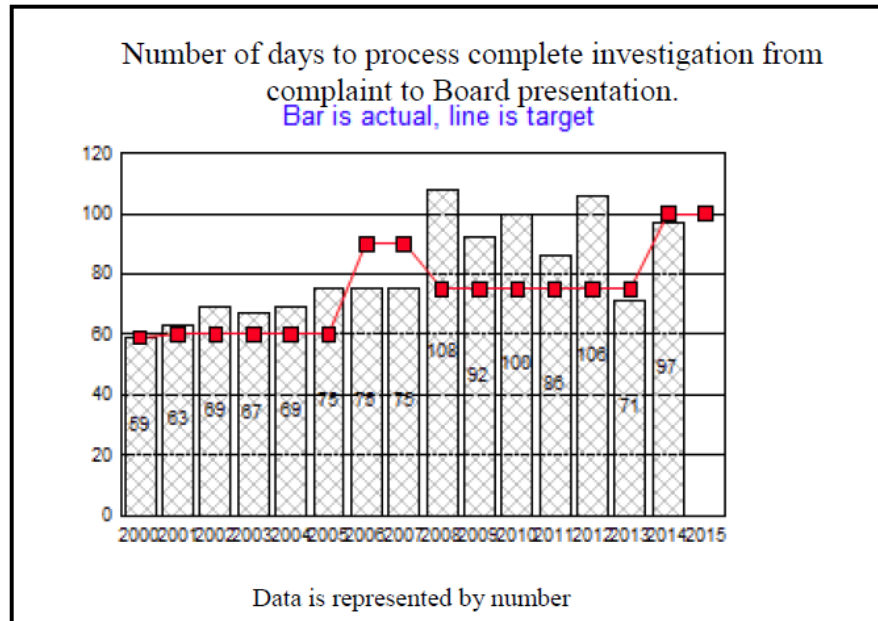
KPM # 3 - Percent of pharmacies inspected annually





2. Provide excellent customer service; and,

KPM #4 - Average number of days required to complete an investigation. The target for this measure was increased to 100 days by the 2013 Education Ways and Means Committee. Statutorily, this requirement is 120 days or an exception must be documented by the Board.

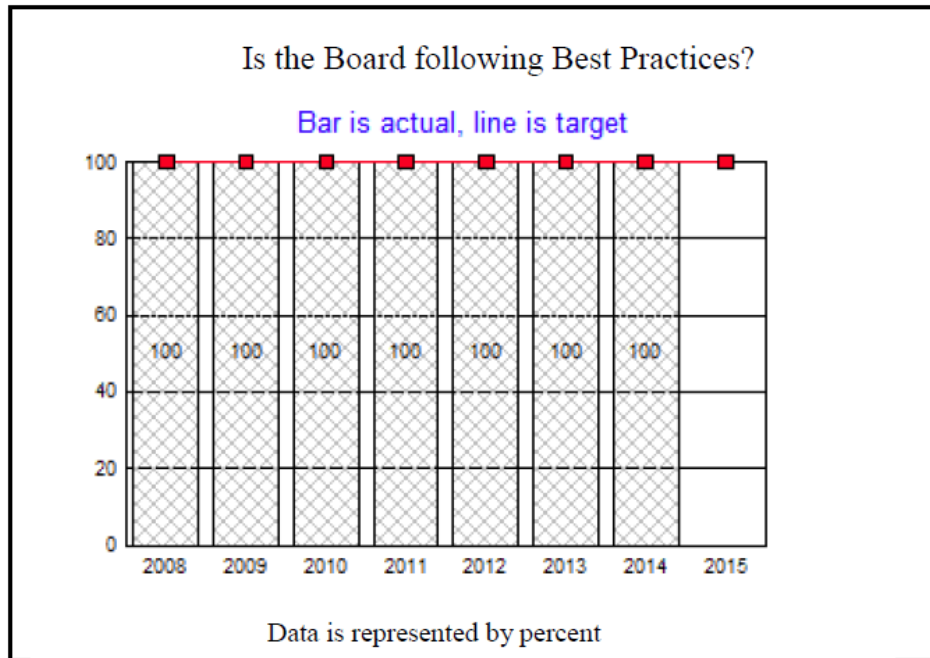


KPM #5 - Percent of customers rating their satisfaction with the agency’s customer service as “good” or “excellent”; overall, timeliness, accuracy, helpfulness, expertise, availability of information.



3. Conduct business in a manner that supports a positive environment for the pharmacy industry.

4. Follow board best practices (established by the 2007 Legislature)  
KPM #6 - Percent of total best practices met by the Board.

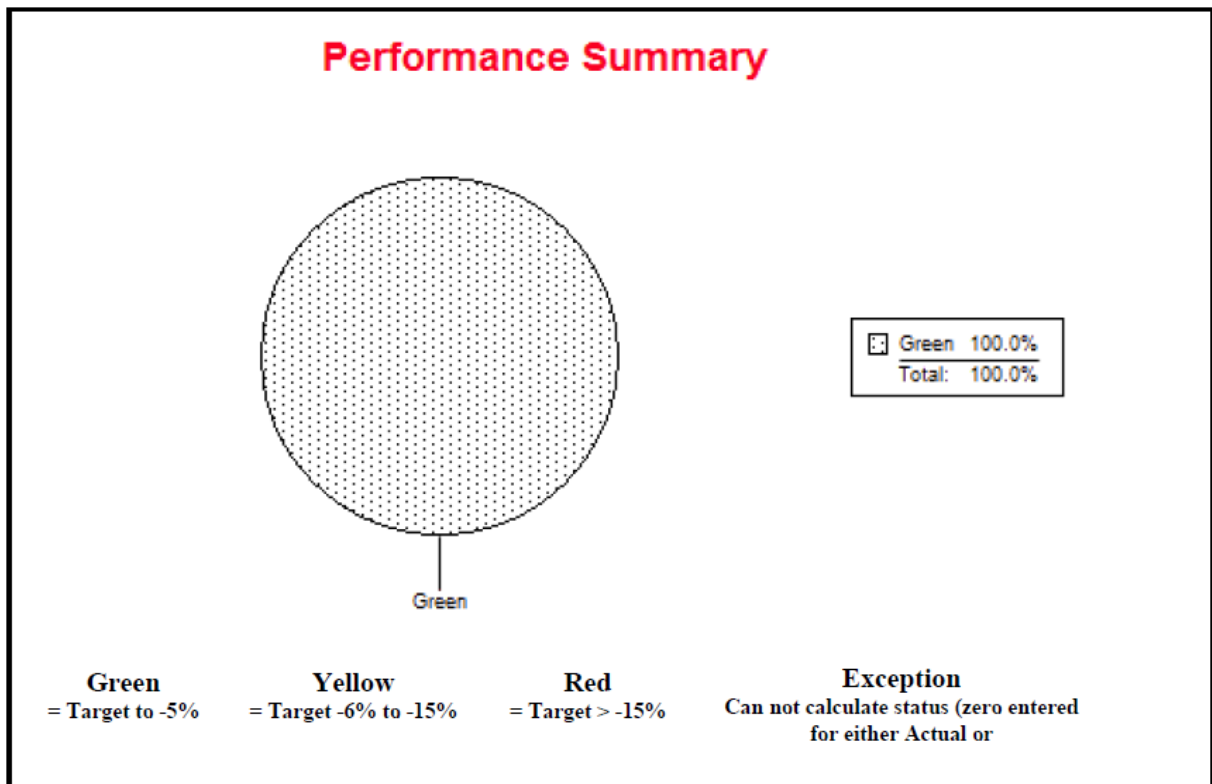


In its ongoing efforts to achieve these goals the Board will:

- Continue to assure the competency level of pharmacists through testing, peer review, and improved continuing education
- Maximize the use of onsite inspections of the various drug outlets
- Focus on timely investigation of consumer complaints and allegations of diversion and other drug distribution violations and medication dispensing errors.
- Work closely with the Medical, Nursing, Dental, Optometry, Naturopathic and Veterinary Boards and their Associations (i.e. health professions with authority to prescribe drugs), the Oregon State University College of Pharmacy and the Pacific University College of Health Professions School of Pharmacy, and the state and federal drug enforcement agencies in the ongoing effort to eliminate the diversion of drugs from legitimate distribution channels to illegal street markets and harmful recreational use (*prescription drug abuse*).

To measure the Agency's progress toward achieving its stated goals, the Board continues to track the outcome measures listed above. The Agency Management Report for KPM's reporting year 2014 (*calendar year 2013 data*) indicates the following:

Over all, the 2014 report continues to reflect the Agency is meeting all Key Performance Targets.



A complete copy of the [2014 Annual Performance Progress Report](#) that reflects 2013 data can be found in the Governor’s Budget Binder starting at page 33.

**2015-17 Budget**

The Board’s 2015-17 proposed budget includes an Other Fund expenditure limitation request of **\$6,872,049**, a 16.93% increase over the 2013-15 Legislatively Adopted Budget.

The following Packages support the agencies activities and provide opportunities for a transition to biennial licensure, changing personnel needs, database upgrade & improved customer service, enhanced liability coverage for IT Professional Services and a continuation of the 13-15 paperless solution. Packages 090, 100, 101 and 103 all support recommendations identified in the 2012 Operational Review.

2015-17 Essential Packages

**Package 090 Analyst Adjustments**

This package reduces the Other Fund revenue estimate to provide for a transition to biennial licensure for Pharmacists, Pharmacy Technicians and Certified Oregon Pharmacy Technicians at a reduced rate. This package will allow the Board to adjust the workload associated with two of its largest renewal cycles to alternate years and allow the Board to reduce its large ending balance that resulted from an accounting error in the 2009-11 biennium. This change will result in improved operational

efficiencies and customer service. It is not expected to negatively impact consumer protection as the Board has added additional reporting requirements during the interim and adjusted standards for continuing education accordingly. This change will impact a onetime reduction in revenue for each category adjusted and achieve a reduction to ending balance as required by the Agency's 2013-15 Legislatively Adopted Budget. The conversion to biennial licensure is being implemented in April 2015 for Pharmacists and the other categories will follow in 2016. The savings for the other categories will be realized in the revenue estimates for 2017-19 as part of the ongoing plan to reduce our ending balance. The total Other Fund revenue reduction is anticipated to be approximately -\$806,548.

### **2015-17 Policy Packages**

#### **Package 100 Personnel Management**

The package adds one new position (1.0 FTE) to meet the growing and changing personnel needs of the agency, as well as the Services and Supplies associated with adding new personnel. This package also includes resources to contract with the Department of Administrative Services (DAS), Enterprise Human Resource Services in 2015-17 and increases funding for the "other differential" budget object for the Executive Director and the Compliance Director positions in order to align compensation with market rates and address salary compression in the agency. These were approved by the Department of Administrative Services (DAS) Director and the Chief Human Resources Office (CHRO). The new position is responsive to the 2012 Agency Operational Review recommendations. The total cost of this package is \$363,604.

#### **Package 101 Business Improvement Database Upgrade**

The purpose of this package is to upgrade the Agency's Licensing and Compliance database and enhance online e-government opportunities for applicants and licensees, as well as improve the online Licensee Look Up & Verification system. This upgrade enhances the Boards current database that was implemented in 2003. This proposed change will shift to a more advanced web-based platform and increase options for expansion and configuration. This proposal includes adding two suites that will eliminate the need for hybrid systems for online renewals and license verifications to be created and maintained external to the database. The upgrade will also allow us to configure online applications, applicants will be able to check the status of their license applications online and licensees will be able to renew and make changes to their home address, telephone, email or employer changes. These are things that are not all possible today with our existing program. This package has been reviewed by the Chief Information Office and is recommended for approval. Note the Board received a unique one time civil penalty in July 2014 which will more than cover the expenses associated with this policy package. This will allow us to upgrade our systems with no additional cost to our licensees. The total cost of this package is \$316,756 (Note – a large portion of this funding is designated as IT Capital Outlay).

#### **Package 102 IT Professional Services**

This package is created to meet the DAS Risk Management recommendation to require increased Professional Liability Insurance limits for IT Professional Service providers to cover any damages by an error, omission or any negligent acts of the Contractor, its sub-contractors, agents, officers, or employee's performance under their contract. The

combined single limit per occurrence shall not be less than \$100,000. Annual aggregate limit shall not be less than \$250,000. The total cost of this package is **\$25,000**.

### **Package 103 Paperless Records Retention Part 2**

This package continues the Board's 13-15 policy package to move toward paperless records retention and establishes permanent funding to operate. During the current biennium, the Board implemented its contract for the State Archives Oregon Records Management Solution (ORMS) and has contracted to scan all licensing files. ORMS requires end users to use HPTrim for records management, staff is being trained to use HPTrim now and it is used to access all of the scanned electronic records. Once the document scanning conversion is complete, staff will be equipped to create and index new records for ongoing continuity for electronic recordkeeping and long term records retention. The state contract requires a monthly per user fee for access to HPTrim for all users. As more agencies utilize this enterprise contract, the individual user fee will eventually decrease. The cost of this package is: **\$22,770**.

### **Ending Balance**

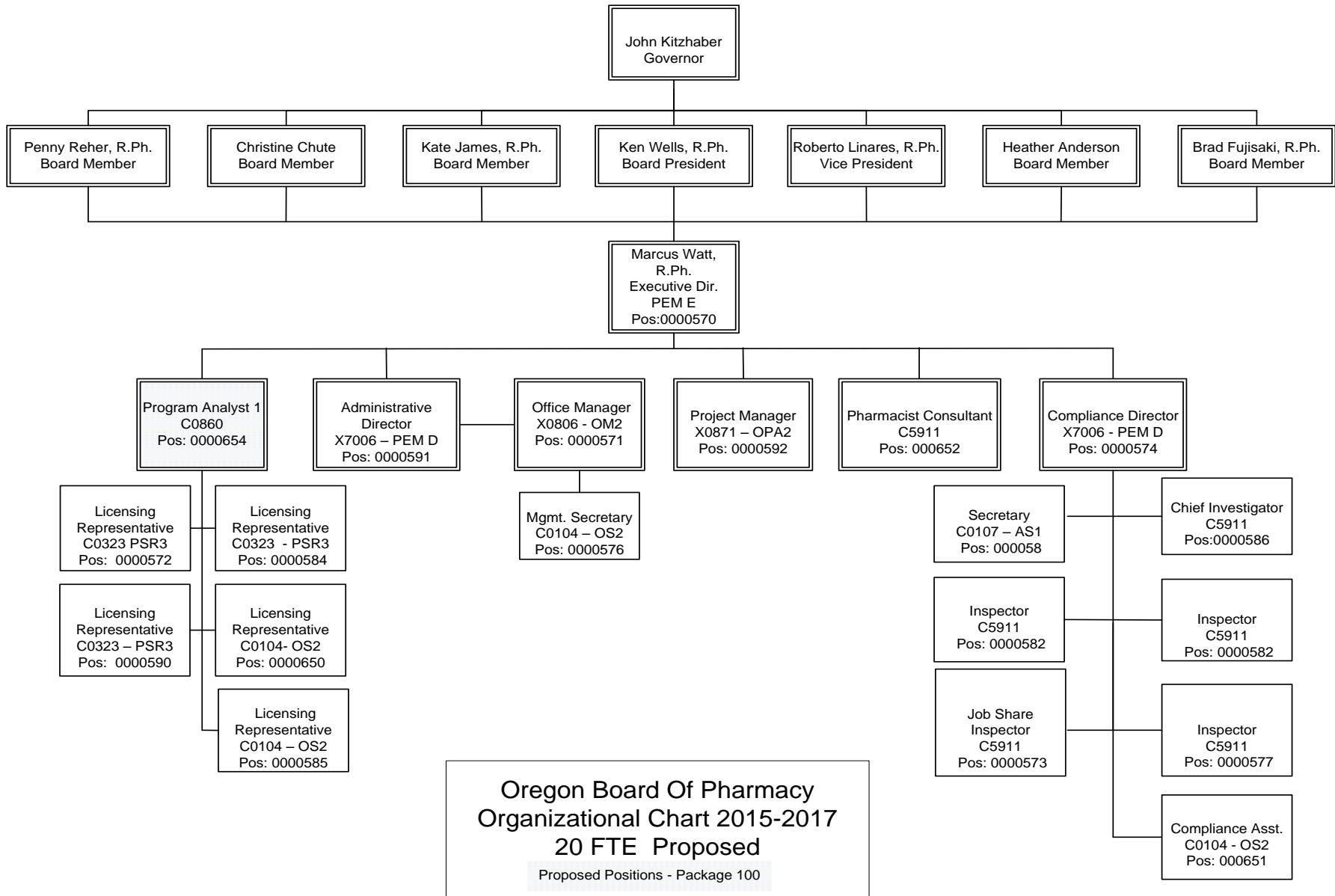
Assuming the Governor's Budget is approved, the Board will have a 9.52 month ending balance at the end of 2015-17 or \$2,726,616.

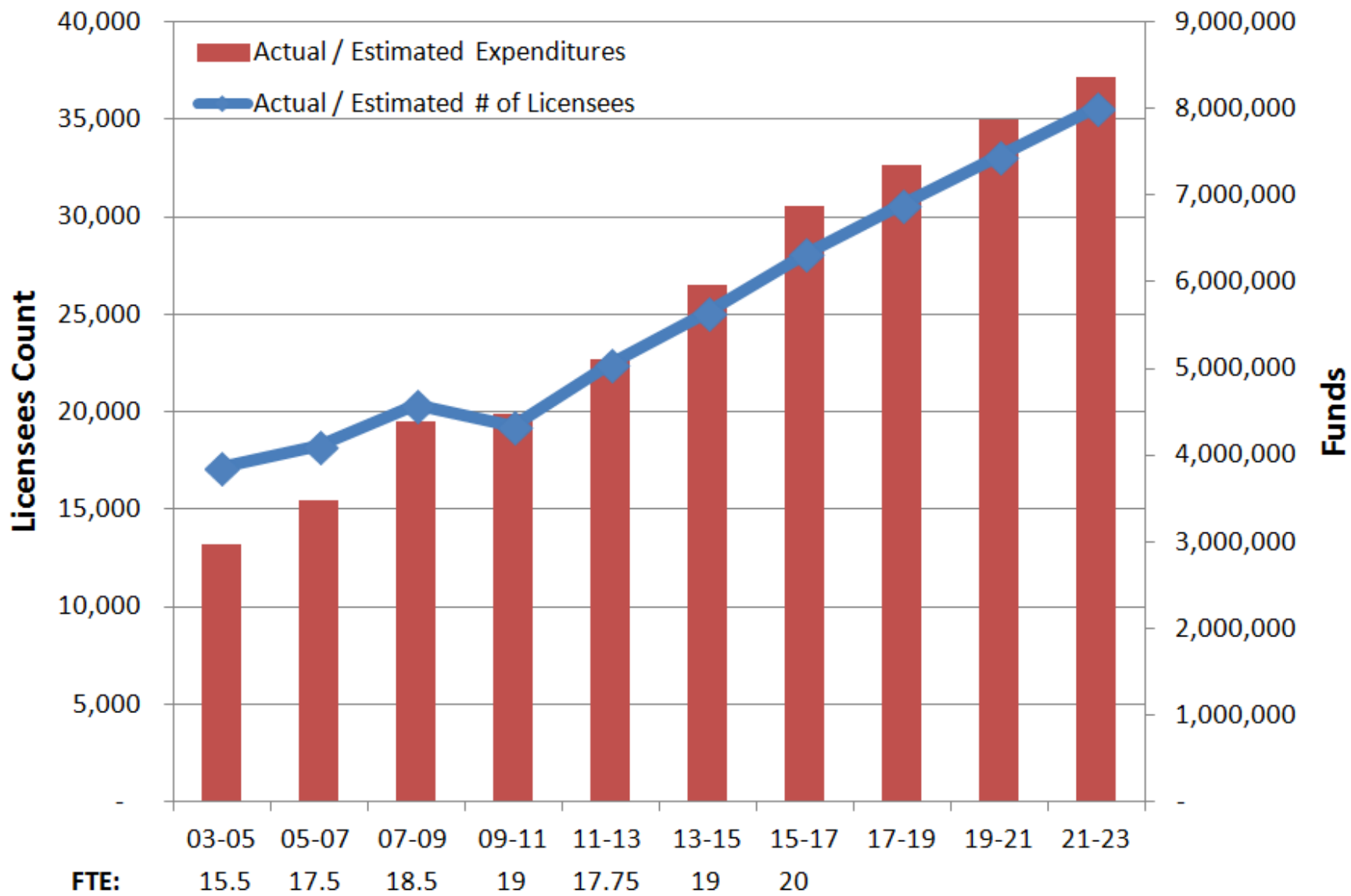
Note: The 2013-15 Legislatively Adopted Budget includes a temporary reduction of fees that had been approved and implemented in 2011-13. The Board implemented fee reductions beginning in May of 2013 to further reduce the impact of a growing ending balance and proposes to continue those fee reductions in 2015-17. The move to biennial licensure combined with not changing the license fee will also help reduce the ending balance as previously noted.

The Board's revised 2013-15 ending balance is projected to be higher than anticipated in part due to a unique one time civil penalty in the amount of \$540,304.75 received in July 2014 for a pharmaceutical manufacturer case we assisted the Department of Justice in to achieve voluntary compliance that resulted in a settlement in excess of \$2.3 million dollars that was allocated to a number of different agencies to further public health. As noted in Policy Package 101, if this package is approved, this settlement will more than cover the cost of the package with no additional cost to our licensees.

## APPENDIX

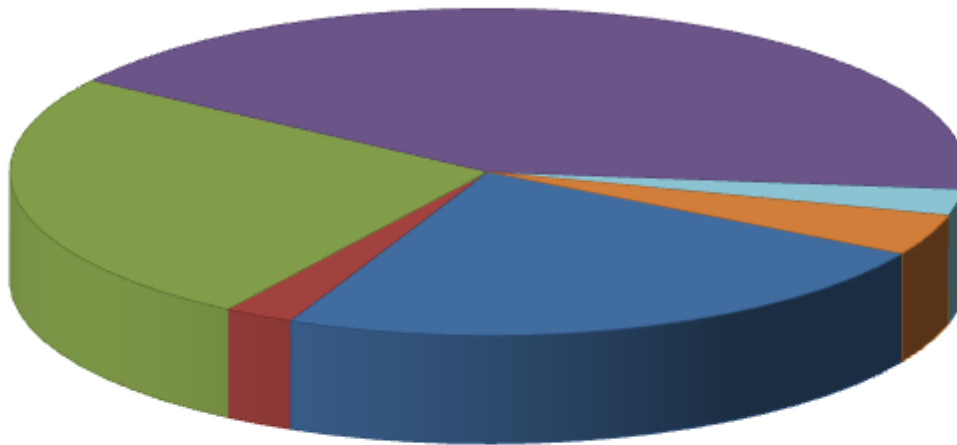
- Page 15 - Organizational Chart
- Page 16 - Licensee count / Funds /FTE
- Page 17 - 15-17 Program Allocation
- Page 18 - 15-17 Expenditures by type
- Page 19 - Licensee Category by type
- Page 20 - Compliance Cases 2004
- Page 21 – Top Compliance Categories
- Page 22 - 2013-15 Recruitment/New Hire Information
- Page 23 - 2013-15 Reclassifications & Position Changes
- Page 24 - Ending Balance Form







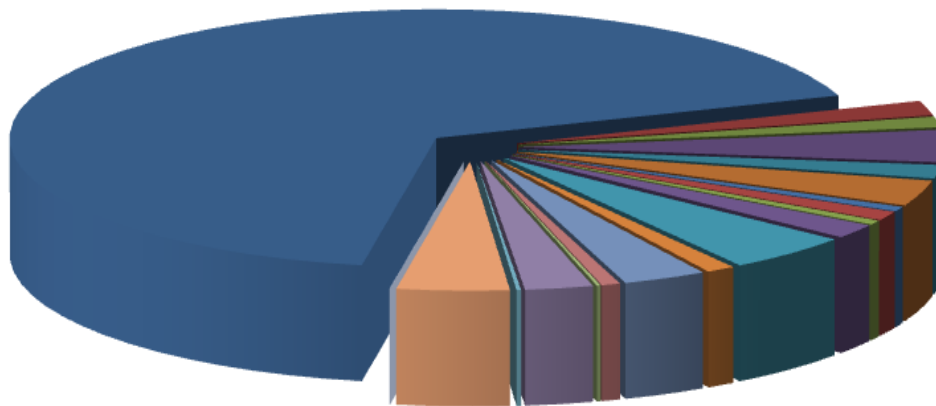
## 2015-2017 Program Allocation



- Operations & Admin 23.42% (Includes fingerprinting \$221,248 pass-thru) \*
- Board Member Activities 2.38%
- Licensing 25.33%
- Compliance 42.23%
- Health Professionals Service Program (HPSP) 2.57%
- Capital Outlay (IT - Database Upgrade) 4.06%

\* InterAgency Activities – Payment for PMP & WDC of \$349,445 are now reflected in revenue as a pass through

## 2015-2017 Expenditures by Type \$6,872,049

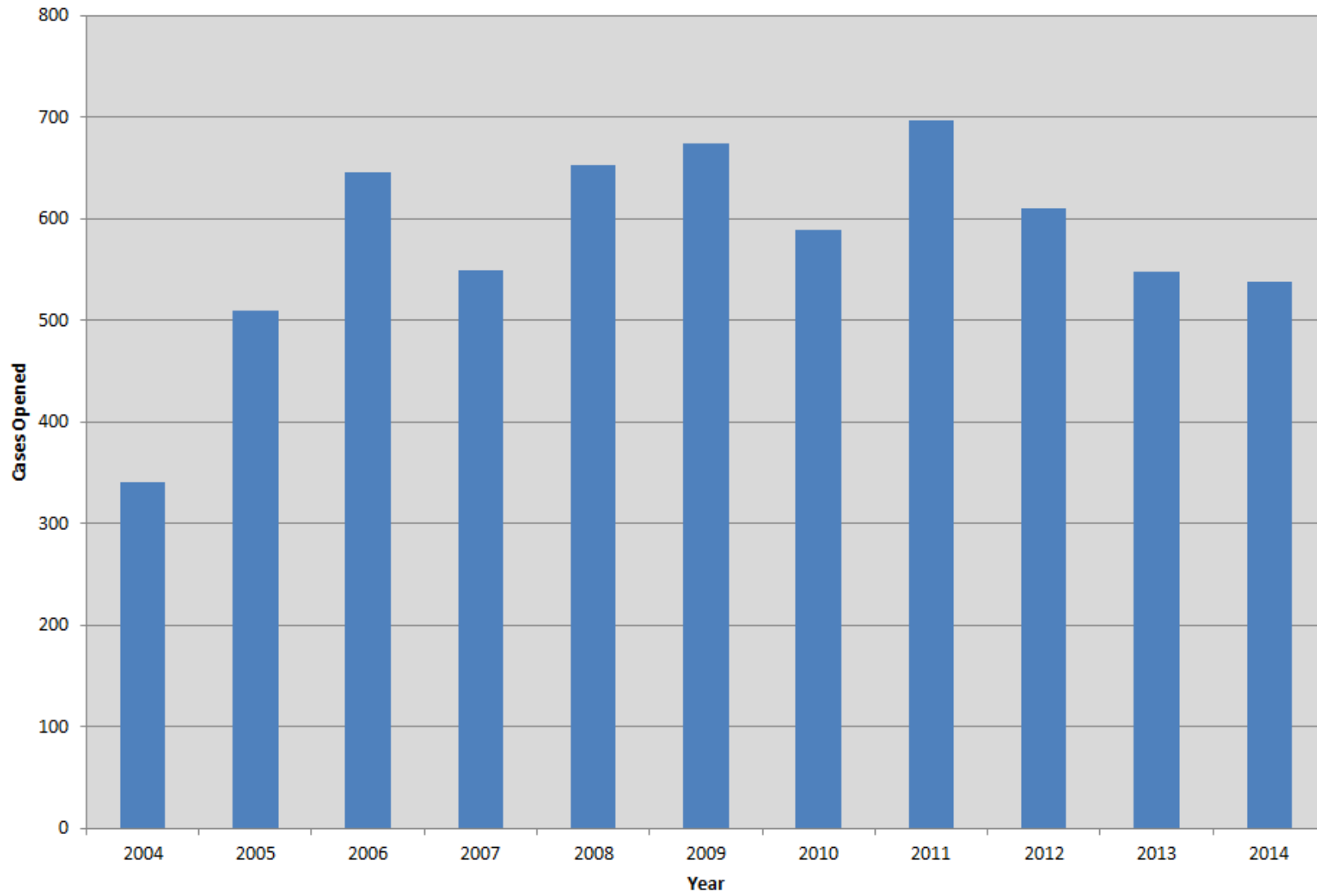


Personel	66.87%
Travel	1.84%
Data Processing & Telecommunications	5.41%
Capital Outlay (IT - Database Upgrade)	4.06%
Prof. Services/Hearings Panel	1.70%
Agency Program Related S & S (Fingerprinting)	3.22% *PASS THRU
IT Expendable Property	.59%
IT Professional Services	1.14%
Publicity & Publications	.55%
Office Expenses/Supplies (Includes Storage Fees & Postage)	1.80%
Attorney General	4.78%
State Government Service Charges	1.08%
Facilities & Rent	3.17%
Employee Training	.71%
Expendable Property	.15%
OHA Health Professional's Service Program	2.57%
Other Special Payments	.17%
Other Services & Supplies	4.25%
Medical Services & Supplies	.02%

The budget is comprised of 67% for Personnel, 29% for Services and Supplies and 4% for Capital Outlay.



### Compliance Cases 2004-Present



**2014 Top Discipline Categories**

58	Dispensing Errors
24	Unprofessional Conduct
14	Personal Diversion
12	Unregistered Drug Outlet
11	Grounds for Discipline
9	Fraud or Misrepresentation
8	Patient Counseling
8	Theft
7	Prospective Drug Utilization Review
6	Illegal Use of Drugs
6	Labeling Requirements Wrong Directions for Use
6	Theft Drugs, Medications, or Devices
5	Confidentiality
5	Customer Service
5	Habitual or Excessive Abuse

**2013-2015 Recruitment/New Hire Information**

Name	Date	Position Number / Position	Classification	Step Hired	Comments
Hill, Kathryn	10/11/13	0000584 Licensing Representative	C0323 Public Service Rep 3	Step 4 \$2546	<i>.5 Job Share, Kate was hired at step 4 to with many years of experience working at another health licensing board.</i>
Karbowicz, Fiona	11/25/13	0000592 Pharmacist Consultant	C5911 Healthcare Investigator/Advisor	Step 5 \$8214	<i>Lateral hire into a new position, same classification and salary range – original hire date 3/14/11.</i>
Thorsen, Susan	1/7/14	0000585 Receptionist	C0104 Office Specialist 2	Step 5 \$2702	<i>Susan was hired at step 5 with many years of experience in explaining rules, regulations, requirements and processes.</i>
Cooper, Brianne	1/21/14	0000577 Pharmacy Inspector	C5911 Healthcare Investigator/Advisor	Step 4 \$7952	<i>Brianne was hired at step 4 to get closer to market salary ranges. The Board does not currently hire any pharmacist into this class at less than step 4.</i>
Emerson, Devin	5/15/14	0000590 Licensing Representative	C0323 Public Service Rep 3	Step 4 \$2584	<i>Devin is currently licensed as a Certified Pharmacy Technician. His education, experience and knowledge of the licensing process warranted step 4.</i>
Watt, Marcus	2/3/14	0000570 Executive Director	MEAHZ7008 PEM E	Step 9 \$8450	<i>+ Differential of \$3033.00 required for hiring purposes, this was negotiated thru DAS.</i>
Hummel, Jennifer	7/13/14	0000585 Licensing Representative	C0323 Public Service Rep 3	Step 4 \$2584	<i>Returned to the agency after 7 months to the prior salary range.</i>
Arigbon, Bayo	11/5/14	0000650 Licensing Representative	C0323 Public Service Rep 3	Step 4 \$2636	<i>Bayo was hired at step 4 with many years of experience in explaining rules, regulation, requirements and processes.</i>

### **Reclassifications and position changes implemented during 2013-15**

- 1) The Project Manager position #0000592, classification X0854, SR 26 was reclassified with 2013 Legislative Approval to an Operations Policy Analyst, classification X0871 – SR27.
- 2) The Receptionist position #0000584, classification C0103, SR12 was reclassified with 2013 Legislative Approval to a Office Specialist 2, classification C0104, SR15.
- 3) Office Specialist 2 position #0000650 was increased from .75 FTE to a 1 FTE with 2013 Legislative Approval.
- 4) Position #0000650, was also reclassified from C0104, Office Specialist 2, SR 15 to a C0323 Public Service Representative 3, SR15 by the Department of Administrative Services in 9/2014 for consistency purposes within the Licensing Representative positions. There was no fiscal impact.

