

Oregon Board of Pharmacy
2019-21 Budget Presentation
(Governor's Budget)



Joint Ways and Means
Education Subcommittee
February 12, 2019
8:30 AM – Room H-170

Presented by:
Joseph Schnabel,
Pharm D., R.Ph., BCPS
Executive Director

Karen S. MacLean
Administrative Director

“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. In addition, the Board has authority and responsibilities contained in ORS Chapter 475, the Uniform Controlled Substances Act to oversee drugs with abuse or addiction potential and the research and scheduling of controlled drugs in Oregon. The practice of pharmacy in the State of Oregon is declared 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 *nine* board members appointed by the Governor and subject to Senate confirmation, comprised of *two* public members, *five* pharmacists and *two pharmacy technicians* in active practice. In addition, 2017 HB 2397 added the *seven* member Public Health and Pharmacy Formulary Advisory Committee made up of *three* pharmacists, *two* physicians and *two* advanced practice nurses. This Committee, appointed by the Governor was established to review concepts for a formulary or protocol whereby pharmacists may safely prescribe for Oregon patients and make recommendations to the Board for adoption by rule. The agency's staff currently consists of *twenty* FTE.

The 2019-21 Proposed Organizational Chart is located in the Appendix of this presentation on pages 17 and 18 and includes two new positions. A detailed description of ongoing operational tasks can be found in the agency Governor's Budget binder.

Summary of Program

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 pharmacist 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. All “people” (pharmacist, technician and intern) licenses now renew on a biennial cycle. The OBOP has an established electronic online renewal process for most licenses. Pharmacy Technicians must obtain experience and become nationally certified within two years of initial Oregon licensure, then apply to be a Certified Oregon Pharmacy Technician to continue working as a technician. All “outlet” registrations renew annually. Pharmacies, pharmaceutical manufacturers & wholesalers, non-prescription drug 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 all complaints and allegations of violations of Oregon law (ORS Chapters 689) and corresponding administrative rules (OAR Chapter 855), as well as any violations of state (ORS Chapter 475) or federal laws and rules related to controlled substances.

Information and Education: Customer Service is one of the Board’s high priorities. All incoming phone calls are answered by a staff member, and then routed to the appropriate personnel for assistance. This differentiates us from other Boards of Pharmacy. The OBOP staff receives questions from licensees, other healthcare professionals, the media and the public. The Board has a philosophy of compliance through education and responds to many requests for appearances and presentations to pharmacy professional associations and pharmacy schools regarding pharmacy and drug law and licensing issues. The Board conducted 60 outreach programs altogether in 2017 and 2018.

Public Health and Pharmacy Formulary Advisory Committee: This new Committee’s role is to evaluate concepts for recommendation for the Board of Pharmacy to adopt by rule of protocols, drugs and devices fitting for pharmacists to prescribe to Oregon patients. OBOP staff support the committee’s work by preparing the concepts for review, public meeting requirements and then taking the recommendations in the form of draft rules to the Board for rulemaking consideration.

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:

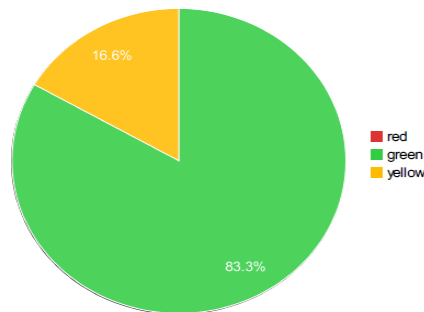
- Goal #1: Protect Oregon consumers by regulating the practice of pharmacy and distribution of drugs
- Goal #2: Provide excellent customer service
- Goal #3: Conduct business in a manner that supports a positive environment for the pharmacy industry

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*)

The Board has six Key Performance Measures:

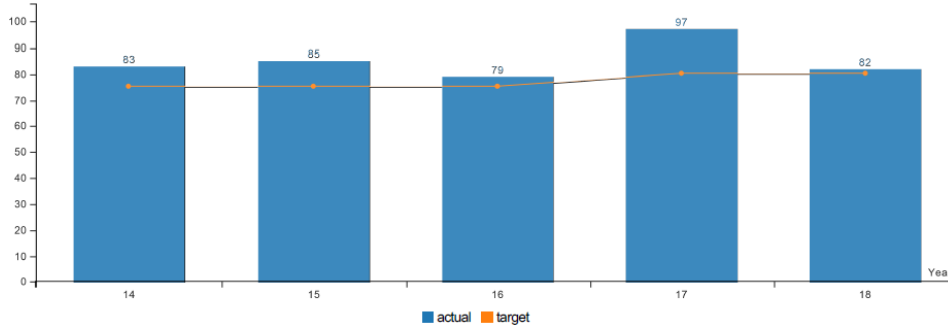
- 1) Percent of annually inspected pharmacies that are in compliance with pharmacy laws & rules
- 2) Percent of audited pharmacists who have completed their continuing education (CE) on time
- 3) Percent of pharmacies inspected annually
- 4) Average number of days required to complete an investigation.
- 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.
- 6) Percent of total best practices met by the Board.



Performance Summary	Green	Yellow	Red
	= Target to -5%	= Target -5% to -15%	= Target > -15%
Summary Stats:	83.33%	16.67%	0%

The chart above reflects that overall, our agency targets and actual performance is very close to expected outcomes. Four of the six measures we currently have measure the performance of the Board, measures #3-6. Measures #1-2 are dependent on the licensee’s ability to comply with Agency laws and rules upon inspection or audit.

Measure #1 - Percent of inspected pharmacies that are in compliance annually.

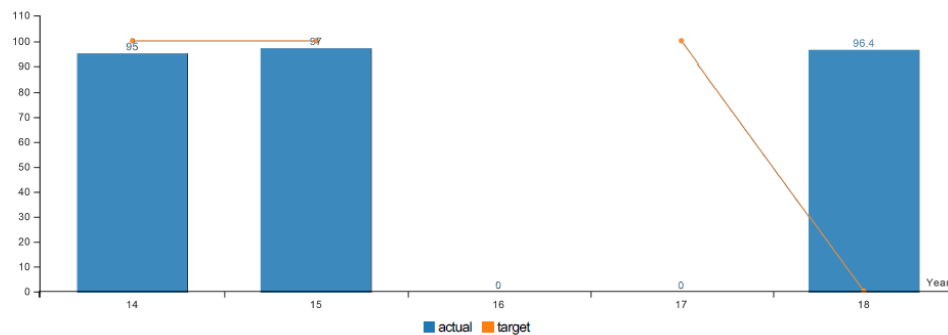


Report Year	2014	2015	2016	2017	2018
Percentage of Pharmacies that are in compliance annually.					
Actual	83%	85%	79%	97%	82%
Target	75%	75%	75%	80%	80%

Measures #1 and #3 relate to the number of pharmacies in compliance upon inspection and the number of pharmacies inspected annually. Board Inspectors utilize an annually updated Pharmacy Self-Inspection report as a tool for inspections. Those pharmacies that are not in compliance upon inspection have the opportunity to correct violations of best practices within 30 days. If corrective action is not completed, the Board will review violations for possible disciplinary action. The Board reviews this information throughout the year as a regular activity during the Compliance portion of each regularly scheduled Board meeting. Staff uses this information to assist with workload balancing and to measure our progress towards achieving key performance measures.

Measure #2 - Percent of audited pharmacists who complete continuing education on time.

* Upward Trend = positive result

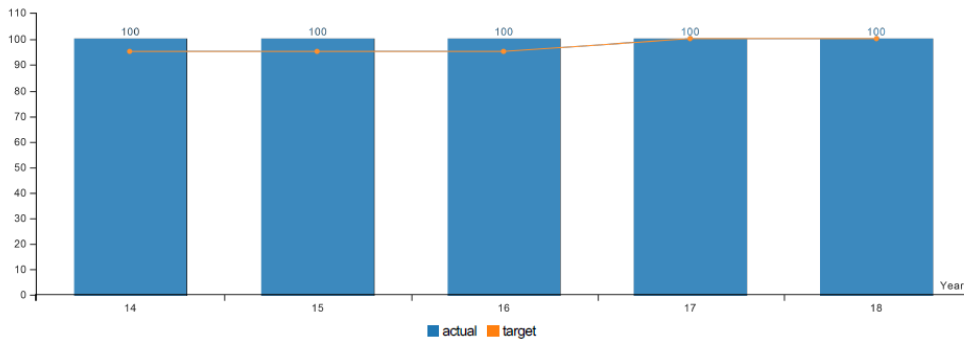


Report Year	2014	2015	2016	2017	2018
Percentage of audited pharmacists who complete continuing education on time.					
Actual	95%	97%	No Data	No Data	96.40%
Target	100%	100%	TBD	100%	0%

Measure #2 identifies the percentage of audited pharmacists who renewed their license in 2017 that completed the continuing education (CE) on time. Pharmacists either did or did not complete CE on time and attest honestly, when renewing their license. The Board expects this to be 100%, but there are always people that do not complete the requirement on time; or are from another state that is on a different schedule and they miss it. The 2017 pharmacist biennial renewal was the first biennial renewal cycle that included updated CE requirements

to match the biennial time-frame and moved the due date to the expiration date of the license rather than the early renewal date as it was in the past. In 2017, the decision was made to double the number of individuals audited which resulted in the audit being completed in 2018, which reflects the 17-18 discrepancy in target to actual on the chart. Overall, the actual percentage of 96.40% of audited pharmacists in compliance is reflective of 20% of all licensed pharmacists and the compliance is comparative to that in prior years. The next renewal cycle is in spring 2019 and complete audit results will be available in 2020.

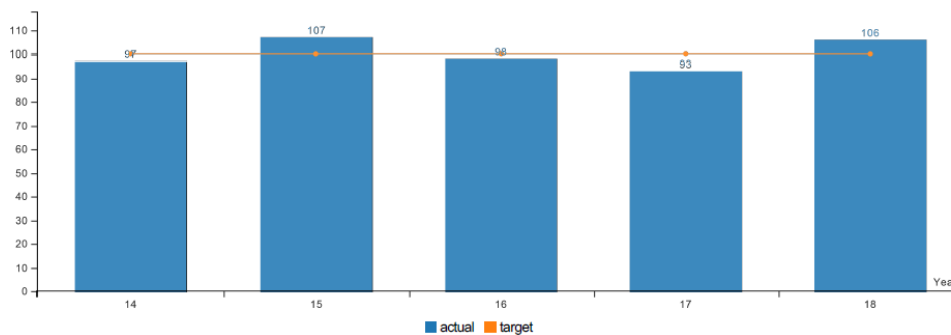
Measure #3 - Percent of pharmacies inspected annually



Report Year	2014	2015	2016	2017	2018
Percent of pharmacies inspected annually					
Actual	100%	100%	100%	100%	100%
Target	95%	95%	95%	100%	100%

Measure #3 - Board staff strives to complete 100% of retail and institutional pharmacy inspections in Oregon annually; we have reached 100% annually since 2011. While this measure is specific to these two categories, inspectors also inspect other in-state outlets on a rotating schedule from year to year. Board staff reports progress on the number or percent of outlets inspected at each Board meeting.

Measure #4 - Average number of days to complete an investigation from complaint to board presentation.

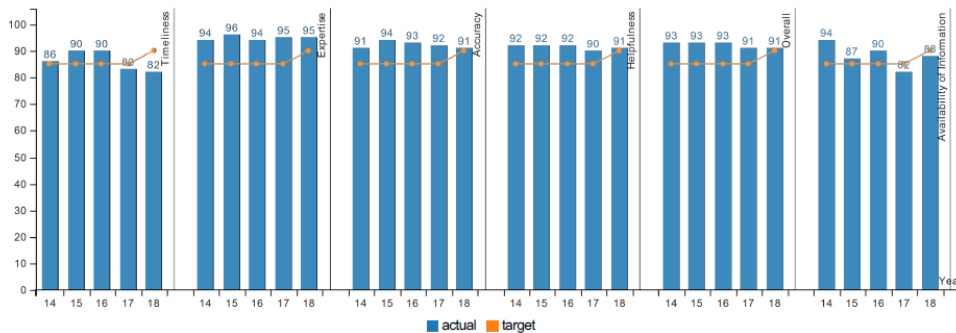


Report Year	2014	2015	2016	2017	2018
Number of days to process complete investigation from complaint to Board presentation.					
Actual	97	107	98	93	106
Target	100	100	100	100	100

Measure #4 - Board staff work diligently to complete investigations from complaint to board presentation within the target of 100 days. The statutory guideline in ORS 676.165(4) allows up to 120 days or an extension be documented. Depending on timing and the complexity of

cases, this number will vary from year to year. Board staff use the information regularly and report cases that will exceed the 120 days to request and account for needed extensions. The Board is experiencing a larger number of cases than ever before. In 2018, 802 cases were opened compared to 566 in 2017. The results for this measure are specific to complaints, however the measure results are impacted by the other types of issues that result in cases such as Board initiated cases, cases initiated because of inspection deficiencies or notifications of non-compliance, license application cases etc.; all of which have a public safety concern to be addressed.

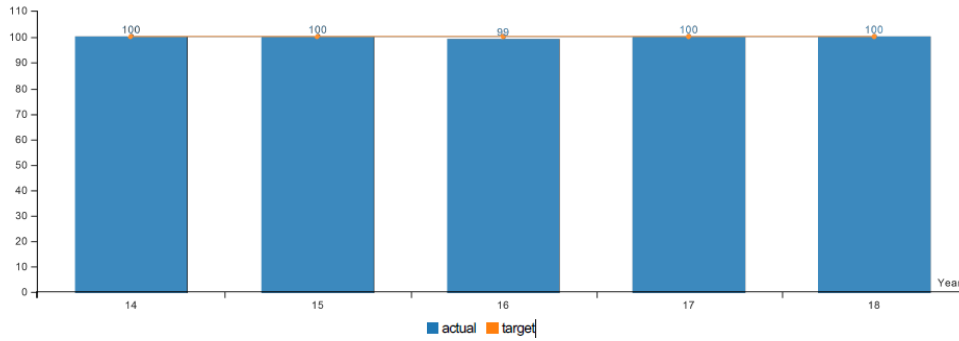
Measure #5 – Customer Service – Percent of customers rating their satisfaction with the agency’s customer service as “good” or “excellent”: Overall customer service, timeliness, accuracy, helpfulness, expertise, and availability of information.



Report Year	2014	2015	2016	2017	2018
Timeliness					
Actual	86%	90%	90%	83%	82%
Target	85%	85%	85%	85%	90%
Expertise					
Actual	94%	96%	94%	95%	95%
Target	85%	85%	85%	85%	90%
Accuracy					
Actual	91%	94%	93%	92%	91%
Target	85%	85%	85%	85%	90%
Helpfulness					
Actual	92%	92%	92%	90%	91%
Target	85%	85%	85%	85%	90%
Overall					
Actual	93%	93%	93%	91%	91%
Target	85%	85%	85%	85%	90%
Availability of Information					
Actual	94%	87%	90%	82%	88%
Target	85%	85%	85%	85%	90%

Measure #5 – The Board’s target changed from 85% to 90% in 2018 for all customers (*new license applicants*) rating the service as “good” or “excellent”. The data reported in 2018 Annual Report was for calendar year 2017. Overall, we had a combined rating of 91% with some variations within the attributes. We review this information monthly and evaluate how we can improve service regularly.

Measure #6 - Percent of total best practices met by the Board.



Report Year	2014	2015	2016	2017	2018
Is the Board following Best Practices?					
Actual	100%	100%	99%	100%	100%
Target	100%	100%	100%	100%	100%

Measure #6 – The Board annually reviews the list of best practices. Staff regularly reports to the Board on many of the best practice items and/or the Board reviews materials throughout the year.

Over all, the 2018 report continues to reflect the Agency is meeting all Key Performance Targets. The Board serves its licensees and the people of Oregon. A complete copy of the [2018 Annual Performance Progress Report](#) (linked here) is available online that reflects 2017 data..

2019-21 Summary of Program

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
- Public Health and Pharmacy Formulary Advisory Committee 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 is a variety of ongoing operational responsibilities to achieve the Agency’s mission of public safety for Oregonians and regulatory oversight to almost 30,000 licensees spread over 34 categories of individuals and drug outlets both in-state and out of state, a chart reflecting these categories is in the Appendix on page 24. The 2019-21 Governor’s Budget supports these activities 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
- Provide support to the Board and Formulary Advisory Committee

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; and
- 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.

Major budget drivers, budget risks, and environmental factors

This budget includes fee increases to increase revenue for overall agency operations. Agency costs are primarily reflected in staff payroll. Ongoing expenses for “services and supplies” are inherent and tend to not fluctuate significantly. The top four budget drivers reflected in the Agency’s 2019-21 budget are:

Need for Increased Revenue

A policy package to increase Other Fund licensing fees is proposed. The last permanent fee increase was in 2001. Without a fee increase, current agency operations will be compromised and expenditure policy packages for 2019-21 will go unfunded which would create operational challenges and an inadequate ending balance.

Staffing is the largest single expenditure since what the agency does involves people working with people, licensing, investigations and outreach.

Attorney General is the second largest expenditure. This is due in part to the large number of cases and hearing requests we receive associated with notification of Board discipline and the changing practice of pharmacy within the state or nationally. In 2018, there were 802 cases and we currently have 39 hearings requested and being managed.

IT Professional Services is the third largest expenditure for the 2019-21 budget, as it includes a policy option package the agency is requesting to pay for continued cloud hosting – maintenance and operations for a previously approved database upgrade. In addition, there is a need to carrying over funds from 2017-19 to finish implementing a business upgrade we have been working with multiple agencies such as Office of the State Chief Information

Officer, the Enterprise Security Office, Treasury, Oregon State Police, Procurement and DOJ for a number years.

Environmental Factors

Current environmental factors include a new Executive Director, starting in February 2019, expanding automation and technology in drug distribution, growing implementation of regulating pharmacist prescribing, increasing complexity and scope of investigations, changing pharmacist and pharmacy technician roles and challenges to drug supply security and integrity.

Administrative initiatives and projects such as budget preparation, database upgrade, document security and move to electronic documents, business continuity, workforce data 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. Examples of these include: revising rules for Naloxone dispensing and the associated outreach, increased pharmacist prescribing options, immunization changes, public health emergencies, Opioid reduction efforts, biosimilars, and Health Professionals Service Program, among others.

Prescription drug abuse or overutilization 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 staff are common. Other issues such as Drug Take Back, multiple Naloxone Taskforces, the Opioid Prescribing Taskforce to address opioid abuse and addiction continue 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.

Major Changes in the Last 6 Years

Longtime Executive Director Gary Schnabel retired in late 2013, Executive Director, Marcus Watt served from early 2014 to late 2018 and new Executive Director Joseph Schnabel starts in February 2019.

Implementation of the Public Health and Pharmacy Formulary Advisory Committee (2017 HB 2397) effective January 2018. Committee members appointed. Committee established core elements of pharmacist prescribing and approved 5 concepts for the Formulary or Protocol Compendium for approval and recommended the Board adopt by rule. This legislation was unfunded. Policy Package 105 is included in the 2019-21 Budget for consideration.

Implementation of the Shared Academic & Regulatory Fellowship Program for Post-Graduate Learners with Pacific University School of Pharmacy (PUSOP) and the Oregon Board of Pharmacy (OBOP) was started in 2017. This Fellowship is the first of its kind and established a reoccurring one-year program designed to transition the fellow from a general practitioner to a regulatory pharmaceutical specialist and clinical educator. Upon successful completion of the PUSOP-OBOP Fellowship, graduates will be on track to pursue careers in: 1) Regulatory oversight services at a State Board of Pharmacy, and 2) Academic/faculty positions that involve pharmacy practice, experiential teaching responsibilities, and school service, as well as

preceptor development opportunities. This program was initiated in 2017-18, the Fellow did not complete the full year. There was only one candidate for the 2018-19 year and no selection was made. At this time, the program is currently under reevaluation. A policy package to increase funding for a cost of living is not included in the Governor's Budget.

Longtime Compliance Director Gary Miner retired January 2017 and a new director, Brianne Efremoff assumed this position. Brianne promoted into this position, which left a vacancy in one of our Compliance Investigator/Inspector positions to fill and train. Today, all positions in this section are filled and ongoing training occurs.

Implemented legislatively approved Licensing Program Supervisor in 2015-17 to more directly oversee licensing activities. All positions in this area are filled.

Finished implementing all of its "people" licenses from annual licensure to biennial licensure in 2016.

Implemented 2015 OR legislation and rules allowing pharmacist to prescribe contraception and remove barriers to access throughout the state. Oregon is the first state to implement pharmacist prescriptive authority for contraceptives and we have received national attention and inquiry.

Federal regulations that influence the work of the OBOP and its licensees continue to force change. One of the most significant current FDA activities relates to the Drug Quality Safety Act (DQSA) which includes pharmacy compounding and the Drug Supply Chain Security Act (DSCSA) related to "Track & Trace". The Board is expected to understand and facilitate compliance with FDA regulations as they establish their guidance on these subjects. The Board has to write rules and re-evaluate the ways that we regulate certain licensees. This is ongoing and will likely require additional rulemaking through 2023, as there is a lengthy federal roll-out related to this topic.

The Board participates in the Health Professionals Service Program (HPSP) for impaired professionals. 2016 legislation shifted operational management from Oregon Health Authority to a Work Group of Health Boards effective July 1, 2017. This change has been effective. The Board continues to monitor these individuals through probation agreements.

The Board amended, adopted or repealed 53 rules in 2017 and 9 rules in 2018 in response to legislative action, review and streamlining efforts or needed updating.

The reinstatement of the Pharmacist Consultant position in 2013-2015 continues to have a significant effect on the Boards ability to work proactively to identify and address issues that affect it. Staff strives to react to evolving issues and develop strategies to address them more effectively as well as more efficiently coordinate over 60 outreach efforts in the last two years.

Process Changes for Efficiency

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

- Transitioned various IT services (network servers, e-mail and system management) previously managed by contract externally to the state's Enterprise Technology Services (ETS) team.
- Upgrading the licensing database will modernize the process for licensees to more efficiently renew online and update their own information while ensuring greater security for agency data overall. Applicants will eventually be able to apply for licensure online.
- License verifications will be upgraded with the database modernization project, this will simplify the process for making public records available to the public and is expected to streamline staff work in the process.
- The pharmacist licensure process has been streamlined and simplified to improve customer service and faster processing time.
- Continue to move towards paperless operations and record storage.
- Cross-training of some staff continues 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.
- Flat-rate agreement with the Department of Justice for legal services.
- Move human resource functions to the Department of Administrative Services (DAS), Enterprise Human Resource Services (EHRS).
- For more efficient orientation of new employees, complete and detailed desk manuals have been created for key positions.
- Implemented more categories for online license renewals for interns, non-prescription drug outlets as well as retail and institutional drug outlets.
- Revision of Board meeting dates to better utilize staff time and meeting coordination efforts.
- The Board continues to conduct most of the Board's meetings in Portland, rather than in locations around the state in order to keep travel expenses down.
- Executive Director or designee meets monthly with other Health Professional Regulatory Boards to foster interagency communication, eliminate duplication and share resources.
- Streamlined investigative case report development and presentations for the Board.

2019-21 Budget Information

The Board's 2019-21 proposed budget includes an Other Fund expenditure limitation request of **\$8,550,886**, a 14.6% increase over the 2017-19 Legislatively Adopted Budget.

The following packages support the agencies activities as described and provide an opportunity for Other Fund licensing fee increases to continue agency operations, DOJ expenditure increase, IT Professional Services for Database Cloud Hosting – maintenance and operations, the addition of 2 FTE for Compliance and Licensing and funding for the Public Health and Pharmacy Formulary Advisory Committee which was unfunded.

2019-21 Essential Packages include Package 022 that phases out a portion of the 2017-19 Legislatively Adopted Budget (LAB) policy package for a business upgrade for the agency database. Due to the timing of contracting and anticipated project completion, there is a need to carry-over \$288,415 of this funding past June 2018. The Department of Administrative Services (DAS), Chief Financial Officer – Budget Analyst (CFO) and

Legislative Fiscal Office (LFO) support this effort. This was not included in the Governor's Budget, however is supported. Packages 031, 091, 092 include other minor DAS adjustments.

2019-21 Policy Packages

Package #101 License Fee Increases

The purpose of this package is to implement updated licensing fees. The last overall fee increases for OBOP were in 2001. There was a fee increase in 2011-13 for a number of categories; however, the majority of these were reversed in 2013 back to the 2001 rates due to an unanticipated high ending balance and through the temporary fee reduction process that has been continued ever since. Since then biennial licensure was implemented beginning in 2015 without a fee adjustment, pharmacists, certified pharmacy technicians and pharmacy technicians have received a two year license for the price of one. New fees for these categories will not impact current licensees until the next renewal in 2020 or 2021. Any new applicants in these categories are projected to be impacted effective 7/1/19. Other categories for new and renewing licensees/registrants are projected to be impacted effective 7/1/19. This package increases Other Fund Licensing Fee Revenue by **\$2,411,800**. Note, approximately \$1,350,670 of this increase is related to the adjustment for biennial licensure.

Package #102 DOJ Expenditure Increase

This package seeks to increase the agencies expenditure limitation for DOJ. Since 2011, the Board has utilized the DOJ flat-rate agreement to better anticipate legal costs. More recently, this has helped the agency through two senior staff changes (Executive Director and Compliance Director) and the implementation of legislation that was unfunded, in addition to a higher than normal season of contested hearings during the 2015-17 biennium. The flat-rate is evaluated each biennium based the past 36 months of legal services usage. 2015-17 usage caused the rate for 2017-19 to be \$144,000 higher than Legislatively Approved Budget allocation for DOJ; the agency has worked to absorb this overage. However, even with a reduction of legal services during the first eighteen months of 2017-19, it is anticipated that with the 2019-21 pricelist inflation adjustment, an additional \$174,862 of DOJ resources is anticipated. We also have a new Executive Director starting February 2019. Total Other Funds Request **\$174,862**.

Package #103 IT Cloud Hosting – Maintenance and Operation

This package seeks to add ongoing resources to the agency's limitation for IT Professional Services for cloud hosting - maintenance/operation of the upgraded database that was previously approved by the Legislature. With the technology support and infrastructure changes made in the last two years and increased requirements for state enterprise security, establishing maintenance and operations through a Federal Risk and Authorization Management Program (FedRAMP) and Criminal Justice Information Services (CJIS) secure hosting solution was determined to be the best solution for the agency/state. The Office of the State Chief Information Officer (OSCIO), Enterprise Security Office (ESO) and Oregon State Police CJIS Information Security Officer have evaluated and signed off on this solution. This Other Funds request is **\$279,021** and includes ongoing database administration, maintenance, operation and hosting services.

Package #104 Compliance and Licensing Staffing

This package seeks to increase staff with two FTE. One position, a pharmacist to be shared between Compliance and Administration to support the work of inspections and investigations, as well as rulemaking efforts for the Board and Formulary Advisory Committee with the Pharmacist Consultant. In addition, one additional staff member for Licensing is requested to address workload associated with the increased number of applicants, licensees and growing number of complex outlet license categories. These new positions are expected to support the work of the Board, Formulary Advisory Committee and add to existing staff where workload has caused delays in processing licenses or investigations being conducted in a timely manner. At the current staffing level, it is very difficult to meet all of the demands of our licensees or stakeholders efficiently. Issues of public safety always come first and this can cause delays in our ability to be responsive to evaluate new applications and requests of the Legislature, Board, Formulary Advisory Committee and stakeholders. The total cost of this Other Funds package is: **\$468,403**.

Package #105 Formulary Per Diem & Expense Funding

The purpose of this package is to fund the Public Health and Pharmacy Formulary Advisory Committee, implemented and effective 1/2018 that was not funded in 2017. The Committee meets four times a year to respond to any concepts submitted for consideration to the formulary or protocol listing. This package will cover ongoing costs for daily per diem, travel and program related services and supplies. This cost is currently being absorbed by the agency, however we request these Committee positions be funded as authorized and the associated expenses for this new and ongoing work. Staffing for this committee is absorbed by existing staff, with the exception of the shared position previously mentioned in Package 103 to assist with rulemaking that is a result of this Committee's recommendations for the Board to adopt items for formulary or protocol by rule. The total cost of this Other Funds package is **\$16,027**.

Summary of Proposed Legislation

The agency doesn't have any proposed legislation.

The following are some of the 2019 bills the agency is tracking that are pharmacy related and may impact the agency or have a budgetary impact.

[HB 2065](#) – Establishes a Drug Take Back program that the Department of Environmental Quality will administer and the Board of Pharmacy will need to incorporate new criteria related to this into routine inspections, adopt new rules, investigate issues of non-compliance and assess fines for violations.

[HB 2303](#) - Deletes requirement that pseudoephedrine be classified as Schedule III controlled substance. Directs State Board of Pharmacy to adopt revised rules for the dispensing of pseudoephedrine. Includes a variety of new requirements that will need to be managed, new recordkeeping, identification checking and training requirements apply.

[HB 2669](#) – Authorizes Board to inspect pharmacy and determine whether pharmacy compounds drugs. Directs board to register outsourcing facility that complies with requirements established by rule and inspect registered outsourcing facilities. Directs board to consider certain factors in determining whether drug is misbranded or mislabeled. The Board already has authority within existing statutes and inspects and registers. The Board is

in the process of updating rules associated with this topic that encompass changes occurring on a federal level that apply.

[SB 409](#) and [HB 2689](#) – Relate to developing a program to allow wholesale importation of prescriptions into Oregon from Canada. The Senate bill directs the Board of Pharmacy to develop a program. The House bill makes this requirement of the Oregon Health Authority. [HB 2680](#) also authorizes the Oregon Prescription Drug Program to cooperate with Canadian provinces or territories in bulk purchase of prescription drugs. Each of these may impact the Board or practice of pharmacy.

[HB 2753](#) – Requires pharmacist to substitute prescribed brand name drug with generic name drug product. [HB 2754](#) – Requires pharmacy or pharmacist to substitute prescribed biological product with interchangeable biological product. [HB 2755](#) – Requires pharmacy or pharmacist to substitute prescribed brand name drug product and to substitute prescribed biological product with interchangeable biological product.

[HB 2801](#) and [SB 698](#) – Requires pharmacists to label prescription drugs in language other than English if patient to whom prescription drug is dispensed is person of limited English proficiency.

[SB 9](#) – Allows pharmacists to prescribe and dispense emergency refills of insulin and associated insulin-related devices and supplies. Also requires medical assistance plans and health benefit plans to reimburse for prescriptions made by pharmacists. Requires training program, patient assessment etc.

Reduction options in Governor's budget

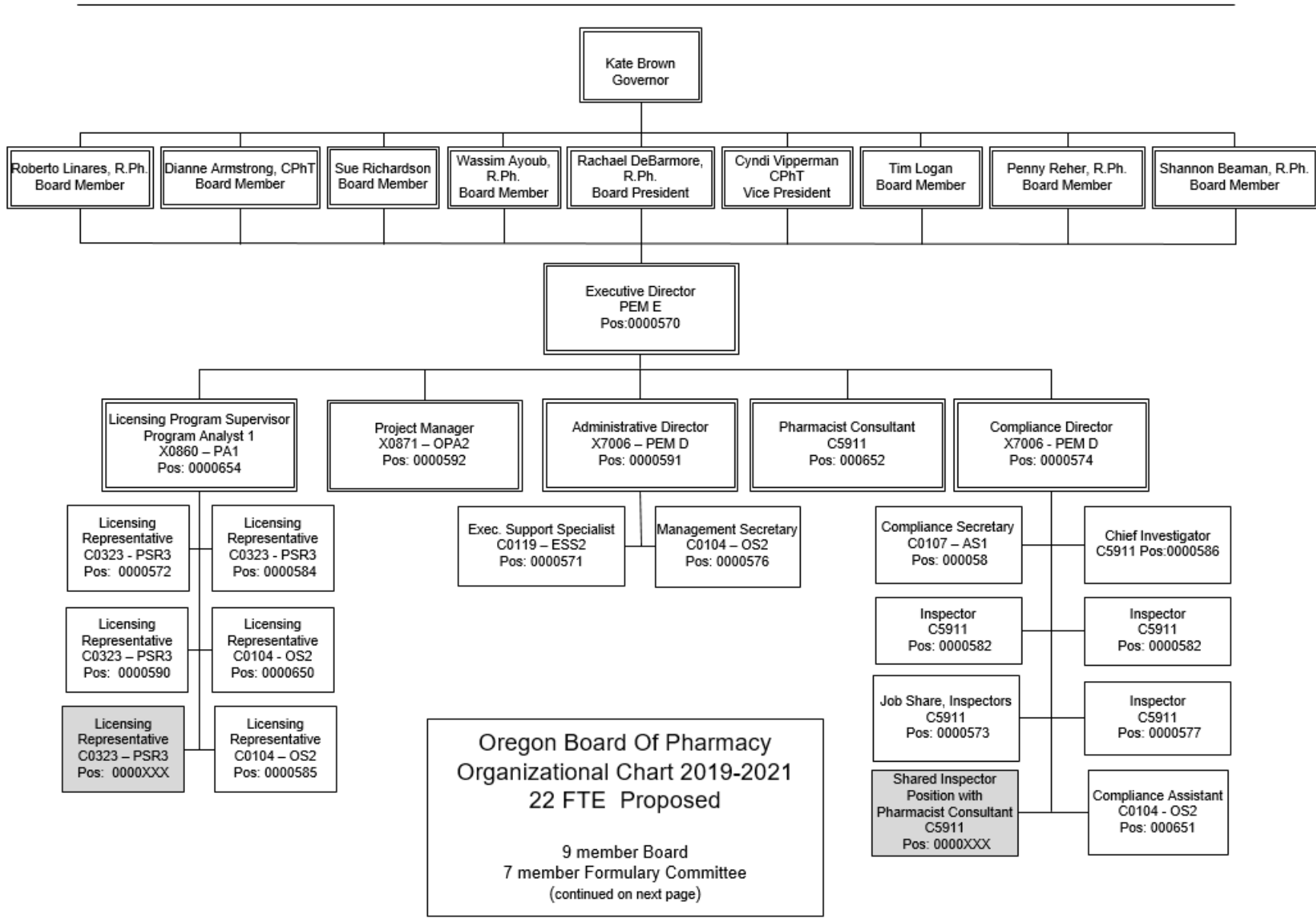
The Governor's budget did include minor reductions; none from the reduction options list.

Ending Balance

Assuming the Governor's Budget is approved; the Board will have a 4.4 month ending balance at the end of 2019-21 of \$1,673,833.

APPENDIX

- Pages 17-18 - Organizational Charts
- Page 19 - Licensing total/new licensee comparison chart
- Page 20 – Licensee count / Funds /FTE
- Page 21 – Compliance Case and Inspection Charts
- Page 22 – 2019-21 Program Allocation
- Page 23 – 2019-21 Expenditures by type
- Page 24 - Licensee Category by type
- Page 25 - Ending Balance Information





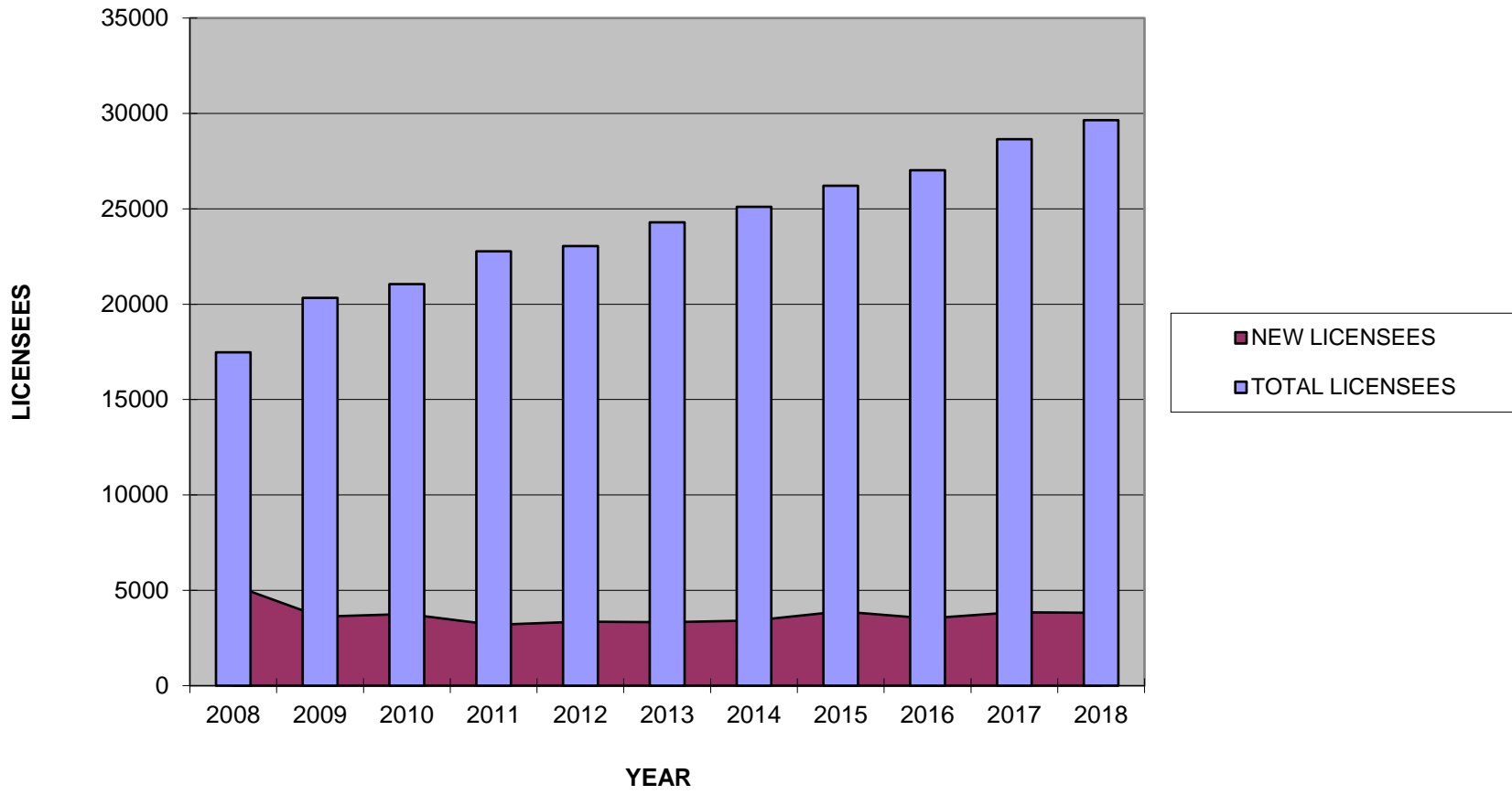
PUBLIC HEALTH AND PHARMACY FORMULARY ADVISORY COMMITTEE

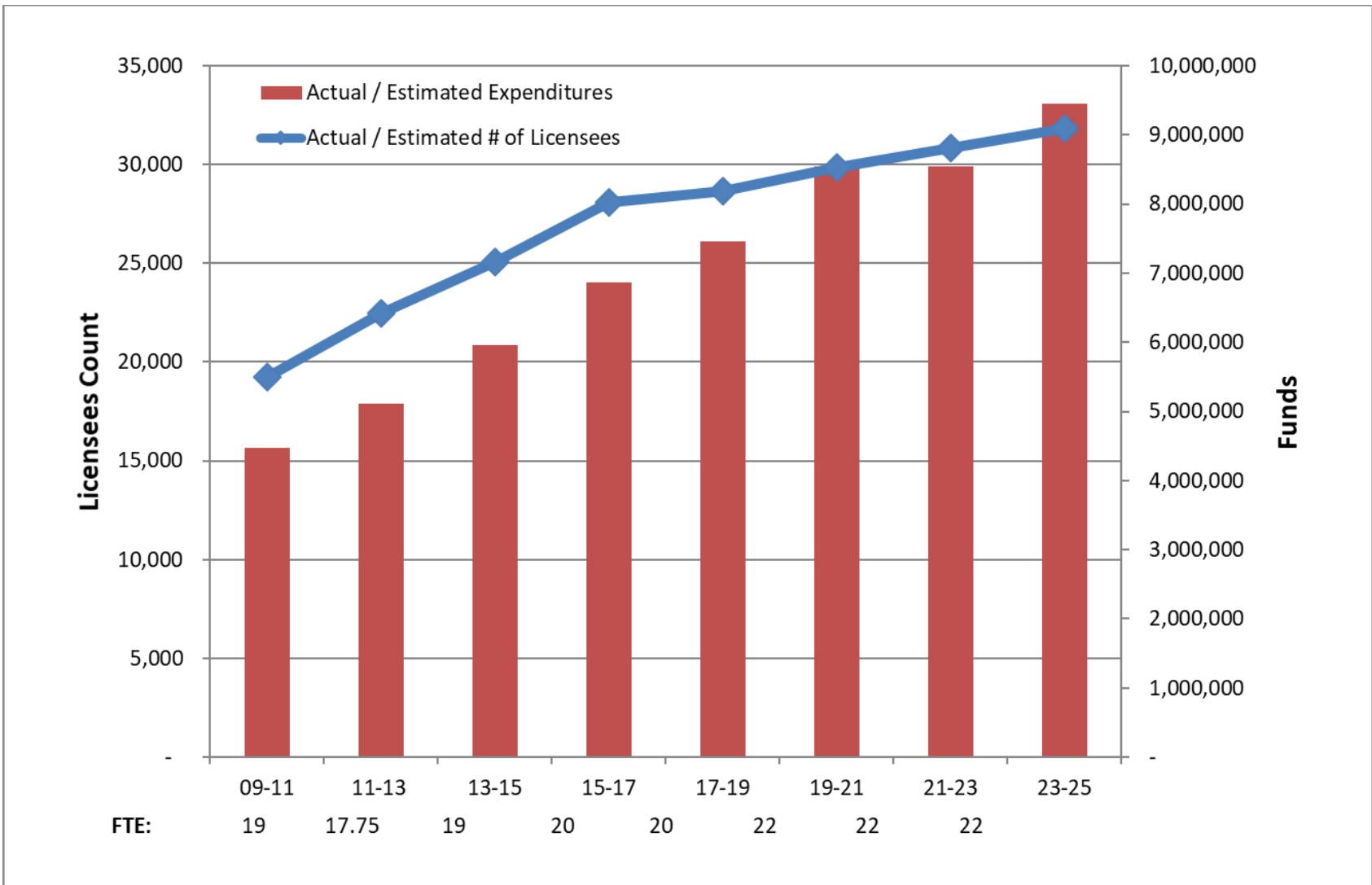
Established January 1, 2018

2 year terms

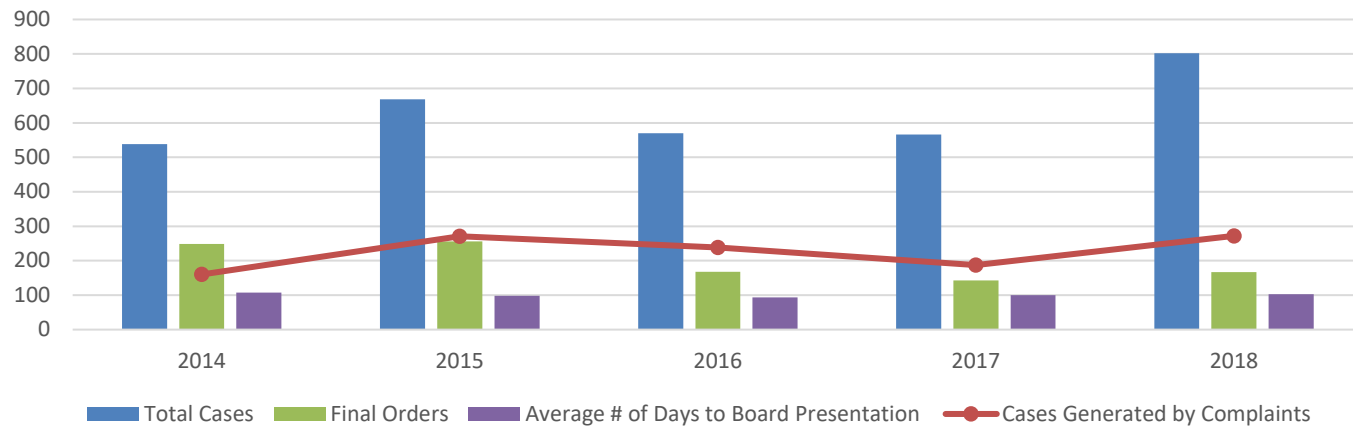
Members are appointed by the Governor to make recommendations to the Oregon Board of Pharmacy regarding pharmacist prescriptive authority

ALL LICENSEES

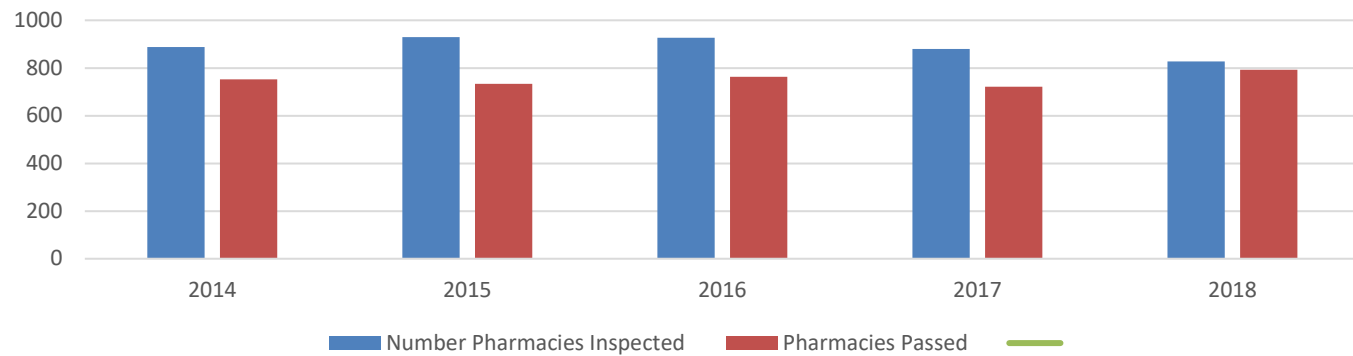




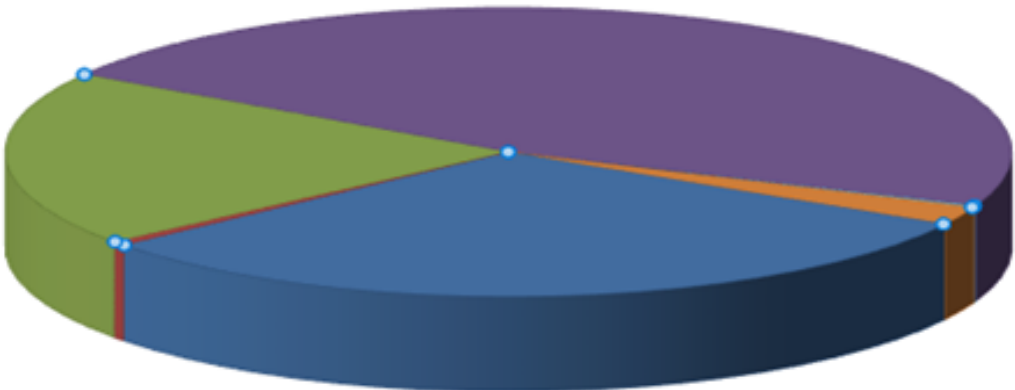
OBOP Compliance Cases (2018 data)



OBOP Pharmacy Inspections (2018 Inspections completed thru 12/31/2018) *(Inspection year runs 2/1 - 1/31 annually)*

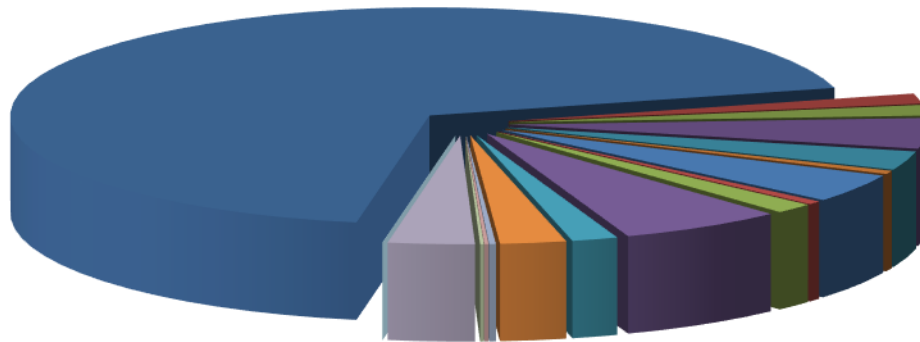


2019-2021 Program Allocation



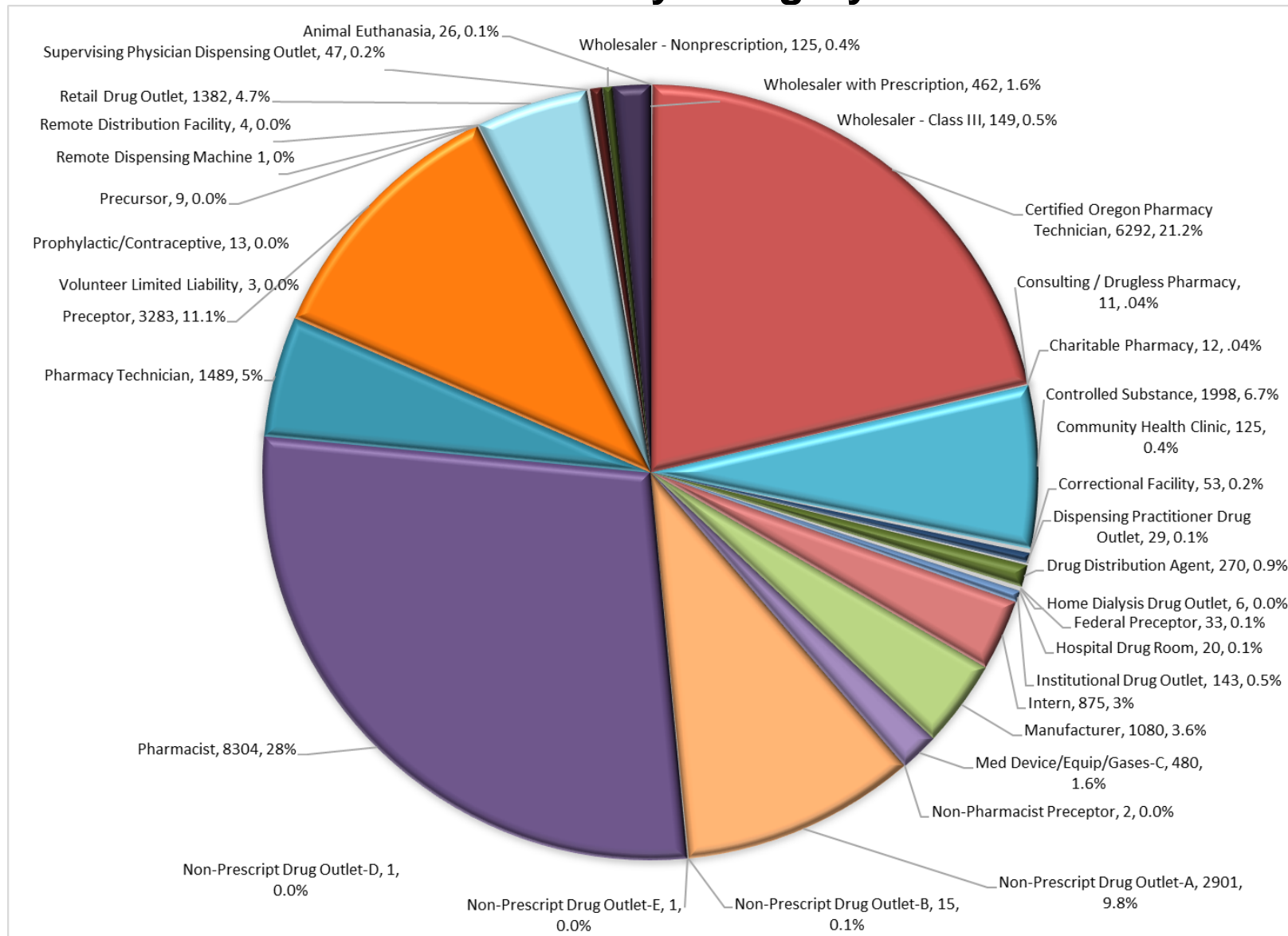
- Operations & Admin 30.81%
- Board Member Activities .45%
- Licensing 18.93%
- Compliance 47.55%
- Formulary Committee .19%
- Health Professionals Service Program (HPSP) 2.07%

2019-2021 Expenditures by Type \$8,550,886



- Personnel Services 68.16%
- Travel 1.53%
- Data Processing & Telecommunications 1.60%
- Prof. Services/Hearings Panel 2.56%
- Agency Program Related S & S (Fingerprinting) 2.81% *PASS THRU
- IT Expendable Property .51%
- IT Professional Services 4.26%
- Publicity & Publications .46%
- Office Expenses/Supplies (Includes Storage Fees & Postage) 1.52%
- Attorney General 6.36%
- State Government Service Charges 1.77%
- Facilities & Rent 2.54%
- Employee Training .26%
- Expendable Property .16%
- Other Special Payments .15%
- Other Services & Supplies 3.33%
- Medical Services & Supplies .01%

Licenses by Category



Ending Balance Information

UPDATED OTHER FUNDS ENDING BALANCES FOR THE 2017-19 & 2019-21 BIENNIA											
Agency: 85500 Oregon Board of Pharmacy											
Contact Person (Karen MacLean & 971-673-0005):											
(a)	(b)	(c)	(d)	(e)	(f)		(g)		(h)	(i)	(j)
Other Fund Type	Program Area (SCR)	Treasury Fund #/Name	Category/Description	Constitutional and/or Statutory reference	2017-19 Ending Balance		2019-21 Ending Balance		In CSL	Revised	Comments
					In LAB	Revised	In CSL	Revised			
Limited	85500-001-00-00-00000	1171 OF State Board of Pharmacy Account	Operations	ORS 689.135	1,843,804	2,904,711	7,698,155	171,246			The 2019-21 includes proposed fee increases in POP 101 to ensure Agency Operations are appropriately funded in 2019-21. Most of the increases restore fees to what they were before a temporary fee reduction 2013, others are adjusted as proposed.
											2,904,711 (g)
											5,380,836 CSL Revenue
											(416,146) CSL Transfer Out
											(7,698,155) CSL Expenditures
											171,246 (i)