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## Keeping Complaints and Investigations at Bay: The Characteristics of Complaints and Inspection Violations Received by the Washington State Pharmacy Quality Assurance Commission 2014

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### Research Article

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### INTRODUCTION

The Washington State Pharmacy Quality Assurance Commission (PQAC), formerly known as the Washington State Board of Pharmacy, was authorized established by the legislature in 1891. The duties of its fifteen members include the oversight of thirteen credentials totalling 33,780 licensees and the management of the sale of OTC drugs used to manufacture methamphetamine<sup>[1]</sup>. The Commission regulates the profession by adopting rules to establish qualifications, competencies, and standard of practice for dispensing, distribution, wholesaling and manufacturing of drugs and devices.

The mandate of the Pharmacy Commission is to protect the public's health and safety and to promote the welfare of the state by regulating the competency and quality of professional healthcare providers under its jurisdiction<sup>[2]</sup>. To wit, PQAC's mandate of protecting the public is facilitated through judicious regulatory oversight of the laws and rules governing the practice of pharmacy and through a complaint driven investigative process.

### PURPOSE

The Health Systems Quality Assurance Division of the Washington State Department of Health (DOH) publishes a bi-annual summary of the complaints and disciplinary process for all health professionals, including pharmacy. Statistics from this supplemental report are reported for the years 2013-2015. This broad statistical report is interesting, but lacks specific descriptive information. Therefore, a random sample of pharmacy related complaints filed in 2014 and inspection infractions for 2014 are reported, as it may be more meaningful to licensees to review the nature of the activity of the Commissions' tasks. This is a learning opportunity for licensees who might wish to improve their job performance. It should be noted that to protect the identity of the individuals and firms involved, these summaries do not include any outcomes or correlations related to the complaints or inspection infractions reviewed and that the data provided is meant to be informative only.

### PROCESS

In August of 2015, all files containing PQAC related complaints for the 2014 calendar year were transferred to the DOH office in Tumwater. Then, a random sample containing 75% of the files were reviewed to obtain the type of the information found in the following **(Tables 1-6)**. These tables characterize the type of Pharmacy, Respondents, and Whistleblowers as well as the nature of the complaints. The data was then entered into Microsoft Excel® spreadsheets to generate the tables presented later in this document.

The four-year summary of statistics was provided by the Washington State Department of Health on October 23, 2015.

**Table 1.** Investigation Activity.

| Profession                                | Carry Over From FY13 | Complaints Received | Total Complaints | Investigations Completed | Unlicensed Practice Investigations | Total Investigations |
|---|----------------------|---------------------|------------------|--------------------------|------------------------------------|----------------------|
| Pharmacies and Other Pharmaceutical Firms | 69                   | 274                 | 343              | 108                      | 29                                 | 137                  |
| Pharmacist                                | 142                  | 432                 | 574              | 266                      | 2                                  | 268                  |
| Pharmacist Intern                         | 2                    | 11                  | 13               | 4                        | 0                                  | 4                    |
| Pharmacy Assistant                        | 38                   | 124                 | 162              | 61                       | 1                                  | 62                   |
| Pharmacy Technician                       | 55                   | 106                 | 161              | 66                       | 3                                  | 69                   |
| <b>Total</b>                              | <b>306</b>           | <b>947</b>          | <b>1253</b>      | <b>505</b>               | <b>35</b>                          | <b>540</b>           |

**Table 2.** Complaints Closed Prior to Disciplinary Action.

| Profession                                | Total Complaints | Closed Prior To Investigation | Closed After Investigation | Closed with Notice of Decision | Charges or Allegations Withdrawn | Total Closed |
|---|------------------|-------------------------------|----------------------------|--------------------------------|----------------------------------|--------------|
| Pharmacies and Other Pharmaceutical Firms | 343              | 92                            | 104                        | 0                              | 1                                | 197          |
| Pharmacist                                | 574              | 146                           | 218                        | 0                              | 0                                | 365          |
| Pharmacist Intern                         | 13               | 2                             | 3                          | 1                              | 0                                | 6            |
| Pharmacy Assistant                        | 162              | 31                            | 39                         | 12                             | 0                                | 82           |
| Pharmacy Technician                       | 161              | 20                            | 42                         | 3                              | 0                                | 65           |
| <b>Total</b>                              | <b>1253</b>      | <b>291</b>                    | <b>406</b>                 | <b>16</b>                      | <b>1</b>                         | <b>715</b>   |

**Table 3.** Complaints Resolved after Adjudicative Proceedings.

| Profession                                | Informal Disposition | Agreed Order | Default Order | Final Order | NOD       | Total      |
|---|----------------------|--------------|---------------|-------------|-----------|------------|
| Pharmacies and Other Pharmaceutical Firms | 4                    | 4            | 0             | 0           | 0         | 8          |
| Pharmacist                                | 39                   | 15           | 0             | 0           | 0         | 54         |
| Pharmacist Intern                         | 0                    | 1            | 1             | 0           | 1         | 3          |
| Pharmacy Assistant                        | 9                    | 7            | 10            | 1           | 12        | 39         |
| Pharmacy Technician                       | 12                   | 10           | 14            | 1           | 3         | 40         |
| <b>Total</b>                              | <b>64</b>            | <b>37</b>    | <b>25</b>     | <b>2</b>    | <b>16</b> | <b>144</b> |

**Table 4.** Unlicensed Practice Closures and Resolutions.

| Profession                                | Carry Over from 2011 | Cases Received | Total Cases | Closed Prior to Investigation | Closed after Investigation | Cease & Desist Order Issued | Total Closed |
|---|----------------------|----------------|-------------|-------------------------------|----------------------------|-----------------------------|--------------|
| Pharmacies and Other Pharmaceutical Firms | 4                    | 29             | 33          | 6                             | 17                         | 2                           | 19           |
| Pharmacist                                | 4                    | 2              | 6           | 2                             | 2                          | 3                           | 5            |
| Pharmacist Intern                         | 0                    | 0              | 0           | 0                             | 0                          | 0                           | 0            |
| Pharmacy Assistant                        | 1                    | 1              | 2           | 1                             | 0                          | 0                           | 0            |
| Pharmacy Technician                       | 0                    | 3              | 3           | 1                             | 2                          | 0                           | 2            |
| <b>Total</b>                              | <b>9</b>             | <b>35</b>      | <b>44</b>   | <b>10</b>                     | <b>21</b>                  | <b>5</b>                    | <b>26</b>    |

**Table 5.** Sanctions Imposed by Profession.

| Profession          | Remove from Practice (Revocation, Indefinite, Inspection) | Removal with Conditions (Suspension for Specific Period) | Rehabilitative (Probation, Limitation, or Restriction) | Deterrent (Reprimand, Fine) | Voluntary Surrender | Total      |
|---------------------|---|--|--|-----------------------------|---------------------|------------|
| Pharmacist          | 7   | 40   | 6  | 0                           | 2                   | 55         |
| Pharmacist Intern   | 2   | 0  | 1  | 0                           | 0                   | 3          |
| Pharmacy Assistant  | 15  | 7  | 5  | 0                           | 4                   | 31         |
| Pharmacy Technician | 21  | 9  | 5  | 0                           | 4                   | 39         |
| <b>Total</b>        | <b>45</b>   | <b>56</b>  | <b>17</b>  | <b>0</b>                    | <b>10</b>           | <b>128</b> |

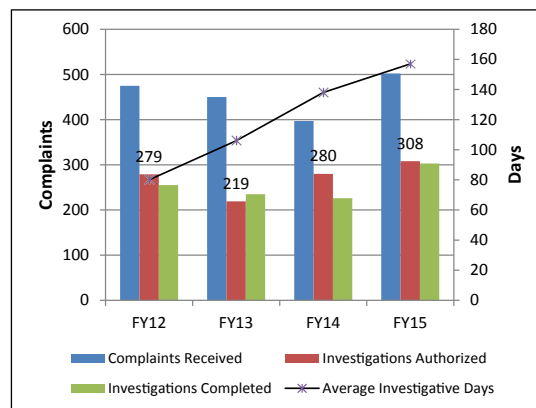
**Table 6.** Criminal Background Reports.

| Profession          | Total Applicant Checks Made | WATCH Reports Produced | Cases Opened on Applicants | Self-Disclosed |    | % Disclosed | Actions Taken |
|---------------------|-----------------------------|------------------------|----------------------------|----------------|----|-------------|---------------|
|                     |                             |                        |                            | Yes            | No |             |               |
| Pharmacist          | 1652                        | 5                      | 2                          | 0              | 2  | 0%          | 1             |
| Pharmacist Intern   | 865                         | 3                      | 4                          | 3              | 1  | 75%         | 1             |
| Pharmacy Assistant  | 5679                        | 160                    | 40                         | 27             | 13 | 68%         | 9             |
| Pharmacy Technician | 1424                        | 69                     | 4                          | 3              | 1  | 75%         | 1             |
| Total               | 9620                        | 237                    | 50                         | 33             | 17 | 66%         | 12            |

## THE FOUR YEAR DISCIPLINARY SUMMARY

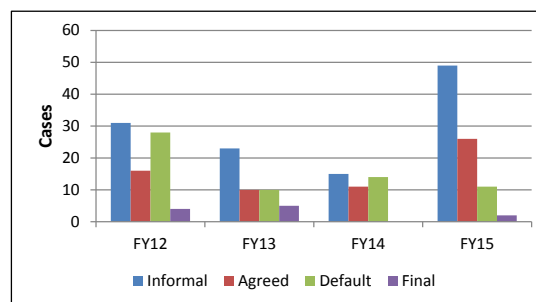
### 2013-2015 UDA Pharmacy Data

The Pharmacy Commission continues to receive on average 450 complaints per year. The number of investigations authorized has increased in the last two years. We authorize on average 60% of all complaints for investigations. The average number of days to complete an investigation increased in FY15 due to a small subset of complicated cases that were conducted concurrent with federal authorities. Despite their complex nature, the average investigative days remained compliant with statutory timelines (**Figure 1**).



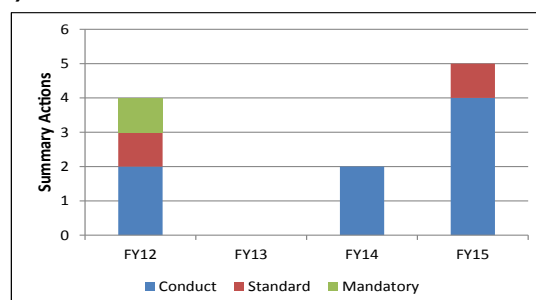
**Figure 1.** Complaints.

During the 2013-2015 biennium, the Pharmacy Commission has authorized a higher percentage of cases for investigation and discipline. The Pharmacy Commission uses informal orders as the leading type of discipline it issues. If the Pharmacy Commission cannot settle a matter through an informal order, it often proceeds with a formal order (**Figure 2**).



**Figure 2.** Cases.

The Pharmacy Commission takes summary action at a rate of approximately 2-5 orders per fiscal year. Summary action is taken when the Commission finds that a licensee poses an immediate threat to the public health and safety. During the current biennium, the Commission received a slight increase in the number of cases alleging that licensees posed an immediate threat to the public health and safety (**Figure 3**).



**Figure 3.** Summary actions.

## THE COMPLAINT DATA FOR 2014

Of the 236 cases reviewed specifically in 2014, four variables were considered. What pharmacy type received the most complaints? Which Respondents received the most complaints? Who made the complaints (whistleblowers)? And what are the exact natures of the complaints?

### Pharmacy Type

**Table 7** shows the raw data provided in the “Pharmacy Type” table. Of note, chain drugstores received 37% of the complaints, with independent practices getting 10% and hospitals receiving 7% of grievances. It should be noted that not all complaints warranted investigation. In fact, the HRSQ document for the 2011-2013 biennium notes that only 13% of the all complaints on all health care providers resulted in discipline <sup>[3]</sup>. It is not the intent of this paper to tie complaints to any variables.

**Table 7.** Pharmacy type.

| Pharmacy type          | Total |
|------------------------|-------|
| Central Fill           | 1     |
| Chain                  | 88    |
| Clinic                 | 5     |
| Closed chain           | 1     |
| Compounding            | 5     |
| DME                    | 1     |
| Home infusion          | 1     |
| Hospital               | 16    |
| Independent            | 24    |
| Infusion care          | 1     |
| LTC                    | 7     |
| Mail order             | 22    |
| Medical marijuana shop | 1     |
| Mental health          | 1     |
| Military               | 2     |
| None noted in file     | 2     |
| Nursing home           | 3     |
| Office                 | 1     |
| Online pharmacy        | 2     |
| Pharmacy               | 1     |
| Non-resident pharmacy  | 2     |
| Unknown                | 41    |
| Vendor                 | 1     |
| Wholesaler             | 1     |
| Grand Total            | 6     |
|                        | 235   |

### Respondents

Pharmacists received the majority of the complaints at 54%, pharmacies at 14%, Non-Resident Pharmacies (PHNR) at 9%, Pharmacy Technicians at 9%, and Pharmacy Assistants at 7%. Sometimes the respondent is unknown until the complaint is investigated.

### Whistleblowers

Patients were mostly likely to file a complaint at 28% with DOH (Department of Health) slightly lower at 26%. It should be noted that the majority of complaints filed by the DOH were on licensees who did not complete their continuing education (CPE) or had misrepresented themselves on their application and received a watch hit on a background check. Other sources of complaints were providers, employers, employees, other Boards and Commissions, peers, and self-report.

### Nature of the Complaints

Prescription miss fills resulted in 10% of the complaints followed by no continuing education participation at 8%. Of note, there were 9 diversions of controlled substance cases, 7 cases where a licensee failed two consecutive inspections, 6 cases for HIPAA violations, and 6 cases where a pharmacist refused to fill a patient’s prescription. Also of note, there were 17 complaints lodged by the DOH against applicants who misrepresented the legal questions asked on the application resulting in a hit during the background check.

The remainder of the complaints is as follows in alphabetical order (with multiple complaints noted where applicable):

Abusing billing practices; Abusing nursing home patient; Action taken in another state; Aiding and abetting unlicensed practice; Asked for PPI (patient's personal information); Automated refill system not working; Clinical study irregularities; Compounding issues; Controlled substance prescription shorted; Delay in filling prescriptions; Denied prescription for pain; Did not fill prescription in timely manner; Did not receive prescription; Did not sign Sudafed log; Discharged from clinic where patient accused of malfeasance; Disciplinary action in other states; Dismissive, offensive rude behavior by pharmacy staff; Dispensed medication to wrong patient; Diversion (9 cases), Diversion by nurse at Pyxis®; Diversion of antibiotics; Dog and child behind pharmacy counter; Domestic violence charges; DUI (3 cases); Excessive prescription errors by employee; Failed 2 successive inspections (7 cases); Failed to counsel; Failed to dispense full quantity of prescription; Failed to provide oversight at HCE(health care entity) clinic; Failed to transfer prescription; Failed to fill a prescription; Falsifying documents, Filled beyond allowed refills; Filled fake prescriptions called in by patient; Filled prescription for patient who was allergic to medication; Filled prescription with generic not brand; Filled prescription without authorization from provider; Filled forged controlled substance prescriptions; Forged controlled substance prescriptions by pharmacy personnel; Fraudulent billing practices; Fraudulent insurance billing submitted by pharmacy personnel ; Giving wrong immunization; Handling dangerous drugs; HIPPA violations( 6 cases); Improper storage of drugs; Improper research project; Improper transfer of prescriptions; Inadequate care in reporting losses; Incorrect injection technique of immunizations; Incorrect compounded prescriptions, Insurance complaint; Inventory management complaint; Lack of sterility of compounded products per FDA; Left pharmacy with no staff supervision; Misbranding (2 cases), Miscommunication during counseling; Misfiled prescriptions (25 cases), Mislabeled prescriptions (3 cases); Mobile blood drawing business: Multiple prescriptions errors unreported and covered up; Multiple errors and resistant to procedures to avert errors; No C5 registration log available and patient could not get codeine cough syrup without prescription (6 cases); No counseling provided to patient(2 cases), No CPE (continuing education) documented(20 cases); No current license to sell OTCs(over-the-counter products); No due diligence with controlled substance drugs to prevent diversion; No laminar flow hood on premises for compounding; No license to practice pharmacy; No specific patient prescription for compounding (acting as a manufacturer); No pharmacy credential (6 cases); No pharmacy license at site; No PIC(person-in-charge) designation: No response to CPE( continuing education credit) audit (2 cases); No prescription on file for prescription; No valid credential; Not adhering to 1:3 pharmacist to tech ratio; Nursing home infraction; On-line vendor with no license to distribute medication in WA state; Order entry errors; Other board or commission discipline out of state; Patient given wrong medication; Patient ran out of medication; Patient shorted controlled substances and alleges theft by pharmacy personnel; Pharmacy hours not posted; Physical harm to a patient in nursing home setting; Practicing beyond scope of license; Practice without a pharmacy license; Professional incompetence; Redistribution of returned drugs; Refusal to fill a prescription(6 cases); Refused to fill L&I(labor and industry) papers for a patient; Refused to fill a pain prescription; Refused to give flu shot; Refused to get a pharmacist for a patient; REMS (Risk Evaluation and Mitigation Strategies) violation (2 cases); Represented self as physician to a patient; Required patient to enroll in chain discount program; Rude to physician on phone; Rx(prescription) dispensed to patient with drug allergy for that medication; Shoplifting, Shorted patient on available refills; Stealing drugs; Stolen food; Technician providing medication counseling; Theft of drug samples; Unable to practice safely; Unauthorized personnel in pharmacy; Under the influence at work; Unauthorized refill dispensed; Unlicensed pharmacy providing services(2 cases); Unlicensed technician working in pharmacy(2 cases); Unlicensed wholesaler providing goods in WA State(2 cases); Unprofessional conduct; Unsecured pharmacy; Used a contaminated tray to prepare prescriptions; Verbal abuse and accusations made to complainant; Verbal abuse to patients in nursing home (2 cases); watch hit(charges found on background checks) (17 cases); Working without supervision of a pharmacist; Wouldn't change 90 day supply to 30 day supply.

It should be noted that when individuals hold more than one credential, the PQAC may refer a complaint to another Board or Commission if warranted (**Tables 7-9**).

**Table 8.** Respondents.

| Pharmacy type          | Total |
|------------------------|-------|
| Central fill           | 1     |
| Chain                  | 88    |
| Clinic                 | 5     |
| Closed chain           | 1     |
| Compounding            | 5     |
| DME                    | 1     |
| Home infusion          | 1     |
| Hospital               | 16    |
| Independent            | 24    |
| Infusion care          | 1     |
| LTC                    | 7     |
| Mail order             | 22    |
| Medical marijuana shop | 1     |

|                       |     |
|-----------------------|-----|
| Mental health         | 1   |
| Military              | 2   |
| None noted in file    | 2   |
| Nursing home          | 3   |
| Office                | 1   |
| Online pharmacy       | 2   |
| Pharmacy              | 1   |
| Non-resident pharmacy | 2   |
| Unknown               | 41  |
| Vendor                | 1   |
| Wholesaler            | 1   |
| Grand Total           | 6   |
|                       | 235 |

**Table 9.** Count of whistleblowers.

| Count of Whistleblowers                   | Total |
|---|-------|
| Anonymous                                 | 2     |
| Attorney                                  | 2     |
| Caregiver                                 | 1     |
| Citizen                                   | 1     |
| Other Board of Pharmacy                   | 4     |
| DEA                                       | 1     |
| DOH (Dept of Health)                      | 61    |
| DOSH (Occupational Health and Safety)     | 1     |
| DSHS (Dept of Social and Health Services) | 4     |
| Employee                                  | 12    |
| Employer                                  | 9     |
| ER physician                              | 1     |
| FDA                                       | 1     |
| Insurance company                         | 4     |
| NABP                                      | 3     |
| Nurse                                     | 2     |
| Nursing assistant                         | 1     |
| Nursing board                             | 2     |
| OTJ trainee (on the job)                  | 1     |
| Patient                                   | 70    |
| Peer                                      | 5     |
| Pharmacist                                | 2     |
| Physician                                 | 1     |
| Police                                    | 1     |
| Provider                                  | 25    |
| Self report                               | 16    |
| Surveyors from DOH                        | 2     |
| Technician                                | 1     |
| Grand Total                               | 236   |

### The Inspection Process for 2014:

Washington State Pharmacy Investigators conduct routine pharmacy inspections to ensure that all pharmacies in the state meet minimum standards of operation and practice as defined by rule and statute. **WAC 246-869-190** states, (1) all pharmacies shall be subject to periodic inspections to determine compliance with the laws regulating the practice of pharmacy. (2) Each inspected pharmacy shall receive a classification rating which will depend upon the extent of that pharmacy's compliance with the inspection standards. This fundamental process is used to ensure the safe delivery of medication and services to the public.

### The Inspection Data

This data was collated by the Department of Health Chief Investigator. The de-identified data has been provided. It is meant as a teaching tool only to aide in improving the process for individuals and protection of the citizens of Washington State.

Violations for the year 2014 are listed in the table below. The inspectors, who are registered pharmacists, found that upon inspection of licensees, 35 percent of the violations were due to lack of allergy and chronic medical conditions collected for patients and this information was absent on patient profiles. No authorization for child resistant caps accounted for 9 percent of all violations. And 9 percent of pharmacies were found to have drugs that were outdated. Next, 8 percent of pharmacies had mislabeled drugs with the majority of this violation involving a drug expiration date on the label exceeding the actual expiration date of the drug stock bottle/package and/or incorrect beyond use dates placed on labels of compounded products. The rest of the violations are noted in **Table 10** with the corresponding Washington Administrative Code (WAC).

**Table 10.** Violation Citation Code.

| <b>Violation Citation Code</b>  | <b>Total Violations per WAC per visit</b> |
|---|---|
| WAC 246-875 Patient Medication Record Systems   | 763                                       |
| WAC 246-887-070 Responsible Pharmacy Manager  | 230                                       |
| WAC 246-869-100 Prescription Record Requirements  | 224                                       |
| WAC 246-869-230 Child Resistant Containers  | 202                                       |
| WAC 246-869-210 Prescription Labeling   | 196                                       |
| WAC 246-869-150 Physical Standards for Pharmacies – Adequate/ Outdated Stock                    | 174                                       |
| WAC 246-887-020 – Uniformed Controlled substances   | 133                                       |
| WAC 246-901 Pharmacist to Technician Ratio  | 92  |
| WAC 246-869-160 Physical Standards for Pharmacies - Adequate Facilities                         | 67  |
| WAC 246-869-180 Physical Standards for Pharmacies - Adequate Equipment                          | 32  |
| WAC 246-863-095 Pharmacist's professional responsibilities                                      | 30  |
| WAC 246-873-080 Drug Procurement, distribution, control   | 30  |
| WAC 246-871-020 Parenteral Products Non-hospitalized patients                                   | 22  |
| WAC 246-869-220 Patient counseling required   | 18  |
| WAC 246-871-040 Personnel - Parenteral Products for NonHospitalized Patients                    | 17  |
| RCW 18.64.160 & RCW 18.64.165   | 15  |
| WAC 246-871-080 Quality Assurance   | 15  |
| WAC 246-871-030 Physical Requirements -Parenteral Products for NonHospitalized                  | 14  |
| RCW 18.64.140 Pharmacist License Properly Displayed   | 13  |
| WAC 246-873-060 Emergency Outpatient Medications  | 11  |
| WAC 246-873-070 Physical Requirements - Hospital  | 11  |
| WAC 246-899 & RCW 69.41 Drug Product Substitution   | 11  |
| WAC 246-873-040 Personnel - Hospital  | 10  |
| WAC 246-869-020 Pharmacies and Differential Hours   | 8   |
| WAC 246-873-090 Administration of Drugs - Hospital  | 8   |
| WAC 246-869-200 Poison Control Number Posted  | 7   |
| WAC 246-871-060 Antineoplastic Medications  | 6   |
| WAC 246-869-170 Physical Standards for Pharmacies - Sanitary Conditions                         | 4   |
| WAC 246-871-050 Drug Facilities Extended Care Facility  | 4   |
| WAC 246-873-050 Drug Distribution and Control -Parenteral Products for NonHospitalized Patients | 4   |
| WAC 246-873-110 Additional Responsibilities of Pharmacy Service - Hospital                      | 4   |
| RCW 18.64.043 Pharmacy License Properly Displayed   | 3   |
| WAC 246-869-190 Pharmacy Inspections -(7) Non compliance with Ancillary Staff                   | 3   |
| WAC 246-865-030 Emergency Kit Extended Care Facility  | 2   |
| WAC 246-865-050 Drug Facilities Extended Care Facility  | 2   |
| WAC 246-865-060 Pharmaceutical Services Extended Care Facility                                  | 2   |
| WAC 246-865-070 Provision for Continuity of Drug Therapy for Residents Extended Care            | 1   |
| WAC 246-871-070 Clinical Services   | 1   |
| WAC 246-873-100 Investigational Drugs   | 1   |
| WAC 246-887-030 Dispensing Controlled subs  | 1   |
| <b>Total violations 2014</b>  | <b>2489</b>                               |

**Limitations**

Washington State has been under a rulemaking moratorium since December 2012. Since then, a quorum has been established on the Pharmacy Quality Assurance Commission, and key topics for rule making has begun to update the WACs

now in use. The Rules Rewrite Project for Pharmacy has targeted rule writing for compounding sterile products; core functions and licensing standards for pharmacists and interns; pharmacy operations and business practices; technology; and ancillary personnel. New rules may limit the usefulness of the data gathered for this project.

**Current Legislation and policy activity since 2014 is listed below**

- Engrossed Substitute House Bill 1625, passed in 2014, restricts retailers from selling over-the-counter (OTC) products that contain dextromethorphan (DXM) to persons under eighteen. The law creates civil penalties for selling or purchasing OTC DMX products in violation of the restrictions in the law and preempts local ordinances regulating the sale, distribution, receipt, or possession of DXM. The law does not apply to DXM containing products sold by prescription.
- Substitute House Bill 1625, passed in 2015, allows pharmacies operated by a hospital to provide medication to ambulance and aid services for uses associated with provided emergency medical services. The commission is working with the department of health to develop a model protocol related to the transfer of medications from the hospital pharmacy to the ambulance or aid service.
- Engrossed Substitute House Bill 1671, passed in 2015, increase access to opioid overdose medications to persons at risk or persons in a position to assist a person at risk of experiencing and opioid-related overdoses.
- Substitute Senate Bill 5293, passed in 2015 authorizes pharmacies to dispense hydrocodone combination products prescribed by Washington licensed optometrists.
- Engrossed Senate Bill 5268, passed in 2015, allows a pharmacist to dispense one early refill for topical ophthalmic products under conditions defined in law.
- Engrossed Senate Bill 5935, passed in 2015, defines interchangeable biological products and establishes conditions and process for when a pharmacist can substitute. The commission has posted a link to the federal drug enforcement agency's list of interchangeable biological products (purple book).
- Engrossed Substitute Senate Bill 5460, passed in 2015, establishes standards for dispensing outpatient medications from a hospital emergency department. The law redefines health care entity to include freestanding outpatient surgery centers, residential treatment facilities, and freestanding cardiac care centers that are not otherwise licensed by the state to acquire or possess legend drugs. The law also provides options hospital owned and operated include individual practitioner officer or multi-practitioner clinics to be added by application or renewal to the hospital pharmacy license.
- Engrossed Substitute Senate Bill 6052 - (budget proviso- effective June 30, 2015) mandating that the commission engage interested parties and stakeholders in a process for developing statutory standards and protocols for long-term care pharmacies. The commission must draft a letter report with proposed language and submit it to the legislature by November 15, 2015.

**The Most Current Rules and Policies are listed below**

- The commission adopted rules to amend WAC 246-887-020 and repealed WAC 246-887-030 to clarify the electronic prescription and dispensing requirements for Schedule II through Schedule V controlled substances. These changes make the rules consistent with state and federal law.
- The commission is amending chapter 246-872 WAC, WAC 246-869-120, and will be adding a new chapter related to the use of technology in pharmacy practice. Technological advances in pharmacy practice have occurred rapidly. Currently, very few rules address contemporary technology in pharmacy practice such as, robotics, remote prescription dispensing, centralized pharmacy services, shared hospital services, remote medication order processing, and workload balancing. Stakeholder work is ongoing.
- The commission is amending chapter 246-869 WAC, WAC 246-863-060, WAC 246-901-100, -120, and -130. Current rules need to be amended to establish standards for pharmacy business practices as it relates to shared accountability of the pharmacist in charge and the business license holder, quality controls or improvements in error reduction, and quotas and performance metrics on clinical and prescription services. The commission continues to work with stakeholders through the Pharmacy Business Practice Committee.
- In response to a rulemaking petition, the commission is considering amending WAC 246-887-040 and -045 to add Lisdexamfetamine, a Schedule II nonnarcotic stimulant for the treatment of binge eating disorder (BED). Lisdexamfetamine is currently approved by the federal Food and Drug Administration for use in the treatment of BED
- The commission is amending chapters 246-878 WAC, 246-871 WAC, 246-903 WAC, and 246-873 WAC to update sterile pharmaceutical compounding standards. Commission is evaluating nationally recognized compounding standards to update and set practice and quality standards for the compounding of sterile and non-sterile preparation in all practice settings. The commission continues to work with stakeholder on draft revisions.



- The commission has begun the rulemaking process to amend WAC 246-869-190 related to pharmacy inspections. The commission plans to consider evaluating the rules on how pharmacy facility inspections are currently conducted using a points-based system.

- The commission is considering updating WAC 246-860-100 related to sexual misconduct rules to include sexual contact that involves force, intimidation, lack of consent, or conviction of a sex offense listed in RCW 9.94A.030. The change in rule will provide clear standards of conduct and assist the commission in complying fully with an Executive Order from former Governor Gregoire.

- The commission has adopted WAC 246-869-105 under the provision for emergency rulemaking to allow pharmacists to provide a temporary prescription refill for patients when the patient's pharmacy access is disrupted. The intent of the rule is to provide continuity of care during a proclaimed emergency. The emergency rule will remain in effect for 120 days. The commission will begin rulemaking to consider permanent rules in this matter.

## **SUMMARY**

With the increased influx of prescriptions and patients due to enactment of the Affordable Care Act, it is incumbent upon pharmacists to be qualified, competent and to practice at the highest standards. Examples of these standards include DUR (drug utilization review) evaluation, allergy review, and patient counseling <sup>[4]</sup>. These processes are linked to improved medication adherence and positive clinical outcomes. It also helps detect and prevent medication errors, and prevent patient harm. In addition, pharmacies must meet a standard of practice for dispensing and distribution.

This report is a snapshot in time focusing on investigational activity, complaints and inspection results highlighting some areas for heightened awareness, as the complaints and inspection violations cover a wide spectrum of topics. It is meant to provide a basis of discussion providing increased safe practice for Washington State citizens.

The ISMP (Institute for Safe Medication Practices) offers a root cause analysis to learn how and why errors occur for further interest in this matter <sup>[5]</sup>.

## **REFERENCES**

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