



**KEEPING COMPLAINTS AND INVESTIGATIONS AT BAY: A LOOK
AT THE CHARACTERISTICS OF COMPLAINTS AND INSPECTION
VIOLATIONS RECEIVED BY THE WASHINGTON STATE
PHARMACY QUALITY ASSURANCE COMMISSION 2014.**

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ABSTRACT

Objective: To provide a summary view of the nature of the complaints filed at the Washington State Pharmacy Quality Assurance Commission and secondly to provide a summary of the inspection violations for the year 2014 for an opportunity for licensees to learn from others. **Methods:** All complaint files were gathered at the

Tumwater, WA Department of Health site. Each file was read manually to collect the following characteristics:

1. Who were the Respondents
2. Who were the Whistleblowers
3. What was the Pharmacy location
4. What were the exact nature of the complaints

In Part two of this document, as summary of the violations found during investigation are presented and were prepared by the Chief Pharmacy Investigator for the Commission.

Results: This report is a snapshot in time. The findings were varied as to the types of complaints received, as were the inspection violations. The intent of this report was of the educational nature providing focus on some areas for heightened awareness, as it is every pharmacists horror to be involved in an error, or and investigation. No correlations were made in the interest of privacy. Conclusions are left to the reader. **Conclusion:** With the increased influx of prescriptions and patients due to enactment of the Affordable Care Act, it is incumbent upon pharmacists to participate in DUR (drug utilization review) evaluation,

allergy review, and patient counseling.^[4] This process is linked to improved medication adherence and positive clinical outcomes. It also helps detect and prevent medication errors, and prevent patient harm.

KEYWORDS: OTC drugs use, increased influx, prevent medication.

INTRODUCTION

The Washington State Pharmacy Quality Assurance Commission (PQAC), formerly known as the Washington State Board of Pharmacy, was established by the legislature in 1891. The duties of its fifteen members include the oversight of thirteen credentials totaling 33,780 licensees and the management of the sale of OTC drugs used to manufacture methamphetamine.^[1]

“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.”^[2] 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. A random sample of pharmacy related complaints filed in 2014 were reviewed to determine their nature and to look for patterns. A summary of this information has been provided as a learning opportunity for licensees.

A similar review of inspection infractions was undertaken and a summary of this information has been provided as a learning opportunity for licensees in part two of this paper.

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. 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 Complaint Data

Of the 236 cases reviewed, 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 1 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.^[3] It is not the intent of this paper to tie complaints to any variables.

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-reports.

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 diversion of controlled substance cases, 7 cases where a licensee failed two consecutive inspections, 6 cases for HIPPA 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 with out 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.

Table 1. 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
Grand Total	235

Table 2.

Respondents	Total
Assistants	17
DVM (veterinarian)	1
Pharmacy Intern	3
Manufacturer	1
Methadone clinic	1
Pharmacist	128
Pharmacy	32
PHNR (non-resident pharmacy)	21
Specialty pharmacy	1
Technician	22
Unknown	1
Wholesaler	8
Grand Total	236

Table 3.

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

Part Two the Inspection Process

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.

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 4 with the corresponding Washington Administrative Code (WAC).

Table 4.

Violation Citation Code	Total Violations per WAC per visit
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 Non Hospitalized 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
Total violations 2014	2489

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 rulemaking 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.

SUMMARY

With the increased influx of prescriptions and patients due to enactment of the Affordable Care Act, it is incumbent upon pharmacists to participate in DUR (drug utilization review) evaluation, allergy review, and patient counseling.^[4] This process is linked to improved

medication adherence and positive clinical outcomes. It also helps detect and prevent medication errors, and prevent patient harm. This report is a snapshot in time of some areas for heightened awareness, as the complaints and inspection violations cover a wide spectrum of topics. 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.^[5]

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