



2015 Pharmacy Law

Pharmacy Quality Assurance Commission

Cheryl Adams, PharmD

PUBLIC HEALTH
ALWAYS WORKING FOR A SAFER AND
HEALTHIER COMMUNITY



Presentation Topics

- Pharmacy Quality Assurance Commission
Vision and Mission
- 2015 legislative statutes relevant to pharmacy
- Overview of PQAC subcommittee rules work
- Patient counseling responsibilities
- Pharmacy technicians
- Pharmacy inspections

PQAC Mission and Vision

- **Mission Statement:** The mission of PQAC is to promote public health and safety by establishing the highest standards in the practice of pharmacy and to advocate for patient safety through effective communication with the public, profession, Department of Health, Governor, and the Legislature.
- **Vision Statement:** The Washington State Pharmacy Commission leads in creating a climate for the patient-focused practice of pharmacy as an integral part of an accessible, quality–based health care system. As a result, the citizens of Washington State:
 - Are well informed about their medication therapy;
 - Take responsibility and actively participate in their health outcomes;
 - Utilize pharmacists and other health care providers appropriately; and
 - Experience the highest level of health and wellness.

2015 Legislation

SHB 1625 – Providing Drugs to Ambulances: Effective July 24, 2015

Allows hospital-operated pharmacies to provide drugs to ambulance or aid services for use associated with providing emergency medical services to patients.

SHB 1625 – Providing Drugs to Ambulances

Provided that:

1. The hospital is located in the same or adjacent county to the county in which the ambulance or aid service operates;
2. The medical program director requests the drugs for ambulance or aid service from the hospital based on agreed patient care.

ESHB 1671 – Opioid Overdose Medications: Effective July 24, 2015

The law is intended to increase access to opioid overdose medications.

Health care practitioners may administer, prescribe, and dispense opioid overdose medications to people at risk of experiencing a drug overdose.*

*directly or by collaborative drug therapy agreement or standing order

ESHB 1671 – Opioid Overdose Medications

The law requires pharmacists who dispense opioid overdose medication to provide written instruction on the proper response to an opioid overdose at the time the prescription is dispensed.

SSB 5268 – Eye Drop Refills: Effective July 24, 2015

Permits a pharmacist to obtain a new prescription, or to refill a prescription for topical ophthalmic products, at 70% of the predicted days of use.

This legislation does not require the insurance carrier to pay for the early refills.

ESSB 5441 – Patient Medication Coordination: Effective July 24, 2015

Requires health benefit plans that provide prescription coverage to implement a medication synchronization policy for the dispensing of prescription drugs for the 2016 plan year.

ESSB 5460 – Prepackaged ER Medications (Multiple Parts): Effective May 11, 2015

The law permits physicians and nurses to dispense prepackaged emergency medications to patients being discharged from a hospital emergency room (ER) during times when community or outpatient hospital pharmacies are not available within 15 miles by road, or when a patient has no reasonable ability to reach the local or community pharmacy.

ESSB 5460 – Prepackaged ER Medications (cont.)

- The pharmacy director must develop policies and procedures.
- Set the dispensing limit to no more than a 48-hour supply, at a maximum, except when community or outpatient hospital pharmacy services will not be available. In no case may the policy allow a supply exceeding 96 hours.

ESSB 5460 – Prepackaged ER Medications (cont.)

- Other provisions of the law:
 - Permits a hospital pharmacy to distribute medication intracompany (common ownership or control) without a wholesaler's license.
 - Permits single or multi-practitioner clinics owned or operated by a hospital to be listed under the hospital pharmacy license for the possession of drugs.
 - Redefines what facilities may be licensed as a health care entity (HCE) to include residential treatment facilities.

SB 5935 – Biologic Products: Effective July 24, 2015

When authorized by the prescriber, the law allows a biological product to be substituted if the federal Food and Drug Administration (FDA) has determined that the biological product is interchangeable with the prescribed biological product. If “dispense as written” is indicated, an interchangeable biological product may not be substituted.

New Pharmacy Sign Required RCW 69.41.160

“Under Washington law, a less expensive interchangeable biological product or equivalent drug may in some cases be substituted for the drug prescribed by your doctor. Such substitution, however, may only be made with the consent of your doctor. Please consult your pharmacist or physician for more information.”

SSB 5293 – Concerning the Use of Hydrocodone Products by Licensed Optometrists in Washington State: Effective July 24, 2015

Law allows WA licensed optometrists to prescribe, dispense, purchase, possess, or administer Schedule II hydrocodone combination products.

ESSB 5557 – Pharmacists as Providers: Effective July 24, 2015

The law prohibits a health plan from denying benefits for health care services performed by a pharmacist under certain circumstances.

ESSB 5577 – Pharmaceutical Waste: Effective July 24, 2015

The law requires the Washington State Department of Ecology (DOE) to convene a workgroup by September 1, 2015 to identify problems with proper management of pharmaceutical waste, and develop recommendations to the legislature by December 31, 2015.

ESSB 6052 Budget Proviso Long Term Care Pharmacies

The Legislature directed the Pharmacy Commission to work with stakeholders to develop statutory standards and protocols for long term care pharmacies.

Rules in Progress

The Commission re-prioritized rulemaking efforts in October 2015 to focus on:

- Pharmacy Technology
- Pharmacy Inspections

Participate in Rulemaking

The Commission welcomes stakeholders to become involved in rulemaking efforts.

Sign up to receive ListServ notices on the Commission website:

<http://listserv.wa.gov/cgi-bin/wa?SUBED1=WSBOP-RULES&A=1>

Pharmacy Basics

- Patient Counseling
- Pharmacy Technicians
- Pharmacy Inspections

Patient Counseling

WAC 246-869-220

- In Washington State, the pharmacist must counsel their patients about their medications.
- The pharmacist must counsel patients about new prescriptions and when required on refill prescriptions.
 - A renewal of an old prescription is considered a new prescription for which counseling is required.
- Only the pharmacist can accept the rejection of a counsel by the patient.

Pharmacy Technician Ratio

RCW 18.64A. - 010(6)(a) and - 40

- The ratio of **one pharmacist to a maximum of three technicians** is established for each pharmacy, provided an ancillary utilization plan (AUP) is submitted to the Commission.
- Pharmacy technicians “in training” are counted in 3:1 ratio per RCW and must work under the immediate supervision of a pharmacist preceptor or a delegated alternate pharmacist.
- AUPs must be on file in the pharmacy and must be up to date.
- Responsible Pharmacy Manager and entity license are held accountable.

Pharmacy Technician Functions

WAC 246-901-020

- Pharmacy technicians may perform certain non-discretionary and specialized functions consistent with their training in pharmacy practice while under the immediate supervision of a pharmacist.
 - Entry of new medication orders;
 - Retrieval of the drug product to fill a prescription;
 - Provide medication data when no interpretation is required
 - Pharmacy Technicians CANNOT initiate transfer of prescriptions, either by phone or fax. Initiation must be done by a pharmacist, not delegated.
- **WAC 246-901-090** Pharmacy ancillary personnel shall wear badges or tags clearly identifying them as pharmacy assistants or technicians.

Technician Specialized Functions

WAC 246-901-035

- **WAC 246-901-035 Pharmacy technician specialized functions.** A pharmacy technician who meets established criteria for employment, experience, training and demonstrated proficiency may perform specialized functions. The criteria shall be specified in the utilization plan of the pharmacy for pharmacy technicians.
- See **WAC 246-901-100** for specific requirements needed with the utilization plan submitted to the Commission.
- Technician Specialized Functions include, but are not limited to:
 - Unit-Dose medication checking
 - Intravenous admixture and other parenteral preparations
 - Medication reconciliation

Pharmacy Inspection Process

WAC 246-869-190

(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.

Pharmacy Inspection Process

WAC 246-869-190

Classification Rating:

Class A – score of 90 or better

Conditional – score of 80-89

Unsatisfactory – scores below 80

Pharmacy Inspection Process

WAC 246-869-190

- Conditional rating (score of 80-89)
 - 60 days to raise inspection score rating to 90 or better.
 - If upon reinspection, the pharmacy fails to receive a rating of 90 or better, then the pharmacy will be subject to disciplinary action.

Pharmacy Inspection Process

- Unsatisfactory rating (score below 80)
 - 14 days to raise inspection score rating to 90 or better.
 - If upon reinspection, the pharmacy fails to receive a rating of 90 or better, then the pharmacy will be subject to disciplinary action.

Pharmacy Inspection Process

Noncompliance with the provisions of chapter 18.64A RCW (pharmacy assistants) and, chapter 246-901 WAC (pharmacy assistants) resulting in a deduction of at least five points shall result in an automatic unsatisfactory rating regardless of the total point score.

Top Violations

Community/Retail Inspections

1. WAC 246-875: Patient Medication Record Systems (35%)
2. WAC 246-869-230: Child-resistant containers (9%)
3. WAC 246-869-150: Physical Standards for Pharmacies – Outdated Stock (9%)
4. Violations of WAC 246-869-210: Prescription Labeling (8%)
5. WAC 246-869-100: Prescription Record Requirements (7%)

These five violations represent **68% of all violations** cited in community/retail pharmacy inspections.

Pharmacy Inspection Stakeholders Wanted

Join in with the Pharmacy Inspection Rulemaking Committee and participate as a stakeholder.

To join, send an email to:

Pharmacyinspectionrules@doh.wa.gov

Commission Members

- Albert Linggi, R.Ph., MBA, Chair
- Dan Rubin, MPP, Public Member, Vice Chair
- Cheryl Adams, PharmD
- Steve Anderson, R.Ph.
- Chris Barry, R.Ph.
- Olgy Diaz, Public Member
- Judy Guenther, Public Member
- Gary Harris, R.Ph.
- Nancy Hecox, PharmD, CDP
- Elizabeth Jensen, PharmD
- Tim Lynch, PharmD
- Maureen Sparks, CPhT
- Matthew Ronayne, R.Ph.
- Arun Sambataro, Public Member
- Sepi Soleimanpour, R.Ph., MBA-HA

Commission Staff Members

- Executive Director
(360) 236-4853
- Doreen Beebe
Program Manager
(360) 236-4834
- Lisa Roberts PharmD
Pharmacist Consultant
(360) 236-4999
- Cathy Williams RPh, MBA,
MHA
Pharmacist Consultant
(360) 236-4875
- Rules Coordinator
(360) 236-4861
- Leann George
Senior Secretary
(360) 236-4946
- Irina Tiginyanu
Pharmacy Tech Analyst (360)
236-4827

Office of Investigation & Inspections

Pharmacist Investigators

- Grace Cheung
 - NW King
 - (253) 395-6714
- Julie Faun –
 - E King & NC WA
 - (253) 395-6719
- Tina Lacey
 - NW WA
 - (360) 236-4648
- Greg Lang
 - Seattle
 - (253) 395-6721
- G Stan Moore
 - Pierce & SE King
 - (360) 236-4635
- Pam Sanders
 - Olympic Peninsula
 - (360) 236- 2923
- Heidi Welborn
 - SW King
 - (253) 395-6718
- Brad Dykstra
 - SW WA
 - (360) 236-4833
- Tyler Varnum
 - Near East WA
 - (509) 574-0140
- Eleanor Doss
 - Far East WA
 - (509) 329-2206
- Gordon MacDonald
Pharmacist Investigator
Supervisor
 - (360) 236-4817

Pharmacy Commission Info

- Visit the Commission website to sign up to receive important notices from the Commission:
- Quarterly Newsletter, meeting notices, stakeholder meetings:
- For newsletters: <http://listserv.wa.gov/cgi-bin/wa?SUBED1=WSBOP-NEWSLETTER&A=1>
- For forms and info: <http://listserv.wa.gov/cgi-bin/wa?SUBED1=WSBOP-RULES&A=1>
- Mail: PO Box 47852, Olympia, WA 98504-7852

Discussion Recap

- 2015 legislative statutes relevant to pharmacy
- Overview of PQAC subcommittee rules work
- Patient counseling responsibilities
- Pharmacy technicians
- Pharmacy inspections

Questions?

PUBLIC HEALTH

ALWAYS WORKING FOR A SAFER AND

HEALTHIER WASHINGTON