OREGON BOARD OF PHARMACY – LAW UPDATE

OSPA Lane County Seminar
February 2020

1

The Oregon Board of Pharmacy serves to promote and protect public health, safety, and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.

2

Objectives

- Discuss new laws as well as current and proposed rules related to Oregon pharmacy practice
- Examine unique perspectives from Board members and staff about contemporary issues in pharmacy
- Review compliance expectations for existing laws and rules created to ensure safe and effective delivery of care
- Develop strategies to utilize the Board of Pharmacy's website and available resources

3

Overview

- 2019 Legislative Session impacts to Oregon pharmacy
- Recent rules review
- PHPFAC / Prescribing Update
- Common compliance issues
- Agency changes on the horizon

4

2019 Legislative Session

A number of Senate Bills (SB) and House Bills (HB) impacting Oregon pharmacy passed during the 2019 session. Highlights:

- SB698 & HB2935 – Labeling requirements and prescription readers
- SB910 & HB2257 - Relating to naloxone and PDMP
- HB2011 – Mandates cultural competency CE for health board licensees (operative 7/2021)
- HB3273 - Drug Take-Back

5

New Rules

In response to 2019 legislation, the Board of Pharmacy adopted a number of rules:

- Naloxone access
- SB 9 – Prescribing emergency insulin refills and supplies
- Agency related issues (FPGEC and "temp auths")
- Division 080 – Animal Euthanasia drug outlet revisions

And… rules already in the active "pipeline" also adopted:

- DRUG COMPOUNDING

6

Insulin Access

KEY POINTS:

- *Always… assist a diabetic patient in need*
- *Never… allow a patient to leave your pharmacy without critical, life-saving medications (or at least a warm referral)*

LEGALITIES:

- SB 9 – RPh educational training required → NTE 30 day rxs / max of 3x/year → Payment mandate (for rx AND for RPh assessment)
- Other considerations

7

Public Health Pharmacy Formulary Advisory Committee (PHPFAC) Updates

Background Refresh - Two main statutory mandates:

- Committee develops Statewide Drug Therapy Management Protocols for a pharmacist to provide patient care services. These typically consist of a standardized patient assessment process and treatment care plan under which a pharmacist may prescribe and dispense a drug or device to a patient.
- List of post-diagnostic drugs and devices that a pharmacist may prescribe
- All prescribing is pursuant to foundational elements outlined in Division 020 rules
  - Assess patient; collect subjective/objective re: health history and clinical status
  - Utilize info to evaluate and develop patient-centered care plan
  - Implement care plan (incl. treatment goals, monitoring and follow-up)
  - Provide notification to PCP/others within 5 days of prescribing
  - Retain documentation of all associated records

8

Public Health Pharmacy Formulary Advisory Committee (PHPFAC) Updates

Formulary currently includes:

- Devices & Supplies
  - Diabetic blood sugar testing supplies
  - Nebulizers and associated supplies
  - INR testing supplies
  - Enteral nutrition supplies
  - Injection supplies
  - Inhalation spacers
  - Peak flow meters
  - Ostomy products and supplies
- Continuation of Therapy
- Cough/cold/symptom management: PSE, benzonatate, SABAs, intranasal corticosteroids
- EC
- Male/Female condoms

Each has its own set of parameters as recommended by the Committee and adopted by OBOP rules

9

Sample SDTM Protocol

COUGH AND COLD SYMPTOM MANAGEMENT - PSEUDOEPHEDRINE

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe pseudoephedrine.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- INCLUSION CRITERIA: Age 18 and older, verified by positive ID
- EXCLUSION/REFERRAL CRITERIA:
  - Age < 18

PRESCRIBING PARAMETERS:

- Pharmacist must review PDMP prior to issuing prescription, and retain documentation of review
- Maximum quantity: 3.6g or a 60 count quantity per prescription, whichever is less
- Maximum frequency: 3 prescriptions in a 12 month period

But … PSE is a Controlled Substance…

10

Public Health Pharmacy Formulary Advisory Committee (PHPFAC) Updates

On the horizon, for rulemaking in 2020:

- Tobacco Cessation (both NRT and non-NRT)
- Travel Health Services Medications, including
  - Malaria prophylaxis
  - Traveler's diarrhea
  - Acute mountain sickness
  - Motion sickness
- Post Exposure Prophylaxis (PEP)
- ?? What will YOU submit as a concept ??

*Note: Expect each to come with a patient questionnaire and assessment/treatment plan algorithm; OBOP to determine any professional criteria (such as certification, CE, etc.)

11

Scope of Practice & Legal Risk

Scope of practice, generally, refers to the boundaries within which a health professional may practice. For pharmacists, the scope of practice is established by state legislatures (ORS 689) and regulated by a board or agency… here, the Oregon Board of Pharmacy.

Food for thought:

- Prescribing under a Collaborative Drug Therapy Management Agreement vs. prescribing via Formulary and Division 020?
- What does "provider status" really mean?
- When a pharmacist is working for any pharmacy drug outlet, not independently owned, how much autonomy does that pharmacist have when prescribing? If an error occurs, is it the fault of the pharmacist or the pharmacy who billed on behalf of the RPH services provided?

12

Compliance / Enforcement

- Controlled substance accountability
- Drug storage / Temperature monitoring

13

CS Accountability

- Continues to be a FOCUS for annual inspections
- Why? National landscape - Opiate Epidemic AND ongoing non-compliance issues continue to be cited
- BOP is a partner – Rules attempt to help pharmacies comply with DEA regs
- PIC and all pharmacy personnel have shared responsibility with pharmacy drug outlet – all licenses and registrations carry legal risks and responsibilities

14

CS Accountability – Self Inspection Form

Please list where the following items are located inside the pharmacy. Be as specific as possible; there can be many filing cabinets and binders.

Current written annual controlled substance inventory: _____

Controlled Substance Invoices for the last 3 years: _____

Completed CII order forms (DEA form 222) for last 3 years: _____

Quarterly Schedule II reconciliation with explanations documented: _____

- Be organized! Know where all supportive documentation is kept (for CS drugs, inventories, quarterly reconciliations)
- Empower all staff members to participate in good inventory management procedures, including:
  - Stocking shelves, keeping shortest dated product in front
  - Maintaining inventory – clearly marking short-dated products; send unwanted or expired drugs back immediately
  - Quarterly reconciliation – be sure to include all notes related to count discrepancies
  - Annual inventory
  - Does your pharmacy use a perpetual inventory log? Do you back count when dispensing CS Rxs?

15

Drug Storage / Temperature Monitoring

- Continues to be a FOCUS for annual inspections
- Why? Foundational expectation: Patients have to be able to rely upon their pharmacy to be dispensing drugs that have been properly stored
- PIC and all pharmacy personnel have shared responsibility with pharmacy drug outlet

16

Drug Storage / Temperature Monitoring

Please list where the following items are located inside the pharmacy. Be as specific as possible; there can be many filing cabinets and binders.

Temperature Logs: _____

Quarterly Validation of Cold Storage Equipment: _____

- Be organized! Know where all supportive documentation is kept
- Be knowledgeable! Learn about your drug storage equipment and what to do when things go wrong
- Empower all staff members to participate in drug storage oversight expectations:
  - Understand how to monitor the system and read the data reports
  - Recognize how to handle system alerts and proactive QA procedures
  - Do you know the steps to take when your refrigerated drug products have gone out of range?

17

Agency News

- Website migration
  - Coming very soon!
  - Easier to navigate organized and progressive content for licensees and stakeholders
- Online services (eGov)
  - Live in late fall 2019
  - Renew online
  - License and registration verification
  - Ability to update your contact information (address, phone, email and employment) – coming soon!

18

QUESTIONS

19