

# Safe Pharmacy Practice Conditions

---

OREGON BOARD OF PHARMACY

WORKGROUP– JANUARY 25, 2022



# OBOP MISSION



- *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.*

# Roll Call

---

- Safe Pharmacy Practice Workgroup Participants

- Lincoln Alexander, RPH, OSPA
- Molly Bloom, RPH
- David Bowman, Public
- Victoria Kroeger, RPH, NACDS
- Damion Meany, RPH
- Benjamin Mitchell, COPT
- Kathryn Radloff-Francis, Public
- Anthony Sterlinski, RPH
- Christopher Ward, COPT
- Katie Yabut, RPH, OSHP
- Ken Zientara, RPH

- Board Members Present

- Wassim Ayoub, RPH
- Shannon Beaman, RPH

- Staff Members Present

- Jennifer Davis, Pharmacist Consultant
- Rachel Melvin, Operations Policy Analyst
- Joseph Schnabel, Executive Director
- Joanna Tucker-Davis, Assistant Attorney General

# Reminders

---

- Please be aware that any investigatory information is confidential and should not be discussed in a public meeting.
- When using examples, it is suggested that you phrase as the examples as hypothetical.

# Workgroups

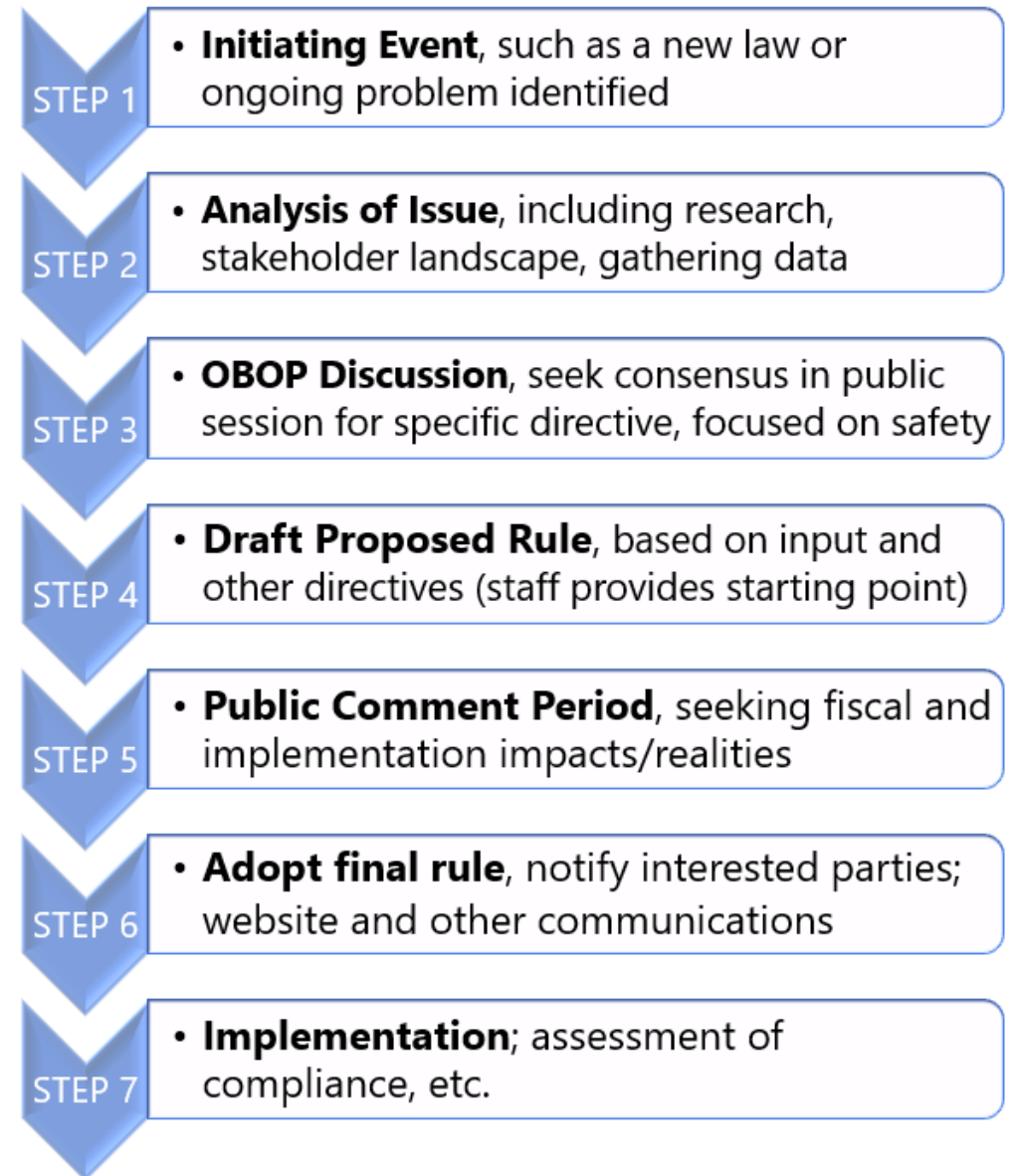
---

- *What is a Workgroup?*
  - A Workgroup may be established and used for to collect information on a specific topic and provide advice on rules in which there are issues that may substantially impact the interests of persons or entities (“stakeholders”), who will likely be affected by the proposed rulemaking.
- *What is the purpose of a Workgroup?*
  - Involve the public in the development of public policy
  - Estimate financial and racial equity impact on interested persons/entities
  - Members must represent the communities of persons likely to be affected by the rule

\*A Workgroup’s role is advisory only.\*

# Rulemaking Process

- Workgroup provides advice to agency
- Agency drafts rules
- Draft rules are filed with Secretary of State and notice given to interested parties
- Public may comment on rules before rules are enacted
- Agency considers public comment, discusses and determines final rules
- Rules are filed with Secretary of State



**Steps 3 & 4 are repeated as necessary to build consensus**

# Proposed Timeline- DRAFT

---

- January 2022: Initial Workgroup meeting- 1/25/2022
- February 2022: Send survey to licensees
- March 2022: Review survey data with Workgroup, discuss primary targets for rule revision
- April 2022-June 2022: Board staff draft proposed rules
- May 2022- July 2022: Review draft rules with Workgroup
- August 2022– December 2022: Board staff ongoing revision of proposed rules
  - June 2022: Board 1st look at proposed rules
  - August 2022: Board 2nd look at proposed rules
  - October 2022: Board 3<sup>rd</sup> look at proposed rules
  - November 2022: Rulemaking
  - December 2022: Board adoption of proposed rules

**Typical rules process can take 2-3 years**

**This timeline will be adjusted based on board priorities**

Safe Pharmacy Practice Conditions



Promote, Preserve and Protect  
PUBLIC Health, Safety and Welfare

# Introductions

---

- Name
- License type
- Current practice setting
- Previous pharmacy practice experience
- Why you wanted to serve on this workgroup

# Workgroup Training

January 25, 2022

Assistant Attorney General Joanna Tucker Davis

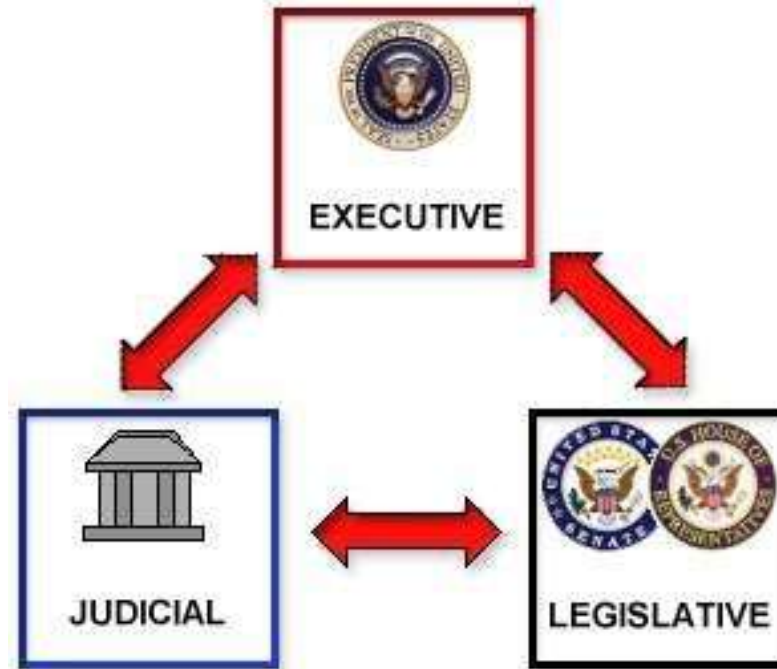
Board of Pharmacy

# Three Branches of Government

Legislature:  
Makes the Laws

Executive Branch:  
Carries out the  
Laws

Judicial Branch:  
Interprets the  
Laws



# What are statutes?

- Laws that are enacted (created) by the legislature.



Agencies only have the powers given to them by statutes.

- A state agency "has no inherent power, but only such power and authority as has been conferred upon it by its organic legislation."
- *Ochoco Const., Inc. v. Department of Land Conservation and Development, 295 Or 422, 426, 667 P2d 499 (1983).*



# What are rules?



- Laws that are promulgated (created) by agencies.
- Agency's power to create rules is grounded in its governing statutes.
- An agency is a creature of statute. It has no inherent power, but only such power and authority as has been conferred upon it by its organic legislation. This power includes that expressly conferred by statute as well as such implied power as is necessary to carry out the power expressly granted. Stated somewhat differently, a statute which creates an administrative agency and invests it with its power is likewise the measure of its power.
- *Ochoco Construction, Inc. v. Department of Land Conservation and Development*, 56 Or App 32, 40 (1982).

# What is a rule?

- ORS 183.005(9): “Rule” means any agency directive, standard, regulation or statement of general applicability that implements, interprets or prescribes law or policy, or describes the procedure or practice requirements of any agency. \* \* \*.
- Rules can:
  - Create prohibitions: tell person affected what the person should not do.
  - Create mandates: tell person affected what the person must do.
  - Interpret laws: tell person affected how agency views a statute so that person affected has clarity.
  - Create entitlements: give person legal right to something (like a license if application requirements are fulfilled).
  - Describe procedure or policy of agency: give person knowledge about how agency will act.
  - **RULES SHOULD GIVE PUBLIC AND LICENSEE CLEAR NOTICE OF WHAT IS MUST BE DONE (OR NOT DONE) UNDER THE RULE.**

# A Vocabulary Detour

- ORS = Oregon Revised Statute  
“ORS 689.005”
- OAR = Oregon Administrative Rule  
“OAR 855-001-0000”



# ORS 689.205

**689.205 Rules.** The State Board of Pharmacy shall make, adopt, amend and repeal such rules as may be deemed necessary by the board, from time to time, **for the proper administration and enforcement of this chapter.** Such rules shall be adopted in accordance with the procedures specified in ORS chapter 183. [1979 c.777 §17; 1985 c.565 §103]

# ORS 689.025

## **689.025 Policy; purpose.**

(1) The practice of pharmacy in the State of Oregon is declared a health care professional practice **affecting the public health, safety and welfare** and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this chapter, merit and receive the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy in the State of Oregon. This chapter shall be liberally construed to carry out these objects and purposes.

(2) It is the purpose of this chapter to **promote, preserve and protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy** and of the registration of drug outlets engaged in the manufacture, production, sale and distribution of drugs, medications, devices and such other materials as may be used in the diagnosis and treatment of injury, illness and disease.

# ORS 689.155

**689.155 Authority of board over medications, drugs, devices and other materials; rules.** The State Board of Pharmacy shall also have the following responsibilities in regard to medications, drugs, devices and other materials used in this state in the diagnosis, mitigation and treatment or prevention of injury, illness and disease:

(1) The **regulation of the sale at retail**, the administering by pharmacists to the extent provided in ORS 689.645 and 689.655 and the dispensing of medications, drugs, devices and other materials \* \* \* \* \*.

(2) **The specifications of minimum professional and technical equipment, environment, supplies and procedures for the compounding, administering and dispensing of such medications, drugs, devices and other materials within the practice of pharmacy and any drug outlet.**

(3) **The control of the purity and quality** of such medications, drugs, devices and other materials within the practice of pharmacy and any drug outlet.

# What is authorized under these statutes?

## Rules

- For the purpose of promoting, preserving and protecting the PUBLIC health, safety and welfare.
- Regulation of drug and device sales.
- Specifications of minimum professional and technical environments.
- Rules regarding the control of the quality and purity of drugs.

# What to avoid?

- Board doesn't have authority to dictate business practices that don't affect public safety or don't relate to the quality or purity of drugs.
- Board isn't a union or professional organization for pharmacists or technicians—Board is here for public protection.
- Board can't pass rules that conflict with labor laws. Need to be careful about not dictating things like how long lunch hours are (that's a labor and employment issue).

# Current Rules

- OAR 855-041-1170

Grounds for Discipline

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:

\* \* \* \* \*

(3) Failure to provide a working environment that protects the health, safety and welfare of a patient which includes but is not limited to:

(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety.

(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.

(c) Adequate time for a pharmacist to complete professional duties and responsibilities including, but not limited to:

(A) Drug Utilization Review;

(B) Immunization;

(C) Counseling;

(D) Verification of the accuracy of a prescription; and

(E) All other duties and responsibilities of a pharmacist as specified in Division 19 of this chapter of rules.

# OBOP Working Conditions History

---

- 2011 1<sup>st</sup> survey
- 2012 “Working Conditions” rules adopted- OAR 855-041-1170
- 2013 2<sup>nd</sup> survey
- 2016 3<sup>rd</sup> survey

# Oregon Pharmacy Working Conditions Survey 2011, 2013, and 2016

## Pharmacy Working Conditions Survey Results Comparisons

### July 2013

Number of active RPh	5847
Number of RPh Email Addresses	5812
Number of Undelivered Emails	-2
	<small>Note: There were 997 more email addresses in 2013 than 2011</small>
Number of Responses	1647 (492 or 30% included written comments)
Response Rate	28.35%

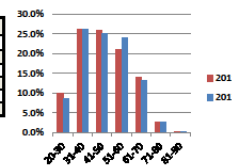
Q. 7 Years Licensed in Oregon (includes all out of state pharmacists)	Number of all OBOP Licensed Pharmacists	Percentage of All OBOP Licensed Pharmacists	Percentage that Responded to Survey	Percentage that Responded to Survey Compared to 2011
Less than 5 years	1963	33.57%	10.80%	-2.66%
5-10 Years	856	14.64%	16.47%	-4.86%
10-15 Years	580	9.92%	36.38%	6.95%
15-20 Years	646	11.05%	24.46%	-2.37%
20-25 Years	483	8.25%	28.16%	-3.54%
More than 25 Years	1319	22.56%	36.01%	0.70%

### July 2011

Number of active RPh	5316
Number of RPh Email Addresses	4954
Number of Undelivered Emails	-141
	<small>(518 or 37% included written comments)</small>
Number of Responses	1401
Response Rate	29.11%

Q. 7 Years Licensed in Oregon (includes all out of state pharmacists)	Number of all OBOP Licensed Pharmacists	Percentage of All OBOP Licensed Pharmacists	Percentage that Responded to Survey
Less than 5 years	1575	29.63%	13.46%
5-10 Years	661	12.43%	21.33%
10-15 Years	717	13.49%	29.43%
15-20 Years	589	11.08%	26.83%
20-25 Years	429	8.07%	31.70%
More than 25 Years	1345	25.30%	35.32%

All OBOP Licensed RPh Age Breakdown



### Response Counts:

	2011	2013
All Pharmacists	1393	1647
Staff Pharmacist	652	760
Clinical/Specialty Pharmacist	173	255
Pharmacy Manager/PhC	403	452
Regional Pharmacy Manager/VP	42	36
Relief Pharmacist	90	107

# Ohio Survey 2021

---



## Pharmacist Workload Advisory Committee

Approved 4/20/2021

Pursuant to rule 4729-2-01 (B) of the Ohio Administrative Code, the State of Ohio Board of Pharmacy proposes the creation of a Pharmacist Workload Advisory Committee to ensure compliance with the following Ohio laws and rules:

- Section 4729.55, which states: *Adequate safeguards are assured that the applicant will carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner.*
- Rules 4729:5-9-02 and 4729:5-9-02.1 (pending) of the Administrative Code which state: *The pharmacy shall be appropriately staffed to operate in a safe and effective manner pursuant to section 4729.55 of the Revised Code.*

### Issue:

In July 2020, the State of Ohio Board of Pharmacy disseminated a workload survey to all pharmacists working in Ohio. The intent of the survey was to capture feedback on pharmacist working conditions in the state.

Capturing this data is important as pharmacist working conditions have been identified as a concern among licensees, state regulators (several of which have issued similar surveys), and national organizations. For example, in 2019, the American Pharmacist Association conducted a national survey and reported "pharmacists' perceptions of their workload continues to increase in a number of settings."<sup>8</sup>

The data revealed in this survey found similar trends reported by national organizations and other states. For example, almost half of survey respondents (49%) indicated that they did not have adequate time to complete their job in a safe and effective manner. The survey also found that 57% of pharmacists reported they felt pressure by their employer or supervisor to meet standards or metrics that may interfere with safe patient care.

Peer reviewed studies also indicate increasing pharmacist workload poses an increased risk to patient safety:

- One [study](#) found that there was an increase in the risk of dispensing a potential drug-drug interaction with higher pharmacist and pharmacy workload, use of specific automation, and dispensing software programs providing alerts and clinical information.
- A [recent 2020 study](#) found reduced pharmacist workload allows re-allocation of pharmacy time to provide prescription suggestions and, more recently, decrease dispensing errors.

77 South High Street, 17th Floor, Columbus, Ohio 43215

T: (614) 466.4143 | F: (614) 752.4836 | [contact@pharmacy.ohio.gov](mailto:contact@pharmacy.ohio.gov) | [www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov)



# Discussion Items

---

- Survey

- Audience

- Practice Site/Setting
    - Position Type/Primary Role
    - Shift Hours
    - Weekly Hours Worked
    - Prescriptions per RPH
    - Other demographics

- Content

- Core Questions
    - Safe Practice
    - Comments

- Length

# Audience: Practice Site/Setting

---

- Community Pharmacy - Chain
- Community Pharmacy- Independent
- Mail Order Pharmacy
- In-Patient Hospital Pharmacy
- Out-Patient Hospital Pharmacy
- Health Center Pharmacy
- Long Term Care Pharmacy
- Ambulatory Care
- Compounding Pharmacy
- Other
- Large Chain (more than 12 locations): Standalone
- Large Chain (more than 12 locations): Grocer
- Small Chain (more than one but less than 12 locations)
- Independent (one location)
- Mail Order
- Inpatient Hospital
- Outpatient Hospital
- Long-Term Care
- Other (PBM, prefer not to say, compounding, VA, nuclear, specialty, academia, etc.)

# Audience: Position Type/Primary Role

---

- Pharmacy Manager/PIC
- Staff Pharmacist
- Relief Pharmacist
- Clinical/Specialty Pharmacist
- Regional Pharmacy Manager/VP
- Responsible Person / Manager
- Staff Pharmacist
- Relief/Floater Pharmacist
- Other
- Prefer not to Answer

# Audience: Shift Hours

---

- <4
- 4-5.9
- 6-7.9
- 8-9.9
- 10-11.9
- 12-13.0
- >14
- <5.9
- 6-7.9
- 8-9.9
- 10-12.9
- >13

# Audience: Weekly Hours Worked

---

- <20
- 20-29.9
- 30-39.9
- 40-49.9
- 50-59.9
- >60
- <20.9 (Typo?)
- 30-39.9
- 40-49.9
- 50-59.9
- >60

# Audience: Prescriptions per RPH

---

## PER RPH SHIFT

- <50
- 51-99
- 100-199
- 200-299
- 300-399
- 400-499
- >500
- Not Sure
- Not Applicable

## PER RPH HOUR

- 0-10
- 11-25
- 26-50
- 51-75
- 76-100
- 101+

# Audience: Other Demographics

---

- Gender
- Years of Practice
  - < 5 years
  - 5-10 years
  - 10-15 years
  - 15-20 years
  - 20-25 years
  - > 25 years
- State of Primary Practice?
- Years of Practice
  - <3 years
  - 3-9 years
  - 10-19 years
  - 20-29 years
  - 30 or more years

# Content: Core Statements

---

- I have adequate time for breaks/lunches at my primary practice site.
- I am satisfied with the amount of time I have to do my job.
- My employer provides a work environment that is conducive to providing safe and effective patient care.
- My site has adequate Pharmacist staff to provide safe and effective patient care.
- My site has adequate Technician staff to provide safe and effective patient care.
- My site has adequate Clerk staff to provide safe and effective patient care.
- I am given the opportunity to take lunch breaks or other breaks throughout the workday.
- I feel that I have adequate time to complete my job in a safe and effective manner.
- I feel that my employer provides a work environment that allows for safe patient care.
- I feel that my work environment has sufficient pharmacist staffing that allows for safe patient care.
- I feel that my work environment has sufficient pharmacy technician staffing that allows for safe patient care.
- I feel that the workload to staff ratio allows me to provide for patients in a safe manner

# Content: Additional Statements

---

- I feel that inadequate staffing at my pharmacy results in delays in patients receiving medications in a timely manner.
- I feel pressure by my employer or supervisor to meet standards or metrics that may interfere with safe patient care.
- I feel safe voicing any workload concerns to my employer.

# Content: Safe Practice / Comments

---

- Technician Related
  - Reduced Staffing Hours
  - Lack Training
  - Limited Availability
- Pharmacist Workload
  - Pharmacist Schedule (extended hours, reduced overlap, mandatory OT, no OT, etc.)
  - Increase in Demands Placed on Pharmacist
- Patient Safety Related
- Meal Periods and Breaks
  - Able to Take Meal Periods and Breaks
  - Challenges Related to Taking Meal Periods and Breaks
- Inadequate support staff (i.e. not enough technicians and support staff to safely handle the required workload)
- Inadequate pharmacist staffing (i.e. not enough pharmacists on staff to safely handle the required workload)
- Inability to properly counsel patients
- Focus on metrics (i.e. filling a specific number or prescriptions per day, etc.)
- Too many non-clinical duties (i.e. filing, prior authorizations, making refill phone calls, etc.)
- Providing vaccines and other non-dispensing duties
- Lack of scheduled breaks
- Other

# Future Meetings

---

- Survey will be sent to workgroup members by 1/31/2022 to determine best day/time for future meetings
- Each meeting is anticipated to last 3 hours
- Meetings are planned for:
  - March 2022
  - May 2022
  - July 2022
  - September 2022- tentative

# FINAL THOUGHTS

THANK YOU FOR YOUR  
PARTICIPATION!

