Oregon Board of Pharmacy REVISED BOARD MEETING AGENDA

Meeting Location: Conference Call November 17-18, 2021

Public Attendance by Phone (503) 446-4951 Phone Conference ID: 599 316 080#

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.

Wednesday, November 17, 2021 @ 8:30AM Thursday, November 18, 2021 @ 8:30AM

- All Board meetings except Executive or Closed Sessions are open to the public. Pursuant to ORS 192.660, Executive Sessions are closed, with the exception of news media and public officials
- No final actions will be taken in Executive Session
- When action is necessary, the board will return to Open Session
- To sign up for Public Comment, email your request to Karen MacLean by 4:30PM on 11/17/2021.

The meeting is accessible to persons with disabilities. A request for hearing impaired assistance and accommodations for persons with disabilities may be made via email to <u>Karen MacLean</u> or by calling 971-673-0001 with at least 48 hours' notice.

WEDNESDAY, November 17, 2021

- I. OPEN SESSION, Wassim Ayoub RPh, Presiding
 - a. Roll Call
 - b. Agenda Review and Approval

Action Necessary

c. Welcome/Introduction – Schnabel/Pande

II. GENERAL ADMINISTRATION

- a. Consider Adoption of Temporary Rules- Schnabel
 - i. Division 041- Operation of Pharmacies (Pharmacy Closures) #A

Action Necessary

III. STRATEGIC PLANNING -

- a. Progress & Trends
 - i. Strategic Review Schnabel/Ayoub #B
 - ii. Board Comments/Roundtable
 - iii. "Big Picture" Trends, Challenges & Opportunities PESTLE
 - iv. PESTLE Debrief

Lunch Break

- b. Board Information/Orientation
 - i. Legislative Concepts MacLean
- c. Priority Evaluation & Direction
 - i. Technicians
 - ii. Technology

Adjourn Action Necessary

THURSDAY, November 18, 2021

- I. OPEN SESSION, Wassim Ayoub RPh, Presiding
 - a. Roll Call

II. STRATEGIC PLANNING

- a. Priority Evaluation & Direction Continued
 - i. Licensing
 - ii. Regulation

III. PUBLIC COMMENT

a. The Board will not deliberate any issues or requests during Public Comment such as formal requests, issues currently under investigation, requests pending before the Board or currently proposed rules.

Lunch Break

- b. Communication
- c. Summary & Next Steps Schnabel/Pande
- d. Board Member Concluding Comments & Direction- Ayoub

Adjourn Action Necessary

Division 007/041: Public Health Emergency/Operation of Pharmacies (Temporary Closure)

Filing Caption (max 15 words):

Requires pharmacies to post accurate hours of operation and to update them when there is a temporary closure.

Need for Rules:

During the COVID-19 pandemic, pharmacies are experiencing an increase in temporary closures due to extenuating circumstances (e.g. illness, staffing shortages). Accurate pharmacy hours of operation must be available to patients and providers to ensure timely access to prescription medication.

Justification of Temporary Filing:

Pharmacies must have accurate hours of operation posted at all times. If a pharmacy must temporarily close, Oregonians will be unable to access their medications in process or filled by that pharmacy. Failure to adopt this temporary rule could result in patients and healthcare providers being unable to determine if the pharmacy is operating and patients being unable to access medications in process or filled by the pharmacy. Inability to access prescription medications in a timely manner is a danger to the public health and safety.

Fiscal Impact:

None anticipated

Documents Relied Upon:

Surescripts: Emergency Response Action Plans

NCPDP: Emergency Preparedness Guidance (v. 1.9)

Rules Summary:

This rule requires pharmacies to post accurate hours and to update operating hour information in the event of a temporary closure. Accurate pharmacy operating hours must be available to patients and prescribers so they can seek alternate sources of prescription medication when a pharmacy is temporarily closed.

Division 7

PUBLIC HEALTH EMERGENCY

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855-007-0120

Damage to a Pharmacy and Drug Integrity

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(1) If a pharmacy prescription department sustains damage, whether by flood or otherwise, the entire drug inventory, including any prescriptions that are awaiting pickup, is unfit for dispensing, shall be classified as adulterated and must be destroyed unless, in the pharmacist's professional judgment, any items are deemed safe for dispensing. Any incident of this nature must be reported to the Board within three working days.

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(2) If a pharmacy loses power that affects temperature or humidity controls such that USP standards for proper storage of drugs have been violated, such drugs shall be classified as adulterated and may not be dispensed.

NOTE: for those drugs labeled for storage at "controlled room temperature," the acceptable range of temperature is 68° to 77°F with allowances for brief deviations between 59° to 86°F.

(3) Controlled substances damaged, lost or stolen shall be documented and reported to the DEA and the Board on DEA Form 41 or DEA Form 106 as appropriate.

(4) A pharmacy that is required to temporarily close or relocate due to an emergency must report this event to the Board within three working days according to OAR 855-041-1015.

Division 41

OPERATION OF PHARMACIES

855-041-1015

Operation of a Pharmacy (Both Retail and Institutional Drug Outlets)

(1) Supervision. A pharmacy may only be operated when a pharmacist licensed to practice in this state is present. This means that the pharmacist must be physically present in the pharmacy or institutional facility.

(2) Sanitation:

(a) Pharmacies shallmust be kept clean.

(b) Persons working in a pharmacy shallmust practice appropriate infection control.

(3) A Pharmacy must conspicuously display accurate hours of operation at each pharmacy entrance, on each telephone greeting, and the internet (e.g. website, social media, mobile applications).

(4) Temporary Closing. If a pharmacy is temporarily closed to the public the pharmacy must:

(a) Post updated hours as required in (3) as soon as the need to deviate from the posted hours is known by the pharmacy, but no later than 2 hours after the temporary closure begins;

(b1) Include the period of time the pharmacy will be closed and the name, street address and telephone number of a nearby pharmacy that is available to serve the public during the period of closure on the notice.

(b2) When possible, the pharmacy should provide notice of alternative options for prescription pickup and the date and time the pharmacy will reopen to the public.

POLICY DISCUSSION: Requirement

- 60 (c) Configure systems to provide notification to providers and patients of the temporary closure and prevent receipt of new prescriptions or refill requests; and
- (d) Notify the board office as soon as possible but no later than 72 hours after the temporary closure
 begins.
- 66 (5) Federal and state holidays are exempt from the requirements of (4)(b), (4)(c), and (4)(d).

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OREGON BOARD OF PHARMACY STRATEGIC PLAN 2020-2024



OREGON BOARD OF PHARMACY STRATEGIC PLAN 2020-2024





INTRODUCTION

On behalf of the Board members and staff of the Oregon State Board of Pharmacy, I am pleased to present the Board's Strategic Plan for 2020-2024. The purpose of this plan is to outline the direction and priorities for change which have been established by the Board and which we believe will ensure that pharmacy practice is regulated in the interest of public health and safety, result in exceptional service to our licensees, and advance the health of Oregonians.

In the past two years, four new Board Members have been appointed, and one Inspector and one Licensing Representative have been added to the Board staff. In addition, seven members were appointed to the newly established Public Health and Formulary Advisory Committee. This group of new Board/Committee members and staff represent a diverse mix of highly qualified individuals that will result in effective deployment of our mission on behalf of the citizens of Oregon. We are committed to continuing to improve our affirmative action, diversity, equity and inclusion efforts in recruitment and retention of Board and Committee members and staff.

We would like to acknowledge the input of stakeholders who share their views on priorities for pharmacy regulation in order to allow pharmacists, pharmacy technicians and drug outlets to provide the best possible care to all Oregonians. The practice of pharmacy and pharmaceutical supply chain have

continued to undergo profound change due to technological advances, changes in healthcare delivery, increasing complexity in the supply chain, fragmentation of care, "remote" practice, social and political shifts, drug shortages, health disparities, access issues, opioid abuse, compounding and medication safety, internet access to medications, natural disasters, and a variety of political and economic forces.

The five strategic goal areas outlined in this Strategic Plan will guide the work of the Board and staff to create the regulatory structure necessary to incorporate and encourage the best pharmacy practices to ensure public health and safety. This plan will be reviewed and updated annually to make sure that desired outcomes are being met and to encourage safe and contemporary pharmacy practice. The five strategic goal areas include:

- **Technicians**
- **Technology**
- Licensing
- Regulation
- Communication

As we begin to implement these initiatives, we encourage continued active engagement with the Board and participation in Board Meetings, Committee Meetings, Rules Hearings, and other Board activities.

Joe Schnabel, Pharm.D., R.Ph.

Executive Director

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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.

VISION

Partners for a Healthy Oregon

VALUES

These values reflect both how our Board and staff strive to conduct ourselves, and the behaviors we seek to instill across the practice of pharmacy in Oregon.

VALUES

Quality

We strive to deliver a consistent standard of excellence

- Excellence
- Value
- Worth

OREGON BOARD PHARMACY

Safety

We are committed to protecting the health, safety and welfare of the public

- Protection
- Security
- Care

Integrity

We meet commitments to public health and safety and are accountable for our words and actions

- Honesty
- **Ethics**
- Respect

Professionalism

We are committed to promoting excellence in pharmacy practice

- Expertise
- Commitment
- Competence

Accountability

We accept responsibility for our actions, products, decisions and policies

- Trust
- Responsibility
- Transparency



A variety of trends in the practice of pharmacy are impacting the Board's regulatory activities, daily work and strategic priorities. Many of these changes offer potential benefits to the public, the pharmacy profession and health care—while others pose clear risks. All, however, require careful monitoring and response from the Board to ensure public safety is maintained and that licensing, regulation, enforcement and outreach efforts keep pace with the evolving landscape.

Some of the issues facing the Board of Pharmacy include:

- Access and distribution: New options to obtain prescription and over-the-counter medicines are being proposed and/or implemented. These must be examined to ensure that public safety is not jeopardized in the name of convenience.
- Changing business models: Consolidation in the retail pharmacy business and hospital/health care networks mean large organizations have increasing influence on the practice of pharmacy, including

- policies and procedures, staffing levels, and economics.
- Regulation trends: As in many regulated industries, there are often external pressures to relax regulation to mitigate economic realities. The Oregon Board of Pharmacy strives to maintain a regulatory environment focused solely on public health and safety, while enabling practices that improve efficiency and access. The Board supports rule changes only when the outcomes are assured to maintain protection of the public.
- **Pharmacy and Clinical Collaboration:** Increasingly, other healthcare providers are engaging with pharmacists as partners in developing more effective care plans particularly for patients with chronic conditions and in providing preventative care services to improve public health.

The Board encounters the effects of these and other issues and trends on a daily basis. In this strategic plan, goals have been outlined to address them directly and/or to position the Board to adapt and more effectively fulfill its public safety-focused mission.





At its annual Strategic Planning meeting in November 2019, the Board, Executive Director and the staff leadership team identified and evaluated a wide range of trends and challenges facing the practice of pharmacy and our agency. This process and deliberation led to agreement on five critical Strategic Areas and goals on which attention and resources will be focused.

Technicians

Goal: Articulate the regulatory structure where the accountabilities of pharmacists and the role of pharmacy technicians are aligned to enhance safety, access, service and efficiency

Technology

Goal: Articulate the regulatory structure where the accountabilities of pharmacists and the use of technology are aligned to enhance safety, access, service and efficiency

Licensing

Goal: Clarify drug outlet licensing and standards to promote appropriate licensure

Regulation

Goal: Systematically refresh rules and standardize the rule development approach to improve clarity and compliance

Communication

Goal: Improve and maintain stakeholder and public engagement through proactive communication strategies

The Board gave clear direction to the Executive Director and staff that meaningful progress should be made toward accomplishing these goals over the next two to four years—while recognizing that these will remain important issues over an even longer time span. We will regularly assess progress and refine our goals and resource commitments as we work to achieve these key objectives.

Background on each goal, key actions and outcome measures are provided.





Goal: Articulate the regulatory structure where the accountabilities of pharmacists and the role of pharmacy technicians are aligned to enhance safety, access, service and efficiency

The Board seeks to develop clear rules to ensure that pharmacists understand their legal scope of practice and their accountability to provide patient care services and safe pharmacy practices. Permitting pharmacists to more fully and effectively utilize technician support must be structured to improve safety. access and patient care services.

The Board seeks rule alignment to clearly describe the role of pharmacy technicians and how they assist the pharmacist in the practice of pharmacy. Regulatory structures developed for technician roles should delineate requirements for training, quality assurance, and pharmacist supervision.



Key Actions:

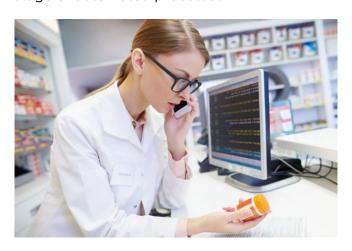
- 1. Review and evaluate applicable statutes for development of rules that clearly articulate the role of a pharmacist and functions that only a pharmacist may perform. (June, 2020)
- 2. Review and evaluate applicable statutes for development of rules for requirements for training and guidelines for adequate supervision of technicians who assist the pharmacist in the practice of pharmacy. (August, 2020)
- 3. Review and evaluate applicable statutes and rules for technician licensure to determine if changes in rules are necessary to facilitate roles. (December, 2020)

- Draft rules for Board consideration that clearly delineate the role of the pharmacist and practices of pharmacy that must only be performed by a pharmacist.
- Draft rules for Board consideration that clearly delineate requirements for training and supervision of technicians.
- Draft rule update for licensure of Pharmacy Technicians and Certified Oregon Pharmacy Technicians.
- Increase in pharmacist provision of patient care services while maintaining safety in dispensing services.



Goal: Articulate the regulatory structure where the accountabilities of pharmacists and the use of technology are aligned to enhance safety, access, service and efficiency

The Board seeks to develop clear rules to ensure that pharmacists understand their scope of practice and their accountability to provide patient care services and safe pharmacy practices while permitting the use of technologies that improve safety, access, service and efficiency. Regulatory structures developed for use of technology should be function-based and delineate individual pharmacist accountabilities for each critical stage of automated processes.



Key Actions:

- 1. Review and evaluate industry trends and applicable statutes and rules for use of technology to develop clear, function-based rules and pharmacist accountabilities. (October, 2020)
- 2. Clearly outline requirements for quality assurance and accountability for each critical stage of automated processes. (December, 2020)

- Draft rules for Board consideration that clearly delineate the use of technology and pharmacist accountabilities in the practice of pharmacy.
- Defined accountabilities for each critical step in automated processes.
- Increase in pharmacist provision of patient care services while maintaining safety in dispensing services.
- Effective quality assurance plan applied to all automated pharmacy processes.



Goal: Clarify drug outlet licensing and standards to promote appropriate licensure

The Board promotes patient safety through appropriate licensing and regulation of all drug outlets engaged in the manufacture, dispensing, delivery or distribution of drugs and medical devices. License categories should clearly guide applicants to the appropriate license type.

Key Actions:

- 1. Create and implement a consistent, ongoing process to review and evaluate applicable statutes for each drug outlet licensing authority, leading to development of rules that clarify the appropriate license category. (August, 2020)
- 2. Review and evaluate legislative and budgetary considerations that may be required to implement changes to drug outlet categories. (October, 2020)



- Draft rules for Board consideration that clarify the appropriate license category for each outlet category.
- Decrease in questions from applicants regarding appropriate license type for which to apply.





Goal: Systematically refresh rules and standardize rule development to improve clarity and compliance

The Board proactively reviews and updates rules to provide clear expectations to licensees and registrants to promote compliance and patient safety. Rule updates should emphasize clarity and durability to allow practice variation that improves safety, access, service and efficiency.



Key Actions:

- 1. Create standard procedures and schedule to accomplish five-year rule review that emphasizes clarity and compliance. (August, 2020)
- 2. Conduct routine, scheduled, and systematic review of Board of Pharmacy rules by section and draft revisions for Board consideration. (December, 2020)

- Rule review standards and guidelines are implemented and used to prepare all rule updates.
- At least four rule sections are reviewed. updated and presented to Board for consideration annually.





Goal: Improve and maintain stakeholder and public engagement through proactive communication strategies

The Board communicates through multiple platforms to collaborate, educate, promote patient safety and enhance consumer protection.

Key Actions:

- 1. Develop and implement a communication plan at all levels of the agency to improve access to relevant information and streamline communications. (June, 2020)
- 2. Create and maintain a new website as the Board's primary communication tool. (June, 2020)
- 3. Develop a consistent process to review and update FAQs related to licensing and compliance. (October, 2020)
- 4. Develop standardized methods to triage and respond to correspondence to improve timely communications that are maintained in accordance with public records retention requirements. (December, 2020)



- Create modern materials for agency communications, including branding and plain language used for presentations and other public documents.
- Webpages updated to provide focused information.
- Updated FAQs published.
- Transition to an enhanced list-serve email service.



