Statewide Formulary: Novel Practices with Reimbursement

LORINDA ANDERSON, PHARMD, BCPS AMY VALDEZ, RPH

Disclosures

Lorinda Anderson and Amy Valdez have no relevant financial relationship(s) with ineligible companies to disclose.

Objectives

- Review the available statewide protocols in Oregon that allow pharmacists to prescribe under and what the overarching rules and regulations are that govern them.
- Explain how to engage with the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) process from submitting ideas to serving as a subject matter expert.
- ▶ Identify the statewide protocols that the PHPFAC is currently working on, and others that could be potentially developed.

Pre-Assessment Questions

Answer ALL that apply:

Which of the following are conditions included in Oregon's protocol compendium of protocols that pharmacists are able to prescribe under?

- A. Strep throat
- B. HIV PEP and PrEP
- c. COVID treatment
- D. Vulvovaginal candidiasis
- E. Contraception

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Defining Prescriptive Authority

- ► The American College of Clinical Pharmacy (ACCP) has put forth a definition of prescribing.
- ACCP notes that prescribing is "no longer [just] the act of writing medication instructions." 1
- Instead, prescribing consists of a broad set of medication-related activities: selecting, initiating, monitoring, continuing, discontinuing, modifying, and/or administering drug therapy.

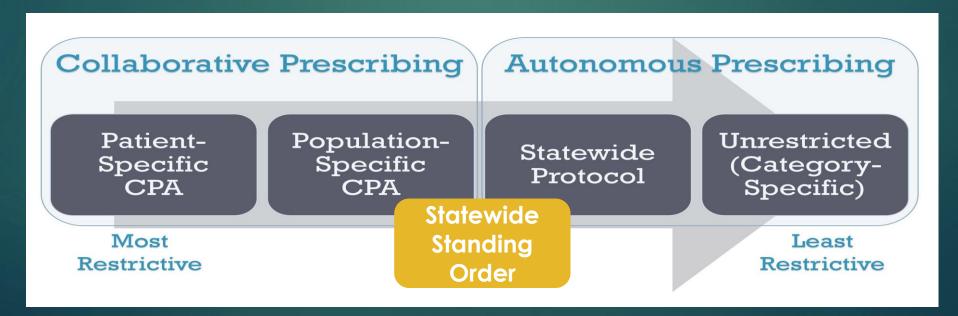
Defining Prescriptive Authority

Of Note:

- ► There are few state-level limitations on physician prescribing, with limitations typically articulated only for self-use or for close family members if inconsistent with their practice.²
- Prescriptive authority for "non-physicians" is typically more limited and driven as "opt-in".

Continuum of Pharmacist Prescriptive Authority

► This authority has been described to exist somewhere along a continuum from more dependent (delegated through a collaborative practice agreement) to more independent (authority comes directly from the state, no delegation required) authority.³



Differences in Models

- Patient Specific CPA- single or group of patients, single or group of providers, limited to current panel of participating providers or require referral. Used mostly for chronic disease management.
- ▶ Population Specific CPA- applies to broad categories of patients, can be used for acute or preventive care situations, allows for care in absence of PCP.

Differences in Models

- ▶ Statewide Protocols-defined for populations, set by authorized body of government rather than prescribers, typically no diagnosis needed so usually more narrow in scope than CPA, difficult to change.
- Unrestricted Category Specific- limited range of drugs or devices, follow clinical guidelines rather than protocol, no diagnosis or post-diagnostic.

What is the Pharmacy Formulary?

- House bill 2397, passed in 2017, changed the name of the Public Health Advisory Committee to Public Health and Pharmacy Formulary Advisory Committee. 4
- It directs the State Board of Pharmacy to establish by rule a formulary of drugs and devices that pharmacists may prescribe and dispense to patients under specified conditions.
- ▶ It directs the committee to recommend drugs and devices for inclusion on the formulary.

Who is on the Committee?

The Public Health and Pharmacy Formulary Advisory Committee consists of ⁴:

- ▶ Two physicians licensed to practice medicine
- Two advanced practice registered nurses who have prescriptive authority and who are licensed by the Oregon State Board of Nursing
- Three pharmacists licensed by the State Board of Pharmacy

Committee members are appointed by the governor and serve a two year appointment.

Current Appointees

Pharmacists

- Lorinda Anderson, RPH
 - Term: 4/22/2022 4/21/2024
- Andrew Gibler, RPH
 - Term: 5/1/2023 4/30/2025
- Ellisha Lee, RPH
 - Term: 4/22/2022 4/21/2024

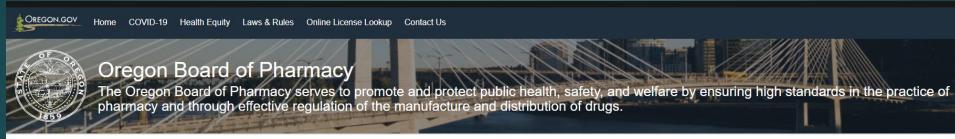
<u>Advanced Practice Nurses</u>

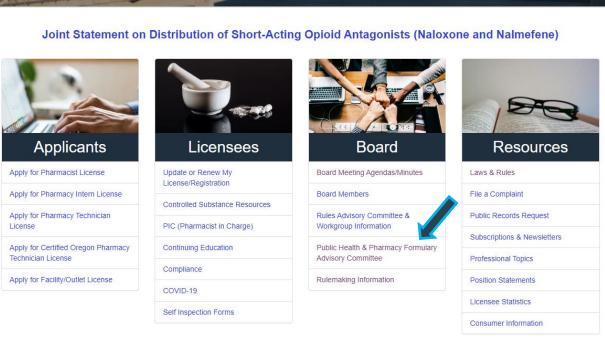
- Katherine Hammond, APRN
 - Term: 5/1/2023 4/30/2025
- Sarah Wickenhagen, APRN
 - 4/22/2022 4/21/2024

Physicians

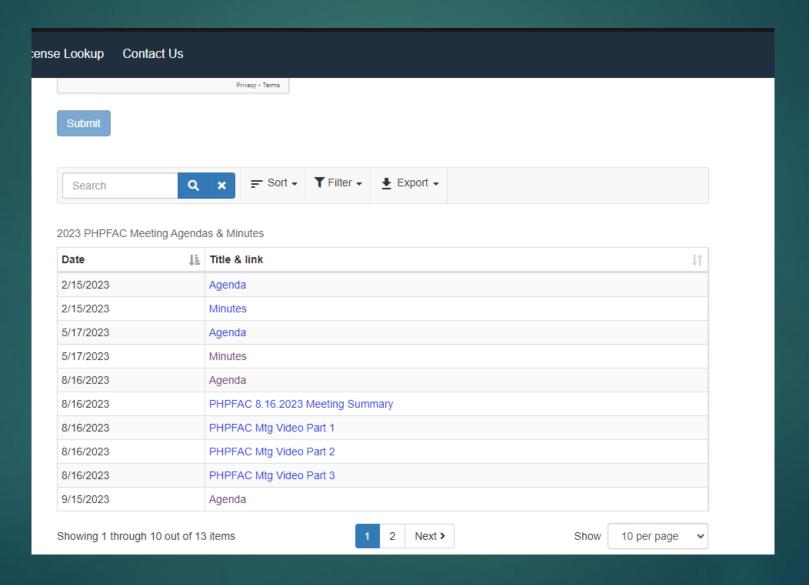
- Sean Jones, MD
 - Term: 12/1/2019 11/30/2021
- Mark Meyers, MD
 - Term: 5/1/2023 4/30/2025

How to Find?

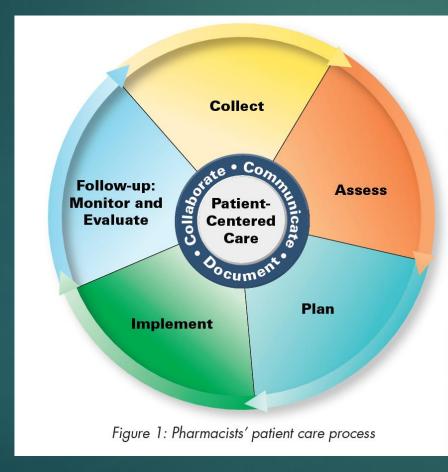




Meeting Agendas & Minutes



JCPP Pharmacists' Patient Care Process 5



Pharmacists' Patient Care Process

Pharmacists use a patient-centered approach in collaboration with other providers on the health care team to optimize patient health and medication outcomes.

Using principles of evidence-based practice, pharmacists:

Collect

The pharmacist assures the collection of the necessary subjective and objective information about the patient in order to understand the relevant medical/medication history and clinical status of the patient.

Assess

The pharmacist assesses the information collected and analyzes the clinical effects of the patient's therapy in the context of the patient's overall health goals in order to identify and prioritize problems and achieve optimal care.

Plan

The pharmacist develops an individualized patient-centered care plan, in collaboration with other health care professionals and the patient or caregiver that is evidence-based and cost-effective.

Implement

The pharmacist implements the care plan in collaboration with other health care professionals and the patient or caregiver.

Follow-up: Monitor and Evaluate

The pharmacist monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed.

Sample Visit Summary

Chief	Name:Subjective Data	Objective Data	DOB: History of Present Illnes
Complaint	□ On Back	□ On Back	On Back
	□Allergies		
	□Past Medical History		
	□Social History		
	Medications	Post-diagnostic? ☐No ☐Yes	
	Adherence	Diagnosis:	
	□Past 90 day use	☐ Therapy Initiation	
		☐ Extension of Therapy	
	Safety	☐ Device	
	Relevant Medications	Other	
ssess and Eva	luate		
Per Drug Thera Management Prot	_		
☐ Inclusion Criteri	a Met		
☐ Exclusion Criter	ia Met		
☐ Referral Criteria	Met		
esource(s) Used	<u> </u>		
.g. Protocol, Guideline lanagement Protocol)		etc. (Note: this information shall be reference	ed in the established Drug Therapy
			ed in the established Drug Therapy
lanagement Protocol)	e Plan	For	
reatment Care	e Plan Is		ed in the established Drug Therapy Date
reatment Care ☐Treatment Goa	e Plan Is ameters	For Address	
reatment Care Treatment Care Treatment Goa Monitoring Par	e Plan Is ameters	For Address	Date
reatment Care Treatment Care Treatment Goa Monitoring Par	e Plan Is ameters	ForAddressRx#	Date
reatment Care Treatment Goa Monitoring Par	e Plan Is ameters	For — Address — Rx # — RPh Signature — Address	Date

Subjective Data
Objective Data
,
History of Present Illness
Assessment
Assessment
Care Plan
ample Template: Please feel free to customize this document, however you must retain <u>all elements</u> included. Oregon Board of Pharmacy v. 2018

Sample Patient Intake Form

REALD Data Collection Form Date of Birth ____/___ Age____ Legal Name Preferred Name _ 1. Which of the following describes your Racial or Ethnic identity? Please check ALL that apply. American Indian and Alaska Asian Hispanic and Latino/a/x □ Central American Native □ Asian Indian □ Cambodian □ Mexican □ American Indian □ Chinese □ South American □ Alaska Native □ Other Hispanic or □ Communities of Myanmar □ Canadian Inuit, Metis, or Latino/a/x □ Filipino/a First Nation □ Hmong □ Indigenous Mexican, Native Hawaiian and Pacific □ Japanese Central American, or South Korean □ CHamoru (Chamorro) □ Laotian □ Marshallese South Asian **Black and African American** □ Communities of the □ Vietnamese ☐ African American Micronesian Region □ Other Asian □ Afro-Caribbean □ Native Hawaiian □ Ethiopian □ Samoan Other Categories □ Somali □ Other Pacific Islander □ Other (please list) □ Other African (Black) □ Other Black White □ Don't know □ Eastern European Don't want to answer Middle Eastern/North African □ Middle Eastern □ Western European □ North African Other White 2. If you checked more than one category above, is there one you think of as your primary racial or ethnic identity? □ Yes. Please circle your primary racial or □ N/A. I only checked one category above. ethnic identity above. □ I do not have just one primary racial or Don't want to answer ethnic identity. ☐ No. I identify as Biracial or Multiracial. Language (Interpreters are available at no charge) 3. What language or languages do you use at home? → Skip to question 9 if you indicated English only In what language do you want us to communicate in person, on the phone, or virtually with you? In what language do you want us to write to you? Do you need or want an interpreter for us to communicate with you? ☐ Yes ☐ No ☐ Don't know ☐ Don't want to answer

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

REALD Data Collection Form

7.	If you need or want an interpreter, what type of interpreter	preter	for DeafBling	d, additi		riers, or b	oth
	→ Skip to question 9 if you do not use a language of	her tha	n English or	sign lan	guage		
3.	How well do you speak English? □ Very Well □ Well □ Not Well □ Not at all	□ Don'i	t know 🗆 Do	on't wa	nt to ans	swer	
	Disability Your answers will help us find health and service differences among people with and without functional difficulties. Your answers are confidential.	Yes	*If yes, at what age did this condition begin?	No	Don't know	Don't want to answer	Don't know what this question is asking
9.	Are you deaf or do you have serious difficulty hearing?						
10.	Are you blind or do you have serious difficulty seeing, even when wearing glasses?						
11.	Do you have serious difficulty walking or climbing stairs?						
12.	Because of a physical, mental or emotional condition, do you have serious difficulty concentrating, remembering or making decisions?						
13.	Do you have difficulty dressing or bathing?						
14.	Do you have serious difficulty learning how to do things most people your age can learn?						
15.	Using your usual (customary) language, do you have serious difficulty communicating (for example understanding or being understood by others)?						
16.	Because of a physical, mental or emotional condition, do you have difficulty doing errands alone such as visiting a doctor's office or shopping?						
17.	Do you have serious difficulty with the following: mood, intense feelings, controlling your behavior, or experiencing delusions or hallucinations?						

All health care providers must begin collecting and reporting REALD data in accordance with <u>current REALD</u> <u>standards and Oregon Disease Reporting rules</u> starting October 1, 2021.

Authority, Laws, & Rules

icense Lookup Contact Us

Statutory Authority

The multidisciplinary Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) was convened in 2018 pursuant to ORS 689.645 and 689.649.

Laws & Rules

The rules in OAR 855-020 establish the pharmacist's authority and responsibilities to prescribe drugs and devices, pursuant to the formulary and protocols developed and recommended by the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC). These rules articulate the authority and legal expectations for an Oregon licensed pharmacist and practicing in Oregon, to voluntarily participate in providing patient assessment and patient care services that may result in the issuance of a prescription by a pharmacist for an identified medical need.

The rules describe the Board's compliance expectations for pharmacy practice and prescribing from the formulary and protocol compendia. Standards defined include: (1) education and competency; (2) patient assessment and referral criteria; (3) collaboration with other healthcare, providers, including mandated notification; (4) treatment and follow-up care planning; (5) documentation and record-keeping; and (6) prohibited practices.

Oregon Board of Pharmacy laws and rules related to PHPFAC:

- ORS 689.645, ORS 689.649, ORS 689.689
- OAR 855-020

Rules Pertaining to Prescribing

Division 20 ⁶ PHARMACIST PRESCRIPTIVE AUTHORITY

855-020-0110

Prescribing Practices

- Consistent with the parameters of the Formulary and Protocol Compendia, and in accordance with federal and state regulations
- Create, approve, and maintain policies and procedures
 - Patient inclusion and exclusion criteria
 - Explicit medical referral criteria
 - ▶ Care plan preparation, implementation, and follow-up
 - Patient education
 - Provider notification
 - Maintaining confidentiality

Rules Pertaining to Prescribing

- The Pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond their expertise by consulting with or referring patients to another health care provider
- Ensure training and education requirements have been met prior to engaging in prescribing activities and documentation of training retained for 6 years or uploaded in electronic licensing record
- Assess patient and collect subjective and objective information, including the diagnosis for Formulary Compendia items, about the patient's health history and clinical status
- The Pharmacist's physical assessment must be performed in a face-to-face, in-person interaction and not through electronic means
- Utilize information obtained in the assessment to evaluate, develop, and implement an individualized patient-centered care plan, to include appropriate treatment goals, monitoring parameters, and follow-up
- Provide notification to the patient's identified primary care provider or other care providers when applicable within five business days following the prescribing
- The Pharmacist must maintain all records associated with prescribing and other related activities performed for a minimum of 7 years, and they must be made available to the patient, provider, or board upon request
 - Records must be stored onsite for at least one year and then may be stored in a secure off-site location if retrievable within three business days
 - Records and documentation must be written, electronic or a combination of the two.
- ▶ If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use an audiovisual communication system to conduct the consultation.

Rules Pertaining to Prescribing

Division 20 PHARMACIST PRESCRIPTIVE AUTHORITY

855-020-0120

Prescribing Prohibited Practices

- A Pharmacist must not prescribe a drug or device to self, specified family members, or other individuals for whom a Pharmacist's personal or emotional involvement may render the Pharmacist unable to exercise detached professional judgment
- An Intern must not prescribe a drug or device
- A Pharmacist must not require, but may allow, a patient to schedule an appointment with the Pharmacist for the prescribing or administering of an injectable hormonal contraceptive or the prescribing or dispensing of a self-administered hormonal contraceptive

Protocol & Formulary Compendia

Resources

Protocol Compendium:

- Continuation of Therapy including Emergency Refills of Insulin
- Cough & Cold: Benzonatate
- Cough & Cold: Intranasal Corticosteroids
- Cough & Cold: Pseudoephedrine
- Cough & Cold: SABAs
- Conditions: COVID-19 Antigen Self-Test
- Conditions: Vulvovaginal Candidiasis (VVC)
- · Preventative Care: Condoms
- Preventative Care: Contraception
- Preventative Care: Emergency Contraception
- Preventative Care: Tobacco Cessation NRT (Nicotine Replacement Therapy) and Non-NRT
- · Preventative Care: Travel Medications
- Preventative Care: HIV Post-Exposure Prophylaxis (PEP)
- Preventative Care: HIV Pre-Exposure Prophylaxis (PrEP)

Formulary Compendium:

· Formulary: Devices & Supplies

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How to Engage with the PHPFAC

- Submit a concept for the committee to consider as having developed and included as a statewide protocol
- Serve as a subject matter expert who will help develop a protocol that is presented to the PHPFAC
- Provide feedback to the PHPFAC

Submitting a Concept

ine License Lookup Contact Us Concept Submission Form Complete the concept submission form below, attach all supporting documents and submit at least 42 days (6 weeks) prior to the date of the next committee meeting for consideration and potential review at an upcoming meeting. Questions? Email all Public Health & Pharmacy Formulary Advisory Committee related inquiries to pharmacy.formulary@bop.oregon.gov Public Health & Pharmacy Formulary Advisory Committee Concept Intake Form Name (required)* Oregon Pharmacist License # (required)* Employer (required)* Email (required)* Phone (required)* Todays Date (required)* (MM/DD/YYYY) 1. PROVIDE A SHORT EXPLANATION OF THE NEED FOR THE DRUG(S) OR DEVICE(S) TO BE ADDED TO THE FORMULARY COMPENDIUM RULES: What is the public health need or patient care problem you are trying to address? What post diagnostic drug or device are you proposing to be prescribed by a pharmacist? - OR - What drug or device that does not require a diagnosis by a healthcare practitioner are you proposing to be prescribed by a pharmacist? What is the rationale to adding this drug or device to the formulary compendium - Change in federal/state law? Change in technology or business environment? Clinical gap in patient care? Emergency access? Change in national recommendations? Other? (required)*

Submitting a Concept

(required)*	at are the likely concerns? Are the concerns significant?
	" OF THE CHANCES THE PROPOSED BUILD WAVE.
Considerations: What ex res, please list all applica	OF THE CHANGES THE PROPOSED RULE WOULD MAKE: isting current regulations may conflict with this proposal? Have other states addressed this issue? If able states and how the addressed the issue. Please submit any studies that exist involving a
Considerations: What ex res, please list all applica pharmacist prescribing to the potential unintended	isting current regulations may conflict with this proposal? Have other states addressed this issue? If
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Submitting a Concept

OR ASSESSMENT, IDENTIFYING INCLUSION, EXCLUSION AND REFERRAL CRITERIA, AS WELL AS A CONSISTENT REATMENT CARE PLAN.		
Signature: (required)*		
Every concept submission is s	ubject to Oregon Public Records Laws and may be disclosed upon request.	
Attachment(s) Choose Files No file choser	1	

Providing Feedback

	Email Address (required)*	
Provide Feedback (required)*		

Attachment(s) Choose Files No file chosen		

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What's Next?

Immunization Protocols

- Moving from OHA to OBOP
- ► Work commended in February 2023
- ► SME's: Amy Valdez & Crystal Sharp, along with Fred Meyer & Albertsons-Safeway Residents across 2 different residency years
- Phase 1: Development of standard protocol template, assessment & treatment pathway, adverse events protocol
 - ▶ Will appear similar to current OHA protocols, repetitive or "standard" elements removed for simplicity
- ▶ Phase 2: Travel Vaccines & Phase 3: Routine Vaccines
 - ▶ Updated using ACIP, CDC, Package Inserts and applied approved standard template

What's Next?

Immunization Protocols

- ▶ Final vaccine package approved by committee and recommended to Board on September 15, 2023.
- After that: as they sometimes say "It's Complicated"
 - ▶ The short version: The board will add to agenda for rulemaking and adoption
 - ▶ The long version: The board has already approved moving all of the rules related to prescribing to the "new" Division 115
 - ▶ The implementation date for Division 115 is 3/1/24
 - ▶ We cannot easily update the prescribing compendia until this goes live
 - ▶ The board has communicated a plan to proceed with updating as if it is Division 20 and then have a simultaneous update for the "move" to Division 115
 - ▶ We are anticipating being able to use the new protocols around 3/1/24, but subject to change
- Result: There will no longer be separate rules related to immunizing

Quick Note on Reimbursement

- Could be its own hour
- There are pathways that have been built for reimbursement through Medicaid in Oregon, and many other insurances follow similar mechanisms

Answer ALL that apply:

Which of the following are conditions included in Oregon's protocol compendium of protocols that pharmacists are able to prescribe under?

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References

- ▶ 1. Carmichael, JM, O'Connell, MB, Devine, B. Collaborative drug therapy management by pharmacists. Pharmacotherapy. 1997;17:1050-1061.
- ▶ 2. Safriet, BJ.: Closing the gap between can and may in health-care providers; scope of practice: a primer for policymakers. Yale Journal on Regulation. 2002; 19:301-334.
- ▶ 3. Adams AJ, Weaver KK. The Continuum of Pharmacist Prescriptive Authority. Annals of Pharmacotherapy. 2016; 9:778-784
- 4. Oregon Board of Pharmacy. https://www.oregon.gov/pharmacy/Pages/PFAC.aspx Accessed 10/2/2023
- 5. Joint Commission of Pharmacy Practitioners. Pharmacists' Patient Care Process. May 29, 2014. Available at: https://jcpp.net/wp-content/uploads/2016/03/PatientCareProcess-with-supporting-organizations.pdf
- ► 6. Oregon Board of Pharmacy.
 https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3968 Accessed 10/2/2023

Questions?