**Public Health and Pharmacy Formulary Advisory Committee Meeting**  
**May 3, 2019, 8:30am**  
**Portland State Office Building, 800 NE Oregon St. Portland, OR 97232**  
**Conference Room 1E**

### Committee Members
- Evon Anukam, RPh (excused)
- Kat Chinn, RN MSN
- Sean Jones, MD
- Amy Valdez, RPh
- Amy Burns, RPh (by phone)
- Mark Helm, MD
- Helen Turner, DNP

### OBOP Staff to Committee
- Joe Schnabel, Executive Director
- Fiona Karbowicz, Pharmacist Consultant
- Karen MacLean, Administrative Director
- Brianne Efremoff, Compliance Director

<table>
<thead>
<tr>
<th>Agenda Item</th>
<th>Desired Outcome</th>
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<tr>
<td>Welcome</td>
<td>Roll call</td>
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<td>Agenda review and approval</td>
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<td><strong>Motion to approve agenda was made and unanimously carried (Motion by Turner, second by Helm).</strong></td>
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<td>2.1.19 Minutes review and approval</td>
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<td><strong>Motion to approve 2/1/19 Minutes was made and unanimously carried (Motion by Jones, second by Turner).</strong></td>
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<td>Committee Business</td>
<td>There were no high priority items to discuss.</td>
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<td>There have been no new concepts submitted for Committee review.</td>
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<td>- Committee discussions:</td>
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<td>- Pharmacist Consultant Fiona Karbowicz provided the Committee with a presentation to address: 1. Welcome new Executive Director Joe Schnabel, 2. Statutory and legal scope review, 3. Committee business, focusing on expectations and processes, 4. Committee business, reviewing Committee recommendations</td>
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<td>1. Executive Director Joe Schnabel introduced himself and thanked the Committee for their excellent and groundbreaking work so far and for work that is to come.</td>
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<td>2. Statutory and Legal Scope Review:</td>
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<td>- ORS 689.649 states that the Committee shall recommend a formulary of drugs and devices that a pharmacist may prescribe and dispense to a patient:</td>
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<td>- Items must be pursuant to a diagnosis by a health care practitioner qualified to make the diagnosis and who has prescriptive authority (ORS 689.645)</td>
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<td>- The Board may adopt the recommendations by rule</td>
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<td>- The Committee shall periodically review the formulary and recommend revisions to the board</td>
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<td>- ORS 689.645(6) states “The formulary may include post-diagnostic drugs and devices such as diabetic testing supplies, emergency refills of insulin, albuterol inhalers, epinephrine autoinjectors, smoking cessation aids, discharge medications for transitions of care, rapid strep tests and spacers.”</td>
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|             | - ORS 679.645 states that a pharmacist may provide approved patient care services pursuant to a statewide drug therapy management protocol:
- Developed by the Public Health and Pharmacy Formulary Advisory Committee; and;
- Adopted by rule of the Board.
- Patient care services include smoking cessation and travel health services are mentioned in statute
- Pharmacist to establish ‘P&Ps/protocols’ for the prescription and administration of vaccines and the provision of patient care services [under sub (1) which allows a pharmacist to provide patient care services via statewide drug therapy management protocols developed by the Committee]
- Note: For the purposes of the conversation and past minutes (10/26/2018), a statewide protocol consists 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, pursuant to legal scope articulated in ORS 689.

o Board Rules overview:
- Division 019 – added a rule to establish an Oregon pharmacist’s authority to prescribe pursuant to scope authorized by 2017 HB 2397
- Division 020 - Codify recommendations of items added to the Formulary and Protocol Compendia; Codify the “core elements” that all prescribing processes must adhere to, including:
  - Oregon pharmacist, located and licensed in Oregon only; responsibility to recognize limits of own knowledge and experience – refer when necessary
  - Utilize drug therapy management protocol based on current clinical guidelines, including inclusion, exclusion and referral criteria
  - Collect subjective and objective info about patient’s health history and clinical status
  - Evaluate and develop individualized patient care plan, within parameters (when defined)
  - Implement care plan, including treatment goals, monitoring and follow-up
  - Notify patient’s care provider(s) within 5 days of issuing prescription
  - Maintain records (visit summary, dispensing files, etc.)
- Check and adjust*: Rule edits need to be drafted – need to align processes with statute, in particular OAR 855-020-0110(3) will need to be re-written to make it clear that a pharmacist may prescribe via post-diagnostic drugs and devices adopted by Board rules on the Formulary Compendia or via statewide drug therapy management protocols developed by the Committee and adopted by Board rules on the Protocol Compendia. The statute does not permit a pharmacist to create his/her own protocol; rather, a pharmacist may provide approved patient care services pursuant to the statewide drug therapy management protocol that is developed by the Committee and adopted by rule of the Board. A pharmacist may develop policies and procedures to implement and document the provision of patient care services pursuant to the statewide drug therapy management protocol.
- The Committee and staff had a robust discussion about what a “sample” statewide drug therapy management protocol will look like, particularly regarding the level of detail needed. Is this still considered “pharmacist prescribing”? Yes, due to scope of practice articulated by Oregon law; the scope and risk are connected to the pharmacist.
3. Committee Business, Expectations and Processes:
   - Pharmacist Consultant Karbowicz outlined the roles and responsibilities for
     Committee members, Board members and the staff that works to integrate each.
     - Committee members meet regularly to develop, recommend and review items
       on the formulary and statewide drug therapy management protocols. They
       discuss and provide unified recommendations and revisions, via formal vote, to
       the Board’s Formulary and Protocol lists. A focus is on assessment of clinical
       elements and are tasked with anticipating patient safety “boundaries” such as
       pharmacist education, assessment details (i.e. inclusion/exclusion criteria), and
       required care plan elements, etc.
     - Board members focus on patient safety and legal scope by promulgation of rules
       and/or policy, including interpretation of laws defining Oregon pharmacist scope
       of practice. They review Committee recommendations and create rules for
       addition to the Formulary and Protocol lists. They remain aware of and help
       facilitate implementation, for patient access to safe provision of pharmacy
       services. Additionally, they direct compliance and enforcement.
     - Staff is tasked with legal scope review, as defined in statute, rules and policy, at
       direction from the Executive Director, Legal Counsel, etc. Staff is also tasked with
       general process, including monitoring and preparing concepts submitted,
       acquiring SMEs, meeting facilitation and creating draft agendas/minutes.
       Additionally, staff is to facilitate all communications between the Board,
       Committee and stakeholders (including pharmacists, pharmacies, the public,
       etc.); all communications are subject to public record which must be managed
       appropriately pursuant to state agency requirements.
   - Regarding expectations and processes:
     - For Committee business and communications, we must utilize the formulary email
       (cc’d correspondence). It is pharmacy.formulary@oregon.gov
     - Outreach is created by staff and speaker(s) determined by Executive Director; any
       inquiries, such as from the pharmacy associations to be directed to Executive
       Director
     - If Committee and Board members receive inquiries related to the regulations,
       implementation, etc. please pass along to Executive Director for prompt attention
       by appropriate staff member – legal scope is not discretionary
     - We will be scheduling an annual (or semi-annual) meeting devoted to review of
       prior items added for clinical appropriateness;
     - Any Committee member may make a request for an item to be reviewed for
       Formulary/Protocol recommendation – make request via form and cc the
       formulary email

4. Committee Business, Reviewing Recommendations
   - We are continuing development of a clear and consistent methodology for
     Committee to utilize for reviewing items, in order for a consistent review process
     which can help properly “build” each concept/recommendation. We will continue
     to work through the process for the management and distribution of the
     protocols, particularly pursuant to Board direction. Additionally, the Committee
     plans to utilize the ‘minutes review’ meetings to assess any new concepts, to
     essentially determine the first analysis question, “Is this a concept the Committee
     wants to consider?” It is anticipated the phone call may take longer by
     incorporating this preliminary review; this may adjust the timing of the phone call
     meetings – staff to evaluate and bring back for further discussion and scheduling,
though some is a “wait and see”, depending on the number of concepts that continue to be submitted, or not.

- Analysis questions include:
  - Is this a post-diagnostic drug or device? Or, is this suited for a statewide drug therapy management protocol?
  - Are clinical parameters needed? This includes the development of standardized patient assessment process and treatment care plan, with defined inclusion, exclusion and referral criteria, based on current and referenced clinical guidelines, and articulating any prescribing parameters, monitoring requirements and follow-up.
  - Is a Subject Matter Expert (SME) needed? Is there a specific clinical guideline or other mandated resource required?
  - Does the Committee want to recommend an additional mandated education requirement?

- The Committee proceeded to re-review the concepts discussed at the January 11, 2019 meeting, considering them as statewide drug therapy management protocols. Fiona entered the January discussion elements in to a slide for each item, to engage Committee dialogue. The general plan is to request SMEs to return to future meeting(s) to continue work on level of depth required. Legal counsel and Board direction will be needed.
  - Smoking Cessation – non-NRT
  - Pre-Travel Consult Medications
  - Non-Occupational Post Exposure Prophylaxis (nPEP)

- Additional points shared during Committee dialogue included:
  - Updates should be made to the Concept Intake Form, to provide additional clarity to what the Committee and Board are seeking when a concept is submitted.
  - Regarding new items received, staff will shift from a general “pass along” to a more detailed “work-up” moving forward, in attempt to bring forth solid “packages” of items for Committee and Board review. This will require additional staff resources; the 0.5FTE pharmacist position is envisioned to assist.
  - Helpful verbiage may be found in OAR 855-019-0260, Collaborative Drug Therapy Management

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**Upcoming Meeting Schedule – subject to change**

- **Next meeting**
  - May 29, 2019 at 6:00pm – *(brief conference call to approve minutes – note date and time change; call to include pre-view of any new concepts)*
  - July 12, 2019 – room 1E
  - TBA – *(brief conference call to approve minutes and pre-view new concepts)*
  - October 25, 2019 – room 1D
  - TBA – *(brief conference call to approve minutes and pre-view new concepts)*

Motion to adjourn at 12:57PM was made and unanimously carried (Motion by Turner, second by Helm)
Public Health and Pharmacy Formulary Advisory Committee

2019

Objectives

- Statute and Legal Scope Review
- Committee Business – Expectations and Processes
- Committee Business – Review of Committee Recommendations
Statutory Directives

ORS 689.649(7) states that the Committee shall recommend a formulary of drugs and devices that a pharmacist may prescribe and dispense to a patient

- Items must be pursuant to a diagnosis by a health care practitioner qualified to make the diagnosis
- The Board may adopt the recommendations by rule
- The Committee shall periodically review the formulary and recommend revisions to the board

Statutory Directives

ORS 689.645(1)(b) states that a pharmacist may provide approved patient care services pursuant to a statewide drug therapy management protocol

- Developed by the Public Health and Pharmacy Formulary Advisory Committee; and
- Adopted by rule of the Board
- Patient care services include smoking cessation and travel health services
Statutory Directives

ORS 689.645(4-6) states that the Board shall adopt rules:

- Requiring pharmacists to establish protocols for the prescription and administration of vaccines... and the provision of patient care services [under subsection (1) – which allows a pharmacist to administer vaccines, and provide patient care services via statewide drug therapy management protocols developed by the Committee]
- To establish the formulary of drugs and devices, that a pharmacist may prescribe and dispense to a patient pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis
- The formulary may include post-diagnostic drugs and devices such as diabetic testing supplies, emergency refills of insulin, epinephrine autoinjectors, smoking cessation aids, discharge medications for transitions of care, rapid strep tests and spacers

Board Rules – Divisions 019 and 020

- Division 019
  - Establish an Oregon pharmacist's authority to prescribe pursuant to scope authorized by 2017 HB 2597 (located and licensed in Oregon)

- Division 020
  - Codify the "core elements" that all prescribing processes must adhere to, including:
    - RPH responsibility to recognize limits of own knowledge and experience – refer when necessary
    - Utilize drug therapy management protocol based on current clinical guidelines, including inclusion, exclusion and referral criteria
    - Collect subjective and objective info about patient's health history and clinical status
    - Evaluate and develop individualized patient care plan, within parameters (when defined)
    - Implement care plan, including treatment goals, monitoring and follow-up
    - Notify patient's care provider(s) within 5 days of issuing prescription
    - Maintain records (visit summary, dispensing files, etc.)
    - Codify recommendations of items added to Compendia

- We will be drafting rule edits needed to align processes with statute
  - OAR 855-020-0110(3)
Roles and Responsibilities

**PHPFAC Members**
- Meet regularly to develop, recommend and review:
  - Formulary; and
  - Statewide Drug Therapy Management Protocols
- Discuss and provide unified recommendations and revisions (via formal vote) to the Board's Formulary and Protocol lists
- Assess clinical elements
- Anticipate patient safety "boundaries", such as RPH education, inclusion/exclusion criteria, required care plan elements, etc.

**Staff**
- Legal scope - defined by statute, rules and policy (direction from Executive Director, Legal Counsel, etc.)
- All communications - between Board, Committee and stakeholders (pharmacists, pharmacies, public, etc.)
- General process, including monitoring/preparing concepts submitted, acquiring SMEs, meeting facilitation, agendas/minutes
- Communications subject to public record (to be managed appropriately by state agency requirements)

**Board Members**
- Legal Scope - Promulgates rules and/or policy for Oregon pharmacist scope of practice
- Reviews Committee recommendations and promulgates rules for addition to Formulary/Protocol lists
- Facilitate implementation - patient access to safe pharmacy services
- Compliance and enforcement

Expectations

- Utilize formulary email for all communications
  - Pharmacy.formulary@oregon.gov
- Outreach is created by staff and speaker(s) determined by Executive Director
- If Committee and Board members receive inquiries related to the regulations, implementation, etc. please pass along to Executive Director for prompt attention by appropriate staff member – legal scope is not discretionary
- We will be scheduling an annual (or semi-annual) meeting devoted to review of prior items added for clinical appropriateness
- Any Committee member may make a request for a item to be reviewed for Formulary/Protocol recommendation – make request via form and cc the formulary email
Review – Committee Recommendations

- Continuing development of consistent methodology for Committee to review items
  - Consistent review process
  - Helps to properly “build” each recommendation

- Analysis questions include:
  - Is this a concept that the Committee wants to consider?
  - Is this a post-diagnostic drug or device? Or, is this suited for a statewide drug therapy management protocol?
  - Clinical parameters needed? Development of standardized patient assessment process and treatment care plan, with defined inclusion, exclusion and referral criteria, prescribing parameters, monitoring requirements, follow-up.
    - Is a Subject Matter Expert (SME) needed?
    - Is there a specific clinical guideline or other mandated resource required?
    - Does the Committee want to recommend an additional mandated education requirement?

- Is this a concept that the Committee wants to consider? YES
- Is this a post-diagnostic drug or device? Or, is this suited for a statewide drug therapy management protocol? ADD TO PROTOCOL LIST – Which drugs? Bupropion and Varenicline (others!)
- Is a Subject Matter Expert (SME) needed? Yes, RPH KL provided concept and detailed background information
- Is there a specific clinical guideline or other mandated resource required? Addressed below
- Clinical parameters
  - Development of standardized patient assessment process – STANDARDIZED QUESTIONNAIRE (to include all elements presented, as well as PHQ2 and suicide question)
  - Defined exclusions: < 18, positive screen on PHQ2, yes on suicide question, or any other elements from questionnaire
  - Defined referrals: PERFECTMENTAL HEALTH ASSESSMENT TOOL and PROVIDE OREGON SUICIDE HOTLINE (or similar) and ACTIVE REFERRAL TO QUIT LINE (or equivalent)
  - Prescribing: 1st EX UP TO 30 DAYS, MAX DURATION 12 WEEKS, MAX FREQUENCY 2x in ROLLING 12 MONTHS
  - Follow-up: WITHIN 7-21 DAYS (Phone consult permitted)
- Does the Committee want to recommend an additional mandated education requirement? 1 TIME COURSE, MINIMUM 2 HOURS CE

Smoking Cessation - nonNRT
CONCEPT
Preventative travel medications including:
1. Malaria Prophylaxis: chloroquine, atovaquone/proguanil, mefloquine, doxycycline
2. Traveler's Diarrhea Prevention and Treatment: ciprofloxacin, azithromycin
3. Acute Mountain Sickness (Altitude Sickness) Prophylaxis: acetazolamide
4. Motion Sickness: Scopolamine patches, promethazine tablets/suppositories, medicine tablets
These medications would be prescribed in accordance with the recommendations outlined in the CDC Health Information for International Travel guidelines (Yellow Book)

Per January 11, 2019 meeting:
• The Committee discussed a desire to provide recommendations to the Board in a format that would permit a pharmacist to utilize current guidelines and not to specify specific drug classes, drugs or devices.
• Staff stated that the law states that the Committee is to provide recommendations to the Board via drug or device but that there is a specific carve out to allow for protocol recommendations for travel medications and smoking cessation.
• Staff stated that they would confer with counsel on this and inform the Committee on how to proceed.

Pre-Travel Consult Medications

- Is this a concept that the Committee wants to consider? YES
- Is this a post-diagnostic drug or device? Or, is this suited for a statewide drug therapy management protocol? ADD INDIVIDUAL ITEMS TO PROTOCOL LIST
- Is a Subject Matter Expert (SME) needed?
- Is there a specific clinical guideline or other mandated resource required?
- Clinical parameters:
  - Standardized patient assessment process — INCL. ROUTINE VACCINATION ASSESSMENT
  - Defined exclusions:
  - Defined referrals:
  - Prescribing:
  - Follow-up:
- Does the Committee want to recommend an additional mandated education requirement? YES:
  - COMPLETE APhA IMMUNIZATION TRAINING (or equivalent) PLUS 4 HOUR TRAVEL VACCINATION CLASS (or equivalent)
  - COMPLETE 1 HOUR TRAVEL MEDICATION-RELATED CE EVERY 2 YEARS

Pre-Travel Consult Medications
CONCEPT
Time-sensitive access to non-occupational post-exposure prophylaxis (nPEP) treatment

- Tenofovir disoproxil fumarate 300 mg/emtricitabine 200 mg (Truvada) one tablet by mouth daily, plus either raltegravir 400 mg (Isentress) one tablet by mouth twice daily; OR
- Dolutegravir 50 mg (Tivicay) one tablet by mouth daily for 28 days

Per January 11, 2019 minutes:
- The Committee discussed a desire to say “Follow per nPEP clinical guideline and chose appropriate drug and durations”. If not, then they would like to recommend by drug class.
- Discussion to be continued at next meeting

Non-Occupational Post Exposure Prophylaxis (nPEP)

- Is this a concept that the Committee wants to consider? YES
- Is this a post-diagnostic drug or device? Or, is this suited for a statewide drug therapy management protocol? ADD INDIVIDUAL ITEMS TO PROTOCOL LIST
- Is a Subject Matter Expert (SME) needed?
- Is there a specific clinical guideline or other mandated resource required?
- Clinical parameters:
  - Standardized patient assessment process
  - Defined exclusions:
  - Defined referrals: MANDATORY REPORT OF ABUSE of MINORS
  - Prescribing:
  - Follow-up:
- Does the Committee want to recommend an additional mandated education requirement?