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Oregon State Board of Pharmacy News

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No. 635 New Statewide Drug Therapy Management Protocols Approved by the Board

In August 2020, the Oregon State Board of Pharmacy adopted four new statewide drug therapy management protocols:

- Conditions: Vulvovaginal Candidiasis (VVC)
- Preventative Care: Tobacco Cessation – NRT (Nicotine Replacement Therapy) and Non-NRT
- Preventative Care: Travel Medications
- Preventative Care: HIV Post-Exposure Prophylaxis (PEP)

These protocols were developed by Oregon's Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) with assistance from subject matter experts. Each protocol utilizes a standardized patient assessment process, which includes a patient intake form, assessment and treatment care pathway, and referral guidelines. When applying these protocols to offer services that may include the prescribing of therapy, pharmacists must comply with Board rules for Pharmacist Prescriptive Authority, which are found in Oregon Administrative Rules (OAR) 855-020. Pharmacists can submit concepts for new protocols and/or feedback on current protocols to the committee for consideration via forms on the PHPFAC web page. The committee reviews information provided and makes recommendations to the Board. The Board then considers the recommendations received and may choose to adopt them into the Division 20 rules as deemed necessary.

No. 636 Public Health Partnership Supports Pharmacist Assessment and Prescribing of Tobacco Cessation Products

By J. Hildegard "Hilde" Hinkel, MPH, Health Systems Policy Specialist, Oregon Health Authority, and Paige Clark, RPh, Director of Alumni Relations and Professional Development, Oregon State University College of Pharmacy

The Oregon Health Promotion and Chronic Disease Prevention Section of the Oregon Health Authority (OHA) and Oregon State University (OSU) College of Pharmacy's Department of Continuing Education have partnered to support pharmacist engagement in tobacco cessation efforts. These efforts focus on pharmacist-driven patient assessment and prescribing pursuant to a statewide protocol developed by PHPFAC and adopted by the Board. This partnership provides Oregon pharmacists with a state-specific Tobacco Cessation Patient Assessment and Prescribing for Pharmacists continuing education (CE) program. It outlines and guides the pharmacist through the processes of providing tobacco cessation services, including patient assessment and prescribing of smoking cessation products utilizing the statewide protocol. The program also includes county-specific patient referral resources to support the pharmacist in efficiently managing the required patient referral to the Oregon Tobacco Quit Line or other resources for support, such as tobacco cessation counseling.

This collaboration and the resulting pharmacist CE program encompass each element of the assessment and management protocol as outlined by the PHPFAC and adopted by the Board to ensure patient safety when providing tobacco cessation services. By participating in this initiative, Oregon pharmacists can readily provide accessible tobacco cessation services, prescribe the full spectrum of tobacco cessation products, refer patients to the Oregon Tobacco Quit Line, and be reimbursed by Oregon Medicaid. This innovative approach to leveraging pharmacists as a convenient access point for patient care related to tobacco cessation advances Oregon's goal to reach more patients who seek tobacco cessation assistance.

In an unprecedented act of partnership and support, OHA is sponsoring 400 pharmacist registrations for this CE program. In addition, OHA is also supporting this initiative by investing in a statewide advertising campaign to inform Oregonians who would like treatment for nicotine dependence to talk to their pharmacist.

Pharmacists must be credentialed and enrolled with OHA in order to bill Oregon Medicaid. Because of Oregon's existing hormonal contraceptive prescribing authority, many Oregon pharmacists working in community pharmacies have been previously credentialed and enrolled as a prescribing professional. Pharmacists interested in becoming a credentialed and enrolled prescribing pharmacist may apply through Oregon Health Plan provider enrollment. Pharmacist-conducted patient assessment associated with prescribing for a patient is billed using the same codes and is reimbursed at the same rate for all prescribers by Oregon's Medicaid program.

For further details or questions about accessing the course, please contact Paige Clark by email at paige.clark@oregonstate.edu. For more information from OHA related to

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National Pharmacy Compliance News

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The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids, OUD Treatment

Recognizing the importance of discussing naloxone with patients receiving opioids or medications to treat opioid use disorder (OUD), Food and Drug Administration (FDA) recommends that health care providers include such discussions as a routine part of prescribing these medications. Further, the agency is requiring label changes to these medications to include this recommendation. The revised labels will encourage health care providers to discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. The labeling changes also suggest that providers prescribe naloxone to patients being prescribed opioids who are at increased risk of opioid overdose.

"Even during this global pandemic, we have continued to prioritize addressing the opioid crisis," said FDA Commissioner Stephen M. Hahn, MD, in a press release. "Today's action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose. We will use all available tools to address this crisis, and we know efforts to increase access to naloxone have the potential to put an important medicine for combatting opioid overdose and death in the hands of those who need it most – those at increased risk of opioid overdose and their friends and family."

The complete list of changes is available through an July 2020 Drug Safety Communication.

Proposed Rule to Require Electronic Submission of DEA Form 106

A proposed rule requiring accurate electronic submission of DEA Form 106 was published by Drug Enforcement Administration (DEA) in the *Federal Register* on July 29, 2020. The form, used by DEA registrants to report thefts or significant losses of controlled substances (CS), would also need to be submitted within a 15-day time period under the proposed rule. DEA registrants who experience theft or loss of CS would still be required to notify the DEA Field Division Office in their area, in writing, within one business day of discovery. According to the announcement published in the *Federal Register,* this requirement will impact the remaining 0.5% of DEA Form 106 responses that are reported by paper.

Inappropriate FentaNYL Patch Prescriptions at Discharge for Opioid-Naïve, Elderly Patients

ISMP Institute for Safe Medication Practices An ECRI Affiliate

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk-reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at* www.ismp.org.

ISMP recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of transdermal fenta**NYL** patches for elderly patients. In most cases, the pharmacists reviewing the patients' orders determined that the fenta**NYL** patches had been inappropriately prescribed for opioid-naïve patients, sometimes to treat acute pain rather than chronic pain. One of the more common underlying causes appears to be a knowledge deficit about the dangers of prescribing this opioid analgesic to opioid-naïve patients. Several of the events began in a hospital, with opioid-naïve patients receiving prescriptions for fenta**NYL** patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fenta**NYL** patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose.

In one event, an 88-year-old resident from a LTC facility fell and was taken to a local hospital ED, where multiple rib fractures were diagnosed. Upon discharge

from the ED, the resident was prescribed a fenta**NYL** patch, 25 mcg/hour, every 72 hours. At the LTC facility, a consultant pharmacist reviewed the medication orders and the resident's medication history. The pharmacist determined that the resident had not received a prescription for opioids in the past year, revealing he was opioid-naïve. The consultant pharmacist contacted the prescribing ED physician to discuss the order for the fenta**NYL** patch. The ED physician reported that the resident had received "three small IV push doses" of fenta**NYL** in the ED, mistakenly believing this meant the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fenta**NYL** patch because the resident had a documented allergy to codeine. The ED physician mistakenly believed the fenta**NYL** patch was the only viable option. The consultant pharmacist clarified that the LTC records indicated that the resident had experienced mild nausea and an upset stomach while taking **HYDRO**codone and acetaminophen when he was younger, which is not an allergy but rather a mild intolerance. The ED physician changed the resident's analgesic to oral oxy**CODONE** 5 mg as needed every four to six hours.

Reliance on product labeling and practitioner education alone will not prevent life-threatening errors with fenta**NYL** patches. Yes, health care practitioners should be educated about safe prescribing, and their competency should be verified as a prerequisite to prescribing. But there will always be those who are unaware of the risks they take prescribing fenta**NYL** patches to opioid-naïve patients to treat acute pain. Thus, system safeguards must be established to avoid the risk of harm.

Fenta**NYL** patches should only be prescribed for patients who are opioid-tolerant with persistent, moderate-to-severe chronic pain that requires around-the-clock, long-term opioid administration. In 2018, ISMP called for the elimination of prescribing fenta**NYL** patches for opioid-naïve patients and/or patients with acute pain in our *Targeted Medication Safety Best Practices for Hospitals*. In 2020, this best practice was incorporated into a new best practice (No.15) to verify and document the patient's opioid status and type of pain before prescribing and dispensing extended-release opioids.

When entering discharge and transfer orders, interactive alerts requiring confirmation that the patient is opioid-tolerant and experiencing chronic pain might help prevent inappropriate prescribing, as might hard stops if patients do not meet prescribing criteria. Consider creating a daily list of discharge prescriptions and transfer orders for fenta**NYL** patches generated from the order entry system, and requiring a hospital pharmacist to review them to verify that the patient is opioid-tolerant and has chronic pain.

Engage patients. Educate all patients prescribed a fenta**NYL** patch and their caregivers about how to use the patch safely.

SAMHSA Health Privacy Rule Revised to Better Integrate, Coordinate Care for Patients With SUD

A revised Substance Abuse and Mental Health Services Administration (SAMHSA) rule will make it easier for people diagnosed with substance use disorders (SUDs) to receive integrated and coordinated care. The revisions to the agency's Confidentiality of Substance Use Disorder Patient Records regulation, 42 CFR Part 2, advances the integration of health care for individuals with SUDs while maintaining critical privacy and confidentiality protections.

According to a US Department of Health and Human Services (HHS) press release, under Part 2, a federally assisted SUD program may only disclose patient identifying information with the individual's written consent, as part of a court order, or under a few limited exceptions. In addition, health care providers, with patients' consent, will be able to more easily conduct quality improvement, claims management, patient safety, training, and program integrity efforts.

The revised rule modifies several major sections of Part 2, including provisions related to records, consent requirements, and research, among others. For a list of changes in the final rule, visit the HHS Fact Sheet.

HHS Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, MD, PhD, the head of SAMHSA, further stated, "Modernizing 42 CFR Part 2 will strengthen the nation's efforts to reduce opioid misuse and abuse and to support patients and their families confronting substance use disorders. The rule will make it easier for primary care clinicians to treat individuals with substance use disorders."

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this partnership and program, please contact Hilde Hinkel by email at janet.h.hinkel@dhsoha.state.or.us. The Tobacco Cessation Patient Assessment and Prescribing for Pharmacists CE is available here.

Note: The Board adopted the Tobacco Cessation – NRT and Non-NRT protocol in August 2020. A minimum of two hours of Accreditation Council for Pharmacy Education CE related to pharmacist prescribing of tobacco cessation products is required prior to utilizing this statewide protocol. The OSU CE program is one option for meeting this requirement.

No. 637 Drug Take-Back Program Rules Adopted by DEQ

By Michael Lee, Operations and Policy Analyst, Oregon Department of Environmental Quality

The Oregon Legislature passed House Bill 3273 in 2019, establishing a drug take-back program in Oregon and requiring the Oregon Department of Environmental Quality (DEQ) to adopt rules for that program. This program is a statewide product stewardship program for safely disposing of unused medications. The 2020 drug take-back rulemaking was adopted by the Environmental Quality Commission on September 17, 2020. You can find the official, published version of the rules in OAR 340-098.

Oregon's drug take-back law (Oregon Revised Statutes (ORS) 459A.200 to 459A.266) requires drug manufacturers to fund and participate in a statewide drug take-back program for Oregon residents and other covered entities. Such programs must provide convenient service throughout Oregon and offer safe and secure collection, transportation, and disposal of unwanted prescription, over-the-counter, brand, and generic drugs. Programs will be developed and implemented by program operators, who must first submit program plans to DEQ for approval. You can find more background information about the drug take-back program here.

The new rules do the following:

- Require a drug take-back plan or updated plan to include either the Board-issued registration number for each participating manufacturer or a statement that the manufacturer is not required to register with the Board;
- Ensure access for minority, low-income, rural, and other historically underserved communities;
- Describe factors to be considered for granting waivers or approvals related to services and collection events in place of required drop-off sites;
- Designate DEQ to act on the Environmental Quality Commission's behalf for enforcement and discipline under ORS 459A.239; and
- Establish fees reasonably calculated to cover DEQ's administrative costs, as required by ORS 459A.242.

DEQ staff report to the Environmental Quality Commission, which maintains copies of the adopted rules and amendments that are available here. After programs have been established and approved by DEQ, pharmacies may request to become authorized collectors under the program. Pharmacies must comply with Board rules for Secure and Responsible Drug Disposal, which are in OAR 855-041-1046. Drug Enforcement Administration controlled substance disposal regulations are located in Title 21 Code of Federal Regulations Part 1317 Subpart B.

If you have any questions, please contact drugtakeback@deq.state.or.us.

No. 638 Fifty-Year Pharmacists

The Board is pleased to recognize pharmacists who have been licensed in Oregon for 50 years. The Board appreciates their many years of service and contributions to the profession and to the health and safety of Oregonians. These distinguished individuals should be proud of their accomplishments, and they have earned the gratitude and honor of their profession. The following is a list of pharmacists who have reached this milestone in 2020:

- Gary Balo, Portland, OR
- Stanley Baron, West Springfield, MA
- Robert Burr, Willamina, OR
- Cabot Clark, Eugene, OR
- Kalman Kallay, Portland
- Ruby Letcher, Eugene
- Marilyn Levy, Sheridan, OR
- Edwin Schneider, Oregon City, OR
- Gilbert Seid, Corvallis, OR
- Gary Snodgrass, Diamond Springs, CA
- Anthony Taylor, Junction City, OR
- Madalyn Whitaker, Hillsboro, OR

No. 639 Applying for Board-Approved Continuing Education

Oregon is one of a diminishing number of states that allow licensees to apply for CE approval as a provider or attendee. To allow time to evaluate and approve applications prior to the program, the application must be submitted at least 30 days prior to the date of the program to be considered for approval. Additional information is available on the CE Information page of the Board's website.

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Joe Schnabel, PharmD, RPh, BCPS - State News Editor

Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Amy Sanchez - Communications Manager