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No. 568: Naloxone Prescribing by Oregon Pharmacists

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The abuse and dependence of opioids is a genuine public health issue. The number of opioid overdoses has drastically increased over the years. According to the Centers for Disease Control and Prevention, drug overdose is the main cause of accidental deaths, surpassing automobile collisions. Opioid overdose can also be incidental; individuals may misread their prescriptions or not realize that they have already taken their medication. Naloxone can reverse the effects of opioid overdose.

House Bill 4124, signed into Oregon law in April 2016, permits pharmacists to prescribe unit-of-use naloxone to a person who conducts training pursuant to protocols established by the Oregon Health Authority (OHA) or who has successfully completed approved training. This law was created as a way to increase access to naloxone, with an end goal to diminish the dangers related to opiate overdose. The law allows a pharmacist to prescribe to two types of authorized recipients. First, a pharmacist can prescribe to a trainer or an organization that shall possess and distribute naloxone to trainees. Second, a pharmacist can prescribe naloxone and the necessary supplies to administer it to trained individuals who may possess and administer naloxone to an individual experiencing an opiate overdose. Both of these options are permitted when the pharmacist is familiar with opiate overdose and naloxone rescue **and** works in a pharmacy that has policies and procedures developed to offer these services.

The OHA training is available online in both video and written format at *https://public.health.oregon.gov/ProviderPartnerResources/EMSTraumaSystems/Pages/epi-protocol-training.aspx#naloxone.* It covers signs and symptoms to look for during an opiate overdose and a general treatment overview. The training covers how to respond to an opiate overdose by checking responsiveness and calling 911 if there is no response, how to perform CPR, and how to properly administer naloxone and to continue CPR, if needed, until help arrives. Pharmacists must become familiar with this document, opiate overdose, and naloxone rescue to provide effective information and counseling to individuals seeking naloxone.

On September 2, 2016, the Oregon State Board of Pharmacy passed a temporary rule that outlines the requirements for an Oregon pharmacist to prescribe and dispense naloxone. Oregon Administrative Rule (OAR) 855-019-0460 states a pharmacist can prescribe naloxone and the necessary medical supplies for opiate overdose to an OHA-authorized person or organization and to an individual who has completed an OHA-approved training. The pharmacist shall determine that the individual seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone. Naloxone may not be dispensed without providing oral counseling to the authorized recipient, to include dose, effectiveness, adverse effects, storage conditions, and safety. This means that the individual receiving the naloxone prescribed by a pharmacist cannot waive the consultation. The pharmacist must document the encounter and the prescription and maintain records for three years.

In school, pharmacists are trained and educated in pharmacology, pharmacokinetics, and drug-drug and drug-illness state interactions. A pharmacist is to use professional judgment in determining whether to complete additional education in opiate overdose prior to prescribing naloxone. A pharmacist can be an impactful member of the team by communicating with providers, giving instruction to patients, and increasing education throughout a community. Avoiding opioid overdose-related deaths should be one of many priorities to the pharmacy profession, since pharmacists are medication experts. Pharmacists are in an influential position to identify high-risk patients. A pharmacist can determine at-risk patients by obtaining a patient's medication history and identifying patients who are taking high doses of opioids for long-term management of chronic pain; have a confirmed history of substance abuse, dependence, or non-medical use of prescription or illicit opioids; or are completing a mandatory opioid detoxification or abstinence program. At-risk patients can complete the OHA training while waiting for their prescriptions to be filled.

Permitting Oregon pharmacists to prescribe naloxone and provide counseling to authorized individuals will broaden access to the medication, assist in preventing opioid overdose deaths, and give patients a chance to get suitable treatment. For related information, please visit the Board's website at *www.oregon.gov/pharmacy/Pages/Naloxone.aspx.*

No. 569: Oregon PDMP

The Board office receives regular updates from the Oregon Prescription Drug Monitoring Program (PDMP). It has come to the Board's attention that while hundreds of thousands of prescriptions are uploaded to the database annually with minimal errors, the program still does receive incorrect entries. Please take some time to review these opportunities with your staff to confirm that prescription data are being entered correctly into your systems, and in turn, being correctly uploaded to the PDMP.

- Be sure to enter the Drug Enforcement Administration (DEA) number provided on the prescription whenever available. There are many clinicians who practice in various locations with different DEA numbers (but who are the same practitioner). Entering the correct DEA number will ensure that the provider's associated information, such as practice address and phone number, will also be correct. This is important to ensure the most efficient communication with the correct office when calling for clarifications and renewing ongoing drug therapies.

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National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Improper and Unsafe Vaccine Storage

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropr iate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter[1] contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.[2]

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

(1) Read and follow the label.

(2) Know which medicines contain acetaminophen.

(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org*.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at *www.fda.gov/MedWatch*. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm*.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia,* a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm*.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online interest form available in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at *www.nabp.pharmacy*, or contact CompAssess@nabp.pharmacy.

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- Do not use "dummy" DEA numbers, eg, AR1111119. The pharmacist has a corresponding responsibility to ensure that prescriptions are completed accurately.
- Input the correct original date for each prescription. The original date is not always the date that the pharmacy is processing the prescription.
- Use only a single profile for each patient. Unfortunately, having two active profiles for the same patient, sometimes with a "nickname" or other anomaly, creates confusion for providers' effective use of the PDMP database. Pharmacists should follow company procedure to merge profiles when encountering this scenario at their pharmacy to ensure that the most accurate information is being documented and submitted to the database.

No. 570: Compliance Pearls

Return to Stock: Did you know that pharmacists must verify and document their verification of all "return to stock" (RTS) medications that are relabeled by a technician? Compliance staff has noticed that many pharmacists are not aware of this requirement for pharmacist verification. Regulations that address this requirement include:

- OAR 855-025-0025(4), which states that "Work performed by Pharmacy Technicians and Certified Oregon Pharmacy Technicians assisting the Pharmacist to prepare medications must be verified by a Pharmacist prior to release for patient use. Verification must be documented, available and consistent with the standard of practice."
- OAR 855-019-0200(2), which states that "Only a pharmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require the professional judgment of a pharmacist include but are not limited to: . . . (i) Final verification of the work performed by those under their supervision."

Please note that the Board does not require a pharmacy to relabel RTS medications.

Counseling: Did you know that solely asking a patient "Do you have any questions on your prescription?" does not constitute appropriate counseling for a new prescription? Please ensure that you provide all information necessary to promote the safe use of medication and to facilitate an appropriate outcome. Patients often do not know what questions to ask. Health care providers and patients are relying on the pharmacist's expertise to educate patients about what to expect from medications and how to use them properly.

Allergies: Did you know that putting a note regarding a medication intolerance in the patient comment field of your computer system, rather than in the allergy field, is acceptable? Please note that this determination should be made by a pharmacist because it may affect a pharmacist's decision when performing a drug use review (DUR) and which medications are flagged for a DUR by the computer software.

No. 571: Fifty-Year Pharmacists

The Board is pleased to acknowledge the pharmacists who have been licensed in Oregon for 50 years. The Board recognizes their many years of service and contributions to the profession and to the health and well-being of the citizens of Oregon. These distinguished individuals should be proud of their accomplishments, and they deserve the recognition and acknowledgement of their profession. The following is a list of pharmacists who reached this milestone in 2015 and 2016.

Gary Brew, Medford, OR	**Lee Land,** Eugene, OR
James Burch, Portland, OR	**Robert Lovitt,** Hayden, ID
David Bystrom, Westerville, OH	**Richard Lundgren,** Salem
William Carson, Lake Oswego, OR	**Joe McCann,** Lake Oswego
Daniel Cooke, Bend, OR	**Robert McGill,** Grand Coulee, WA
Michael Douglas, Newberg, OR	**Raymond Michael,** Boardman, OR
Daniel Ferry, Anderson, CA	**William Milne,** Wilsonville, OR
James Frahm, Vancouver, WA	**Conrad Reinmiller,** La Pine, OR
Harlen Hendrickson, Henderson, NV	**Leroy Roberts,** Springfield, OR
Mark Hyman, Portland	**Gerald Rood,** Warren, OR
Robert Ingram, Salem, OR	**Bruce Sharrah,** Baker City, OR
Richard Irwin, Newberg	**Mary Lou Wacek,** Portland
Lawrence Kralman, Milwaukie, OR	**James Wells,** Litchfield Park, AZ
William Labberton, Beaverton, OR	**Willard Wilson,** Black Butte Ranch, OR

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