



Washington State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

Dept. of Health • PO Box 47863 • Olympia, WA 98504-7863
www.doh.wa.gov/hsqa/Professions/Pharmacy/default.htm

No. 1096 Use of Opioids in the Treatment of Chronic Non-Cancer Pain

New chronic non-cancer pain management rules for physicians and physician assistants became effective January 2, 2012. Other prescribers, such as advanced registered nurse practitioners, osteopathic physicians, and physician assistants, dentists, and podiatrists have similar rules that became effective in 2011.

The goal of the prescribing rules is to provide direction for practitioners who treat patients with chronic non-cancer pain. Pain management is a dynamic and challenging area of medical care that often includes opioids.

An increase in overdose deaths and hospitalizations in Washington State due to prescription opioids parallels an increase in the prescribing of opioids.

The rules encourage all practitioners who prescribe long-acting opioids to have at least four hours of continuing education on that topic.

Practitioners who have 12 continuing education credits on the topic of chronic pain management within the prior two years are exempt from the requirement for a pain management consultation when prescribing 120 mg or more morphine equivalents per day.

- ◆ Pharmacists are not required or expected to enforce these rules.
- ◆ Pharmacists are required to provide safe patient care.
- ◆ If a pharmacist receives a prescription for 120 mg or greater morphine equivalent per day, the pharmacist can contact the prescriber for clarification.

You can find more information on the pain management laws and subsequent rules, as well as guidance and resources, on the Department of Health's Web page: www.doh.wa.gov/hsqa/Professions/PainManagement/.

No. 1097 Requirements for Posting Licenses in Pharmacies

There are several laws and rules that relate to posting licenses and certificates in the pharmacy:

- ◆ RCW 18.64.043(2) requires that all pharmacies exhibit the location/pharmacy license in the pharmacy. RCW 18.64.140 requires that each pharmacist post his or her current license in the pharmacy so that it is clearly displayed to the public.
- ◆ WAC 246-869-190(6) requires that all pharmacies are subject to periodic inspections and that the certificate of inspection is posted in view of the general public and must not be removed or defaced.
- ◆ WAC 246-901-090 requires that all pharmacy ancillary personnel working within the pharmacy and having contact with patients or

the general public wear badges or name tags clearly identifying them as pharmacy assistants or technicians.

Note: there is no requirement to post pharmacy intern registrations or credentials issued to pharmacy technicians or assistants. It is the duty of the responsible manager to ensure that all personnel and location licenses and credentials are current and active.

No. 1098 Pharmacy Technician Continuing Education Rules (Hearing Date Correction)

The Washington State Board of Pharmacy approved proposed rule language on December 15, 2011. The proposed rules will require pharmacy technicians to obtain a minimum of 10 hours of approved continuing education credit hours each year. The Board scheduled a public hearing on the proposed rules for **June 7, 2012**.

No. 1099 Safe Handling of Hazardous Drugs

The 2011 legislature enacted RCW 49.17.465, which required the Department of Labor & Industries (L&I) to adopt rules to minimize or eliminate occupational exposure to hazardous drugs. The legislature required L&I to develop minimal rules consistent with the National Institute for Occupational Safety and Health (NIOSH) 2010 publication *NIOSH Alert*. While the primary concern is antineoplastic drugs, NIOSH included other drugs in its list of hazardous drugs. The law applies to all health care settings that have employees with occupational exposure to hazardous drugs. The use of biological safety cabinets, decontamination, and personal protective equipment are incorporated in the rules as well.

Employers must write a hazardous assessment plan and provide effective, assessment-based precautions designed to minimize or eliminate occupational exposure. At stakeholder meetings pharmacists expressed concern over the NIOSH list of hazardous drugs. The rules WAC 296-62-500 were adopted January 3, 2012, and will be implemented in stages.

Stages of Rule Implementation

- ◆ January 1, 2014, employers must have completed and implemented a written hazardous drugs control program.
- ◆ July 1, 2014, employers must have implemented employee training.
- ◆ January 1, 2015, employers must have completed installation of appropriate ventilated cabinets.

No. 1100 New Pharmacy Intern Renewal Form

Beginning March 16, 2012, the renewal form for pharmacy interns will take on a new look. Pharmacy interns seeking renewal must sign

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DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- ◆ the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- ◆ the prescription contains all the information required by 21 CFR §1306.05; and
- ◆ the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at www.fda.gov/Safety/Recalls/ucm289770.htm.

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes

in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.

With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that “current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

Compliance News to a particular state or jurisdiction should not be assumed (regarding the law of such state or jurisdiction.)



serious harm to patients.” FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm, provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.

Additional details are provided in an FDA Drug Safety Communication, available at www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become “increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV).” The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- ◆ Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- ◆ Insulin pens should be clearly labeled with the person’s name or other identifying information to ensure that the correct pen is used only on the correct individual.

- ◆ Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- ◆ If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice*, prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- ◆ Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- ◆ Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- ◆ Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that “one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models.” The report may be downloaded from the US PHS Web site at www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile Today!

CPE Monitor™ integration is underway. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited providers will require you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity. Many have already begun to do so.

Visit www.MyCPEmonitor.net to set up your e-Profile and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

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the back of the renewal form attesting to current enrollment in an accredited school or college of pharmacy or participation in a residency program reported to the Board. In addition, interns must get the signature and license number of his or her supervising pharmacist.

No. 1101 2012 Legislative Session

March 6, 2012, marked the end of the regular 2012 legislative session. The Board reviewed many bills that proposed drug return and reuse programs, none of which were successful in this legislative session. The following bills passed the legislature and may be of interest to the practice of pharmacy. You can find additional details and updates on other bills on the Washington State Legislature's Web page at <http://apps.leg.wa.gov/billinfo/>.

- ◆ **HB1486** – This bill was reintroduced from 2010. The bill permits Washington State pharmacists to dispense controlled substance prescriptions written by out-of-state advanced registered nurse practitioners – amending RCW.69.50.101. Effective June 7, 2012.
- ◆ **SSB5969** – This bill requires licensing authorities to establish procedures to expedite the issuance of a license, certificate, or permit to a person who:
 - is certified or licensed in another state to perform professional services in that state;
 - whose spouse or registered domestic partner is the subject of a military transfer to Washington; and
 - has left employment in the other state to accompany the person's military spouse to Washington State.

Effective March 14, 2012.

- ◆ **SB6290** – This bill requires that a license of a spouse or registered domestic partner or service member be placed in inactive military status. The Board will return the license to active status for renewal within six months after the service member is honorably discharged from service or sooner if requested. (Pending governor's signature.)

No. 1102 Board Member Appointments

Congratulations to Governor Christine Gregoire's Board member appointees **Sepi Soleimanpour, MS, RPh, Emma Zavala-Suarez, and Dan Rubin, MS**. Their appointments were effective March 1, 2012.

Ms Soleimanpour has held a Washington pharmacist license for 15 years. She earned her bachelor of science in pharmacy from Ohio State University in 1994. She later earned a master's degree in business administration and health care administration from the University of Colorado in 2008. Ms Soleimanpour is a community pharmacy leader at Walgreens. In her current role at Walgreens, she mentors, coaches, and manages pharmacy and store operations in Issaquah, Renton, and Kitsap Peninsula, WA. Ms Soleimanpour's first term expires on January 19, 2016.

Ms Zavala-Suarez graduated from the University of Washington, School of Law. She earned her BA in Latin American studies with distinction from Whitman College. Emma is active in advocacy work on behalf of migrant farm workers and the Latino community. Ms Zavala-Suarez was appointed to complete the unexpired term vacated by the previous public member last year. Her term expires on January 19, 2014.

Mr Rubin earned a master's degree in public health and health policy from the University of California, Berkeley, and the University of Michigan, respectively. He has had an extensive career in health and social services policy and community development. For the past 10 years, he has worked at CHOICE Regional Health Network, a non-profit community health collaborative serving primarily the rural area of southwest Washington. Mr Rubin's first term as a public member on the Board expires on January 19, 2016.

No. 1103 Election of Officers

The Board of Pharmacy held elections for leadership positions at its March business meeting. **Christopher Barry** and **Donna Feild** will serve as the 2012 chair and vice chair, respectively.

No. 1104 Executive Director Retires

Susan Teil Boyer, executive director of the Board of Pharmacy retired at the end of March. Ms Boyer served a total of 11 years with the Board. From 2000 to 2008, Ms Boyer was appointed professional member to the Board. In 2009, she was selected as executive director. Ms Boyer has led the Board to many accomplishments in her tenure. Examples include implementation of the electronic methamphetamine precursor tracking system; working with the Washington Association of Sheriffs and Police Chiefs in developing medication distribution/administration policies; for public health and safety, banning synthetic cannabinoids and cathinones; and working with the federal Drug Enforcement Administration on medication policies for residential treatment facilities. Ms Boyer is a compassionate leader that advocates for the important work of the Board. Ms Boyer stated that working with the Board and Board staff is one of the highlights of her career. "These are dedicated professionals who care deeply about protecting public health and safety, and promoting the profession of pharmacy!"

The Board extends its thanks to Susan Teil Boyer for her many contributions to the practice of pharmacy in Washington State and to her hard work and support of public health and safety. The Board wishes her success in all her future endeavors.

No. 1105 Thank You and Farewell

The Board of Pharmacy wishes to extend its thanks to **Rebecca Hille** and **Albert Linggi** for their extraordinary leadership, devotion, and hard work on issues to protect public health and promote access to safe pharmacy practice.

Rebecca Hille is the longest serving Board member in the history of the Washington State Board of Pharmacy. Governor Gary Locke originally appointed Ms Hille on August 27, 2001, to complete the term of a resigning public member. Governor Locke reappointed her on March 18, 2004. Governor Christine Gregoire appointed her on January 20, 2008, to serve two consecutive four-year terms. Ms Hille served in leadership positions on the Board and acted as the Board's liaison to the Spokane Pharmacy Association. She has been a dedicated and invaluable Board member as she represented the interest of the public.

Governor Gregoire appointed Albert Linggi on March 10, 2008. Mr Linggi served as Board chair in 2011 and led the Board in many projects, such as implementing the National Precursor Log Exchange, adopting procedures for patient notification of closing pharmacies, banning synthetic cannabinoids and substituted cathinones, and the ongoing rules scan and analysis project.

The Board and staff wish them well and success wherever the future leads them.

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The *Washington State Board of Pharmacy News* is published by the Washington State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Susan Teil Boyer - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor

Larissa Doucette - Communications Manager
