



Washington State Board of Pharmacy

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www.doh.wa.gov/hsqa/Professions/Pharmacy/default.htm

No. 1106 Pharmacists and Public Health: Tetanus, Diphtheria, and Pertussis (Tdap) Vaccinations

Washington State is experiencing a whooping cough epidemic. There are more than 2,000 known cases so far in 2012 compared to 146 in 2011. Babies are most at risk for serious disease because they are too young to get enough doses for protection. Whooping cough spreads easily by coughing and sneezing. To contain whooping cough, families, caregivers, and communities need vaccinations.

Pharmacies and pharmacists through their immunization collaborative agreements are important providers of Tdap vaccinations. The Department of Health recommends pharmacies as a source of whooping cough vaccine.

Tdap is not always on the list of vaccines listed in the collaborative drug therapy agreement. This does not need to be an obstacle to providing whooping cough vaccine. Most agreements include the phrase, “. . . and any other vaccines mutually agreed upon.” The pharmacist just needs to follow-up with the physician and document the addition of Tdap to the vaccine list. If there is no “any other” statement, the pharmacist can still contact the physician to gain approval of the Tdap vaccine addition.

The whooping cough epidemic is another opportunity for pharmacists to step forward and demonstrate their contribution to patient care and public health.

No. 1107 Online Renewal Available for Most Pharmacy Professionals

Each year the Health Systems Quality Assurance Division of the Department of Health renews licenses for over 380,000 health care providers (customers) in more than 80 professions. The department’s portion of the current mostly automated paper-based renewal process uses minimal staff time. However, provider feedback told the Department of Health that a vast majority would prefer to renew their licenses online with a credit card instead of mailing a check. So, in December 2011 the department began a phased roll-out of online

renewals. There is a \$2 convenience fee per transaction to help cover costs of making the online system available for credit card processing.

Pharmacy technicians were one of the first four professions to have online renewals available. On January 13, 2012, the first pharmacy technician renewed online. To date, pharmacy technicians are the leading users of the system with over 1,000 renewing online. As of June 2012, pharmacists were able to renew online.

The next steps over the course of the impending 12 months include making online renewals available for most credential types, and allowing eight more health care professions to apply for a credential online.

For additional license renewal information, please visit the Department of Health’s Web site at www.doh.wa.gov/hsqa/Renewals.htm, and click on Health Professions under Online.

No. 1108 Authority to Dispense Prescriptions Written by Out-of-State Licensed ARNPs

Starting June 7, 2012, Washington pharmacies can dispense controlled substance prescriptions written by Advanced Registered Nurse Practitioners (ARNP) licensed in another state (House Bill 1486). The prescription must be within their scope of practice. This law expands on the legislation passed in 2010, which authorized the filling of non-controlled prescriptions written by out-of-state ARNPs and those licensed in British Columbia, Canada. Note: you cannot fill prescriptions for controlled substances written by Canadian licensed ARNPs since Canadian practitioners do not hold a registration from United States Drug Enforcement Administration (DEA).

No. 1109 We’ve Moved

The Washington State Board of Pharmacy along with other offices within Health Systems Quality Assurance Division and its public counter have moved to a new Tumwater, WA,

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FDA Warned Medical Practices About Counterfeits in US and Risks to Patients

In April 2012, Food and Drug Administration (FDA) sent letters to medical practices in several states requesting that they stop administering drugs purchased from any foreign or unlicensed source. FDA's letters were sent in response to the discovery that the medical practices purchased medications from foreign or unlicensed suppliers that sold illegal prescription medications. FDA has advised that these medical practices are putting patients at risk of exposure to medications that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.

In an FDA statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." Further, FDA reminds health care providers, pharmacies, and wholesalers/distributors that they are valuable partners in protecting consumers from the threat of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. FDA advises that the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering such offers.

FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page, available at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm, may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business.

The FDA warning letters were sent following two incidences of counterfeit injectable cancer drugs found in US medical practices, one in February 2012, involving counterfeit Avastin® 400 mg/16 mL, and another in April 2012, involving a counterfeit version of Roche's Altuzan® 400 mg/16 ml (bevacizumab).

More information and a list of the medical practices that were sent warning letters are available on the FDA Web site at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm.

Rethink the Vial



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.

Recently, ISMP has been receiving many reports from consumers who report the pharmacy "shorted them" on a variety of opioid pre-

scriptions. They report that when they call the pharmacy to complain about the missing number of tablets or capsules the pharmacy staff insists the proper quantity was dispensed. ISMP also receives reports from pharmacists reporting this same situation. The concern is that pharmacy personnel may be diverting the medication, the patient may be seeking more medication than what was prescribed, or some of the medication may be taken by someone else in the patient's home.

In the US, we dispense almost all oral solid drugs as loose tablets or capsules in a plastic vial that is labeled for the patient. This manner of dispensing makes diversion of a few tablets or capsules relatively easy. However, in many other countries, unit-dose and unit-of-use packaging is widely used.

It seems to reason that if unit-of-use, manufacturer-sealed containers or individual unit-dose packages of medications were used in the US for these drugs, diversion and/or speculation of diversion could be reduced. Manufacturers could produce unit-dose or unit-of-use packages, in numbered strips for ease of inventory and dispensing. Patients could be asked to sign for and agree to the amount dispensed at the point-of-sale. The numbered packaging would also help patients at home know if they had taken their medication or possibly alert them to diversion within their home. Of course, prescribers would need to prescribe quantities available in patient compliance packs or in multiples of that packaging, and insurance companies would have to pay for this specialized packaging.

Unit-of-use packs would provide other safety benefits. For example, patients would be able to verify the drug name on the label for each dose, which would add a redundancy in checking the pharmacy label to what was actually dispensed. Also, the manufacturer could print and attach the patient information sheet and/or medication guide to the package the patient receives, eliminating extra work in the pharmacy to print and supply these mandated education sheets to the patient.

It is evident that further steps must be taken to reduce and minimize abuse of prescription drugs. It is critical that education be provided to patients, caregivers, and health care providers to increase awareness about the dangers of prescription drug abuse and about ways to appropriately prescribe, dispense, store, and dispose of prescription medications. Development and deployment of consumer-friendly and environmentally responsible prescription drug disposal programs may also help to limit diversion (as well as reduce the risk of accidental ingestion) of drugs by family members and friends. FDA must continue its efforts to require new concepts for risk evaluation and mitigation strategies and provider education for opioid drugs. For more information on understanding prescription drug abuse, and to request Parents' Guide to Understanding Prescription Drug Abuse brochures for distribution to your patients, visit www.SafeguardMyMeds.org.

Counterfeit Vicodin ES Sold Via Rogue Internet Drug Outlet, Abbott Reports

In March 2012, Abbott warned consumers and health care providers about counterfeit Vicodin® ES purchased via the Internet. Abbott reports that the counterfeit product drug and package do not match that of Abbott's FDA-approved Vicodin ES (hydrocodone bitartrate and acetaminophen). Descriptions and images of the counterfeit product and authentic Vicodin ES are shown in a consumer alert posted on the Abbott Web site at www.abbott.com/vicodin-consumer-alert.htm. Abbott advises that anyone who has the counterfeit ver-

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sion should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web site at www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.

PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – including one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site at www.safemedicines.org/resources-for-healthcare-professionals.html. Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

FDA Urges Providers to Help Prevent Children's Accidental Exposure to Fentanyl Patches

FDA issued a safety alert reminding patients, caregivers, and health care providers to appropriately store, use, and dispose of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening. FDA recently evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises that used or unneeded patches are properly disposed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home."

FDA urges health care providers to educate patients and their caregivers about the appropriate use and disposal of fentanyl patches. FDA's consumer Web page provides detailed information for patients and caregivers and is available at www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm. Providers, patients, and caregivers are also encouraged to review the fentanyl patch product label for instructions. The FDA safety alert is available at www.fda.gov/Drugs/DrugSafety/ucm300747.htm. Additional consumer information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWARE_xE[®] Web site at www.awarerx.org/informedSiteMap.php.

Providers Asked to Advise Patients of Acetaminophen Safe Use Steps

With a world of conditions and hundreds of medicines, the Acetaminophen Awareness Coalition asks pharmacists and other health care providers to educate patients and caregivers about the proper use of medications containing acetaminophen. As the most common drug ingredient in America, acetaminophen can be found in over 600 medicines, including many prescription and over-the-counter medicines. The coalition notes that when used as directed, acetaminophen is safe and effective. The coalition asks providers to advise patients that there is a daily dosage limit for acetaminophen and that taking more than directed is an overdose and can lead to liver damage.

The coalition calls on health care providers to participate in the Know Your Dose campaign, by reminding all patients and caregivers to (1) always read and follow the labels on their medicines; (2) know if a medicine contains acetaminophen; and (3) never take or administer two medicines that contain acetaminophen at the same time. Additional medication safety tips for consumers and more information about the Know Your Dose campaign are available on the "OTC Medication Use" page of the AWARE_xE Web site at www.awarerx.org/OTCMedUse.php. The AWARE_xE consumer protection program and the National Association of Boards of Pharmacy[®] (NABP[®]) are part of the Acetaminophen Awareness Coalition.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and
Register for CPE Monitor 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 register for CPE Monitor 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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location. The public counter is located in Town Center 2, 111 Israel Rd in Tumwater. Counter hours of operation will remain 8 AM to 4:30 PM, Monday through Friday. The address for mailing renewal fees and other correspondence that includes payments remains PO Box 1099, Olympia, WA 98507-1099. The Board program's mailing address is PO Box 47852, Olympia, WA 98504-7852 and the fax number, 360/236-2901, also remains unchanged. Visit the Board's [Web page](#) for staff phone numbers.

No. 1110 Pharmacy Technician Continuing Education Requirements

The 2011 Legislature passed House Bill 1353, requiring the Board of Pharmacy to develop rules to establish continuing education (CE) requirements for pharmacy technicians. The effective date of the bill was July 22, 2011.

On May 2, 2012, the Board of Pharmacy filed CR-102, Proposed Rule Making, and WSR 12-10-082. The proposed rule requires pharmacy technicians to complete 10 hours of CE or 1.0 continuing education unit annually. One hour must be in pharmacy law and the remaining nine hours must be in pharmacy technician-related education. The proposed rule mirrors the national CE standards for pharmacy technicians set by the Pharmacy Technician Certification Board and the Institute for the Certification of Pharmacy Technicians.

The language approval came at the public rules hearing on June 7, 2012. The next step in the rulemaking process is filing the CR-103 (rulemaking order) with the Office of the Code Reviser. The rule will be effective 31 days from the date of filing. Watch for a notice of filing on our listserv.

No. 1111 Rules Rewrite Project for Pharmacy

Last fall the Board initiated Rules Rewrite Project for Pharmacy (R2P2). The scope of this project includes an initial rule scan and gap analysis. A future work plan will prioritize how and when any rule changes are initiated. The Board will assess current rules for consistency with statutory authority and federal regulations as well as national standards. R2P2 is an important and necessary investment in the practice of pharmacy in this state. It is consistent with the Health Systems Quality Assurance Division's strategic plan to remove barriers and streamline the regulatory process by ensuring Board rules support the delivery of quality, affordable, and efficient patient care. The Board will continue to seek stakeholder input throughout this process. Interested parties may sign up at [WSBOP – Rules](#).

No. 1112 Pharmacy Differential Hours Operations

Differential hours, as defined in [WAC 246-869-020](#), allow pharmacies located within another business to be open to the public during hours that are different from the rest of the facility. The pharmacy should post its hours of operation in a location visible to the public and to provide services during those times.

As long as a pharmacist is present, the pharmacy may occasionally extend the hours of operation. The most common example is a rush of patients just prior to closing or during a lunch hour. The pharmacy can stay open past its posted closing time to accommodate these patients.

The pharmacy should tell its patients why they are open during a time they are normally closed so the patient will understand this is not a normal occurrence.

No. 1113 Responsibilities of the PPPA, US Code, Chapter 15, Part 1473, Section 4(b), Code of Federal Regulations, Chapter 16, Part 1700, Section 14(a) (10), and Washington State Rule, WAC 246-869-230

The Poison Prevention Packaging Act (PPPA) allows dispensing of prescription drugs in non-child resistant packaging (non-CRP) "only when directed in such order or when requested by the purchaser." Many pharmacies enter the package preference (CRP or non-CRP), in the pharmacy's computerized patient medication profile or in a log book where the request may reside unchanged for an indefinite period (possibly as long as the individual remains a customer of the pharmacy).

The Consumer Product Safety Commission (CPSC) has the responsibility for enforcing the PPPA at the federal level. It states there is no provision in federal law or regulation to prevent a pharmacist from relying on a specific request from a patient, preferably in writing, to have all of his or her medications placed in non-CRP, ie, a blanket waiver. However, a single request from a patient to dispense a specific prescription in non-CRP is not a basis for the pharmacist to infer the patient wants all subsequent prescriptions dispensed in a non-CRP. This is not a blanket waiver.

A patient who previously filed a specific blanket waiver request for non-CRP may later change his or her mind about the use of such packaging because of changing personal circumstances. The patient may not remember to inform the pharmacist of the change in CRP preference. It would be a prudent practice for the dispensing pharmacist to periodically check with all patients who have blanket waiver requests on file to ensure that non-CRP continues to be the preferred packaging choice for the patient's drugs.

The dispensing pharmacist should be aware that it is not up to the pharmacist to decide when to use CRP or non-CRP on prescription drugs. It is the patient's decision to make, although a pharmacist may ask about the patient's preference. The pharmacist may decide to establish some form of record keeping procedure to document full compliance with the PPPA, including signed waiver requests, to document each blanket waiver for a non-CRP on prescription drugs.

The Washington State rule (WAC 246-869-230) requires the authorization by the patient verified with the signature

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of the patient or his or her agent in a statement requesting non-CRP prescription drug containers.

No. 1114 Written Prescriptions Must Have Two Signature Lines

The Board of Pharmacy is working with boards and commissions with prescriptive authority to remind practitioners that the law requires every written prescription to have two signature lines at the bottom of the prescription. RCW 69.41.120 requires:

- ◆ All written prescriptions shall have two signature lines at opposite ends on the bottom of the form. Under the line at the right side shall be clearly printed the words “**Dispense as Written.**” Under the line at the left side shall be clearly printed the words “**Substitution Permitted.**”
- ◆ The practitioner must communicate instructions to the pharmacist by signing the appropriate line.
- ◆ For oral prescriptions, the practitioner or the practitioner’s agent must tell the pharmacist whether a therapeutically equivalent generic drug is an allowable substitute.

This is in addition to the requirement to manually sign all written prescriptions on tamper-resistant paper. See [RCW 18.64.500](#).

No. 1115 System Blocks More Than 9,000 Pseudoephedrine Sales

The National Precursor Log Exchange (NPLEX) computer tracking system that went live on October 15, 2011, monitors the purchases of pseudoephedrine, ephedrine, and phenylpropanolamine (PSE) containing products in real time. The system has logged 715,622 purchases of PSE product and blocked 9,242 purchases from October 15, 2011, to the end of April 2012. This is a total of 25,413 grams of PSE blocked. All pharmacies and retail shopkeepers must hold a Combat Methamphetamine Epidemic Act (CMEA) certification issued by the DEA and must enter transaction data into the NPLEX tracking and monitoring system to sell PSE products at retail.

To set up an account to access and report to NPLEX, visit <https://nplex.appriss.com>. If you do not sell PSE products without a prescription, you must opt out by reporting to the Board. Visit the Board’s [Web page](#) for information to opt out of NPLEX reporting or to request an exemption.

No. 1116 CMEA – Self-Certification

The federal CMEA requires each seller of scheduled listed chemical products at retail (eg, ephedrine, pseudoephedrine, phenylpropanolamine) to self-certify. When self-certifying, the regulated seller is affirming that each employee is trained and understands the requirements that apply to selling these products; the seller will maintain records verifying training; the seller will obtain self-certification approval from DEA; and the seller affirms that it will comply and understands requirements regarding transaction limits, “behind the counter” placement, logbooks, and photo identification requirements. Note: DEA training materials are available at the [DEA Diversion Control Program Web site](#).

Holders of DEA self-certifications need to renew annually to continue selling scheduled listed chemical products at retail.

No. 1117 Notice of Board Member Recruitment

The Board of Pharmacy is looking to fill future pharmacist member vacancies on the Board. A requirement for pharmacist applicants is licensing by Washington State for at least five consecutive years preceding appointment. Public member applicants cannot have any pharmacy affiliation. The Board is looking for individuals interested in participating in state government and advancing the mission and vision of the Board. The governor appoints all members; US citizenship and state residency are requirements. To apply, submit an application on the [governor’s Web page](#). Please contact the Board office at 360/236-4834 or at wsbop@doh.wa.gov for more information. This recruitment closes on September 1, 2012.

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