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Washington State Board of Pharmacy News

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No. 1087 Patient Counseling is Required

Observations during recent on-site inspections of community/retail pharmacies alerted the Washington State Board of Pharmacy to issues relating to patient counseling requirements. Pharmacies using point-of-sale (POS) systems are capturing more than just customers' signatures or method of payments. Investigators witnessed ancillary staff (pharmacy assistants or technicians) prompting the patient to select the option to "decline counseling" from the POS system. This selection is only one out of a number of choices the patient is expected to select, eg, number of prescriptions they are picking up, privacy notification, insurance billing, waiver of child-resistant containers. Using the POS system in this manner does not comply with the patient counseling requirements in rule, which state:

WAC 246-869-220

> The purpose of this counseling requirement is to educate the public in the use of drugs and devices dispensed upon a prescription.
>
> (1) The pharmacist shall directly counsel the patient or patient's agent on the use of drugs or devices.
>
> (2) For prescriptions delivered outside of the pharmacy, the pharmacist shall offer in writing, to provide direct counseling and information about the drug, including information on how to contact the pharmacist.
>
> (3) For each patient, the pharmacist shall determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective administration of the medication and to facilitate an appropriate therapeutic outcome for that patient from the prescription.
>
> (4) This rule applies to all prescriptions except where a medication is to be administered by a licensed health professional authorized to administer medications.

While pharmacies are not prohibited from using POS systems, its use must not interfere with a pharmacist's interaction with the patient. Having ancillary staff guide patients to select the "decline" check box is clearly not appropriate and is even more troublesome when the person picking up the prescription does not read English.

The patient counseling rule clearly states that a pharmacist must personally counsel on the proper use of medications every time a prescription is dispensed. The rule does not make a distinction between refills and new prescriptions but instead the intent is to ensure the pharmacists perform safe and appropriate counseling whenever they dispense a prescription.

It is a common misconception that all refills may be automatically dispensed with no pharmacist intervention. The rule states a pharmacist must, for each patient, "determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective administration of the medication and to facilitate an appropriate therapeutic outcome for that patient from the prescription." Therefore, the pharmacist must use his or her professional judgment to assess the extent of counseling needed each time a prescription is dispensed.

Furthermore, the Board clarified that patients with **new prescriptions,** including those that are issued new prescription numbers, **must** be counseled by the pharmacist and that the patient/agent must **communicate** any refusal to receive counseling to the pharmacist.

Counseling is not a new concept. Pharmacists and interns are held professionally responsible for providing meaningful counseling to patients. They are the only individuals in the pharmacy with the appropriate knowledge, skill, and ability to do so. The Washington State Board of Pharmacy feels strongly that patient counseling is paramount to delivering safe and effective medication therapy and strongly urges all pharmacists to understand the necessity and intent of the current Washington Administrative Code (WAC). Compliance to uphold the patient counseling WAC is the professional responsibility of all licensed pharmacists as well as all licensed support staff employed by the pharmacy.

FDA Recommends Use of Sterile Needle and Syringe for Administration of Inactivated Influenza Vaccines

Food and Drug Administration (FDA) recommends that health care providers use a sterile needle and syringe to administer inactivated influenza vaccines. The recommendation was released in response to questions regarding the use of jet injector devices to administer inactivated influenza vaccines. FDA advises that "inactivated influenza vaccines that are approved by FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration." Further, FDA clarifies its October 21, 2011 communication "to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector." FDA also notes the following:

- Currently, there is only one vaccine, Measles, Mumps, and Rubella (MMR), that is approved and specifically labeled for administration by jet injector.
- Safety and effectiveness information that would support labeling inactivated influenza vaccines for delivery by jet injector have not been submitted to FDA.
- At this time, there are no inactivated influenza vaccines that are approved and specifically labeled by FDA for administration by jet injector.

FDA recommends that all approved vaccines, including influenza, be administered in accordance with their approved labeling, and FDA advises that if a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling. Additional background information is available in the communication posted on the FDA Web site at *www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm276773.htm.*

The Centers for Disease Control and Prevention continues to encourage people to get vaccinated throughout the flu season, which can begin as early as October and last as late as May. For information about the flu vaccine visit *www.cdc.gov/flu.*

'Tell Back' Works Best to Confirm Patient Understanding

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.*

In the past few years, multiple studies have demonstrated that patients often leave medical encounters with a poor understanding of their health conditions and recommended treatment. One recent study on this subject demonstrates the low level of understanding patients have about follow-up care and medication therapy upon discharge from the emergency department (Engel KG et al. Patient Comprehension of Emergency Department Care and Instructions: Are Patients Aware of When They Do Not Understand? Ann Emerg Med. Available on the journal Web site).

Given the importance of patient understanding of medical information, there are surprisingly few studies that point out how to approach this task. However, a study published in 2008 offers some insight into what approach to assessing understanding of medical information patients most prefer and perceive to be the most effective (Kemp EC, et al. Patients Prefer the Method of "Tell Back-Collaborative Inquiry" to Assess Understanding of Medical Information. J Am Board Fam Med 2008;21(1):24-30). Researchers tested three types of inquiry about the patient's understanding:

- Yes-No
- Tell Back-Directive
- Tell Back-Collaborative

The Yes-No approach asked closed-ended questions to assess patient understanding. (Example: "I've given you a lot of information. Do you understand?") The Tell Back-Directive method used open-ended questions that were physician-centered and paternalistic in that it was clear authority and control still remained with the physician. (Example: "It's really important that you do this exactly the way I explained. What do you understand?") The Tell Back-Collaborative approach used open-ended questions that were patient centered, making it clear that power and responsibility were shared between the health care provider and patient. (Example: I imagine you are really worried about your blood pressure. I've given you a lot of information. It would be helpful to me to hear your understanding about your clot and its treatment.)

Patients showed a significant preference for the Tell Back-Collaborative inquiry over other tested approaches. Because of the potential for embarrassment if patient misunderstandings are exposed, one might anticipate health care providers' reluctance to put patients "on the spot" with open-ended questions. But a collaborative approach to Tell Back allows the patient to save face for misunderstandings by acknowledging the large amount of information being provided. Patients might also view the request for Tell Back as evidence of the health care provider's care and concern for them personally, or evidence of the provider's attention to detail and competence. So, when counseling patients about their medications, instead of asking "Do you have any questions?" or "Do you understand?" ask them to restate their understanding of the information you provided in their own words within a shame-free, blame-free environment.

DEA Clarifications on Certification Process for Audits of EPCS Software

Drug Enforcement Administration (DEA) emphasizes that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable requirements in DEA regulations, including security, and must address "processing integrity" as set forth in the regulations. Further, DEA recommends that where questions or gaps may arise in reviewing a particular applica-

tion, federal guidelines set forth in National Institute of Standards and Technology Special Publication 800 – 53A should be consulted. DEA has also announced the first DEA-approved certification process for EPCS. Certifying organizations with a certification process approved by DEA pursuant to the regulations are posted on DEA's Web site at *www.deadiversion.usdoj.gov/ecomm/e_rx/thirdparty.htm#approved*. Detailed background information is provided in the Federal Register Notice, available for download at *www.gpo.gov/fdsys/pkg/FR-2011-10-19/pdf/2011-26738.pdf*.

'Script Your Future' Provides Tools and Outreach to Encourage Medication Adherence

United States Surgeon General Regina Benjamin called upon pharmacists, physicians, nurses, and other health care providers to talk with their patients about the importance of taking medications as directed to help prevent serious health complications at the recent launch of the national campaign, "Script Your Future." Benjamin also "encouraged patients with chronic conditions to speak with their health care professionals about their medication" as noted in a press release. A survey released by the National Consumer League, the organization that developed Script Your Future, indicates that "patients who do not always take their medication as directed are less likely to have received a full explanation of the consequences of their condition, and are less convinced of the importance of adherence." The Script Your Future campaign is targeting six regional areas with outreach activities and advertising, and more information is available at *www.ScriptYourFuture.org*. The campaign brings together "stakeholders in health care, business, and government to offer practical tools for patients to help them better adhere to their medication, and to help health care professionals better communicate with patients." More information about the campaign is available in a press release at *www.prnewswire.com/news-releases/us-surgeon-general-joins-baltimore-launch-of-the-national-script-your-future-campaign-to-highlight-importance-of-taking-medication-as-directed-133077423.html*.

FDA Releases 'Use Medicines Wisely' Video

FDA Office of Women's Health has released a new public service announcement (PSA) video titled, "Use Medicines Wisely," to help raise awareness about safe medication use. As stated in an FDA news release, "Millions of people benefit from FDA approved medications and are living longer productive lives. However, when medications are used incorrectly, they can cause serious injuries, even death. Many of these injuries can be prevented."

The video shows simple steps women can take to use medications wisely. Viewers are reminded to:

- Make a list of the medications they take
- Keep their medication list with them at all times
- Know the name of each medication, why they are taking it, how much to take, and when to take it
- Talk with their doctor, nurse, or pharmacist to find out how to safely use their medications

In addition to the video, a medications record-keeper, fact sheets, and other safe medication use resources are available on the FDA Web site.

Training Video Provides Tips on Preventing Pharmacy Robbery

Rx Pattern Analysis Tracking Robberies and Other Losses (RxPATROL) has released a training video discussing pharmacy robbery and how to prevent it. The video features a pharmacist and law enforcement liaison as they tour a pharmacy, evaluating security measures and discussing additional steps that can be taken to prevent robbery. RxPATROL is an initiative designed to collect, collate, analyze, and disseminate pharmacy theft intelligence to law enforcement throughout the nation. RxPATROL is designed to gather and disseminate critical information to help protect pharmacists, guard against potential robberies, and assist law enforcement in their efforts to successfully apprehend and prosecute those involved in controlled substance pharmacy crime. The training video can be accessed on the RxPATROL Web site at *http://rxpatrol.org/TrainingVideos.aspx*.

Nearly 20 Products Marketed as Natural Supplements Contain Sibutramine, FDA Warns

FDA has posted public warnings regarding 19 products, frequently marketed as natural supplements, and found to contain sibutramine, a controlled substance that was removed from the US market in October 2010 for safety reasons. These products pose a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. These products may also interact in life threatening ways with other medications a consumer may be taking. FDA warnings included products marketed as "Slender Slim 11," "Dream Body Slimming Capsule," "Acai Berry Soft Gel ABC," and 16 other product names. The products included in the warnings are being sold on Web sites and in some retail stores. FDA advises consumers not to purchase or use the products listed in the warnings. Consumers who have purchased any of these products should stop use immediately. And if consumers have experienced any negative side effects from using these products, they should consult a health care provider as soon as possible. The complete list of warnings is available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234592.htm*.

2012 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2012 *Survey of Pharmacy Law* is now available and can be purchased online for $195 by visiting the NABP Web site at *www.nabp.net/publications*.

The *Survey,* produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, Wholesale Distributor Licensure Requirements, asks which state agency has regulatory authority over medical device distributors. In addition, a newly added question in Section 22, Electronic Transmission of Prescriptions: Computer-to-Computer, asks whether the state allows electronic prescribing of controlled substances.

Updates for the 2012 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of controlled substances in Sections 26 and 27.

All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey,* please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

No. 1088 Board Permanently Bans Synthetic Cannabinoids and Substituted Cathinones

The Washington State Board of Pharmacy adopted rules to add synthetic cannabinoids and substituted cathinones to Schedule I of the Controlled Substances Act. The Board filed the adopted rules with the Code Revisers Office on November 1, 2011 (WSR 11-22-086). The rule became effective December 2, 2011. Convenience stores sell these products as Spice/K2 and bath salts.

The rules give clear authority to law enforcement to prosecute for the distribution, manufacture, sale, and possession of these dangerous substances. It alerts the public to the potential health risks that could result from using them.

The Board will continue to work with prosecutors and the Washington State Patrol Forensic Laboratory to update the list of substances, as needed.

No. 1089 National Precursor Log Exchange – Update

Washington State recently joined several other states that use technology to battle the illegal production of methamphetamine. On October 15, the Department of Health, Board of Pharmacy, announced the implementation of National Precursor Log Exchange (NPLEx). NPLEx is an electronic tracking system that monitors the purchase of over-the-counter medicines containing pseudoephedrine, a key ingredient in meth. It replaces the mandatory paper transaction sales logs that retailers maintained in the past with a real-time electronic tracking system.

The NPLEx database tracks purchases and alerts the retailer to deny the sale if the purchase exceeds the quantities allowed by law. Nearly 1,000 pharmacies across the state are conducting transactions through NPLEx. Nearly 350 law enforcement agencies in the state have access to the data. This saves them days, or even weeks, investigating potential lab suppliers. In the first 30 days, the NPLEx system monitored 122,590 sales and blocked 1,935 purchases that were over the legal limits.

Other states using the NPLEx system include Missouri, Louisiana, Iowa, Kentucky, Illinois, Florida, and Kansas.

In the event a customer's purchase attempt is denied, the retailer can print an inquiry form from NPLEx or simply provide the customer the transaction ID number and direct them to *www.NPLExanswers.com* for more information.

No. 1090 Prescription Monitoring Program – Update

The prescription monitoring program has collected more than two million individual prescription records. Board of Pharmacy investigators are trained on how to use the system and they have their own login credentials. The pilot for providers to try out the program and help the Board test the system started December 1, 2011. Registration for all providers started December 12, 2011. The Board pushed back the registration date to ensure it could test registration with the pilot users first. The Board expects full access for all providers on January 4, 2012.

Below are the top 10 drugs by script count as of December 1, 2011.

Drug Name	Number of Prescriptions	Total Quantity	Total Days Supply
Hydrocodone BIT/ Acetaminophen	622,874	32,383,442	7,200,028
Oxycodone HCL/ Acetaminophen	200,673	10,957,417	2,220,563
Zolpidem Tartrate	185,083	5,756,926	5,523,943
Oxycodone HCL	173,957	16,429,731	3,015,190
Alprazolam	129,672	6,816,304	2,990,446
Lorazepam	120,065	5,489,404	2,466,614
Clonazepam	99,347	5,942,278	2,894,227
Amphet ASP/ Amphet/D-Amphet	88,648	4,789,277	2,655,073
Methylphenidate HCL	78,504	4,176,892	2,423,660
Morphine Sulfate	60,969	4,596,748	1,425,887

No. 1091 Pharmacy Technician Continuing Education Requirements

The Board of Pharmacy began rulemaking on the pharmacy technician continuing education requirements.

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

The Board approved proposed language on December 15, 2011. The rules will require pharmacy technicians to obtain a minimum of 10 hours of Board-approved continuing education each year. A public hearing on the rules is scheduled for April 18, 2012.

No. 1092 Pharmacist Investigators Stan Jeppesen and Richard Morrison Retire

At the end of September Stan Jeppesen and Richard Morrison retired after serving 45 years, collectively, with the Washington State Board of Pharmacy. Mr Jeppesen is a graduate of the University of Washington, School of Pharmacy and worked for the Department of Health, Board of Pharmacy and Office of Investigations as a pharmacist investigator since 1999. He was the Board's in-house expert on quality improvement and very well known for his lectures on the subject. Stan served as the department's liaison to the Department of Ecology on matters of hazardous waste disposal and expert on drug take-back programs at the local, state, and national level. In addi-

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tion, he served on the advisory committee for the Washington Recovery Assistance Program for Pharmacy for many years.

Mr Morrison graduated from the University of Illinois, School of Pharmacy. With background as a former Federal Bureau of Investigation agent, Dick started working for the Board of Pharmacy in 1978 as a pharmacist investigator. In 1989, the Board appointed him chief pharmacist investigator to supervise all staff performing investigation and inspection activities. Dick returned to the field as a pharmacist investigator in 2005. He has a long history working with the National Association Boards of Pharmacy® (NABP®) as a member of the Federal Drug Law Examination Committee, which was later replaced by the Multistate Pharmacy Jurisprudence Examination® (MPJE®). Dick has volunteered for a number of positions with NABP including examination writer, state-specific examination reviewer, a member of the MPJE Review Committee, and Advisory Committee on Examinations. Dick is a clinical associate professor and served on the Pharmacy School Admission Committee at the University of Washington, School of Pharmacy. In addition, Dick is an adjunct clinical assistant professor at the Washington State University, College of Pharmacy.

The Board extends its thanks to Dick Morrison and Stan Jeppesen for their many contributions to the practice of pharmacy in Washington State and to their hard work and support of public health and safety.

No. 1093 Executive Director Retires

The Department of Health is announcing the upcoming retirement of Susan Teil Boyer, MS, RPh, FASHP, executive director, Board of Pharmacy, on March 31, 2012. Susan served as a Board member for eight years, which included serving as Board chair. She has spent the last three years as executive director. The Board will include more information on Susan's tenure in an upcoming *Newsletter*.

The department has begun the recruitment process for a new executive director. If you have interest in the position please visit the Department of Health Employment Web page for the position announcement in January 2012, at *www.doh.wa.gov/job_ann/default.htm*.

No. 1094 New Pharmacist Investigators

The Department of Health, Office of Investigations and Inspections is pleased to announce the hiring of three new pharmacist investigators, Julie Faun, Stan Moore, and Heidi Welborn. Ms Faun is a graduate of the University of British Columbia, College of Pharmacy and has 18 years of experience in retail pharmacy practice. Mr Moore is a graduate of the University of Washington, School of Pharmacy and has 32 years of experience in retail pharmacy practice. Dr Welborn is also a graduate of the University of Washington, School of Pharmacy and has eight years of experience in retail and long-term care pharmacy practice.

Based on the new hires, the Board has reassigned inspection/investigation areas. Visit the Board's Web site for detailed investigator assignments. Please contact the investigator assigned to your geographic area when you have questions, complaints, etc.

Tina Lacey, 360/628-4703, Northwest Washington

G. Stan Moore, 360/236-4635, Southwest Washington

Tyler Varnum, 509/574-0140, South Central Washington

William Kristin, 509/329-2206, Eastern Washington

Gregory Lang, 253/395-6721, Central Seattle

Heidi Welborn, 253/395-6718, Southwest King County

James Doll, 360/236-4833, Pierce and South King Counties

Grace Cheung, 253/395-6714, North Seattle, Northwest King and South Snohomish Counties

Julie Faun, 253/395-6719, Eastern King County

Pamela Sanders, 360/236-2923, Western Washington and Olympic Peninsula

Grant Chester, 360/236-4817, Chief Investigator

No. 1095 Board of Pharmacy Business Meetings – 2012

The Board filed its 2012 business meeting dates with the Washington State Code Reviser's Office. The Board will hold all business meetings at the Highline Community College in Des Moines, WA, or at the Department of Health in Tumwater, WA. For more information visit the Board's Web site.

January 26, 2012	Tumwater
March 8, 2012	Des Moines
April 19, 2012	Des Moines
June 7, 2012	Des Moines
August 16, 2012	Tumwater
September 27, 2012	Tumwater
November 8, 2012	Des Moines

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.

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