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News

Washington State Pharmacy Quality Assurance Commission

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No. 1158 Pharmacy Quality Assurance Commission – New Members and Election of Officers

The Washington State Pharmacy Quality Assurance Commission held its first official meeting on December 5-6, at Highline Community College after an extended break (July 2013) following the legislative change from a seven-member board to a 15-member commission. The following members continue to serve on the Commission: Chris Barry, RPh, chair; Elizabeth Jensen, PharmD, vice chair; Dan Rubin, MPP, public member; Emma Zavala-Suarez, JD, public member; and Gary Harris, RPh, member.

The following members were appointed by Governor Jay Inslee on November 11.

Maura Little, Public Member – Maura is the life science sector lead for the Washington State Department of Commerce. As the state lead, she supports the development and expansion of the life sciences industry, with a goal to recruit, retain, and expand the industry. Previous to her current role, she was the Washington State director of government relations for the American Cancer Society Cancer Action Network. After graduating from the University of Washington, Maura spent five years supporting then Congressman Jay Inslee's legislative agenda as a legislative assistant and community liaison.

Kristina Logsdon, Public Member – Kristina is a second generation Japanese-American. Since moving to Seattle, WA, in 2001, she has worked for and served on the board of a number of nonprofits engaging in issues such as environmental health, sustainable agriculture, and civic engagement of under-represented communities. Her most recent adventure took her outside of the nonprofit world to local government. Kristina currently serves as senior legislative aide to King County Councilmember Rod Dembowski.

Maureen Sparks, CPhT – Maureen is a clinical pharmacy technician instructor with Clover Park Technical College. She has been a member of the Pharmacy Technician Educators Council and served on the board as secretary from 2007 to 2011. She is currently the faculty union president. Since 1999, she has been a per-diem technician for St Clare Hospital, part of the Franciscan Health System. Maureen has been a certified technician in Washington State since 1993.

Governor Inslee appointed the following four members on November 13.

Steven Anderson, BS Pharmacy, RPh – Steve graduated from the University of Wyoming School of Pharmacy in 1980. He has been a licensed pharmacist in the state of Washington since 1980, and was employed as a pharmacy manager with the Bartell Drug Company for 30 years. Steve has been a clinical/affiliate faculty member of the University of Washington School of Pharmacy and preceptor since 1989. He is an American Pharmacists Association immunization instructor and an American Heart Association CPR/first aid instructor. Steve is currently the assistant pharmacy manager at Costco Wholesale's Rx E-Commerce division in Everett, WA.

Timothy Lynch, MS, PharmD – Tim is the associate vice president, pharmacy services for Franciscan Health System of Tacoma, WA. Tim has responsibility for all hospital pharmacy departments, seven retail pharmacy locations, five pharmacy managed pharmacotherapy clinics, a durable medical equipment program, and a pharmacy managed research center. In addition, he is the residency program director for an American Society of Health-System Pharmacists-accredited PGY1 residency program with six residents. Tim received his bachelor of science in pharmacy and his doctor of pharmacy degree from the University of Washington and a master's in health care management from Troy University. He is an affiliate assistant professor at the University of Washington. Tim has been a Washington-licensed pharmacist since 1997.

Albert Linggi, RPh – Al is a consultant/contractor for McKesson Corporation. Prior to June 2013, he served as vice president of corporate business development for McKesson Corporation in San Francisco, CA. He has 40 years of experience in the pharmaceutical industry and spent 23 years with the Franciscan Health System serving St Joseph Medical Center in Tacoma, WA, prior to joining McKesson. He served as an active member of the Washington State Board of Pharmacy from

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Changes to Fentanyl Pain Patch Warnings Required by FDA

To reduce the risk of accidental exposure, Food and Drug Administration (FDA) has announced new requirements that change the appearance of fentanyl pain patch warnings to make them more visible. The change also requires new language in the warning that emphasizes the risk of death from accidental exposure, particularly in children. The announcement coincided with a Consumer Update that stressed the potential danger of improperly discarded fentanyl patches to children and pets. FDA reminded consumers of the agency's previous advice for securely storing unused patches and disposing of used fentanyl patches by folding the sticky sides together and then flushing them down the toilet. The agency also advises patients to cover in-use patches with an adhesive film to keep them from coming loose, and to regularly check patches to ensure they are securely in place. FDA offers additional information for health care providers on the "Fentanyl Transdermal System (marketed as Duragesic) Information" page, available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm114961.htm*. Consumer information about safe drug disposal methods is also available on the AWAR$_X$E® Web site at *www.AWARERX.ORG*.

New: Free ISMP Medication Safety Alert! Newsletter for LTC Facilities

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 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 July, ISMP began publishing *Long-Term Care Advise-ERR,* a new *ISMP Medication Safety Alert!* newsletter for nurses and administrators in long-term care (LTC) facilities. ISMP receives error reports that have occurred in LTC facilities. The newsletter is provided free to LTC facilities in the United States thanks in part to corporate sponsorship from Lilly and for a nominal subscription fee for pharmacies that service LTC facilities and others. Please visit ISMP's Web site at *www.ismp.org/Newsletters/longtermcare* for more information, and let your LTC facilities know about this free offer.

Here are a few excerpts from a recent issue.

Immediate Vs Extended Release Error

A physician called a LTC facility to change a resident's oxycodone order from an extended-release formulation to an immediate release formulation at the same dose and frequency. The nurse receiving the verbal order transcribed it as "Discontinue OxyContin 10 mg BID, Start OxyContin 10 mg IR BID," with "IR" meant to represent immediate release. Although Oxy**Contin**® is a brand of oxy**codone,** it is only available as an extended-release tablet. The pharmacy had previously been dispensing Oxy**Contin** for the resident, so the nurse thought she could communicate the prescriber's order by discontinuing the current Oxy**Contin** order and then ordering Oxy**Contin** as an immediate-release product. The pharmacy continued dispensing Oxy**Contin.** The differences between these products and formulations were brought to the attention of nursing staff via an in-service. To minimize the risk of confusion, do not attach modifiers such as "IR" for immediate-release or "RS" for regular strength unless it is part of the official drug name.

Errors Occur During Transitions of Care

A pharmacist reported the following hazardous situation that can occur during a hospital to LTC transfer. Residents are often admitted to a LTC facility with a list of medications printed from the hospital pharmacy computer. On these printouts, doses are expressed along with the number of tablets. For example, the printout may list hydrochlorothiazide 50 mg/2 tablets daily for an order in which the total dose was 50 mg because the hospital only stocks the 25 mg tablets. During hospitalization the patient required two tablets for each dose; however, the LTC nurse may misinterpret the order to mean two 50 mg tablets, making the total dose 100 mg, or two times more than prescribed. This issue arises every time the resident's total dose in the hospital requires more than one tablet or capsule. Discharge medication summaries and transfer orders should only list the total dose in mg or mcg and other directions for use (ie, frequency, route, drug name) to avoid misinterpretation.

2013 USP Chapter <797> Compliance Survey Shows Compliance Trends Unchanged From 2012

The 2013 United States Pharmacopoeia (USP) Chapter <797> Compliance Survey, the third annual report released since 2011, shows that the overall compliance rate of 77.2% remains nearly unchanged from the 2012 rate. Budgetary restrictions and physical plant limitations were among the top challenges to compliance by survey respondents. The report also details the

survey's findings on what types of facilities are participating in compounding, and compliance in specific domain areas such as environmental sampling and gloved fingertip sampling. Of the survey's 1,045 participants, 97% of the survey's respondents said that USP Chapter <797> "has had a positive influence on patient safety." The report notes National Association of Boards of Pharmacy® (NABP®) efforts to assist state boards of pharmacy in evaluating pharmacy compliance with USP Chapter <797> requirements for sterile compounding in their states. The report also noted that those who participated in the 2011 survey had a higher compliance score than those who did not. The survey's authors encouraged pharmacy owners with multiple areas of noncompliance to target one or two areas to improve. They also encouraged organizations that participated in the survey to make use of the free Action Plan – generated upon completion of the survey – and other free resources to "reshape" their sterile compounding practices. The full report on the survey's results is available in the October 2013 issue of *Pharmacy Purchasing & Products Magazine* and on the magazine's Web site at *www.pppmag.com/article/1403*.

FDA Recommends Schedule II Classification for Hydrocodone Combination Products

FDA planned to submit a formal recommendation to reclassify hydrocodone combination products as Schedule II controlled substances to the Department of Health and Human Services by early December 2013. FDA expects the National Institute on Drug Abuse to concur with the recommendation, indicates a statement on the FDA Web site. FDA also indicates that while "the value of and access to these drugs has been a consistent source of public debate," the agency has "been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse." Drug Enforcement Administration makes the final decision about the appropriate scheduling of these drugs. In January 2013, FDA's Drug Safety and Risk Management Advisory Committee made a recommendation that hydrocodone combination products be classified as Schedule II drugs following a 19-to-10 vote that concluded a two-day meeting during which members discussed the potential for abuse and misuse of the medications and the potential impact of rescheduling the drug products. FDA's statement on the recommendation is available at *www.fda.gov/Drugs/DrugSafety/ucm372089.htm*.

New FDA Drug Info Rounds Training Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest two Drug Info Rounds videos, pharmacists discuss the review and approval of new drug names and the review of marketing and advertising materials for new drugs. The videos can be viewed at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm368620.htm* and *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm371785.htm,* respectively. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

CPPA Developing Specialty Pharmacy Accreditation Program

The Center for Pharmacy Practice Accreditation® (CPPA) has announced the development of a new accreditation program for specialty pharmacy practices. CPPA Executive Director Lynnae Mahaney, MBA, RPh, FASHP, VHA-CM, indicates that "CPPA will be able to develop the new specialty pharmacy standards quickly and efficiently with the existing standards development methodology, infrastructure, and network of specialty pharmacy expertise."

CPPA is a partnership between the American Pharmacists Association, the American Society of Health-System Pharmacists, and NABP. CPPA develops and implements comprehensive programs of pharmacy practice site accreditation, including the promotion, development, and maintenance of principles, policies, and standards. CPPA offers the general public and users of pharmacy services a means of identifying those pharmacies that satisfy the accreditation criteria and are focused on advancing patient care, safety, and quality.

More information may be found in the press release, available at *www.pharmacypracticeaccredit.org/news/2013/10/cppa-to-develop-specialty-pharmacy-accreditation-program*.

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2008 to 2012. Al graduated from the University of Washington School of Pharmacy and has an executive master of business administration from Fuqua School of Business, Duke University. He has held a Washington pharmacist license since 1971.

Nancy Hecox, PharmD, CDP – Nancy is the clinical supervisor for Tieton Village Drugs in Yakima, WA. She received her bachelor of science degree in pharmacy in 1978 from Massachusetts College of Pharmacy and Health Sciences, returning to school in 1994 to obtain her doctorate from Idaho State University. She has worked in retail pharmacy, independent and chain drugstores, and has taught pharmacology at Pacific Northwest University of Health Sciences College of Osteopathic Medicine. She also helped start the Washington Recovery Assistance Program for Pharmacy and worked as the chemical dependency counselor for that organization for six years. She has held a Washington pharmacist license since 1979.

The Commission is also pleased to announce that Emma Zavala-Suarez's **public member** appointment to the Commission was renewed effective January 20, 2014 through January 19, 2018. The current 12 seated members voted on December 6, to extend appointments of the chair and vice chair through 2014.

No. 1159 Leading the Way – Protecting Your Own Health to Protect Community Health

A message from Washington State Secretary of Health John Wiesman, DrPH, MPH

We have all heard the cliché, "If you're going to talk the talk, you have to walk the walk." Clichés often become clichés because there is some element of truth or fact in them. I believe in leading by example – rather than another old cliché, "Do as I say, not as I do."

That is one of the reasons I went to our agency flu vaccination clinic for my annual flu shot. The other reason is simple: it is good for my health and for those around me. Every year we tell the people of our state about the need to protect themselves against the flu. The more people in our community who are vaccinated, the better chance we all have of avoiding this nasty illness. Yet our state's annual flu vaccination rate is usually under 50%.

Public health works to protect and improve the health of all people in Washington, and that starts with each of us. It takes one person to get things started – we are accustomed to showing the way, and flu vaccination is no different.

As public health professionals, we also have the opportunity to advocate for disease prevention. Each of us can serve as a public health spokesperson by reminding people that it is time to get vaccinated against the flu and referring them to the Washington State Department of Health's agency Web site at *www.doh.wa.gov* for helpful information.

Another way you can help your patients is to tell them where to find information on health care reform and how it may impact them.

The Patient Protection and Affordable Care Act is the most comprehensive national health reform legislation enacted in decades. Along with improving health care access and quality, the act's goal is to help our health system continue to move its focus from treating disease to preventing disease.

As health care reform rolls out in Washington, your patients may wonder what this all means to them. Some will want information or help finding the right health care plan. They can find answers on the Coverage Is Here Web site at *coverageishere.wa.gov*. It is a new online resource to help with education and outreach. The site provides other links to help people compare and enroll in health insurance plans. And you can use the site to keep current on the latest health care reform news. Check out the online outreach tools and resources.

Your patients will find specific enrollment and plan information on the Washington Health Benefit Exchange "Health Plan Finder" Web site at *www.wahealthplanfinder.org*. They can compare health plans side by side; learn about eligibility requirements for tax credits or financial help; get answers to specific questions; and review options and enroll. I hope you will encourage them to take advantage of these online resources. They are good tools that I am sure patients will find helpful and informative.

State agencies in Washington are working together to help people find support for healthier lifestyles and better overall access to the health care system. The Washington State Department of Health plays an important role in disease prevention and in helping to build healthier communities. Our agency works to ensure the quality of our health system, and provides the data and information necessary for research and resource planning. We also provide funding and technical assistance to partner organizations working on key prevention issues. Learn more about the state public health role on the Washington State Department of Health Web site.

No. 1160 Prescribing Medication Within Scope of Practice

Several questions come to the Commission wondering if someone is practicing outside their "scope of practice" when he or she writes a prescription. As pharmacists, we all understand that a veterinarian cannot prescribe medication for a human, a dentist cannot prescribe for a diabetic patient, and a podiatrist cannot prescribe for a sleep disorder.

What is not clear is when a medical doctor is prescribing outside of his or her specialty. Can a medical doctor or osteopathic physician, who may be a surgeon, prescribe medication for a dermatological disorder? Can an anesthesiologist prescribe for a sleep medication? Since physicians are all first medical doctors trained and licensed to practice medicine and then choose to specialize or sub-specialize, cannot all doctors write prescriptions outside of their specialty in which they work?

Medical and osteopathic physicians are not licensed within their specialty, but based upon the required training for licensure. If the prescription is legitimate and if there is evidence of a patient-physician relationship and the pharmacist is satisfied that the prescription is for a legitimate medical reason, then the prescription should be considered a legitimate order and not denied based upon perceived violations of scope of practice rules.

No. 1161 Update on Pharmacy Compounding Rule Development

House Bill 1800, which passed during the 2013 legislative session, addresses resident and nonresident pharmacy compounding. The new law also requires that compounded medicinal products meet minimum compendia standards to protect the health and safety of the public.

In May 2013, the process to develop drug compounding administrative rules was started. Since then there have been three public meetings held so that pharmacists, representatives from pharmacies, and others could provide their thoughts and recommendations on how the new rules should be shaped. Following the public meetings, staff has looked at administrative rules from other states and has begun to draft the compounding rules. Given the complexity of drug compounding, work on the draft rules will continue through winter with an opportunity for public review anticipated during spring or early summer 2014. When a draft is ready for review, comments and suggestions will be accepted and encouraged. Interested parties may sign up for updates at *http://listserv.wa.gov/cgi-bin/wa?A0=PQAC-RULES.*

No. 1162 Frequently Asked Questions

Question: Can a compounding pharmacy distribute compounded controlled substance (CS) preparations in Schedules II through V on an invoice to a prescriber for office use within the confines of the facility?

Answer: No. Compounding a CS is, by definition, the act of manufacturing (21 U.S.C. 802(15)). Manufacturing is an activity that **requires** a separate Drug Enforcement Administration (DEA) registration (21 822(a) (1)). A DEA-registered pharmacy is exempted from having to register as a manufacturer only when it compounds a CS pursuant to a **valid patient specific prescription,** and then dispenses this compounded CS directly to the ultimate user or a member of his or her household (21 U.S.C. §§ 802(10) and (27)).

Question: Is it within the scope of practice for naturopathic physicians to prescribe for Vicodin®, Norco®, and other CS?

Answer: While naturopathic physicians can write prescriptions for all legend drugs except Botox®, their authority to write prescriptions for CS is limited. Authorized CS include Schedule III through V codeine and testosterone. Naturopathic physicians may **not** prescribe any other CS.

Question: Have Washington State laws changed regarding the expiration dates of Schedule II prescriptions?

Answer: Yes. The 2013 Washington State Legislature passed a law, effective July 29, 2013, that states all Schedule II prescriptions expire **six months from the date the prescription is written.** The same law eliminated the ability for patients to purchase Schedule V codeine-containing cough preparations without a prescription. Except when dispensed directly by a practitioner, substances included in Schedule III through V must be dispensed by prescription only.

Question: What are ancillary utilization plans?

Answer: An ancillary utilization plan is a document that details the duties and responsibilities of pharmacy assistants and pharmacy technicians specific to the practice of pharmacy in the location where they work. Ancillary staff must work within the scope of their credential. Duties are considered nondiscretionary and must be under the direct supervision of a licensed pharmacist.

All ancillary utilization plans must be approved by the Commission and a copy of the approved plan must be accessible to all pharmacy staff and made available for inspection by the Commission. Ancillary utilization plans are reviewed as part of an inspection for their relevancy, accuracy, and completeness. Changes in the operation of a pharmacy that revises the functions of the ancillary staff must be submitted to the Commission.

All ancillary staff must be duly credentialed and the pharmacy must comply with the 3:1 pharmacy technician to pharmacist ratios or seek an exception by the Commission. The standard ratio includes certified technicians and technicians-in-training.

No. 1163 Farewell William Kristin

At the end of November, William Kristin retired after serving more than 30 years with the State Board of Pharmacy and Pharmacy Commission. "BK" or "Bill," as his many friends and colleagues call him, is a 1970 graduate of Washington State University School of Pharmacy. He began his career in retail practice and in 1983 he became a pharmacist investigator for the Washington State Board of Pharmacy, Eastern Washington region. During Bill's 30 years of service he has performed countless inspections and hundreds of investigations serving the residents of the state of Washington. The Commission extends its warmest thanks to Bill for a job well done. The Commission wishes warm weather, fair winds, manicured greens, and low scores to Bill and his family.

No. 1164 Washington State Pharmacy Quality Assurance Commission 2014 Business Calendar

- January 23, Tumwater, WA
- March 6, Des Moines, WA
- April 17, Des Moines
- May 29, Spokane, WA
- July 10, Tumwater
- September 11, Renton, WA
- October 23, Vancouver, WA
- December 18, Renton

The *Washington State Pharmacy Quality Assurance Commission News* is published by the Washington State Pharmacy Quality Assurance Commission 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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