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News

Washington State Pharmacy Quality Assurance Commission

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No. 1302 Interim Guidance on Collaborative Drug Therapy Agreements

At the December 2018 Washington State Pharmacy Quality Assurance Commission business meeting, the Commission approved the *Interim Guidance on Collaborative Drug Therapy Agreements.* This interim guidance document was developed as part of the Commission's ongoing discussions around the use of collaborative drug therapy agreements (CDTAs) and protocols in different pharmacy practice settings. The *Interim Guidance on Collaborative Drug Therapy Agreements* attempts to differentiate between protocols that are CDTAs and protocols that are **not** CDTAs. The key factor differentiating these types of protocols is answered by the question, "Who is the prescriber?" If the prescriber is a pharmacist, the protocol is a CDTA. If the prescriber is not a pharmacist, then the protocol is not a CDTA. Please contact the Commission if you have any feedback on the interim guidance document.

No. 1303 Opioid Prescribing Rules

In 2017, the Washington Legislature passed a law to focus on improving opioid prescribing and on monitoring prescriptions. The law requires five health care professional boards and commissions – medical, osteopathic medicine, nursing, dental, and podiatry – to adopt new rules for prescribing opioid drugs. The initial rule templates were developed by a workgroup representing the five regulatory boards and commissions with participation by the pharmacy Commission. The requirements for advanced registered nurse practitioners, osteopathic physicians and assistants, and podiatric physicians became effective on November 1, 2018. The requirements for medical doctors and physician assistants were adopted on January 1, 2019, and the proposed rules for dentists were adopted on December 7, 2018.

These rules guide the practice of the other prescribers. However, pharmacists should always use professional judgment and available tools to determine if prescriptions are legitimate and appropriate for each patient. Patient counseling is an important step to make sure the care is appropriate, and the patient understands how to safely take and handle the medication. Patient counseling is also an important educational opportunity to discuss issues such as safe storage, safe disposal, naloxone use, and/or suicide prevention.

The Washington State Department of Health (DOH) website has information and resources for patients, prescribers, and pharmacists. Also visit its Opioid Prescribing web page.

No. 1304 Pharmacy Technician Ratio

The Commission has received several inquiries asking what is happening with the standard technician-to-pharmacist ratio rules. The proposed rules approved in early 2018 have been delayed by competing priorities. Current rules offer a provision to request an exception to the standard ratio. The Commission has implemented an expedited process for review.

Pharmacies seeking an exception must include a Request for Consideration Form and a copy of the pharmacy's service plan. The pharmacy service plan **must** include the following:

1. Diagram or description of the pharmacy's design and equipment
2. Description of the information system(s) used by the pharmacy to manage operations
3. Description of workflow processes used in providing pharmacy services
4. Description of quality assurance procedures in place to ensure patient safety
5. Description of how an exception to the ratio will help in the delivery of pharmaceutical care

Ratio exceptions are part of the business meeting's consent agenda and are considered routine approvals. When pharmacy representatives do not present their proposals, it may be beneficial for them to be at the meeting or on the meeting webinar if questions arise. The Commission will not approve requests for an exception to the ratio that fail to meet all the requirements above. Please note, an updated ancillary utilization plan must be included if an increase in the ratio changes the manner or extent that pharmacy technicians or assistants are used and supervised.

The Commission anticipates holding a public rules hearing on the proposed rule in early spring 2019. The Commission will

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.*

First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Controlled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at *www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.*

ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The "ASHP Guidelines on Preventing Medication Errors in Hospitals" are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy,* the guidelines are available at *www.ajhp.org/content/75/19/1493.* ASHP's October 2, 2018 press release can be found in the News section at *www.ashp.org.*

FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.* In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.*

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.* This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf.*

Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at *https://againstopioidabuse.org.*

Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- generic substitution is recommended as part of the pharmacist's dispensing role;
- pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at *www.fip.org* in their respective sections.

FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes,* will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit *http://fdapasediabetes.e-paga.com.*

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at *www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm.*

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notify interested parties through GovDelivery once the notice of proposed rulemaking (CR-102) document is filed with the Washington State Legislature Office of the Code Reviser and the hearing date is set.

No. 1305 Rule Rewrite Project

The Commission is rewriting 34 chapters of rules, many of which have not been updated since the 1980s. The Commission wants concise rules that provide guardrails for patient safety and allow for a standard of care approach with flexibility to support innovation in technology and service delivery. It wants to move away from very prescriptive procedure-focused rules that become outdated quickly.

The Commission has done an initial draft of the four new chapters: general provisions, operational standards, professional standards, and licensing. The Commission divided the licensing standard by facility types. The Commission will divide the general provision standards into four parts for easier reference. The Commission will also split operational standards into three groups to better align with different types of business. These groups include: facilities and services providing pharmaceutical services such as pharmacies or health care entities, registrants such as animal control or researchers, and distributors or those involved in the drug supply chain.

The Commission also identified several rule chapters that do not appear to be captured in the current draft. These were assigned to Commission and staff to consider if any part of the chapter should be included, and if so, where it should be included, and who the key stakeholders of that chapter are.

No. 1306 Chemical Dependency Professional Committee

A pharmacist, along with the Washington State Pharmacy Association, petitioned DOH to open the chemical dependency professional rules to allow pharmacist training to be eligible as an alternate pathway to qualify for a chemical dependency professional (CDP) credential. DOH has started the rulemaking process to consider this proposal. Any pharmacists interested in providing input should monitor the CDP's rules web page for information on how to participate. You may also contact James Chaney, executive director of the Chemical Dependency Professional Program, at ulysses.chaney@doh.wa.gov.

No. 1307 Washington's Volunteer and Retired Provider Program

Are you interested in volunteering your skills as a health care provider or spreading the word to providers who might be? The Volunteer and Retired Providers (VRP) program needs you! VRP supports health care volunteerism in Washington by paying malpractice insurance premiums for United States-licensed health care volunteers who provide care to underserved patients. Washington license-holders may volunteer on an unlimited basis, while out-of-state volunteers may volunteer for up to 30 days per year. Washington retired volunteers who use their Washington professional license **only** for volunteer work are also eligible for free license renewal. The DOH Primary Care Office (DOH PCO) covers all professional license costs (other than late fees and testing fees).

VRP is a DOH PCO-funded program that supports Washington's health care safety net by leveraging the power of professional health care volunteers and mitigating common financial barriers to health care volunteerism. VRP is administered by means of a contract with the Washington Healthcare Access Alliance, the professional association that supports free and charitable care in Washington. VRP counts more than 2,000 active providers in its roles. This volunteer provider corps was responsible for about 84,000 patient visits in 2017, totaling 52,800 volunteer hours. The value of this level of care in the market is estimated at $126,033,000. DOH is able to operate the program for about $110,000 per year, representing a return on investment of $1,100 for every dollar spent.

The VRP program provides coverage for **noninvasive care,** including administering injections, suturing of minor lacerations, and the incision of boils and superficial abscesses. Obstetric care and procedures coded as surgery are **not** covered under noninvasive medical care. Noninvasive dental care includes diagnosis, oral hygiene, restoration, and extraction. Orthodontia and surgical treatments are not covered by VRP malpractice insurance. The insurance provided by DOH is claims-made and covers $1,000,000 per incident and $5,000,000 aggregate. Professionally employed health care workers with site-specific malpractice insurance coverage **are** eligible for this benefit.

VRP coverage is provided in more than 110 sites throughout Washington to all licensed provider categories, including pharmacists. Please consider joining the more than 2,000 VRP-covered volunteers across Washington providing much needed health care to underserved patients. There is no minimum volunteer time commitment. Clinics wishing to host VRP volunteers must provide services to low-income patients regardless of their ability to pay, and a clinic can be approved by filling out a site application that only takes a few minutes to complete.

For further information about VRP, visit *https://www.wahealthcareaccessalliance.org/volunteers.*

No. 1308 Pharmacy Commission Member Changes

Governor Jay Inslee's office announced the appointment of Bonnie Bush to the Commission. Bonnie is the executive director of the South Puget Sound region of the American Red Cross. Previously, she led organization-wide initiatives focused on improving the patient, physician, and employee experiences in a large health care organization. Bonnie volunteers for the Washington State University Master Gardener program. Other volunteer positions she has held include advisory board member

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at DeVry University, senior examiner for the Washington State Quality Award, and board member for the Prison Pet Partnership. Bonnie is a business administration graduate from the University of Washington. She is a resident of Federal Way, WA, and enjoys gardening, golfing with her husband, and leisure walks with her two black labradors.

Bonnie will assume the public member position held by Arun Sambataro. We thank Arun for her almost five-year term as a public member. She provided a strong public voice for patients and the public.

Cheryl Adams, PharmD, from central Washington, announced at the December 2018 meeting that she is resigning from her position to spend more time with her family. The Commission thanks Cheryl for her service to the people of Washington as a commissioner for the past three-and-a-half years. Cheryl's legacy includes her leadership in the revision of pharmacy inspection processes and rules, as well as her term as Commission vice chair.

We welcome Bonnie Bush to the Commission, while we wish both Arun Sambataro and Cheryl Adams well, and thank them for their public service.

Teri Ferreira, RPh, a member of the Commission since January 2016, was appointed as vice chair until the next scheduled officer election at the June 2019 meeting.

No. 1309 Pharmacy Commission Staff Changes

Stephanie Martin, RPh, is the Commission's newest pharmacist inspector. She has experience in hospital settings as well as other pharmaceutical settings. Stephanie holds pharmacist licenses in Washington and Nebraska, and is board-certified in pharmacotherapy. She graduated with honors from the University of Nebraska and has practiced in Washington since that time. She has served both in-patients and out-patients, from retail, to general medicine, to emergency medicine patients. She enjoys hiking, backpacking, and traveling with her family in her free time.

Caitlin Gates is the Commission's new rules and legislative consultant. Caitlin is originally from Colorado, coming to Washington to obtain her bachelor's degree from the University of Washington. After participating in a legislative internship, she moved on to work for the House of Representatives as a legislative assistant. Recently, she has been doing political consulting and tribal relations work. She enjoys spending time with her family and going on hikes and camping in all the many beautiful places Washington has to offer.

The Commission is very excited to have these two people join its team.

No. 1310 Additional Staff Updates – Inspections and Investigations Realignment

DOH has gone through a couple of reorganizations this past year. As part of one reorganization, facility inspections and investigational functions were split between two offices. The Office of Investigative and Legal Services changed names and functions to handle investigations of health professions and legal services. The Office of Health System Oversight changed names from the Office of Inspections and Investigations, and it handles inspections of the facilities that DOH licenses.

In November 2018, DOH and the Commission decided to split inspections and investigative work similarly to how DOH had earlier in 2018. The change was also done to enhance communication among all areas of the Commission's work. The Commission will have eight pharmacists dedicated to performing inspections of facilities licensed by the Commission and three pharmacists dedicated to performing investigations. These numbers may change in the future based on workload and assignments. Below is a list of inspectors with their assigned areas as well as a list of those assigned as investigators.

Inspectors

- Area 1 – Tina Lacey
- Area 2 – Stephanie Martin
- Area 3 – Shelley Feldner-Schuerman
- Area 4 – Eleanor Doss
- Area 5 – Daniel Lari
- Area 6 – Stan Moore
- Area 7 – Lisa Roberts
- Area 8 – Pam Sanders

Investigators

- Grace Cheung
- Brad Dykstra
- Chris Humberson

Please see the Commission's inspection web page to obtain an update of what each area covers.

No. 1311 Executive Director Announces Plans for Retirement

Executive Director Steven Saxe, RPh, FACHE, notified the Commission at the December 2018 meeting that he is planning to retire in fall 2019. The Commission will work with DOH on the recruitment process. Information will be distributed as it becomes available.

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® (NABPF®) 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 NABPF or the Board unless expressly so stated.

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