October 2018

News

Washington State Pharmacy Quality Assurance Commission

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No. 1294 Rules Rewrite

The Washington State Pharmacy Quality Assurance Commission continues work to rewrite the pharmacy rulebook. Implementing new inspection processes earlier this year affirmed the Commission's goal to update pharmacy rules to be more flexible, allow for innovation, encourage professional judgment, and focus on outcomes by providing guardrails to ensure patient safety.

The four focus areas of the rule rewrite are general licensing, general provisions, professional standards, and operational standards. To date, the Commission has evaluated three of the four initial drafts. Work will begin on the operational standards draft at the October 18, 2018 meeting. A crosswalk between current rules and the drafts will be prepared as part of the analysis to ensure, where needed, that clear boundaries and expectations are defined. In addition, using the philosophy of the rule rewrite project, some procedural requirements that have been in past rules will be replaced by rules that speak to the intended outcomes. This will encourage professional judgment of the pharmacist and the pharmacy permit holder to determine the procedures that are necessary to safely practice in their particular practice environment.

The Commission is using the following questions, provided by Nicole L. Chopski, PharmD, BCGP, ANP, chair of the Idaho State Board of Pharmacy, as a basis to evaluate the need and value of each rule.

- Is the concern relevant to the mission of protecting patient safety? Or by contrast, does the concern focus more on a business issue, such as billing or workflow?
- Is the concern based on credible evidence versus anecdote, speculation, or a one-time issue?
- Is the concern significant? Considerations include severity, frequency, duration, and/or informed choice.
- Does addressing this concern require a new rule, or does an existing law, rule, or other force already address the concern?
- Is the proposed rule narrowly tailored to address the stated concern?

The Commission appreciates your participation and requests your input as new rules continue to be drafted. Meeting attendance is available in person or by webinar. Send comments to pharmacyrule@doh.wa.gov.

No. 1295 Pharmacy Technician to Pharmacist Ratio

Has the ratio of pharmacy technicians to pharmacist changed? No, the rule has not changed. The Commission initiated rulemaking and approved proposed rule amendments based on the work done by its subcommittee and stakeholders. However, the proposed rule must be filed with the Washington State Legislature Office of the Code Reviser before a public rules hearing is scheduled and the proposed rule is considered for adoption.

Current law provides an exception to the standard ratio. The Commission has developed a process to streamline requests for exceptions. Pharmacies seeking an exception must include a Request for Consideration Form and a copy of the pharmacy's service plan in their request. The service plan must include, at a minimum, a description or diagram of the pharmacy's design and equipment, information systems (technology), workflow, and quality assurance procedures. The service plan must also explain how the additional technicians will aid in delivering pharmaceutical care.

As a consent agenda item, requests for exceptions to the ratio are considered routine business matters. However, often these requests are pulled for additional discussion and questions, so a representative of the pharmacy may want to be present to answer the Commission's questions. The Commission will consider all requests that follow the new process. More information is available online.

National Pharmacy Compliance News

October 2018

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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

No. 1296 Pharmacy Program Staff Changes

There have been several changes to the program staff who support the Commission, including the appointment of Tracy West, JD, as deputy director.

Many folks know Tracy from her earlier work with the Commission as a policy analyst and rules coordinator. Tracy has a law degree from New England Law | Boston and a bachelor's degree from the University of New Mexico. In her new role, Tracy's primary focus and responsibility is the day-to-day operations of the Commission and program staff. Executive Director Steven Saxe, RPh, FACHE, will focus on the Commission's strategic and stakeholder work.

Several other positions have opened with the Commission program. The Commission and Washington State Department of Health (DOH) are evaluating how best to staff the Commission program going forward.

The program also said farewell to Lisa Roberts, PharmD, who this past August took a position with the DOH Office of Investigative and Legal Services.

No. 1297 Drug Take-Back Programs

The 2018 Washington State Legislature passed House Bill 1047, which requires drug manufacturers to fund an approved program protecting public health by creating a system for safe and secure collection and disposal of unwanted medications across the state. All manufacturers that sell drugs in Washington must participate. DOH is developing rules to regulate the drug take-back programs. If you are interested in more information on participating in the rules process or being an authorized collector, visit the Washington State Drug Take-Back Program website.

No. 1298 Online Applications and Renewals

If you are looking for a way to expedite your application, consider applying online. In May 2018, DOH launched online applications for new applicants. This includes all applications for pharmacists (eg, license transfer, score transfer, foreign-trained, and by examination), pharmacist preceptors, pharmacy interns, pharmacy technicians, and pharmacy assistants. Check out the features of the online application portal on YouTube.

Online applications are not available to reactivate an expired credential. However, if your credential is active and your name and address on record are current, consider renewing online. It is easy and quick! There is a $2.50 fee for all online transactions.

Note: If you are applying to be a pharmacist preceptor using the mail-in form, please use the examination question sheet as your answer sheet: simply circle the correct answers and submit it with your application.

No. 1299 Recognition of 50 Years of Licensure in Washington State

The Commission wishes to acknowledge and congratulate the following pharmacists for 50 years of licensure in Washington State. Thank you for your dedication to your profession and the practice of pharmacy. The Washington State Pharmacy Association will award certificates of service at its annual meeting in November 2018.

Mary Anderson	Sharon Ormiston	John Somers
Dale Bliss	Norman Reitz	Richard Williamson
Siri Childs	Craig Ritchie	David Wotruba
Daniel Connolly	Jan Rockey	
Susan Mahoney	Fred Simons	

No. 1300 Correction to Article No. 1292 Information Required on a Prescription

The Commission's July 2018 *Newsletter* contained an error in the Consultants' Corner answer to the second question regarding information required on a prescription. The article mistakenly stated that a prescription requires the patient's address. The answer should have stated:

Question: What is required to be on a prescription?

Answer: A prescription must be legible with clear instructions. Legible prescriptions are defined as prescriptions that are hand-printed, typewritten, or electronically generated.

The following is required to be on the prescription, either imprinted or added at the time the prescription is issued:

- date issued;
- patient's name **(the patient's address is required only on electronically generated prescriptions and prescriptions for controlled substances (CS));**
- practitioner's name and address;
- drug name, strength, and dosage form;
- route;
- quantity prescribed;
- directions for use;
- number of refills authorized (if any);
- instructions on whether a therapeutically equivalent generic drug or interchangeable product may be sub-

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stituted in its place (see Revised Code of Washington (RCW) 69.41.120 for two signature line requirements);
- manual (wet) signature of the prescriber; and
- if applicable, the Drug Enforcement Administration registration number (if the prescription is for CS).

Written Washington prescriptions must also be on tamper-resistant prescription paper or pads approved by the Commission, identified by the Commission's "seal of approval." (See RCW 18.64.500 for paper standards and exemptions.)

Electronic transmission of prescription information has additional requirements, including an electronic, digital, or manual signature of the prescriber; a place to note allergies; and a notation of purpose for the drug in addition to the required items listed above.

No. 1301 Commission Meeting Dates 2019

- January 24-25 – TBD
- March 7-8 – Des Moines, WA
- April 25-26 – Tumwater, WA
- June 20-21 – Tumwater
- August 1-2 – TBD
- September 12-13 – Tumwater
- October 24-25 – TBD
- December 19-20 – TBD

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