July 2020

News

Washington State Pharmacy Quality Assurance Commission

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No. 1341 Plan-19

The Washington State Pharmacy Quality Assurance Commission has received several inquiries and questions related to challenges posed by the coronavirus disease 2019 (COVID-19) pandemic. Plan-19 is the Commission's "live" plan to provide emergency updates, Commission actions, and responses to questions related to COVID-19.

COVID-19 has now spread to more than 100 locations globally, including the United States. In response to the COVID-19 outbreak, on January 30, 2020, the International Health Regulations Emergency Committee at the World Health Organization declared a "public health emergency of international concern." On February 29, 2020, the governor issued a proclamation declaring a state of emergency in all counties in the state of Washington due to the outbreak of COVID-19. On March 13, 2020, President Donald J. Trump declared a national emergency for the US.

Different parts of the country are seeing varied activity related to COVID-19. The duration and severity of each phase can vary depending on the characteristics of the virus and the public health response.

In Washington State and nationally, actions are taken to help "flatten the curve" to stop the spread of COVID-19 and to alleviate the burden on the health care system.

To communicate effectively with health care providers and the public, the Commission has developed Plan-19, a comprehensive document to provide its position and to answer questions related to the impact and changing environment due to the COVID-19 pandemic. Click here to view the Commission's Plan-19.

No. 1342 Commission's New Rules – Live Implementation Plan

The Commission has completed a two-and-a-half-year journey to rewrite the pharmacy practice rules. On April 23, 2020, the Commission adopted Chapter 246-945 Washington Administrative Code (WAC). The chapter represents practice standards previously organized in more than 30 chapters that are now in one new chapter covering four areas of pharmacy practice standards:

1. General Provisions
2. General Licensing
3. Professional Standards
4. Operational Standards

The new chapter incorporated current WACs, amended existing WACs, and added new WACs. The new rules modernize outdated practices, eliminate redundancies, and allow for professional judgment while focusing on outcomes, patient safety, and access to quality care.

To assist the regulated community in understanding the changes, the Commission developed informational materials, including the rules implementation "live" plan, and will post other materials on the Pharmacy Commission Laws web page. The Commission's goal with the plan is to help educate licensees, stakeholders, members of the public, and staff members on the new rules scheduled to go into effect on July 1, 2020. This plan provides a general overview of the new rules, along with some of the significant changes and links to helpful resources. To learn more about the "why" behind the rule rewrite, please view the Letter from the Commission Chair.

To find other information about the new rules, please visit Pharmacy Commission Laws.

No. 1343 Delayed Enforcement of CE Rules

While the vast majority of rules contained in Chapter 246-945 WAC will become effective on July 1, 2020, the new continuing pharmacy education requirements for pharmacists and pharmacy technicians will not become effective until March 1, 2021. The **new requirements** for pharmacists include completion of 3.0 continuing education units (CEUs) (30 credit hours) and for pharmacy technicians

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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.

FDA Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a Final Standard Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products, intended to be entered into between the agency and the states. The release of the MOU is required as part of its submission to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close consultation with the National Association of Boards of Pharmacy® (NABP®), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term "inordinate amounts," which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

"We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it," said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an FDA Voices article. "Working together, we can help promote quality compounding practices and better address emerging public health concerns that may affect patients."

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will "look to 503B compounders to grapple with drug shortages" and "turn to 503A compounders to fill in the gaps."

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered "not commercially available," which frees 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at *https://www.fda.gov/media/137125/download.*

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the APhA website.

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

"Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn't have an interest in a fee-for-service type model," said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law.* "The fact that CMS is saying we're now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that's a huge, huge thing."

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA's website by visiting *www.fda.gov/media/136841/download.*

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human Services (HHS) has awarded $20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

"This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs," said HHS Secretary Alex Azar in a press release. "This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure."

HRSA's Maternal and Child Health Bureau awarded a total of $15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA's Federal Office of Rural Health Policy awarded a total of $5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to "spoof" phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at *https://www.cdc.gov/media/phishing.html.*

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the completion of 2.0 CEUs (20 credit hours) offered by an Accreditation Council for Pharmacy Education-accredited program prior to renewing their credential. The rule filed under Washington State Register (WSR) 20-12-072 on June 1, 2020, delays enforcement of WAC 246-945-178 pharmacist continuing education (CE) and WAC 246-945-220 pharmacy technician CE until March 1, 2021. The delay will align the CE rules with changes to the two-year renewal and fee cycle. In the interim, CE requirements will remain 15 credit hours for pharmacists and 10 credit hours (one hour in pharmacy law) for pharmacy technicians. The Commission will issue a policy statement to further educate credential holders on how this transition may affect them. The statement will include situational questions and answers to help clarify the required number of CE credit hours needed and when. Visit the Commission's pharmacy law web page for more information.

No. 1344 New Rules and the MPJE

The Commission has worked closely with the National Association of Boards of Pharmacy® (NABP®) to update the Washington State Multistate Pharmacy Jurisprudence Examination® (MPJE®) in a phased approach to reflect the new chapter, WAC 246-945. **Please read carefully.**

What you need to know:

- The **current Washington MPJE will be in effect until June 30, 2020. (No changes to MPJE)**
- After June 30, 2020, **outdated questions** that contradict the new rules will no longer be included on the Washington MPJE. Everything else will remain unchanged.
- **New** questions related to the new chapter, WAC 246-945, **will not be added until after July 2021 due to NABP's extensive review process.**

In summary, the Commission will not add any new questions to the MPJE for 2020; however, it will remove only outdated questions that contradict the new WACs/rules. Please visit the Commission's website to learn more about the new rules; Chapter 246-945 WAC, effective July 1, 2020; and any corresponding MPJE updates.

No. 1345 Descheduling Epidiolex

The Commission has voted to deschedule Epidiolex® in response to a petition for rulemaking. The emergency rule filed under WSR 20-11-078 was effective May 20, 2020, removing Epidiolex from the list of Schedule V controlled substances (CS). Descheduling Epidiolex aligns Washington State rule with the enactment of the Agriculture Improvement Act of 2018 (2018 Farm Bill), excluding hemp from the Controlled Substances Act definition of marijuana and excluding the delta-9-tetrahydrocannabinol (THC) in hemp from Schedule I.

The 2018 Farm Bill declassified hemp products with less than 0.3% THC from Schedule I. Epidiolex is a Food and Drug Administration (FDA)-approved cannabidiol with less than 0.3% THC on a dry-weight basis. Epidiolex is an FDA-approved cannabidiol with less than 0.3% THC, used to help treat some seizure disorders. Therefore, the Commission authorized rulemaking to permanently remove Epidiolex from Schedule V CS.

No. 1346 Remote Dispensing for Opioid Use Disorder Medications

In order to increase access to medications for vulnerable populations with opioid use disorder, the 66th Legislature passed Substitute Senate Bill (SSB) 6086, which allows pharmacies to extend their pharmacy licenses to include remote dispensing sites. Under this new legislation, pharmacies may register a remote dispensing site with the Commission. Once registered, the pharmacy's license is extended to include the remote dispensing site. SSB 6086 states a remote dispensing site is "where technology is used to dispense medications approved by FDA for the treatment of opioid use disorder."

SSB 6086 requires the Commission to adopt rules establishing minimum standards for registered remote dispensing sites. While the Commission engages in rulemaking specific to registered remote dispensing sites, the Commission will put out a policy statement to clarify regulatory standards and make the registration available for remote dispensing sites on July 1, 2020.

No. 1347 Congratulations Commissioner Anderson

Steven Anderson provided a letter of resignation to the governor and the Commission. He will begin a new chapter by retiring on July 17, 2020. Governor Jay Inslee appointed Steven on November 13, 2013, as a member of the newly established Commission. Steven served as a resident expert in electronic prescription communication systems and other technology. He was also the go-to person on taking, preparing, and passing pharmacy law exams. The Commission and staff will miss Steve's great work ethic and his commitment to pharmacy practice and the mission and vision of the Commission. Good luck, Steve, the Commission will miss you!

No. 1348 Deputy Director Appointed

Christie Strouse joined the Commission team on June 16, 2020, as the deputy director. Christie received her master's degree in social work and public administration from Eastern Washington University while working full-time as a case manager at an AIDS service organization in Spokane, WA. Christie moved to Western Washington in

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2006 and continued her HIV advocacy work as executive director of a local nonprofit. She then transitioned to working with the aging and disabled population by serving as an executive director and home care director of two different organizations providing Medicaid home care services to vulnerable adults. Before obtaining her most recent position of supervisor at Adult Protective Services, she worked for the City of Seattle Area Agency on Aging. She has policy experience, and experience with investigations related to home care services.

Christie also enjoys reading a good book, decorating, vegan cooking, and spending quality time with family and friends (the more laughing, the better).

No. 1349 New Staff Members Join the Pharmacy Commission Team

Danielle Lee is the Commission's new pharmacy inspector assigned to the northeast region of the state. Danielle graduated from pharmacy school at Washington State University in 2008. Go Cougs! Danielle started her pharmacy career in retail pharmacy in Spokane and then lived on the Big Island of Hawaii, where she worked in compounding pharmacy before returning to Washington. Danielle and her three kids love spending time at the beach and finding waterfalls.

Lindsay Trant joined the Commission team in April as the rules and legislative consultant. She earned her master's degree in public policy at Oregon State University. Go Beavs! She has worked as a nonpartisan staffer in both the Oregon and Washington state legislatures. Before joining the Commission, she was a committee assistant for the Washington State Senate Committee on Ways and Means. Lindsay is also an avid disc golfer and competes in local tournaments whenever possible, and enjoys many outdoor hobbies such as hiking and fishing.

Amy Robertson joined the Commission team in May as the administrative assistant. She lives in Tumwater, WA, with her husband of 35 years, Kevin, and two dogs, Gimli Padfoot (standard wirehaired dachshund,15) and Echo (smooth collie, eight). Amy has lived in Panama, Germany, and a few states. Throughout her and her husband's travels, Amy worked as some form of administrative/executive assistant or worked on completing her bachelor's degree in communications (2008). When not at work, you will find Amy on her patio with Gimli and Echo, waiting for Kevin to finish grilling up dinner. She also volunteers for the Department of Washington American Legion and is the master of ceremonies during band performances. Amy is a proud music, computer, and theater geek, loves to read, and tats (lace)!

No. 1350 Commission Meeting Dates

2020 Meeting Dates

- July 16-17, 2020*
- August 27-28, 2020 – Des Moines, WA
- October 1-2, 2020 – Des Moines
- December 3-4, 2020 – Des Moines

2021 Meeting Dates

- January 21-22, 2021*
- March 4-5, 2021 – Tumwater
- April 22-23, 2021 – Tumwater
- June 3-4, 2021*
- July 15-16, 2021*
- September 2-3, 2021*
- October 21-22, 2021*
- December 15-16, 2021*

*Because of the COVID-19 pandemic, all meeting locations are subject to change. Locations will be confirmed as soon as possible.

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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