

Plan-19

Pharmacy Quality Assurance Commission's 2019 Novel Coronavirus (COVID-19) Response Packet 'A Live Plan'

The Pharmacy Quality Assurance Commission (Commission) is issuing Plan-19 in response to the 2019 Novel Coronavirus (COVID-19) public health emergency.

For questions regarding this document, please contact the Commission at WSPQAC@doh.wa.gov.

For questions regarding COVID-19, please visit the Washington State Department of Health's COVID-19 webpage at <https://www.doh.wa.gov/Emergencies/Coronavirus>.

March 19, 2020

Table of Contents

Introduction and Requests	2
Impacts of COVID-19 on Compounding	3
Outpatient and Retail Pharmacy Operation Recommendations.....	5
Delivery of Prescription Medications Outside of a Pharmacy by Pharmacists and Pharmacy Technicians.....	8
Commission Frequently Asked Questions (FAQs)	9
Resources.....	10

Introduction and Requests

The Commission has received a number of inquiries and questions related to the Commission's response to the COVID-19 pandemic.

COVID-19 refers to the "coronavirus disease 2019", a respiratory disease that 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 (WHO) declared a "public health emergency of international concern."¹ 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-19.² On March 13, 2020, the President of the United States declared a national emergency for the United States of America.³

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.⁴

There has now been broad sweeping action to help 'flatten the curve' in Washington state and nationwide to stop the spread of the virus and to help not overburden the healthcare system.

The Commission aims to continuously update Plan-19 to communicate their position on questions and inquiries it receives.

¹ <https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-%282005%29-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-%282019-ncov%29>

² <https://www.governor.wa.gov/news-media/inslee-issues-covid-19-emergency-proclamation>.

³ <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>

⁴ <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html>

Impacts of COVID-19 on Compounding

Licensees of the Commission are required to comply with United States Pharmacopeia (USP) Chapters <795> and <797> (see RCW 18.64.270(2)). The Commission also permits its licensees to become early adopters of USP Chapter <800>.

On March 11, 2020, the Commission's Compounding Subcommittee met to discuss the impacts of COVID-19 on pharmacy compounding operations. The Commission heard from multiple licensees that compliance with USP Chapters has become incredibly challenging due to the supply chain disruptions with personal protective equipment (PPE) and cleaning supplies.

On March 17, 2020, as part of its special meeting, the Commission stated that **it would not find licensees deficient or take enforcement action against its licensees for failure to comply with USP Chapters caused by COVID-19**. If a licensee finds that it is unable to meet the standards in applicable USP Chapters due to COVID-19 Commission expects the licensee to:

1. Create a plan that documents the deviation from standard practice and workflow,
2. Follow the best practices recommendation contained below as it relates to PPE conservation, PPE shortages, and cleaning supply shortages, and
3. Engage with the licensee's infection prevention team (if any) to discuss adoption of modified workflows and standards in the face of COVID-19.

This position will only affect a licensee's standing with the Commission and does not affect obligations a licensee may owe to other local, state or federal regulators e.g. United States Food and Drug Administration and United States Drug Enforcement Administration.

This position will take effect immediately and will remain effective until the Commission withdraws this position at an open public meeting or until the Governor issues a proclamation declaring the termination of the state of emergency declared by Proclamation 20-05, as amended by any subsequent amendatory proclamations, whichever is earlier.

Best Practice Recommendations

PPE Conservation

- Reduce the frequency of compounding staff exiting the compounding area that would require donning of new PPE.
- Reduce unnecessary traffic into the compounding area by non-compounding personnel.
- Reuse PPE, when operationally feasible.
- Do not reuse facemasks or other PPE, if:
 - Visibly soiled
 - Moist
 - Contaminated
 - Wet or damaged and rendered non-usable
- Limit annual sterile compounding recertification to conserve garb supplies to compounding personnel only.
- Purchase premix sterile products as a means of limiting necessity of compounding.

PPE Shortages

- Continue to utilize and maintain environmental controls such as clean rooms and hoods to optimize sterile compounding environments.

- Continue to work with institution's leadership and emergency responders purchase more PPE.
- Reserve remaining PPE for hazardous and batch-compounding operations
- Develop plans for compounding in lieu of or with minimal PPE. Plans should be supportive of quality and safety first, for example:
 - Re-use of non-soiled PPE
 - Working under "immediate-use" level compounding provision (n/a for medium or high risk level compounding), if applicable or Immediate-use level compounding may not apply in all settings i.e., long term care facilities
 - Working under "high-risk" level compounding conditions (which includes compounding without appropriate PPE) and decreasing BUD accordingly
 - Further limiting what may be compounded
- Increasing emphasis on technique
- Resource requests should go through **your emergency preparedness coalition**.
 - Eastern WA: REDI Coalition; 24/7 duty officer number 509-362-0041; general email is hcc@srhd.org
 - Western WA: Northwest Healthcare Response Network; 24/7 duty officer 425-988-2897; general e-mail: info@nwhrn.org
 - Southwest WA: Southwest Healthcare Preparedness Coalition; 24/7 duty officer phone: 800-259-0195; general e-mail is: swhpp@sw-ems.org

Cleaning Supply Shortage

- Increase emphasis on excellent hand hygiene, if surgical gel unavailable (e.g., hand hygiene with every glove change)
- Identify alternative cleaning agents

Outpatient and Retail Pharmacy Operation Recommendations

On March 17, 2020, the Commission adopted the following recommendations related to outpatient and retail pharmacy operations during the COVID-19 outbreak.

Retail and Outpatient pharmacists and pharmacies have a large role in the provision of public health services during a pandemic. Pharmacists and ancillary staff will continue to be on the front line of health care for patients. As we are beginning to see in other countries with directives of limited social interaction and varying degrees of quarantine, retail pharmacies and grocery vendors remain operational to ensure continuity of minimum services. The Commission wants to provide recommendations for operational safety during this pandemic.

There has been a great deal of unspecific direction to the retail pharmacy work environment. Common questions such as 'Am I or my staff at significant risk to contract the virus?' or 'Am I doing everything I can to limit the risk of exposure to my patients?' arise as conscientious caregivers work to assess the risk of Covid-19 in our work environment. The Commission recommends the following:

Step-by-Step

1. Assess the Risk

According to the CDC, exposure risk categories are broken into high, medium and low. Each aligns with a particular recommendation of PPE (personal protective equipment). Brief interactions with a patient regardless of whether the patient is wearing a facemask or not is considered low risk and does not require PPE. Examples of brief interactions include ringing patients up at the register, short consults at the consult window or counter and briefly entering a patient consult room but not having direct physical contact with the patient or the patient's secretions/excretions. Pharmacy staff that walk by a patient or who have no direct contact with the patient, or their secretions/excretions are considered to have no identifiable risk (CDC, 2020)¹. Assess the physical layout of your pharmacy with these CDC exposure risk categories in mind and consider modifications to minimize risk. If a staff member does experience known community exposure, they should have their exposure risk assessed according to CDC guidance (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html#table1>) and contact your organization's occupational health program or your local health department.

2. Clean the work/patient area frequently

Perform routine environmental cleaning of all frequently touched surfaces in the workplace such as register/consult counters, pin pad and payment devices, workstations, and doorknobs. Use the cleaning agents that are usually used in these areas and follow the directions on the label. No additional disinfection beyond routine cleaning is recommended at this time. Provide disposable wipes so that commonly used surfaces (such as doorknobs, keyboards, desk areas) can be wiped down by employees before each use (CDC, 2020)².

3. Create effective social distancing

“Social distancing has proven to be one of the most, if not the most effective ways to slow and lessen the impact of an epidemic like this,” said Fred Hutch oncologist and public health researcher Dr. Gary Lyman (Fred Hutch, 2020)³.

Social distancing refers to maintaining adequate distance between yourself and another person to reduce the risk of breathing in droplets that are produced when an infected person coughs or sneezes, ideally six (6) feet. In the community pharmacy setting, social distancing measures may include discouraging patients from hovering near the pharmacy counter, closing or limiting access to the waiting rooms or rearrange or remove seating, and encouraging distance between patients standing in line. According to Duke University, *“It’s recommended to maintain at least six (6) feet of distance from people and stay out of public places. Symptoms of COVID-19 can take up to 14 days to appear.”* (DUHS, 2020)⁴.

Deploy any technology that allows your patients to enter and leave the pharmacy quickly. Texting prescription completion alerts or allowing patients to pay in advance and pick up at a non-register line window/counter both may be helpful. For those pharmacies that do not deliver prescriptions, consider mailing prescriptions exclusively to your elderly patients.

4. Maximize the use of your drive thru lanes or curbside, if available

A drive thru minimizes direct in-person interaction with pharmacy staff. This may be an ideal method to maintain patient services in a safe and effective manner. Minimize the use of cash transactions, whenever possible.

5. Wear gloves if hand sanitizer is in short supply

This will be important for the staff that are handling cash, credit cards or the old prescription bottles that are handed over the counter to enter the prescription refill number. Hand sanitizer products will become increasingly unavailable. Washing your hands between each ring-up or consult while attending to the normal parade of pharmacy duties is difficult. Change your gloves frequently throughout the day.

The outpatient and retail pharmacies in Washington State play a critical role in this public health crisis. The Commission encourages you to practice safely in service of your patients during this pandemic. There will be difficult days ahead and the Commission is resolved to assist you in the care of your patients and of our professionals.

References:

CDC (2020, March 7th). Interim U.S. Guidance for Risk Assessment of Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus Disease. (COVID-19). Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html#table1>

CDC (2020, February 26th). Interim guidance for businesses and employers to plan and respond to 2019 coronavirus disease 2019 (COVID-19), February 2020. Retrieve from <https://stacks.cdc.gov/view/cdc/85488>

Mapes, Diane/Fred Hutch News Service (2020, March 12th) Stopping a pandemic in its tracks calls for cooperation, patience, handwashing and, yes, isolation. We can do it. Retrieved from <https://www.fredhutch.org/en/news/center-news/2020/03/covid19---social-distancing--in-seattle-and-beyond.html>

Duke University Health System (2020). Help Prevent the Spread of Covid – 19. Retrieved from <https://www.dukehealth.org/covid-19-update>

Delivery of Prescription Medications Outside of a Pharmacy by Pharmacists and Pharmacy Technicians

The Commission interprets existing laws and rules to permit a pharmacist or a pharmacy technician to deliver ***prescribed non-controlled medications*** to a patient, or the patient's agent, outside the physical confines of a pharmacy e.g. a pharmacist delivers prescribed non-controlled medication to the patient's home.

The commission also interprets existing laws and rules to permit a pharmacist or a pharmacy technician to deliver ***prescribed controlled medications*** to the ultimate user (the patient who has been prescribed the medication or a member of the patient's household) outside the physical confines of a pharmacy e.g. a pharmacist delivers prescribed controlled medications to the patient at their home.

When a pharmacy technician is delivering prescribed drugs outside the physical confines of a pharmacy, the pharmacy technician must work under the supervision and control of a pharmacist.

When pharmacists or pharmacy technicians are delivering prescribed drugs outside the physical confines of a pharmacy, the pharmacist must still make a written offer of patient counseling, along with contact information for the pharmacist and information about the medication.

This position only reflects the Commission's understanding of the laws and rules it enforces and does not affect obligations a pharmacist or pharmacy technician may owe to other local, state or federal regulators e.g. United States Food and Drug Administration and United States Drug Enforcement Administration.

Commission Frequently Asked Questions (FAQs)

Can hospital pharmacies permit discharge of patients with albuterol that does not meet outpatient-labelling standards?

The Commission will not find licensees deficient or take enforcement action against its licensees for failure to discharge patients with albuterol that does not meet outpatient-labelling standards.

This position will take effect immediately and will remain effective until the Commission withdraws this position at an open public meeting or until the Governor issues a proclamation declaring the termination of the state of emergency declared by Proclamation 20-05, as amended by any subsequent amendatory proclamations, whichever is earlier.

This position will only affect a licensee's standing with the Commission and does not affect obligations a licensee may owe to other local, state or federal regulators e.g. United States Food and Drug Administration and United States Drug Enforcement Administration.

Can pharmacy technicians perform order entry from a remote location?


Yes, a pharmacy technician may perform order entry from a remote location as long as they are under the supervision and control of a pharmacist. Licensees should familiarize themselves with the Commission's Technology and Services Guidelines #62 when implementing processes and procedures that allow remote supervision of pharmacy technicians by pharmacists.

Should My Pharmacy Remain Open?

The Commission does not have authority to close businesses or pharmacies solely as a result of COVID-19. We encourage you to review the Washington State Coronavirus Response What's Open and Closed, Governor issued emergency proclamations, and follow the guidelines from the Centers for Disease Control and Prevention. Check with your local county health department to determine what activities are also considered essential and non-essential.

Please check our website for the most up-to-date info on Washington's response to COVID-19 at www.doh.wa.gov/coronavirus.

Resources

PQAC Tech Guidance	https://www.doh.wa.gov/Portals/1/Documents/2300/2018/PQAC-62TechServicesGuide.pdf
USP Letter	 2020-03-13 USP letter to state BOPs.

March 13, 2020

To State Boards of Pharmacy:

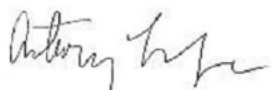
We are aware of, and concerned about, likely garbing and personal protective equipment (PPE) shortages as a result of the COVID-19 outbreak, recently designated by the World Health Organization as a pandemic. CDC has released Interim Guidance on preventing COVID-19 from spreading, which includes *Strategies for Optimizing the Supply of N95 Respirators and Healthcare Supply of Personal Protective Equipment*. See <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html>. FDA is working with PPE manufacturers to help facilitate mitigation strategies. See FDA's statement at <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns>.

As you know, USP's Compounding General Chapters include provisions on garbing and PPE. These provisions, along with the rest of the USP compounding chapters, are science-based, reflect good clinical practice, and are a part of the broader federal and state government framework to help ensure that patients have access to quality compounded preparations.

While USP develops science-based standards that help ensure the quality of compounded drug preparations, it is not an enforcement body. Accordingly, we recognize that State Boards and other regulators may need to make risk-based determinations on the implementation of USP standards, as well as myriad of other choices to address broad public health needs as a result of the COVID-19 pandemic. **We support appropriate risk-based enforcement discretion during the COVID-19 pandemic, in the interest of conserving garbing and PPE.**

As always, protecting and advancing public health is USP's priority, and we are committed to working with State Boards and other stakeholders during this crucial time. If you have any questions, please contact USP Healthcare Quality and Safety staff at CompoundingSL@usp.org.

Sincerely,



Anthony Lakavage, JD
Senior Vice President
Global External Affairs