

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 COVID19.PQAC@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>.

January 22, 2021

Table of Contents

Introduction and Requests	2
Impacts of COVID-19 on Compounding	3
Outpatient and Retail Pharmacy Operation Recommendations.....	5
COVID-19 Testing Information as it Relates to the Practice of Pharmacy in Washington State...8	
Delivery of Prescription Medications Outside of a Pharmacy by Pharmacists and Pharmacy Technicians.....	10
Commission Acts on Hand Sanitizer.....	11
Non-resident Pharmacies.....	12
Commission Frequently Asked Questions (FAQs)	15
Governor’s Proclamations Waiving and Suspending Laws and Rules	20
Resources.....	23

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 six-month 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-assessment-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.

6. Implement the universal use of face coverings

Pharmacists and pharmacy technicians should always wear a facemask while they are in the pharmacy for source control. Medical or surgical facemasks are generally preferred over cloth face coverings for healthcare professionals (HCP) for source control.

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>

ref: CDC (2020, June 28th). Guidance for Pharmacies. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/hcp/pharmacies.html>

COVID-19 Testing Information as it Relates to the Practice of Pharmacy in Washington State

Pharmacist Scope of Practice in WA State:

As part of its business meeting on April 24, 2020, the Pharmacy Quality Assurance Commission (PQAC) clarified some of the following as it relates to Washington licensed pharmacists ordering, administering and reporting results of COVID-19 testing to patients:

- **Screening for patients receiving COVID-19 tests** – A pharmacist or pharmacy intern, under the supervision of a pharmacist, may conduct this screening. It is not within the scope of practice for a Pharmacy Technician to perform discretionary functions. A Pharmacy Technician may only perform screening elements to the extent that could be described as non-discretionary function(s). If the screening includes any form of discretionary decision-making, these decisions must be reserved to the pharmacist or pharmacy intern. Pharmacy assistants cannot conduct screening.
- **Ordering COVID-19 tests** – PQAC will not take enforcement action against pharmacists who order COVID-19 tests consistent with the “[Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act](#)” issued by the U.S. Department of Health and Human Services on April 8, 2020. PQAC will be maintaining this position until it is withdrawn at an open public meeting or Governor Jay Inslee issues a proclamation terminating the state of emergency declared by [Proclamation 20-05](#) as amended.
- **Administering COVID-19 tests** – Pharmacists may administer COVID-19 tests. How to administer test:
<https://www.doh.wa.gov/Emergencies/NovelCoronavirusOutbreak2020COVID19/HealthcareProviders>
- **Reporting COVID-19 test results**- Pharmacists may not diagnose a patient with COVID-19, unless the diagnosis is permitted under the terms of a collaborative drug therapy agreement (CDTA). In the absence of a CDTA, if a pharmacist communicates the COVID-19 test results, the pharmacist shall only provide the results of the COVID-19 test and recommend the patient contact their primary health care provider.

Lab Certification and Requirements:

- Pharmacists in WA need to obtain certification of waiver from the WA State Department of Health indicating they are conducting CLIA waived tests. Under the HHS guidance, only COVID-19 tests with FDA Emergency Use Authorization (EUA) for use in waived settings can be used under a certificate of waiver.
- The Certification of Waiver Medical Test Sites Application link:
<https://www.doh.wa.gov/portals/1/Documents/Pubs/505038.pdf>

- The rules for Medical Test Sites can be found in Chapter 246-338 WAC: <https://apps.leg.wa.gov/WAC/default.aspx?cite=246-338>
- A “medical test site” is a laboratory that must meet the requirements for notifiable conditions to report in the Washington Disease Reporting System (WDRS). Chapter 246-101 WAC <https://apps.leg.wa.gov/WAC/default.aspx?cite=246-101>
- Consider contracting with a health care provider who orders tests and reports via the Washington Disease Reporting System (WDRS) to comply with notifiable condition requirements.
- Employers need to ensure that employees performing the COVID-19 test have sufficient personal protective equipment (PPE) and comply with COVID-19 test manufacturer’s specific manual of instruction. PPE information here: <https://www.doh.wa.gov/Emergencies/NovelCoronavirusOutbreak2020COVID19/HealthcareProviders>
- For questions regarding the application process, you may contact the Medical Test Site Program LQA@doh.wa.gov

Biomedical Waste Requirements:

- Proper disposal of biomedical waste generated from the COVID-19 testing is critical and necessary due to the infectious nature of the coronavirus. [More COVID-19 Information and Resources](#)

Stay up-to-date on the [current COVID-19 situation in Washington](#), [Governor Inslee’s proclamations](#), [symptoms](#), [how it spreads](#), and [how and when people should get tested](#). See our [Frequently Asked Questions](#) for more information.

The risk of COVID-19 is not connected to race, ethnicity or nationality. [Stigma will not help to fight the illness](#). Share accurate information with others to keep rumors and misinformation from spreading.

- [WA State Department of Health 2019 Novel Coronavirus Outbreak \(COVID-19\)](#)
- [WA State Coronavirus Response \(COVID-19\)](#)
- [Find Your Local Health Department or District](#)
- [CDC Coronavirus \(COVID-19\)](#)
- [Stigma Reduction Resources](#)
- [CDC Symptoms](#)

Have more questions about COVID-19? Call our hotline: **1-800-525-0127**. For interpretative services, **press #** when they answer and **say your language**. (Open from 6 a.m. to 10 p.m.) For questions about your own health, COVID-19 testing, or testing results, please contact your health care provider.

Delivery of Prescription Medications Outside of a Pharmacy by Pharmacists, Pharmacy Technicians, or Pharmacy Assistants

The Commission interprets existing laws and rules to permit a pharmacist, pharmacy technician, or pharmacy assistant 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, pharmacy technician, or pharmacy assistant 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 or pharmacy assistant 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, pharmacy technicians, or pharmacy assistants 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, pharmacy technician or pharmacy assistant may owe to other local, state or federal regulators e.g. United States Food and Drug Administration and United States Drug Enforcement Administration.

Commission Acts on Hand Sanitizer

The Pharmacy Commission (Commission) has received several inquiries and innovative collaborative concepts related to the manufacturing of alcohol-based hand sanitizer in light of the present public health emergency posed by COVID-19.

Pursuant to the Commission's discussion and vote during the Special Meeting, March 27, 2020,

the commission will not refer or take enforcement actions against licensees or pharmacies that accept donated or manufactured hand sanitizer (using USP and/or non-USP grade ingredients) without obtaining a manufacturer license for consumer use and for health care personnel for the duration of the public health emergency.

Pursuant to the Commission's discussion and vote during the Special Meeting, March 27, 2020,

the commission will not refer or take enforcement actions against individuals or businesses that accept donated or manufactured hand sanitizer (using USP and/or non-USP grade ingredients) without obtaining a manufacturer license, pharmacy license, or shopkeeper registration for consumer use and for health care personnel for the duration of the public health emergency. The hand sanitizer should be in a manner that is consistent with the guidance issued by the United States Food and Drug Administration (FDA) or the United States Pharmacopeia on preparing alcohol-based hand sanitizer.

The Commission will provide an update when this position no longer effective or applicable. The Commission thanks everyone for their patience and doing their part in providing the best care possible during these unprecedented times.

Non-resident Pharmacies

Policy Statement

For nonresident pharmacies who are required to **renew** their nonresident pharmacy licenses **by May 31, 2020**, the Pharmacy Commission will treat a letter from an approved inspection program, that complies with the criteria below, as meeting the requirement in RCW 18.64.360(1)(b)(i) and (ii) of providing an inspection report conducted by an approved inspection program within the last two years. The letter from the approved inspection program must state: (1) an inspection of the nonresident pharmacy has not been conducted within the last two years, and (2) an inspection cannot be conducted at this time because of the COVID-19 pandemic. A list of approved inspection programs can be found [here](#).

This statement does not affect obligations of applicants for nonresident pharmacy licenses. These applicants will still need to provide an inspection report conducted by an inspection program approved by the Pharmacy Commission that has been issued within two years. A letter that meets the criteria in the paragraph above will not be acceptable for new applicants of nonresident pharmacy licenses.

Background

The Pharmacy Commission has had regulatory authority over nonresident pharmacies that operate in Washington since 1991 (see [Pharmacies – Licensing of Nonresident Pharmacies, Laws of 1991, ch. 87](#)). [RCW 18.64.350](#) through [RCW 18.64.420](#) delineates the Pharmacy Commission's regulatory authority for nonresident pharmacies. The Pharmacy Commission can take enforcement action, among other things, when a nonresident pharmacy fails to comply with any requirement of [RCW 18.64.350](#) through [RCW 18.64.400](#) (see [RCW 18.64.390](#)).

As part of the 2019 legislative session, the Legislature passed [HB 1412](#) and amended RCW 18.64.360(1)(b) to require nonresident pharmacies to submit a copy of an inspection report as part of their initial application and renewal. The inspection had to be conducted by “an inspection program approved by the commission as having substantially equivalent standards to those of the commission” and the inspection report must have been “issued within two years of application or renewal.” [RCW 18.64.360\(1\)\(b\)\(i\) and \(ii\)](#). The Pharmacy Commission has issued a [directive](#) identifying those inspection programs that conduct inspections based on equivalent standards to those of the commission.

Due to the COVID-19 pandemic, nonresident pharmacies have informed the Pharmacy Commission they will be unable to meet the requirement to provide a copy of an inspection report because in-person inspections are not currently being conducted. At its April 24, 2020, business meeting the Pharmacy Commission discussed this issue and stated that for nonresident pharmacies who are required to renew their nonresident pharmacy licenses by May 31, 2020, the Pharmacy Commission will treat a letter, that meets the criteria below, from an approved inspection program as meeting the requirement in RCW 18.64.360(1)(b)(i) and (ii) of providing an inspection report conducted by an approved inspection program within the last two years. The letter from the approved inspection program must state: (1) an inspection of the nonresident pharmacy has not been conducted within the last two years, and (2) an inspection cannot be conducted at this time because of the COVID-19 pandemic. This action does not affect obligations of applicants for nonresident pharmacy licenses. These applicants will still need to provide an inspection report conducted by an inspection program approved by the Pharmacy Commission that has been issued within two years.

Commission Frequently Asked Questions (FAQs)

If proclamation 30-32 ([Department of Health – Healthcare Worker Licensing](#)) expires, can pharmacy technicians continue to engage in remote medication order processing without being under the “immediate supervision” of a pharmacist?

No. If proclamation 30-32 ([Department of Health – Healthcare Worker Licensing](#)) expires, pharmacy technicians must perform tasks under the “immediate supervision” of a pharmacist. Before the Pharmacy Commission’s new rules become effective on July 1, pharmacies who allow for remote supervision of pharmacy technicians should comply with the relevant requirements in [chapter 246-901 WAC](#) and the Pharmacy Commission’s [Technology and Service Guidelines](#). On July 1, 2020, when the Pharmacy Commission’s new rules become effective, pharmacies should ensure that pharmacy technicians are under the “immediate supervision” of a pharmacist as defined in WAC 246-945-001(44).

Proclamation 30-32 ([Department of Health – Healthcare Worker Licensing](#)) waived and suspended the requirement that pharmacy technicians be under the “**immediate**” supervision of a pharmacist in WAC 246-901-010(11), WAC 246-901-020(1), and WAC 246-901-040.

Emergency proclamations issued by the Governor expire after thirty (30) days unless extended by the legislature and if the legislature is not in session, a proclamation may be extended in writing by the leadership of the senate and house of representatives (see [RCW 43.06.220](#)). Proclamation 30-32 was originally set to expire on April 25, 2020, but was subsequently extended by the leadership of the state legislature (otherwise known as the “four corners”) on three occasions. The current extension ([Proclamation 20-32.3](#)) is set to expire on June 17, 2020. If the proclamation expires, then the word “immediate” will no longer be waived and suspended. The Pharmacy Commission does not have authority to extend the proclamation.

Does the Uniform Controlled Substances Act (RCW 69.50) restrict the quantity of controlled substances that may be prescribed?

The Uniform Controlled Substances Act (USCA), RCW 69.50, does not limit the quantity of controlled substances (including those drugs listed in Schedule II) that may be prescribed. However, prescribers, and pharmacists, should be aware of specific prescribing laws that may apply to their profession. For example, a number of prescribing boards and commissions [have specific laws and rules](#) applicable to prescriptions for opioids.

The USCA does prohibit refills for a drug listed in Schedule II (see RCW 69.50.308(d)). The USCA also prohibits filling of a prescription for a drug listed in Schedule II more than six months after the date the prescription was issued (see RCW 69.50.308(d)).

The USCA prohibits more than five refills of a prescription for a drug listed in Schedule III, IV, or V (see RCW 69.50.308(g)).

No. In addition, there are no limits to prescribing controlled substances for health care providers during COVID-19 as long as the provider follow the [rules regarding opioid prescribing](#). In addition, the USCA prohibits filling or refilling of a prescription for a drug listed in Schedule III, IV, or V, more than six months after the date issued by the prescriber (see RCW 69.50.308(g)).

Note: the Pharmacy Commission cannot guarantee that prescriptions of controlled substances for any quantity will be covered by a patient’s prescription drug benefit.

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 a prescription for a substance included in Schedule II be dispensed upon the oral prescription of a practitioner?

A substance included in Schedule II may be dispensed upon the oral prescription of a prescriber in an emergency (RCW 69.50.308(c)). An emergency exists "when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the [prescriber] to provide a written or electronic prescription for the drug at that time" (WAC 246-887-020(6)).

At its special meeting on April 3, 2020, the Commission stated that whether an emergency situation exists pursuant to the laws cited above is a determination made by the prescriber and pharmacist based on the individual facts of a particular medical situation. Further, [and in agreement with the position taken by the United States Drug Enforcement Administration \(DEA\)](#), while an emergency situation does not necessarily exist with regard to every prescription for a substance included in Schedule II issued during the COVID-19 state of emergency, the determination must still be made by prescribers and pharmacists on a case-by-case basis.

How does the waiver of pharmacy license of location extend to controlled substances and DEA registration requirements? What is the turnaround for the temporary registration?

Please send your contact information to Drug Enforcement Administration (DEA) Supervisory Diversion Investigator Craig Tom at craig.w.tom@usdoj.gov. Have your temporary location information, state licenses numbers, and Tax Identification Number readily available."

DEA is working with temporary sites to get them DEA Registrations as quickly as possible to avoid lapse in treatment, please have all of your Washington State controlled substance credentials ready to expedite the process.

For DEA COVID-19 information and latest updates on changes and exceptions to DEA rules: <https://www.deadiversion.usdoj.gov/coronavirus.html>

What is the Commission position on temporary closures of pharmacies?

There is really no role for the Pharmacy Commission when a pharmacy chooses to close temporarily. The pharmacy is still under the jurisdiction of the Commission and applicable laws and rules do apply even if the pharmacy is temporarily closed e.g. WAC 246-869-020 that requires a pharmacy to have adequate security for its drug supplies and records.

We recommend posting your differential hours for patients.

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.

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.

During COVID-19, what are the signature requirements for delivery of prescribed medications?

Effective 03/31/2020, The Health Care Authority is temporarily removing the requirement to obtain a signature from the Medicaid client or the client's designee upon receipt of pharmacy products dispensed and delivered directly to a client. In response to the current public health emergency surrounding the outbreak of the Coronavirus disease (COVID-19), along with the Governor of Washington's emergency proclamations related to COVID-19, [Washington Administrative Code 182-530-5000\(e\)\(i\)](#) has been updated to allow delivery of pharmacy products without signature from the client or the client's designee in order to avoid unnecessary contact between the client and the delivery person.

During the COVID-19, am I required to make customers sign a logbook to purchase over-the-counter pseudoephedrine products?

Yes. A signature to purchase pseudoephedrine (without a prescription) is required as part of the Combat Methamphetamine Epidemic Act of 2005. See [21 U.S.C. 830\(e\)\(1\)\(A\)](#). The Assistant Administrator is not authorized to make an exception to a statutory requirement.

DEA understands the concern that requiring a signature for purchase of pseudoephedrine could undermine public health efforts to combat the spread of the coronavirus. If a customer is worried about using a stylus or pen at the pharmacy, the pharmacy could provide the customer with gloves, a sterilized stylus/pen, or sterilize the stylus/pen after each use at the request of the customer.

Can pharmacies and health care entities manufacture hand sanitizer without obtaining a manufacturer license?

Pursuant to the Governor's Emergency Proclamation 20-36, pharmacies and health care entities can manufacture and distribute hand sanitizer without any additional licensure.

Can individuals or business entities manufacture hand sanitizer for distribution to the public without obtaining a manufacturer license or shopkeeper registration?

Pursuant to the Governor's Emergency Proclamation 20-36, individuals or business entities that manufacture hand sanitizer for distribution to the public in a manner can do so without obtaining a manufacturer license or shopkeeper registration.

Will the Pharmacy Commission find licensees deficient or take enforcement action against licensees whose CDTAs expire during the COVID-19 pandemic?

Pharmacists may prescribe drugs under the terms of a collaborative drug therapy agreement (CDTA) entered into with a prescriber (see RCW 18.64.011(28)). Amongst other requirements, a CDTA is required to contain “[a] time period not to exceed 2 years during which the [CDTA] will be in effect” (see WAC 246-863-100((2)(b))).

On April 10, 2020, as part of its special meeting, the Pharmacy Commission stated that it would not find licensees deficient or take enforcement action against its licensees for prescribing under an expired CDTA if the cause for the failure to renew the CDTA was the COVID-19 pandemic. This position took effect immediately and will remain effective until the Pharmacy 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.

Will the Pharmacy Commission find licensees deficient or take enforcement action against licensees whose CDAs expire during the COVID-19 pandemic?

Pharmacists may prescribe drugs under the terms of a collaborative drug therapy agreement (CDTA) entered into with a prescriber (see RCW 18.64.011(28)). Amongst other requirements, a CDTA is required to contain “[a] time period not to exceed 2 years during which the [CDTA] will be in effect” (see WAC 246-863-100((2)(b))).

On April 10, 2020, as part of its special meeting, the Pharmacy Commission stated that it would not find licensees deficient or take enforcement action against its licensees for prescribing under an expired CDTA if the cause for the failure to renew the CDTA was the COVID-19 pandemic. This position took effect immediately and will remain effective until the Pharmacy 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.

Does a pharmacist have the ability to independently order a COVID-19 tests?

Yes, the Commission adopted HHS’s policy “[HHS Statements on Authorizing Licensed Pharmacists to Order and Administer COVID-19 Tests](#)” and the Commission will exercise prosecutorial discretion for those pharmacist engaging in COVID-19 testing.

Does a pharmacist have the ability to administer a COVID-19 tests?

Yes, pharmacists are allowed to administer tests, including COVID-19 tests. This falls under their scope of practice identified in RCW 18.64.011(28) which states "Practice of pharmacy" includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.”

Are retail and community pharmacist required to complete the Sterile Compounding Self-Inspection Worksheet: USP 797 – Sterile Compounding Addendum?

No. At the April 24 2020 Pharmacy Commission business meeting, the Commission voted to not require the completion of the Sterile Compounding Self-Inspection forms in the retail and community pharmacist setting, when a pharmacist is engaged in low-risk compounding under the immediate use exemption.

Can a pharmacy use transportation network companies (TNCs) such as Uber, Lyft, or Postmates to deliver a patient's prescription medication?

Possibly--Under Washington law, a TNC could transport a patient's prescription medication if they are a "common carrier" or "contract carrier" (see RCW 69.41.030(1) and RCW 60.50.302(c)(2)). If a TNC is a "common carrier" or "contract carrier" the TNC would have to obtain a permit from the Washington State Utilities and Transportation Commission (UTC) unless they are exempt.

Pharmacies should contact the UTC to verify the status of a "common carrier" or "contract carrier". The contact information for the UTC can be found [here](#), and a searchable database of common carriers can be found [here](#).

Pharmacies should consider other applicable laws and other regulators e.g. United States Drug Enforcement Administration, before using TNCs to ship a patient's prescription medications. For example, the DEA has stated registrants are responsible for selecting common or contract carriers that will provide adequate security against in-transit losses or thefts.

Governor's Proclamations Waiving and Suspending Laws and Rules

[Proclamation 20-36.10](#) *(effective until termination of the state of emergency pursuant to RCW 43.06.210, or until rescinded, whichever occurs first)*

On Dec. 9, 2021 [Gov. Inslee modified Proclamation 20-36](#) to give pharmacies the flexibility they will need to store and access COVID-19 vaccines and treatments in locations outside of their pharmacies..

Proclamation waivers to allow off-site storage by pharmacies

The new waivers permit pharmacies to store outside of the pharmacy's main licensed location COVID-19 vaccines and drugs for treating COVID-19 for which the U.S. Food and Drug Administration has issued an emergency use authorization, license, or other approval.

Pharmacists may authorize non-pharmacy staff members to access the areas where these vaccines and drugs are stored without having to immediately supervise the non-pharmacy employees while they are doing so.

For instance, a hospital pharmacy may store COVID-19 vaccines in a hospital lab's ultra-cold freezer. Lab staff members may continue accessing the freezer and the area where the freezer is located without having to be immediately supervised by a pharmacist. Another example is that a retail pharmacy may partner with a private, independent lab or other enterprise to store vaccines in their freezers, and the staff of that lab or other enterprise will not have to be supervised by a pharmacist.

Pharmacies may store COVID-19 vaccines and drugs in locations outside of the pharmacy; however, current pharmacy standards still apply to store the vaccines and drugs in a facility with adequate security to protect them from unauthorized access, acquisition, or use.

Redistributing vaccines

Redistribution of COVID-19 vaccines to facilitate quick and effective vaccination, and to alleviate temporary shortages to aid in ending the COVID-19 pandemic, will be permitted. This qualifies as being done for emergency medical reasons. Redistribution of COVID-19 vaccines and treatments among pharmacies, health care facilities, and health care practitioners will not constitute wholesaling under the current law.

Commingled storage of vaccines and laboratory materials and specimens

Because ultra-cold freezer space is scarce, COVID-19 vaccines may need to be stored in the same freezer unit as laboratory materials and specimens. Unless the FDA's emergency use authorization for a COVID-19 vaccine prohibits it, the Pharmacy Quality Assurance Commission and the Department of Health – as the regulating agencies for pharmacies, medical test sites (laboratories), and hospitals – will permit commingled storage of COVID-19 vaccines and laboratory materials and specimens. The state will apply the standard in the CDC "Pink Book,"

which requires potentially contaminated laboratory items (e.g., blood, urine, and stool) to be properly contained and stored below vaccines to avoid contamination from drips or leaks.

Ancillary Utilization Plans

Pharmacies will not need Commission approval to utilize pharmacy technicians and assistants. Pharmacies that currently do have approval to utilize pharmacy technicians and assistants will also be able to utilize pharmacy technicians and assistants in a manner that is currently inconsistent with their approved AUP. In addition, pharmacy technicians can engage in specialized functions (IV admixture and unit-dose checking) without approval of the Commission.

While the approval of an AUP and specialized functions has been waived and suspended, pharmacy technicians and assistants will need to act within their statutory scope of practice and pharmacies/pharmacists remain responsible for actions taken by pharmacy technicians and assistants acting under their supervision.

License of Location - waived.

The “license of location” requirement for pharmacies has been waived and suspended. Consequently, pharmacies may store drugs outside of the physical confines of the pharmacy. Instead pharmacies could store drugs in other locations e.g. temporary pharmacy space that are not licensed. The pharmacy will still be responsible for drugs it stores outside of the physical confines of the pharmacy.

Differential Hours - waived.

Pharmacies do not need to notify the Commission thirty days before commencing differential hours. Pharmacies will also not need to undergo Commission inspection before commencing differential hours. This will affect pharmacies located within mercantile (retail) establishments

Hand Sanitizer - waived.

All persons engaged in the manufacture and distribution of hand sanitizer to the public, may do so without obtaining a manufacturer license or shopkeeper registration. This includes both entities licensed by the Commission, and those that are not licensed by the Commission.

[Proclamation 20-32.11](#) *(effective until termination of the state of emergency pursuant to RCW 43.06.210, or until rescinded, whichever occurs first)*

"Immediate" supervision of technicians - waived.

On March 26, 2020, the governor issued a proclamation waiving WAC 246-901-010(11), WAC 246-901-020(1) – the following language only: “immediate”, and WAC 246-901-040 – the following language only: “immediate”. This proclamation waives the requirement that a pharmacy technician or pharmacy technician trainee be under the *immediate* supervision of a pharmacist.

While the waiver is in effect, pharmacy technicians will only be required to act under the “supervision and control of a pharmacist” pursuant to RCW 18.64A.030(1). The Pharmacy Commission understands “supervision and control of a pharmacist” to mean that a pharmacist is readily available to a pharmacy technician or pharmacy technician trainee. This does include, but is not limited to, a pharmacist that is readily available via technology e.g. telephone or instant messaging service.

The proclamation does not remove the responsibility of a pharmacy or pharmacist for acts performed by pharmacy technicians or pharmacy technician trainees under their supervision (RCW 18.64A.080). In addition, the proclamation does not remove the requirement that a pharmacist must be on-site when employees of a pharmacy are engaged in sterile compounding (WAC 246-871-040).

Examples: Working remotely with technology, COVID-19 testing sites with access to pharmacists.

Retired Pharmacist license – waived.

The governor waived language in the retired pharmacist rule, which would allow a pharmacist with a retired pharmacist credential to practice pharmacy. The proclamation waived the following language from the rule: “shall not be authorized to practice pharmacy and”.

Continuing Education Requirements for Pharmacist - waived.

This waiver removes the requirement for a pharmacist seeking reinstatement or reactivation of an expired license to provide proof of 15 continuing education hour for the last two most recent years.

This waiver removes the requirement to complete the equivalent of 1.5 continuing education unit (equal to fifteen contact hours) of continuing education for renewing a pharmacist license.

This waiver removes the requirement of a pharmacist to complete the three hours of suicide training from the department of health's model list with content related to imminent harm via lethal means, during the first full continuing education reporting period after initial licensure. Waives CE requirements for **reactivating expired credential** if expired less than one renewal cycle.

Seven hours of HIV/AIDS training for pharmacist – waived.

This waiver removes the requirement for pharmacist applicants to complete seven hours of HIV/AIDS training for initial licensure.

Continuing Education Requirements for Pharmacy Technicians- waived

This waiver removes the requirement for pharmacy technicians to complete the minimum of ten continuing education hours or 1.0 continuing education unit (CEU), with one hour in pharmacy law, every renewal cycle following their first certification renewal. Waives CE requirements for **reactivating expired credential** if expired less than one renewal cycle.

Four hours of HIV/AIDS training for pharmacy technicians and pharmacy assistants – waived.

This waiver removes the requirement for pharmacy technician and assistant applicants to complete 4-hours of HIV/AIDS training for initial licensure. Resources

[Proclamation 20-59.8](#) *(effective until termination of the state of emergency pursuant to RCW 43.06.210, or until rescinded, whichever occurs first)*

Temporary Practice Permits for new graduates.

Proclamation 20.59 waives and suspends portions of the licensing and administrative statutes and rules relating to the issuance of Temporary Practice Permits (TPP) for healthcare workers who have recently graduated from professional health care programs in dentistry, pharmacy, and dental hygiene; and sets criteria for expiration and practice limits for the TPP.

USP Letter	 2020-03-13 USP letter to state BOPs_
Hand Sanitizer	For pharmacists, pharmacies, and health care entities: https://www.fda.gov/media/136118/download , https://www.usp.org/sites/default/files/usp/document/about/public-policy/usp-covid19-handrub.pdf For persons or entities not currently licensed or registered with the Commission: https://www.fda.gov/media/136289/download , https://www.usp.org/sites/default/files/usp/document/about/public-policy/usp-covid19-handrub.pdf
American Red Cross CPR Provisional Certification	https://www.redcross.org/take-a-class/coronavirus-information/provisional-certification