



STATE OF WASHINGTON  
**Pharmacy Quality Assurance Commission**

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**Special Meeting – Amended Agenda**

**April 1, 2020**

7:30 AM (Open Session)

Via webinar due to COVID19 Proclamation 20-05

**CONVENE:** Chairman Tim Lynch called the meeting to order 1 April 2020 at 7:31 a.m.

**Commission Members:**

Teri Ferreira, RPh, Vice-Chair  
Jerrie Allard, Public Member  
Steve Anderson, BSPHarm, RPh  
Bonnie Bush, Public Member  
Olgy Diaz, Public Member  
Patrick Gallaher, BS, BPharm, MBA, MPH  
Judy Guenther, Public Member  
Ken Kenyon PharmD, BCPS  
Craig Ritchie, RPh, JD  
Sepi Soleimanpour, RPh, MBA-HA  
Kat Wolf-Khachatourian, PharmD, MBA

**Staff:**

Lauren Lyles-Stolz, Executive Director  
Chris Gerard, AAG  
Doreen Beebe, Program Manager  
Kris Reichl, Rules, Leg & Implementation Manager  
Marlee O’Neill, Deputy Director – Office of Investigative  
and Legal Services

**Absent Commission Members:**

Uyen Thorstensen, CPhT

1.1 **MOTION:** Teri Ferreira moved to approve the meeting agenda for 1 April. Second, Craig Ritchie. Motion carried. 11-0.

2.1 Update the Commission on Governor Proclamations related to COVID-19.

2.1.1. Manufacturing and distribution of hand sanitizer. As read by the Chair:

*Governor finds that strict compliance with the following statutory and regulatory obligations or limitations on the manufacture and distribution of hand sanitizer will prevent essential workers in Washington State from meeting the demand for essential services required during the COVID-19 State of Emergency under Proclamation 20-05, and that the language of each statutory and regulatory provision specified below is hereby waived and suspended in its entirety, except as otherwise provided herein, until midnight on April 29, 2020:*

1. [RCW 18.64.020](#) License required (pharmacist, pharmacy, wholesaler or manufacturer)– this would allow distillers to distribute hand sanitizers.
2. [RCW 18.64.044](#) Shopkeeper registration - this would allow for the distribution by retail of hand sanitizers without a shopkeeper registration.

3. [RCW 18.64.045](#) *Manufacturers license - this would allow for the manufacturing and distribution of hand sanitizers without a manufacturers license.*
4. [RCW 18.64.250\(1\), \(2\)](#) **Unlawful practice: Waived for hand sanitizer distribution or manufacturing**
  - (1) *Any person not a licensed pharmacist and not having continuously and regularly in his employ a duly licensed pharmacist within the full meaning of this chapter, who shall practice pharmacy; or*
  - (2) *Any person who shall permit the compounding and dispensing of prescriptions, or vending of drugs, medicines, or poisons in his or her store or place of business, except under the supervision of a licensed pharmacist.*

**However,** Pursuant to [RCW 43.06.220\(1\)\(h\)](#) these waivers and suspensions do not apply except to the manufacturing, distributing, selling, and donating of hand sanitizer.

Chair asked for questions/discussion. None presented.

2.1.2. Pharmacies will not need Commission approval to utilize pharmacy technicians and assistants.

[RCW 18.64A.040\(1\),\(2\)](#); [RCW 18.64.060](#); [WAC 246-901-020\(3\)](#); [WAC 246-901-035](#).

*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. The laws waived to facilitate this are [RCW 18.64A.040\(1\)](#), and (2) *Limitations of practice removing requirement for Commission approval*; [RCW 18.64A.060](#) ; *Application for use of ancillary personnel (and approval of AUPs)*; [WAC 246-901-020\(3\)](#) *AUP rule*; [WAC 246-901-035](#) *Specialized Functions*:*

*“A pharmacy technician who meets established criteria for employment, experience, training and demonstrated proficiency may perform specialized functions. The criteria shall be specified in the utilization plan of the pharmacy for pharmacy technicians performing specialized functions required in [WAC 246-901-100\(2\)\(b\)](#). Records of pharmacy technician training and of demonstration of proficiency shall be retrievable within seventy-two hours upon request of the board.”*

*; and [WAC 246-901-100](#) (approval of plans, specialized functions, conditional pilot or demonstration projects). 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.*

*Examples of what is waived:*

- *New pharmacies AUPs or for pharmacies that currently do not use ancillary staff*
- *Locations changes AUPs*
- *Other expanded duties/specialized functions not currently on AUPs, Working remotely*

Chair asked for questions/discussion. None presented.

2.1.3. License of Location for Pharmacies [RCW 18.64.043\(1\), \(2\)\(a\), \(3\)](#)

*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. Pharmacies can store drugs in other locations e.g. temporary pharmacy space, that are not licensed. The laws waived to facilitate this is are [RCW 18.64.043\(1\), \(2\)\(a\), and \(3\)](#). The pharmacy will still be responsible for drugs it stores outside of the physical confines of the pharmacy. (does not waive the requirement for a license but allows the license to apply to multiple sites)*

- *RCW 18.64.043(1) - the following language only: “of location, which shall entitle the owner to operate such pharmacy at the location specified, or such other temporary location as the secretary may approve,”*
- *RCW 18.64.043(2)(a) - the following language only: “of location” in the first sentence.*
- *RCW 18.64.043(3) - the following language only: “and to keep the license of location or the renewal thereof properly exhibited in said pharmacy”*

Chair asked for questions/discussion.

This is for temporary hospital pharmacies and allows the placement of Pyxis machines and other equipment or medication storage devices or medications in those areas for temporary patient care. This waives a number of statutes and rules that apply to hospital licensing as well as the certificate of need program. This will facilitate the ability for all pharmacies and including hospital pharmacies to store drugs outside their licensed premises and be able to store drugs in places that is not normally allowed.

Further questions for 2.1.2 and 2.3

- if there is a pharmacy needing to expand work area (i.e., pharmacy in office building) to create space between employees – can they (the employees) now operate in the space outside of the pharmacy walls itself even though still in the building?
- Would a pharmacy in a large retail facility be able to utilize other department’s computers if that department is closed (i.e., closed optical department) and have technician/pharmacist to do the same thing (load balancing into their own system).

Answer: Yes, with two caveats: the proclamation is in effect until midnight 29 April unless extended by legislature; second, all other laws and rules not waived or commission not provided guidance are still in effect.

Stakeholder comments: would like to advocate for the DEA to relax their requirements. In addition, there are concerns about immunization (most common immunization is for shingles). This is inviting high-risk patients into an environment that potentially could have staff that are asymptomatic for COVID-19.

2.1.4. Notification of Differential Hours. [WAC 246-869-020\(10\)](#)

*Waived and suspends the requirement for notification and inspection for differential hours.*

*(10) Any person desiring to operate a pharmacy within an establishment having hours of business differing from the pharmacy must notify the board of pharmacy at least thirty days prior to commencing such differential hours. In order to constitute notification the applicant must complete the file forms provided by the board providing the required information. Board inspection and approval must be completed prior to the commencing of such differential hours. Such inspection and approval or disapproval shall be within 10 days of receiving notification that the premises are ready for inspection. Approval or disapproval shall be predicated upon compliance with this rule and pharmacy standards under chapter [246-869 WAC](#).*

This is waived which allows pharmacies to operate with expanded/different hours without approval from the commission.

Chair asked for questions/discussion.

2.1.5. Governor Proclamation 20-32, Expired credential – returning to active status when expired for less than one renewal cycle. [WAC 246-12-040 \(3\)\(a\)\(v\), \(b\)\(viii\), \(c\)\(vi\), \(ix\), \(xi\)](#)

*Waives or suspends CE requirements for reactivating expired credential if expired less than one renewal cycle – does not waive late penalty.*

Self-explanatory. Chair asked for questions/discussion. None.

2.2. Discussion of potential Governor Waiver requests and suspension of statutes or rules, emergency rulemaking, or other communication or guidance related to COVID-19.

- Review FAQ, discuss, and then use your decision tree for actions. Staff is tracking questions from stakeholders to develop a frequently asked questions document to provide guidance to stakeholders.

Remind attendees they can send pharmacy inquiries specific to the pandemic to [COVID19.PQAC@doh.wa.gov](mailto:COVID19.PQAC@doh.wa.gov)

### **Question #1: Commissions current position on guidance related to oral CII prescriptions under COVID-19?**

Pharmacists/Pharmacies must adhere to the DEA requirements currently in place concerning CII prescriptions. While the Commission has the right to waive some requirements, the DEA is the one to abide by as a registrant. However, the Commission states in RCW 69.50.308 and WAC 246-887-020(6) “oral CII prescriptions can be transmitted” orally (not written) when there is an emergency. “Emergency” defined as: *an emergency exists when the immediate administration of the drug is necessary for proper treatment and no alternative is available and further it is not possible for the physician to provide a written or electronic prescription.* The DEA did produce guidance on what constitutes an emergency. DEA states: *Whether an emergency situation exists is a determination made by the practitioner based on the individual facts of a particular medical situation and is to be made on a case-by-case basis.* Should the DEA relax their stance on this issue, the Commission will revisit.

Chair asked for Stakeholder questions/discussion.

**Julie Young**, pharmacy student, working with QFC on a rotation. The DEA has issued temporary exceptions. If you look on their website under CORONA Virus Response. They have increased the duration of time that a hard copy must be sent into a pharmacy from 7-15 days. A hard copy no longer

has to be a “hard written copy.” They can be faxed, scanned, or photographed, and sent to the pharmacy. They *do* need to be attached to the written copy that the pharmacist has written out upon receipt of the phone call. The provider must keep the hard copy at their own office in the patients file.

This issue was tabled for further review of the Commission. The definition of “emergency” in regard to CII prescriptions should be better defined.

**Question #2: How does the waiver of pharmacy license of location extend to controlled substances and DEA registration requirements?**

There is no action on this question. However, the Commission will provide FAQ regarding the process for an off-site temporary DEA registration.

**Question #3: What is the Commission position on temporary closures of pharmacies?**

**Answer:** 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. However, pharmacies should exercise best practices to notify patients/staff for adequate consideration of their needs.

Chair asked for questions/discussion. None.

**Question #4: Need for pharmacists’ ability to dispense a therapeutic substitution due to drug shortages and continuity of care without requiring communication the change to the prescriber.**

Continuity of care and the patient’s needs first is important. All members of the patient care team must be informed what is happening with the patient. However, most state statutes do not allow for therapeutic substitutions. The majority of states are still bound by their current restrictions and state law. [RCW 69.41.110\(7\) – 69.41.196](#) states therapeutic substitutions (as a general matter) are not permitted unless there is an exception that applies.

Stakeholder concerns/questions: There may be significant delay contacting the prescriber as they may be out of the office.

How should controlled prescriptions from a home quarantined doctor be handled? (Question was not further clarified as to whether this was an infection control question or another process behind it.)

Lauren Lyles will continue her discussion with WMC to further research a solution to this.

**Question #5: Ease regulatory requirement to allow out-of-state licensed pharmacists to practice in WA or pharmacist seeking WA pharmacist license by reciprocity to waive law examination since testing centers are closed due to the pandemic. Abbreviated or waived licensure process for out-of-state pharmacies (not licensed in Washington) providing shared services to in-state pharmacies.**

Suggestion: Request waiver of [RCW 18.64.080 \(5\)](#) allow reciprocity without taking MPJE.

Commission members agree it would be a temporary waiver of 30 days for out of state licensees unless extended by legislature. This also includes the students/interns graduating from school. This would require a waiver of statute by the governor.

The NABP Passport is also an option. Doreen Beebe will research the passport option for possible use.

Stakeholder comments/questions:

Laurie Walmsley, Walgreen's, Arizona board member: the NABP passport is good for states that participate. The pharmacist simply checks off the states needed.

**MOTION:** Bonnie Bush moved to request waiving [RCW 18.64.080 \(5\)](#); Second, Ken Kenyon. Motion carried. 11-0.

Further clarifying discussion:

Must obtain waiver first, then look into the Passport and how to move forward.

There being no further business, the Commission meeting adjourned at 8:30 a.m.

*Respectfully Submitted by:  
Amy Robertson, Administrative Assistant*



*Approval August 28, 2020  
Tim Lynch, Chair  
Washington State Pharmacy Quality Assurance Commission*