Agenda Item/Title: 4.2 Discuss request received for legislative support to changes to RCW 18.64.450(3) which sets limitations for dispensing legend drugs for health care entities.

Date SBAR Communication Prepared: 10/21/2019

Reviewer: Tracy West, Interim Executive Director

Link to Action Plan:

☑ Action ☑ Information ☐ Follow-up ☐ Report only

Situation: Olympia Bupe Clinic at Capital Recovery Center (Clinic) has submitted a request for consideration to the Commission regarding dispensing from a Health Care Entity (HCE). The clinic is requesting the Commission’s support to change RCW 18.64.450(4) which limits dispensing from an HCE to a 72 hour supply if there is no pharmacist on site. The clinic would like to use an automated drug dispensing device (ADDD), which is why they sought licensure as an HCE.

Background:
RCW 18.64.450 outlines the requirements for a health care entity to obtain licensure. RCW 18.64.011(15) defines an HCE as:

[A]n organization that provides health care services in a setting that is not otherwise licensed by the state to acquire or possess legend drugs. Health care entity includes a freestanding outpatient surgery center, a residential treatment facility, and a freestanding cardiac care center. "Health care entity" does not include an individual practitioner's office or a multipractitioner clinic, regardless of ownership, unless the owner elects licensure as a health care entity. "Health care entity" also does not include an individual practitioner's office or multipractitioner clinic identified by a hospital on a pharmacy application or renewal pursuant to RCW 18.64.043.

As the definition states an individual practitioner or multipractitioner office may elect to license their clinic as an HCE which gives the facility the ability to possess drugs, i.e. store legend drugs and controlled substances for administration to patients of the HCE.

Possession and dispensing of drugs is dependent on whether a practitioner or facility have the statutory authority to possess. Under RCW 69.41.030, practitioners as defined in RCWs 69.41.010(17) and 69.50.101(mm) have independent authority to possess legend drugs and controlled substances unless limited in other statutes.

An HCE’s authority to possess drugs is established under RCW 18.64.450, that section of RCW also states the following regarding HCE dispensing:

(4) A health care entity may only administer, dispense, or deliver legend drugs and controlled substances to patients who receive care within the health care entity and in compliance with rules of the commission. Nothing in this subsection shall prohibit a practitioner, in carrying out his or her licensed responsibilities within a health care entity, from dispensing or delivering to a patient of the health care entity drugs for that patient's personal use in an amount not to exceed seventy-two hours of usage.

The Commission has discussed the limitations on HCE dispensing previously at the May 26, 2016 regularly scheduled Commission business meeting.
The Commission passed the following motion and formalized their position on HCE dispensing by a practitioner in the HCE.

**Health Care Entities Dispensing**

Executive Director, Steven Saxe, and AAG, Joyce Roper led the discussion with the Commission revisiting the interpretation of RCW 18.64.450 (4) Health Care Entities being restricted to dispensing no more than a 72 hour supply of medications. There have been some issues regarding the interpretation of this RCW. The investigators asked for guidance to this RCW for inspections and consistency. If a prescriber violates this RCW the violation will be handled by the Medical Quality Assurance Commission (MQAC).

**MOTION:** Cheryl Adams moved that the Commission’s interpretation of RCW 18.64.450 (4) is “Practitioners can dispense a maximum of 72 hours in an HCE the source is irrelevant anything greater than 72 hours needs to be dispensed by the pharmacist only.” PQAC will educate/inform the public the interpretation of this RCW. If there is need to dispense more than 72 hours it is suggested to contract/find another alternative or have a pharmacist on site. Steve Anderson second. Matthew Ronayne, Arun Sambataro and Ken Kenyon abstained. **MOTION CARRIED: 10-0.**

The Commission’s ADDD rules can be found in chapter 246-874 WAC. Specifically, WAC 246-874-020 states when the rules apply and in what setting. WAC 246-874-020(1) specifically states that the requirements of the chapter (“Part 1”) apply to ADDDs managed by a licensed pharmacy:

(1) Part 1 sets the requirements for an ADDD managed by licensed pharmacies under chapter 18.64 RCW, health care entities as defined in RCW 18.64.011, health care facilities as defined in RCW 70.38.025, assisted living facilities as defined in RCW 18.20.020, nursing homes as defined in RCW 18.51.010, health maintenance organizations as defined in RCW 70.38.025, and public health centers as defined in RCW 70.40.020, and any other entity authorized by the commission, that choose to use them.

The intent of this section and how the Commission has interpreted it is that ADDDs managed and served by a licensed pharmacy can be in specific settings listed, and does not apply to practitioner dispensing. Meaning a practitioner can have an ADDD with their own stock in it.

**Assessment:**

There are a multiple ways dispensing can take place at an HCE, with and without the use of an ADDD:

1. Practitioners can dispense up to a 72 hour supply of medications to a patient of the HCE with or without an ADDD.
2. An HCE can dispense more than a 72 hour supply of medications to a patient of the HCE, with or without an ADDD if there is a pharmacy or pharmacist on-site.

The HCE statute and license is not limited to a specific practice setting or service provided by a clinic. It does not appear to be the intent of the legislature to allow larger than a 72 hour supply to be dispensed to a patient of an HCE without a pharmacist involved. There may be several reasons for this:

1. Need to separate the practice of pharmacy from the practice of a clinic.
2. Need for proper drug utilization reviews.
3. Need for proper labeling and recordkeeping.
4. Clinics desired a way to possess legend drugs without the full accountability and responsibility falling solely on one practitioner’s license or practice.
Staff are concerned and expressed concerns to the Clinic regarding the impact a change to RCW 18.64.450(4) would have, and that it would have a larger impact than clinics solely engaged in buprenorphine treatment. There is an argument that changing the statute could lead to extended dispensing abilities of all HCEs which would really meet the definition of the “practice of pharmacy”, see RCW 18.64.011(28), and therefore meet the definition of “pharmacy”, RCW 18.64.011(26), which requires an appropriate pharmacy license.

**Recommendation:**
At this time, staff recommend not supporting this legislative change, but rather have the Commission and/or staff further engage with the requestor on innovative ideas to support high risk patients with opioid or substance abuse disorders.

**Follow-up Action:** Staff will implement or follow up on direction given by the Commission.
# Request for Consideration by the Pharmacy Quality Assurance Commission

## NOTICE

Documents submitted to the Pharmacy Quality Assurance Commission (Commission) are public records, subject to the Public Records Act, chapter 42.56 RCW, and presumptively open to public inspection and copying. The Commission will make meeting materials available for public inspection and copying on the Commission’s website, including records submitted by you concerning your requests for review or approval to the Commission. If you believe any of these records may be exempt from disclosure under RCW 42.56.270(11)* (“Proprietary data, trade secret, or other information that relates to (a) . . . unique methods of conducting business, (b) data unique to [your] product or services), then do not submit the records. Instead, you may seek a court order protecting those records as authorized in RCW 19.108.020(3), providing notice of the proceeding to the Commission. The materials may be submitted to the Commission in a manner consistent with an order of the court when the legal proceeding has concluded.

<table>
<thead>
<tr>
<th>Requester/Title/Credentials:</th>
<th>Lucinda Grande, MD, Medical Director</th>
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</thead>
<tbody>
<tr>
<td>Contact Email/Phone #:</td>
<td><a href="mailto:lucinda@crcoly.org">lucinda@crcoly.org</a></td>
</tr>
<tr>
<td>Affiliation:</td>
<td>Olympia Bupe Clinic at Capital Recovery Center</td>
</tr>
</tbody>
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Complete the following fields if this request applies to an active or pending license (includes registration, or certification). If needed, include additional information on separate paper.

<table>
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<tr>
<th>License Name:</th>
<th>Health Care Entity</th>
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<tbody>
<tr>
<td>License/site Address:</td>
<td>Capital Recovery Center, 1000 Cherry St., Olympia, WA</td>
</tr>
<tr>
<td>License Number:</td>
<td>pending</td>
</tr>
<tr>
<td>What is your preferred date to have your request considered by the Commission:</td>
<td>1st Date October 25 2nd Date December 20</td>
</tr>
<tr>
<td>What is your expected outcome by the Commission?</td>
<td>[ ] Action [ ] Information [ ] Follow-up [ ] Report only</td>
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Please attach any policies, procedures or other documentation deemed necessary to support his proposal. Visit the commission’s webpage for approved guidelines, review forms or current laws and rules.

This completed form should be no longer than two pages, front to back.

**Situation:** (Briefly describe the current situation. Give a clear, succinct overview of relevant issues)

I am seeking a small change in state pharmacy law to facilitate on-site clinic dispensing of buprenorphine. Lack of immediate access to buprenorphine is a key treatment barrier for high-needs patients with opioid use disorder. High needs patients include those who have unstable housing, unstable employment, behavioral health disorders, and/or recent incarceration. These are the patients at highest risk of overdose death. Buprenorphine reduces risk of overdose death by half or more.

On-site clinic dispensing would facilitate implementation of the Washington State Opioid Response Plan’s Goal 2 Strategy 2, which calls for an increase in low-barrier access to medication.
Request for Consideration by the Pharmacy Quality Assurance Commission

The Olympia Bupe Clinic, established in January 2019, serves a high needs patient population. We have a large and growing volume of 25-30 patients every week night. Our retention rate is high, with nearly half of patients visiting four or more times. We provide on-site dispensing of prescriptions customized to the needs of individual patients, with duration varying from 1 day up to two weeks. We believe that both on-site dispensing and the availability of extended prescriptions are critical to our high patient retention.

Our current strategy for on-site dispensing is delivery of medications to our clinic three times nightly by our contracted pharmacy, Sound Specialty Pharmacy. Intensive pharmacy support like this is inefficient and expensive. It would not be feasible for most ambulatory clinics, particularly those serving rural and tribal communities.

For improved efficiency, we applied to the Department of Health for a Health Care Entity (HCE) license. This license would authorize us to use an on-site automated drug dispensing device (ADDD) controlled by our off-site pharmacist. Unfortunately, we learned that the HCE license limits to 72 hours the period of medication to be dispensed for each patient, unless a pharmacist is on site. 72 hours is not enough to be useful for this medicine, which is used daily for months to years.

**Background:** (Briefly name any laws, rules, or guidelines relevant to the request):

The 72 hour dispensing rule for HCEs is found in RCW 18.64.450 (4). The Pharmacy Commission discussed this statute on May 26, 2016. As noted on page 3 of the minutes of that meeting, there had been some issues regarding the interpretation of this RCW. The interpretation of the Commission was that the HCE is limited to dispensing a 72 hour supply.

My proposal is for explicit wording to be added to the statute to allow dispensing of up to two weeks for opioid treatment medications, and for other medications for patients also prescribed opioid treatment medications at the facility.

Allowing the dispensing of other medications for these patients would facilitate colocation of primary care and behavioral health care at clinics which primarily treat substance use disorders in high needs patients.

**Assessment:** (If approved, what would be the expected outcome for patient safety? What is the consequence if this request is not approved?)

The outcome for patient safety would be a reduction in adverse effects of untreated opioid use disorder such as infection, hospitalization, family disruption, homelessness, unemployment, legal involvement, incarceration, and overdose death. The benefit would be most pronounced in rural and tribal regions, where pharmacy access is most limited. Small jails may also benefit.

If the request is not approved, high needs patients will lose a major opportunity for access to opioid treatment medications. A variety of inefficient and expensive strategies may be developed by specialized clinics in urban areas as a workaround to provide on-site pharmacist dispensing of treatment medications.

**Request:** (What action(s) are you asking the commission to take? What do you want to happen next?)

I would like to have the active support of the Pharmacy Commission for this proposed small change in state pharmacy law. I am separately requesting the Governor’s office to introduce this proposal during the 2020 legislative session, and reaching out to legislators to ask for support.

Attached is a list of those who have already expressed support of this proposal.
Here is a list of individuals who have identified clinic on-site dispensing of buprenorphine as a priority for treatment for high needs patients with opioid use disorder:

- **Richard Reis, MD**, Professor of Psychiatry and Behavioral Sciences at University of Washington, and Director of Outpatient Psychiatry and the Psychiatry Addiction Division at Harborview Medical Center
- **Andrew Saxon, MD**, Professor of Psychiatry and Behavioral Sciences at University of Washington; Director of Center of Excellence in Substance Abuse Treatment Education (CESATE) at VA Puget Sound Health Care System; Director of Addiction Psychiatry Residency Program, University of Washington
- **Joseph Merrill, MD**, Associate Professor of Medicine at University of Washington; Harborview Adult Medicine, Addiction Medicine, AIDS Care, Behavioral Health Care
- **Manuel Pablo**, MAT Program Manager, U.S. Public Health Service/Cowlitz Tribal Health-Seattle.
- **Elizabeth Tail**, Clinic Manager, U.S. Public Health Service/Cowlitz Tribal Health-Seattle.
- **Alisa Solberg**, Director, Meds First Clinic at Tacoma Pierce County Department of Public Health
- **Bekah Carty, RN**, Nurse Care Manager, Meds First Clinic at Tacoma Pierce County Department of Public Health
- **Jeff Allgaier, MD**, President, Ideal Option
- **Eliza Hutchinson, MD**, Country Doctor's Walk-in Buprenorphine Clinic at the Hepatitis Education Project, Seattle
- **Richard Waters, MD**, Neighborcare Homeless and Housing Programs Site Medical Director, Neighborcare Health at Ballard, Seattle