

## Pharmacy Quality Assurance Commission Guidance Document

Title:	Opioid Treatment Program - Drugs that May be Ordered,
	Possessed and Used by an Opioid Treatment Program.
Reference:	RCW 71.24.590,
	RCW 18.64.450, RCW 69.41.095,
	<u>Chapter 246-904 WAC.</u>
Contact:	Executive Director
<b>Effective Date:</b>	June 21, 2019
Supersedes:	N/A
Purpose:	To provide information on options for ordering, possessing,
	dispensing, and administering of drugs by Opioid Treatment
	Programs.
Approved:	
Chair, Pharmacy Quality Assurance Commission	

The Pharmacy Commission (Commission) and the Department of Health frequently get questions on the ability for Opioid Treatment Program (OTP) to order, possess, dispense and administer medications.

An OTP licensed by the Department of Health "engages in the treatment of opioid use disorder with medications approved by the United States Food and Drug Administration (FDA) and provides a comprehensive range of medical and rehabilitative services." As amended by SB 5380 (2019), RCW 71.24.590 provides the OTP with statutory authority to order, possess, dispense and administer medications "approved by the [FDA] for the treatment of":

- opioid use disorder,
- alcohol use disorder,
- tobacco use disorder, and
- opioid overdose (opioid overdose reversal medication)

Further, the statute does allow for an OTP to "...accept, possess, and administer patient-owned medications." These would be medications previously prescribed and dispensed to the patient and brought to the OTP for secure storage and administration to the patient for which they were prescribed. This would allow for observed administration of some medications with significant public health impact such as hepatitis, tuberculosis, etc....



If additional drugs to the ones identified above are to be ordered, possessed and used by an OTP, the OTP must obtain additional licensure as required by the Department, e.g. a Health Care Entity license under RCW 18.64.450. If an OTP does not elect to obtain an additional facility license, an OTP may have additional drugs ordered, possessed and used by an appropriately licensed individual practitioner. This practitioner would be responsible for the ordering, security, use and distribution of these drugs.

## **BACKGROUND:**

The Commission frequently receives questions on whether an OTP may order, possess and use opioid reversal medications such as naloxone. Further, the Commission is often asked about the ability of an OTP to order, possess or use drugs to treat associated disease or illness that may be secondary to the substance use disorder. This might include infections or other illness. In 2019, <u>SSB</u> 5380 amended RCW 71.24.590 and provided additional statutory authority for an OTP to order, possess and distribute specific drugs.

All health professionals and health care facilities must have statutory authority to order, possess, dispense or administer legend drugs. Traditionally, this statutory authority is found in Chapter 69.41 RCW for non-controlled legend drugs and Chapter 69.50 RCW for controlled substances.

For OTPs, the statutory authority to possess certain drugs is provided by RCW 69.41.030, and RCW 71.24.590.

- (4) Opioid treatment programs may order, possess, dispense, and administer medications approved by the United States food and drug administration for the treatment of opioid use disorder, alcohol use disorder, tobacco use disorder, and reversal of opioid overdose. For an opioid treatment program to order, possess, and dispense any other legend drug, including controlled substances, the opioid treatment program must obtain additional licensure as required by the department, except for patient-owned medications.
- (5) Opioid treatment programs may accept, possess, and administer patient-owned medications.
- (6) Registered nurses and licensed practical nurses may dispense up to a thirty-one day supply of medications approved by the United States food and drug administration for the treatment of opioid use disorder to patients of the opioid treatment program, under an order or prescription and in compliance with 42 C.F.R. Sec. 8.12.
- (7) For the purpose of this chapter, "opioid treatment program" means a program that:
- (a) Engages in the treatment of opioid use disorder with medications approved by the United States food and drug administration for the treatment of opioid use disorder and reversal of opioid overdose; and
- (b) Provides a comprehensive range of medical and rehabilitative services.

RCW 71.24.590(4)-(7).



If the OTP will be ordering, possessing and using drugs to treat other secondary illnesses or conditions, additional licensing must be used or obtained. This might include a Health Care Entity license. The laws and rules for this license is found at <a href="RCW 18.64.450">RCW 18.64.450</a> Health care entity—License requirements for legend drugs and controlled substances—Exception and <a href="Chapter 246-904">Chapter 246-904</a> WAC Health Care Entity. If the OTP does not elect to obtain an additional facility license, drugs may be ordered, possessed and used by an appropriately licensed individual practitioner. This practitioner would be responsible for the ordering, security, use and distribution of these drugs.

## **CONCLUSION:**

As <u>amended by SB 5380 (2019)</u>, RCW 71.24.590 provides an OTP with statutory authority to order, possess, dispense and administer medications "approved by the [FDA] for the treatment of":

- opioid use disorder,
- alcohol use disorder,
- tobacco use disorder, and
- opioid overdose (opioid overdose reversal medication)

Further, the statute does allow for an OTP to "...accept, possess, and administer patient-owned medications." These would be medications previously prescribed and dispensed to the patient and brought to the OTP for secure storage and administration to the patient for which they were prescribed. This would allow for observed administration of some medications with significant public health impact such as hepatitis, tuberculosis, etc.

If additional drugs to the ones identified above are to be ordered, possessed and used by an OTP, the OTP may be required to obtain an additional license e.g. a Health Care Entity license under RCW 18.64.450. If an OTP does not elect to obtain an additional facility license, an OTP may have additional drugs ordered, possessed and used by an appropriately licensed individual practitioner. This practitioner would be responsible for the ordering, security, use and distribution of these drugs