

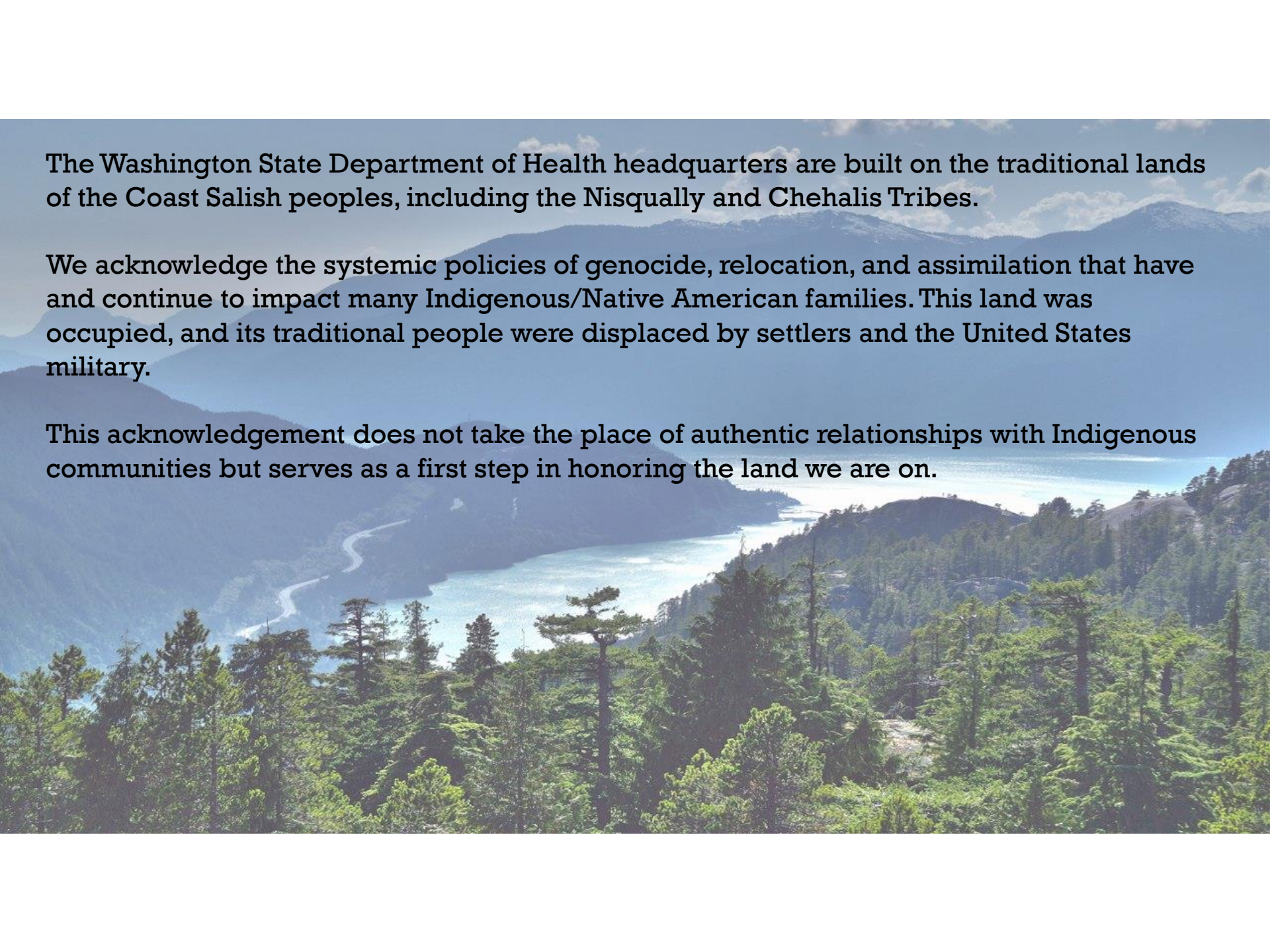


OTP RULE-MAKING WORKSHOP #5
Health Systems Quality Assurance
Office of Community Health Systems
Facilities Program



NISQUALLY INDIAN TRIBE



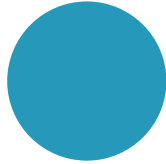
The background image is a scenic landscape photograph. It shows a wide river valley with a winding road on the left side. The river is a light blue color, possibly due to glacial silt. In the foreground, there is a dense forest of tall, green evergreen trees. In the background, there are blue mountains under a clear sky with some light clouds. The overall scene is bright and natural.

The Washington State Department of Health headquarters are built on the traditional lands of the Coast Salish peoples, including the Nisqually and Chehalis Tribes.

We acknowledge the systemic policies of genocide, relocation, and assimilation that have and continue to impact many Indigenous/Native American families. This land was occupied, and its traditional people were displaced by settlers and the United States military.

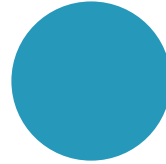
This acknowledgement does not take the place of authentic relationships with Indigenous communities but serves as a first step in honoring the land we are on.

Introductions of DOH Staff



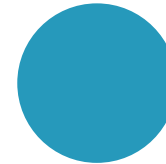
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Zoom 101



- If you need/want captions
- If you require translations or other formats
- If you want to ask a question/add a comment
 - Chat will be followed as closely as possible. Comments will be logged in notes and not necessarily responded to “live”.
 - Raise your hand if you wish to speak.
 - The Q and A will serve as a “Parking lot”. Please post questions here and we will get to as many as we can “live” and respond to the remaining in the session notes that will go out later this week.
 - More information/tutorials can be found at [Zoom Learning Center](#)

Today's Agenda

- Scope of rulemaking project
- Recap of revisions from previous workshops
- Review of changes made since the last workshop
- Review draft language
- Questions?
- Next Steps

Scope of Rulemaking

- General cleanup
- Explore recommendations and input from interested parties
- Align with federal OTP regulations, remove duplication
- Implement [2E2SSB 5536](#) to develop rules for fixed-site medication units.

Work Toward the Common Goal

Improve existing opioid treatment program licensing and certification standards to support agencies in treating individuals for opioid use disorder.



Recap of Workshops

Recap of Workshop #1

- OTP definition
- Policies and procedures to align with 42 CFR Part 8
- Hep A and Hep B vaccination
- Testing and treatment for TB and syphilis
- Accreditation organization requirements
- Central registry
- After-hours service
- Removed duplicative requirements

Recap of Workshop #2

- Finished reviewing General OTP Requirements in WAC 246-341-1000
 - Added definition for Central Registry
 - Removed duplicative language
 - Clarified that death reports are to be done within 48 hours upon learning of the death.
- Reviewed Agency Certification Requirements in WAC 246-341-1005
 - Clarified that certification requirements apply to new programs and programs that are planning to move.
 - Updated community relations plan language to remove outdated references and clarified that the plan is to inform and educate the community about the program.
- Reviewed Agency Staff Requirements in WAC 246-341-1010 and removed duplicative language.

Recap of Workshop #3

- Reviewed individual service record and documentation requirements in WAC 246-341-1015
 - Referred to CFR
 - Removed duplication
 - Added that the record must also be done in accordance with accreditation standards.
- Reviewed medical director responsibilities in WAC 246-341-1020
 - Removed duplication
 - Referred to CFR
 - Removed the annual medical exam requirement
- Reviewed medication management requirements in WAC 246-341-1025
 - Removed duplication and referred to RCW 71.24.594 re: opioid overdose reversal medication

Recap of Workshop #4

- Reviewed the draft language related to fixed-site medication units

(6) An opioid treatment program may operate a medication unit as defined in 42 C.F.R. Part 8.2, that is a brick-and-mortar location, or a mobile narcotic treatment program as defined in 21 C.F.R. Part 1300. An opioid treatment program operating a medication unit must:

- (a) Notify the department in a manner outlined by the department;
- (b) Submit a copy of the Drug Enforcement Administration (DEA) approval for the medication unit; and
- (c) Comply with 21 C.F.R. Parts 1300, 1301, and 1304, 1306, 42 C.F.R. Part 8 and any applicable rules of the pharmacy quality assurance commission.

Revisions Made Since the Last Workshop

- WAC 246-341-0200 - Added the definition of Community Relations Plan

“Community relations plan” means a plan to inform and educate the community about the opioid treatment program, which documents strategies used to obtain community input regarding the proposed location and address any concerns identified by community members near the proposed location of the opioid treatment program.

Revisions Made Since the Last Workshop

- WAC 246-341-1000 – additional clarification for death reporting requirements

Report to the department deaths that occur on the campus of an opioid treatment program as a critical incident according to [WAC 246-341-0420](#) (12).

- WAC 246-341-1010 – removed mention of appointing a program sponsor or medical director
 - *Appoint a program sponsor, as defined in 42 CFR Part 8*
 - *Appoint a medical director, as defined in 42 CFR Part 8, who:*
 - *Is licensed by the department under chapter 18.57 RCW or the Washington medical commission under chapter 18.71 RCW to practice medicine and practices within their scope of practice*

Revisions Made Since the Last Workshop

- WAC 246-341-1020 – Removed a duplicate requirement to provide information to pregnant individuals. This language is referenced in WAC 246-341-1000

Information and education, as appropriate on:

The impact of opioid and opioid use disorder medications during pregnancy according to RCW 71.24.560

Revisions Made Since the Last Workshop

- WAC 246-341-1025 – Removed duplicative language below regarding take-home medications.

An agency providing opioid treatment program services must ensure that all take-home medications are authorized and dispensed in accordance with 42 CFR Part 8.12.



Draft Language Review

Next Steps

- Follow up on any action items from this workshop
- Send out notes, and slides from this workshop
- Internal review of the proposed language
- Survey regarding small business economic impact

Rule-Making Overview

- Goal is to:
 - Use these fall workshops to develop proposed language.
 - Finalize proposed language by spring 2024.
 - Hold a public hearing in late spring 2024.
 - Finalize the rule by summer of 2024.

Resources

- [BHA Rules In Progress Webpage](#)
- Want to get notifications directly? [Subscribe to GovDelivery!](#)
Enter your email address and then under Health Systems Quality Assurance (HSQA), select Opioid Treatment Programs and Behavioral Health Integration.
- [Chapter 246-341 WAC](#) – BHA licensing and certification – DOH Requirements
- [RCW 71.24.590](#) - OTP licensing or certification by department
- [2E2SSB 5536](#) – Controlled Substances, counterfeit substances, legend drugs, and drug paraphernalia – Possession and treatment.
- [42 Code of Federal Regulations Part 8](#) – Federal Opioid Treatment Standards - SAMHSA

Resources Continued....

- [Proposed 42 Code of Federal Regulations Part 8](#) – Federal Opioid Treatment Standards - SAMHSA
- [Federal Opioid Treatment Program Guidelines](#), 2015. SAMHSA
- 21 Code of Federal Regulations – DEA
 - [Part 1300 Definitions](#)
 - [Part 1301 Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances](#)
 - [Part 1304 Records and Reports of Registrants](#)
 - [Part 1306 Prescriptions](#)



QUESTIONS?



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