Washington State Department of Health

CERTIFICATE OF NEED (CN) PUBLIC INFORMATION SESSION

May 25, 2022

DOH 260-046 June 2022

Introductions

John Williams

Acting Executive Director

Community Health Systems

Eric Hernandez

Program Manager

Certificate of Need

Housekeeping

- Other DOH Staff on the call
- **This is not a rule making session**
- Please mute yourself if you are not talking
- Please hold your question until the end or place the question in chat.
- During the question/answer session please use the raise hand feature
- Slides will be posted to our website and a link provided in chat
- Please use the chat feature if you experience technical difficulties

Agenda

Brief Overview of CN

Current Goals

Listening Sessions Outline

Brief Review of Rules Process

Questions

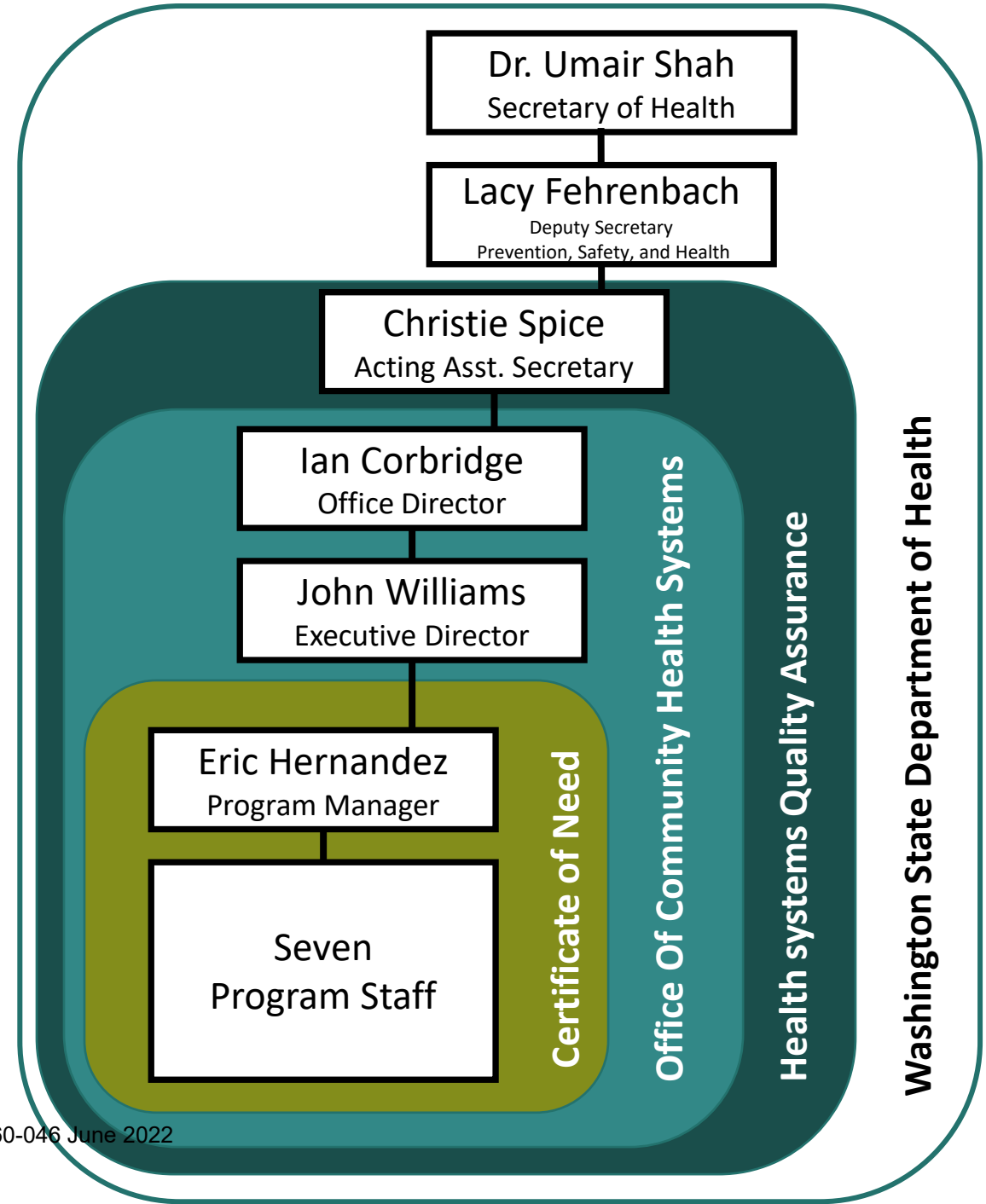
Contact page

Our Mission, Role and Values

Department of Health's mission: Protect and improve the health of people in Washington.

Health System Quality Assurance Division role: Assure people have access to safe, equitable, and high-quality health care services through regulation and education.

Our values: Patient safety, access to care, equity, innovation and engagement.


Dr. Umair Shah
Secretary of Health
Lacy Fehrenbach
Deputy Secretary
Prevention, Safety, and Health
Christie Spice
Acting Asst. Secretary
Ian Corbridge
Office Director
John Williams
Executive Director
Eric Hernandez
Program Manager
Seven
Program Staff
Certificate of Need
Office Of Community Health Systems
Health systems Quality Assurance
Washington State Department of Health

CN in Washington

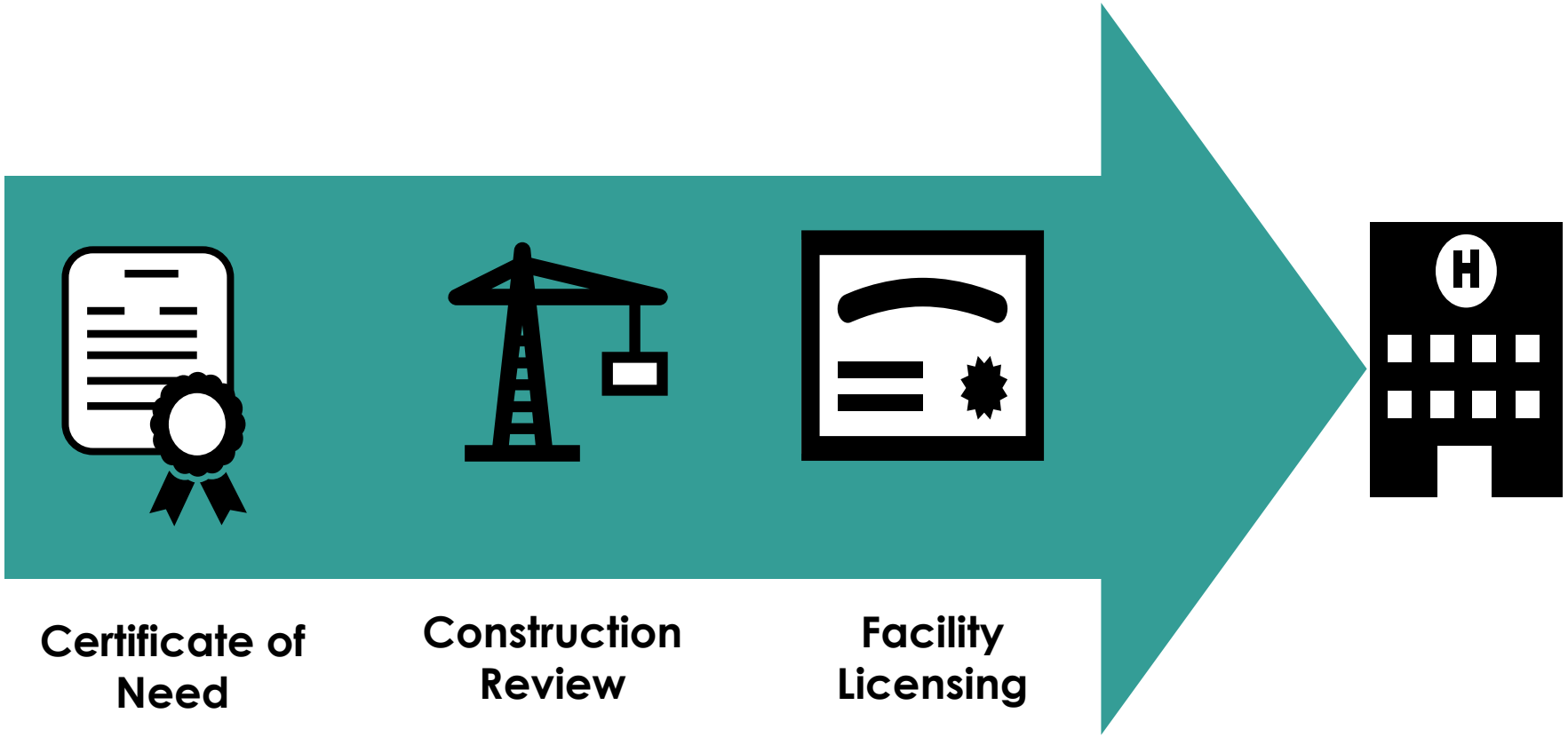
People in communities have access to needed, safe and affordable healthcare.

DOH 260-046 June 2022

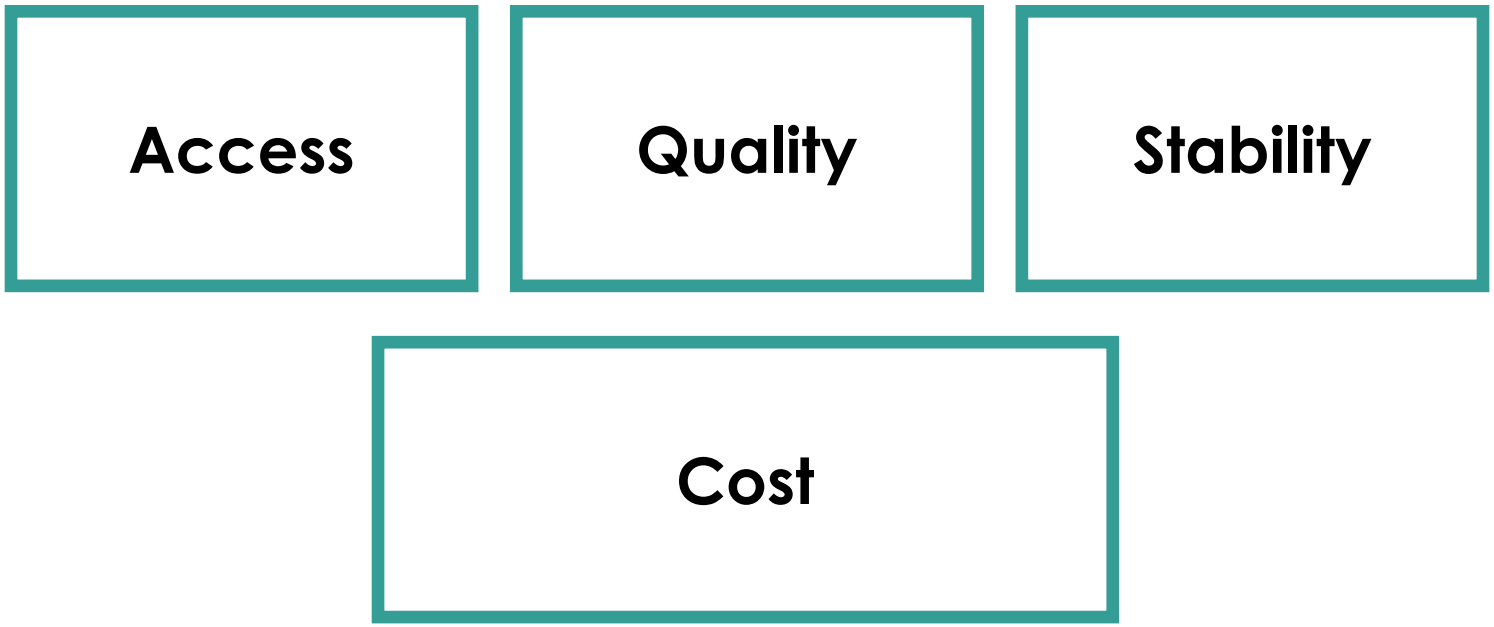
What is Certificate of Need (CN)?

CN promotes the planned and orderly development of healthcare facilities.

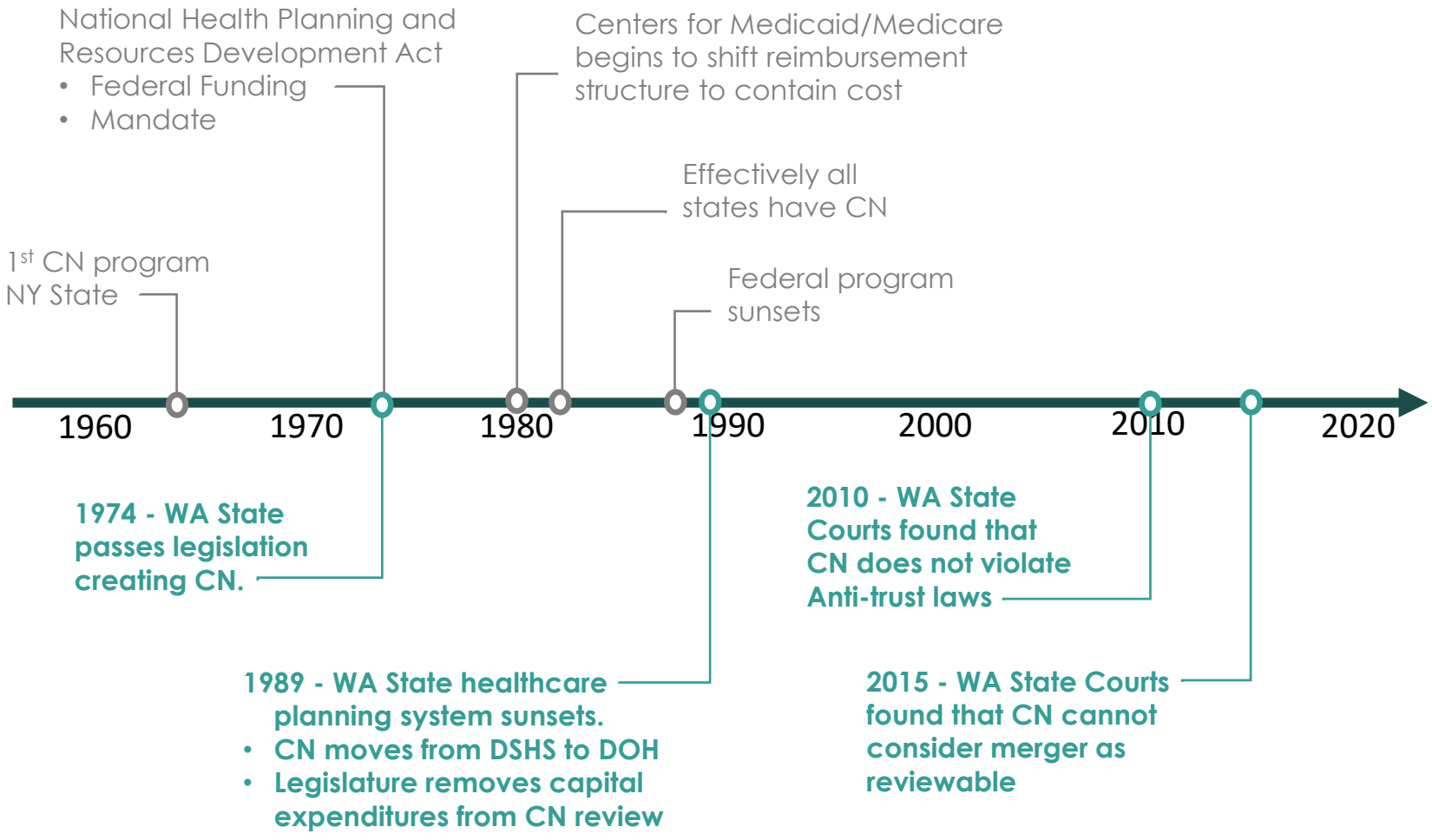
Facility Development Programs



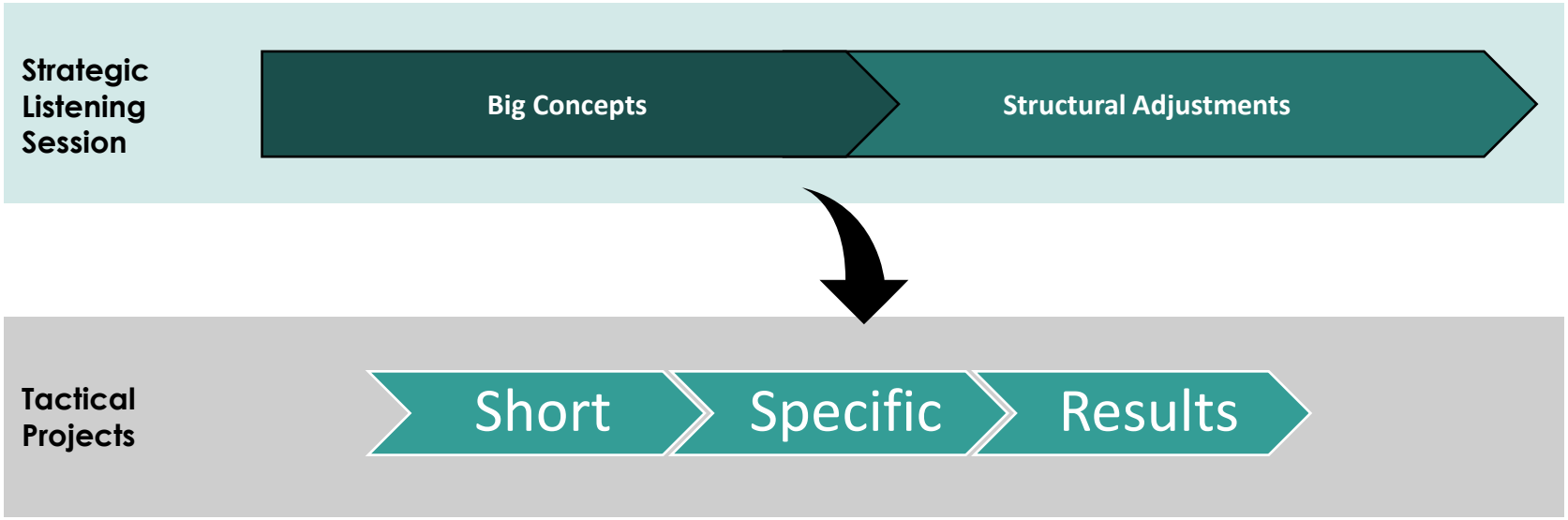
Ideas behind CN



History of CN in Washington



Two Tracks


Strategic Listening Session
Big Concepts
Structural Adjustments
Tactical Projects
Short
Specific
Results

Listening Sessions

Strategic Project

Big Concepts → **Structural Adjustments**

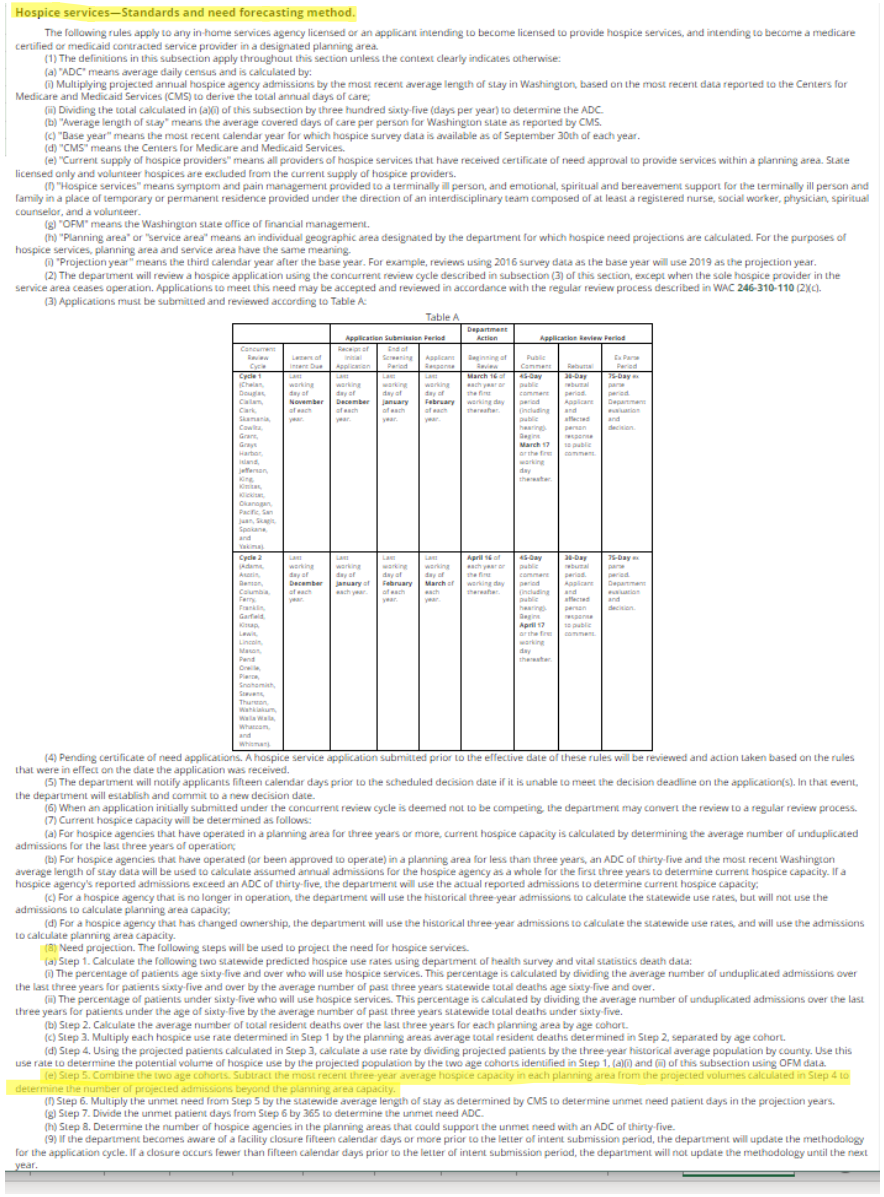
Rulemaking Workshops

Tactical Projects

- Hospice methodology
- PCI hospital volume standards

Hospice methodology

WAC 246-310-290(8)(e)



Hospice services—Standards and need forecasting method.

The following rules apply to any in-home services agency licensed or an applicant intending to become licensed to provide hospice services, and intending to become a medicare certified or medicaid contracted service provider in a designated planning area.

(1) The definitions in this subsection apply throughout this section unless the context clearly indicates otherwise:

(a) "ADC" means average daily census and is calculated by:

(i) Multiplying projected annual hospice agency admissions by the most recent average length of stay in Washington, based on the most recent data reported to the Centers for Medicare and Medicaid Services (CMS) to derive the total annual days of care;

(ii) Dividing the total calculated in (a)(i) of this subsection by three hundred sixty-five (days per year) to determine the ADC.

(b) "Average length of stay" means the average covered days of care per person for Washington state as reported by CMS.

(c) "Base year" means the most recent calendar year for which hospice survey data is available as of September 30th of each year.

(d) "CMS" means the Centers for Medicare and Medicaid Services.

(e) "Current supply of hospice providers" means all providers of hospice services that have received certificate of need approval to provide services within a planning area. State licensed only and volunteer hospices are excluded from the current supply of hospice providers.

(f) "Hospice services" means symptom and pain management provided to a terminally ill person, and emotional, spiritual and bereavement support for the terminally ill person and family in a place of temporary or permanent residence provided under the direction of an interdisciplinary team composed of at least a registered nurse, social worker, physician, spiritual counselor, and a volunteer.

(g) "OFM" means the Washington state office of financial management.

(h) "Planning area" or "service area" means an individual geographic area designated by the department for which hospice need projections are calculated. For the purposes of hospice services, planning area and service area have the same meaning.

(i) "Projection year" means the third calendar year after the base year. For example, reviews using 2016 survey data as the base year will use 2019 as the projection year.

(2) The department will review a hospice application using the concurrent review cycle described in subsection (3) of this section, except when the sole hospice provider in the service area ceases operation. Applications to meet this need may be accepted and reviewed in accordance with the regular review process described in WAC **246-310-110** (2)(c).

(3) Applications must be submitted and reviewed according to Table A:

Table A

		Application Submission Period			Department Action	Application Review Period		
Concurrent Review Cycle	Letters of Intent Due	Receipt of Initial Application	End of Screening Period	Applicant Response	Beginning of Review	Public Comment	Rebuttal	Ex Parte Period
Cycle 1 (Chelan, Douglas, Clallam, Clark, Skamania, Cowlitz, Grant, Grays Harbor, Island, Jefferson, King, Kitsap, Kittitas, Klickitat, Okanogan, Pacific, San Juan, Skagit, Spokane, and Yakima).	Last working day of **November** of each year.	Last working day of **December** of each year.	Last working day of **January** of each year.	Last working day of **February** of each year.	**March 16** of each year or the first working day thereafter.	**45-Day** public comment period (including public hearing). Begins **March 17** or the first working day thereafter.	**30-Day** rebuttal period. Applicant and affected person response to public comment.	**75-Day** ex parte period. Department evaluation and decision.
Cycle 2 (Adams, Asotin, Benton, Columbia, Ferry, Franklin, Garfield, Kitsap, Lewis, Lincoln, Mason, Pend Oreille, Pierce, Snohomish, Stevens, Thurston, Wahkiakum, Walla Walla, Whatcom, and Whitman).	Last working day of **December** of each year.	Last working day of **January** of each year.	Last working day of **February** of each year.	Last working day of **March** of each year.	**April 16** of each year or the first working day thereafter.	**45-Day** public comment period (including public hearing). Begins **April 17** or the first working day thereafter.	**30-Day** rebuttal period. Applicant and affected person response to public comment.	**75-Day** ex parte period. Department evaluation and decision.

(4) Pending certificate of need applications. A hospice service application submitted prior to the effective date of these rules will be reviewed and action taken based on the rules that were in effect on the date the application was received.

(5) The department will notify applicants fifteen calendar days prior to the scheduled decision date if it is unable to meet the decision deadline on the application(s). In that event, the department will establish and commit to a new decision date.

(6) When an application initially submitted under the concurrent review cycle is deemed not to be competing, the department may convert the review to a regular review process.

(7) Current hospice capacity will be determined as follows:

(a) For hospice agencies that have operated in a planning area for three years or more, current hospice capacity is calculated by determining the average number of unduplicated admissions for the last three years of operation;

(b) For hospice agencies that have operated (or been approved to operate) in a planning area for less than three years, an ADC of thirty-five and the most recent Washington average length of stay data will be used to calculate assumed annual admissions for the hospice agency as a whole for the first three years to determine current hospice capacity. If a hospice agency's reported admissions exceed an ADC of thirty-five, the department will use the actual reported admissions to determine current hospice capacity;

(c) For a hospice agency that is no longer in operation, the department will use the historical three-year admissions to calculate the statewide use rates, but will not use the admissions to calculate planning area capacity;

(d) For a hospice agency that has changed ownership, the department will use the historical three-year admissions to calculate the statewide use rates, and will use the admissions to calculate planning area capacity.

(8) Need projection. The following steps will be used to project the need for hospice services.

(a) Step 1. Calculate the following two statewide predicted hospice use rates using department of health survey and vital statistics death data:

(i) The percentage of patients age sixty-five and over who will use hospice services. This percentage is calculated by dividing the average number of unduplicated admissions over the last three years for patients sixty-five and over by the average number of past three years statewide total deaths age sixty-five and over.

(ii) The percentage of patients under sixty-five who will use hospice services. This percentage is calculated by dividing the average number of unduplicated admissions over the last three years for patients under the age of sixty-five by the average number of past three years statewide total deaths under sixty-five.

(b) Step 2. Calculate the average number of total resident deaths over the last three years for each planning area by age cohort.

(c) Step 3. Multiply each hospice use rate determined in Step 1 by the planning areas average total resident deaths determined in Step 2, separated by age cohort.

(d) Step 4. Using the projected patients calculated in Step 3, calculate a use rate by dividing projected patients by the three-year historical average population by county. Use this use rate to determine the potential volume of hospice use by the projected population by the two age cohorts identified in Step 1, (a)(i) and (ii) of this subsection using OFM data.

(e) Step 5. Combine the two age cohorts. Subtract the most recent three-year average hospice capacity in each planning area from the projected volumes calculated in Step 4 to determine the number of projected admissions beyond the planning area capacity.

(f) Step 6. Multiply the unmet need from Step 5 by the statewide average length of stay as determined by CMS to determine unmet need patient days in the projection years.

(g) Step 7. Divide the unmet patient days from Step 6 by 365 to determine the unmet need ADC.

(h) Step 8. Determine the number of hospice agencies in the planning areas that could support the unmet need with an ADC of thirty-five.

(9) If the department becomes aware of a facility closure fifteen calendar days or more prior to the letter of intent submission period, the department will update the methodology for the application cycle. If a closure occurs fewer than fifteen calendar days prior to the letter of intent submission period, the department will not update the methodology until the next year.

new decision date.

(2) The department may not accept new applications for a planning area if there are any pending applications in that planning area filed under a previous concurrent review cycle, or applications submitted prior to the effective date of these rules that affect any of the new planning areas, unless the department has not made a decision on the pending applications within the review timelines of nine months for a concurrent review and six months for a regular review.

(3) If the department determines that an application does not compete with another application, it may convert the review of an application that was initially submitted under a concurrent review cycle to a regular review process.

[Statutory Authority: RCW **70.38.128**. WSR 09-01-113, § 246-310-710, filed 12/19/08, effective 12/19/08.]

PDF **246-310-715**

General requirements.

The applicant hospital must:

(1) Submit a detailed analysis of the impact that their new adult elective PCI services will have on the Cardiovascular Disease and Interventional Cardiology Fellowship Training programs at the University of Washington, and allow the university an opportunity to respond. New programs may not reduce current volumes at the University of Washington fellowship training program.

(2) Submit a detailed analysis of the projected volume of adult elective PCIs that it anticipates it will perform in years one, two and three after it begins operations. All new elective PCI programs must comply with the state of Washington annual PCI volume standards of ((two hundred)) by the end of year three. The projected volumes must be sufficient to assure that all physicians working only at the applicant hospital will be able to meet volume standards of fifty PCIs per year. If an applicant hospital fails to meet annual volume standards, the department may conduct a review of certificate of need approval for the program under WAC **246-310-755**.

(3) Submit a plan detailing how they will effectively recruit and staff the new program with qualified nurses, catheterization laboratory technicians, and interventional cardiologists without negatively affecting existing staffing at PCI programs in the same planning area.

(4) Maintain one catheterization lab used primarily for cardiology. The lab must be a fully equipped cardiac catheterization laboratory with all appropriate devices, optimal digital imaging systems, life sustaining apparati, intra-aortic balloon pump assist device (IABP). The lab must be staffed by qualified, experienced nursing and technical staff with documented competencies in the treatment of acutely ill patients.

(5) Be prepared and staffed to perform emergent PCIs twenty-four hours per day, seven days per week in addition to the scheduled PCIs.

(6) If an existing CON approved heart surgery program relinquishes the CON for heart surgery, the facility must apply for an amended CON to continue elective PCI services. The applicant must demonstrate ability to meet the elective PCI standards in this chapter.

[Statutory Authority: RCW **70.38.135** and **70.38.115**. WSR 18-07-102, § 246-310-715, filed 3/20/18, effective 4/20/18. Statutory Authority: RCW **70.38.128**. WSR 09-01-113, § 246-310-715, filed 12/19/08, effective 12/19/08.]

PDF **246-310-720**

Hospital volume standards.

(1) Hospitals with an elective PCI program must perform a minimum of two hundred adult PCIs per year by the end of the third year of operation and each year thereafter.

(2) The department shall only grant a certificate of need to new programs within the identified planning area if:

(a) The state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area; and

(b) All existing PCI programs in that planning area are meeting or exceeding the minimum volume standard.

[Statutory Authority: RCW **70.38.135** and **70.38.115**. WSR 18-07-102, § 246-310-720, filed 3/20/18, effective 4/20/18. Statutory Authority: RCW **70.38.128**. WSR 09-01-113, § 246-310-720, filed 12/19/08, effective 12/19/08.]

PDF **246-310-725**

Physician volume standards.

Physicians performing adult elective PCI procedures at the applying hospital must perform a minimum of fifty PCIs per year. Applicant hospitals must provide documentation that physicians performed fifty PCI procedures per year for the previous three years prior to the applicant's CON request.

[Statutory Authority: RCW **70.38.135** and **70.38.115**. WSR 18-07-102, § 246-310-725, filed 3/20/18, effective 4/20/18. Statutory Authority: RCW **70.38.128**. WSR 09-01-113, § 246-310-725, filed 12/19/08, effective 12/19/08.]

PDF **246-310-730**

Staffing requirements.

The applicant hospital must:

(1) Employ a sufficient number of properly credentialed physicians so that both emergent and elective PCIs can be performed.

(2) Staff its catheterization laboratory with a qualified, trained team of technicians experienced in interventional lab procedures.

(a) Nursing staff should have coronary care unit experience and have demonstrated competency in operating PCI related technologies.

(b) Staff should be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.

[Statutory Authority: RCW **70.38.128**. WSR 09-01-113, § 246-310-730, filed 12/19/08, effective 12/19/08.]

PDF **246-310-735**

Partnering agreements.

The applicant hospital must have a signed written agreement with a hospital providing on-site cardiac surgery. This agreement must include, at minimum, provisions for:

(1) Coordination between the nonsurgical hospital and surgical hospital's availability of surgical teams and operating rooms. The hospital with on-site surgical services is not required to maintain an available surgical suite twenty-four hours, seven days a week.

(2) Assurance the backup surgical hospital can provide cardiac surgery during all hours that elective PCIs are being performed at the applicant hospital.

(3) Transfer of all clinical data, including images and videos, with the patient to the backup surgical hospital.

(4) Communication by the physician(s) performing the elective PCI to the backup hospital cardiac surgeon(s) about the clinical reasons for urgent transfer and the patient's clinical condition.

(5) Acceptance of all referred patients by the backup surgical hospital.

(6) The applicant hospital's mode of emergency transport for patients requiring urgent transfer. The hospital must have a signed transportation agreement with a vendor who will expeditiously transport by air or land all patients who experience complications during elective PCIs that require transfer to a backup hospital with on-site cardiac surgery.

(7) Emergency transportation beginning within twenty minutes of the initial identification of a complication.

(8) Evidence that the emergency transport staff are certified. These staff must be advanced cardiac life support (ACLS) certified and have the skills, experience, and equipment to monitor and treat the patient en route and to manage an intra-aortic balloon pump (IABP).

(9) The hospital documenting the transportation time from the decision to transfer the patient with an elective PCI complication to arrival in the operating room of the backup hospital. Transportation time must be less than one hundred twenty minutes.

(10) At least two annual timed emergency transportation drills with outcomes reported to the hospital's quality assurance program.

(11) Patient signed informed consent for adult elective (and emergent) PCIs. Consent forms must explicitly communicate to the patients that the intervention is being performed without on-site surgery backup and address risks related to transfer, the risk of urgent surgery, and the established emergency transfer agreements.

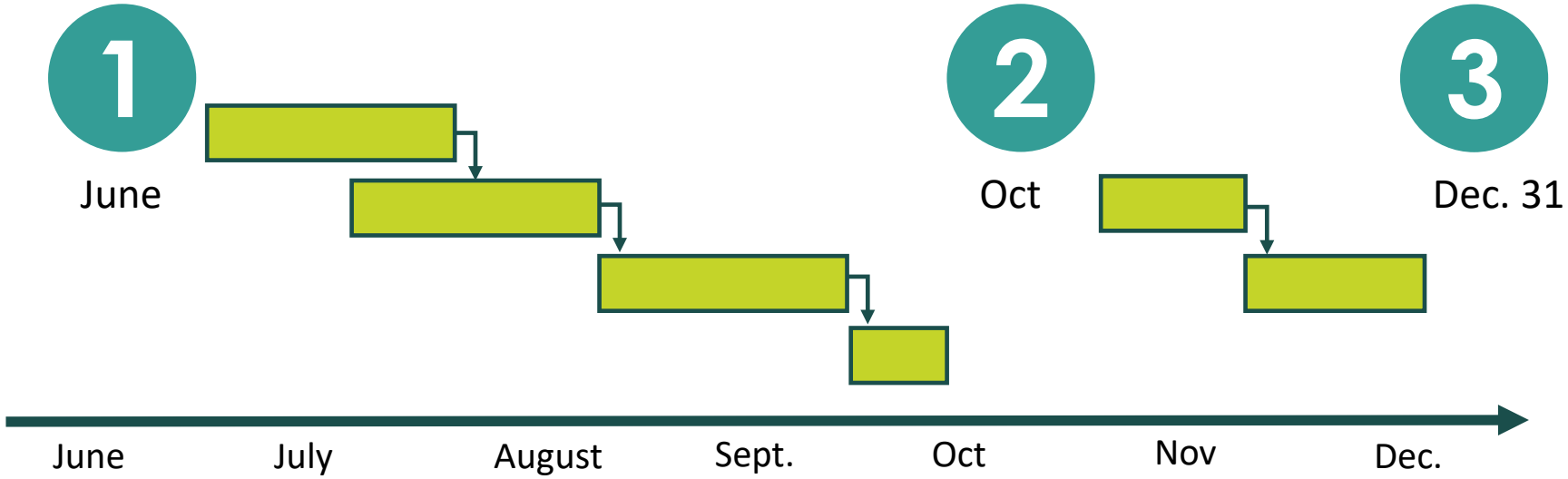
(12) Conferences between representatives from the heart surgery program(s) and the elective coronary intervention program. These conferences must be held at least quarterly, in which a significant number of preoperative and post-operative cases are reviewed, including all transport cases.

(13) Addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.).

[Statutory Authority: RCW **70.38.128**. WSR 09-01-113, § 246-310-735, filed 12/19/08, effective 12/19/08.]

PCI volume standards

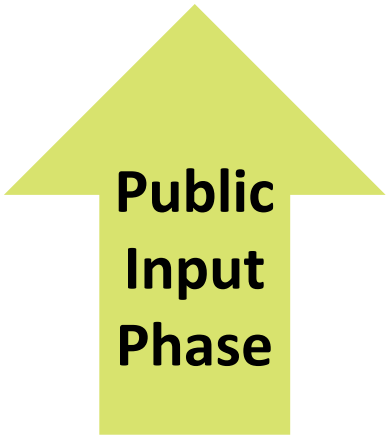
WAC 246-310-720(2)

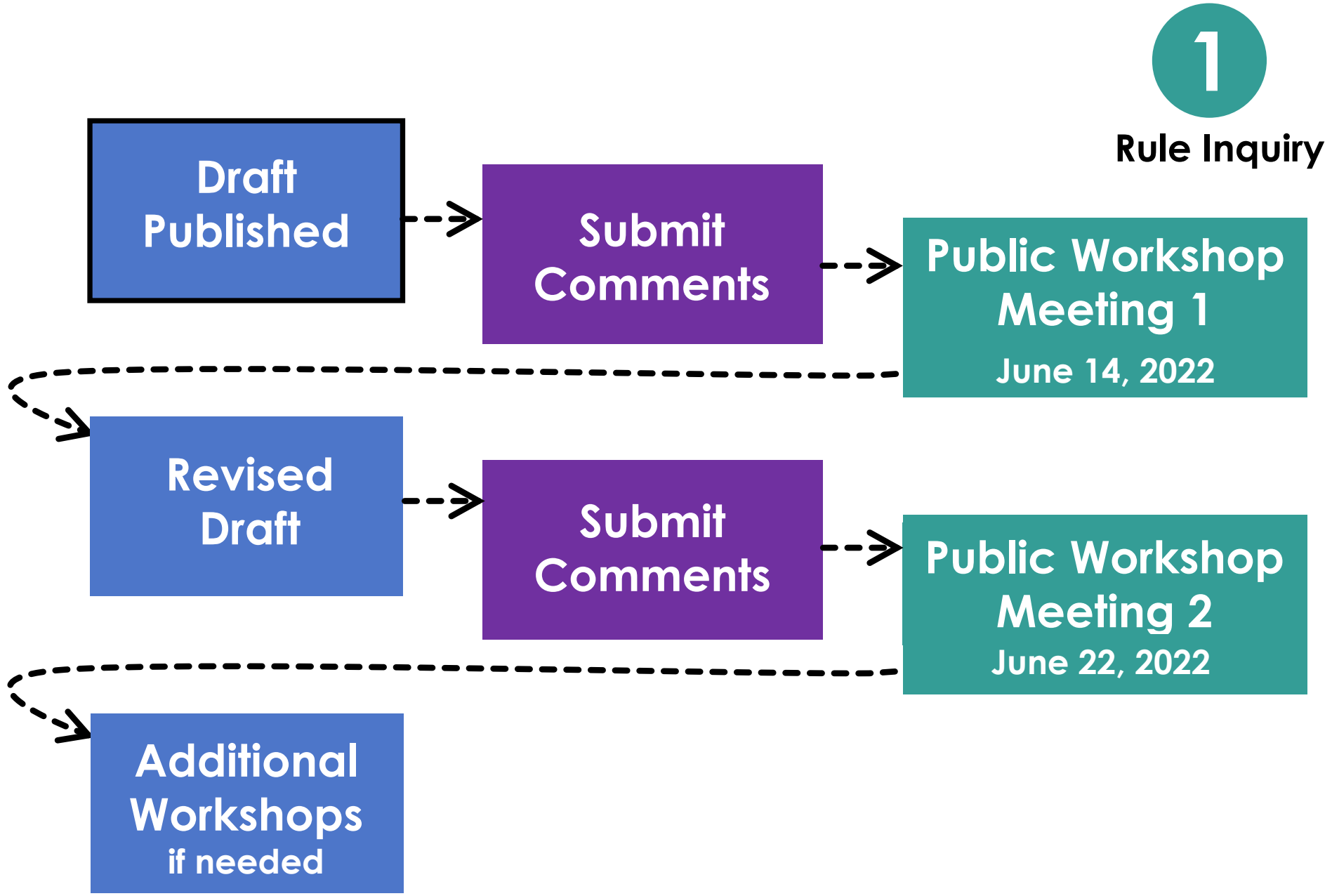


2022

Rule Development Process

1. **Rule Inquiry**
2. **Rule Proposal**
3. **Rule Adoption**

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Rule Inquiry
Draft Published
Submit Comments
Public Workshop Meeting 1
June 14, 2022
Revised Draft
Submit Comments
Public Workshop Meeting 2
June 22, 2022
Additional Workshops
if needed

1

Rule Inquiry

Public Workshop

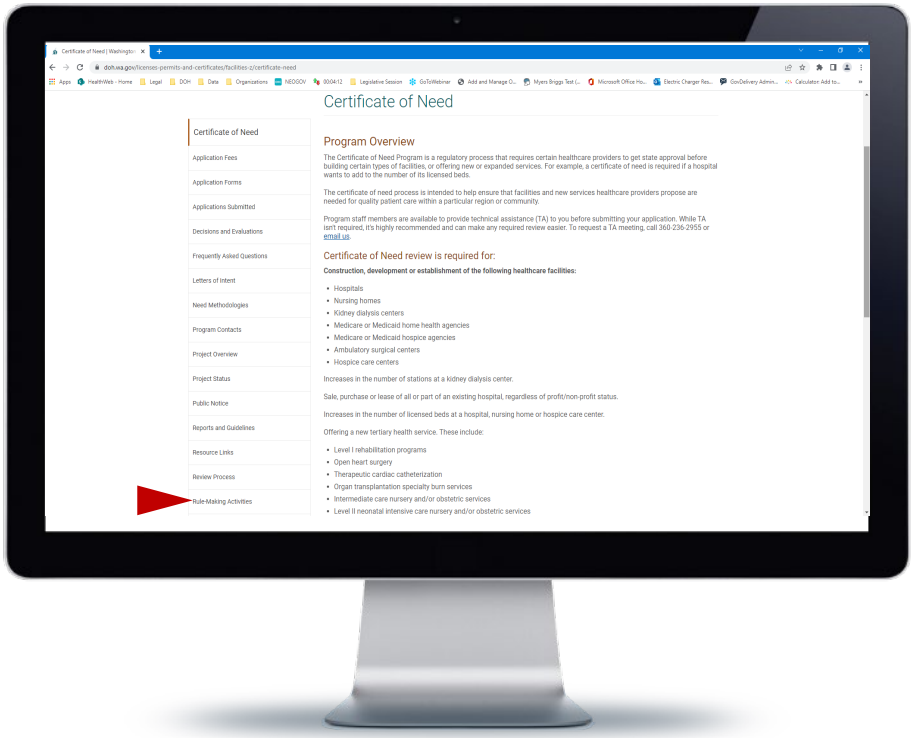
- Topics include:
  - Process overview
  - PCI
  - Hospice methodology
- Provide feedback on the draft (verbal or written)

Draft published:

Hospital volume for PCI

and

Hospice methodology



www.doh.wa.gov/cn

Listserv (GovDelivery)

CNRulemaking@doh.wa.gov

Three Phases of Rule Development

1. **Rule Inquiry**
2. **Rule Proposal**
3. **Rule Adoption**

Public rules hearing date:

Mid-October 2022

Three Phases of Rule Development

1. **Rule Inquiry**
2. **Rule Proposal**
3. **Rule Adoption**

Goal effective date:
end of December 2022

Questions

Certificate of Need Website

www.doh.wa.gov/cn

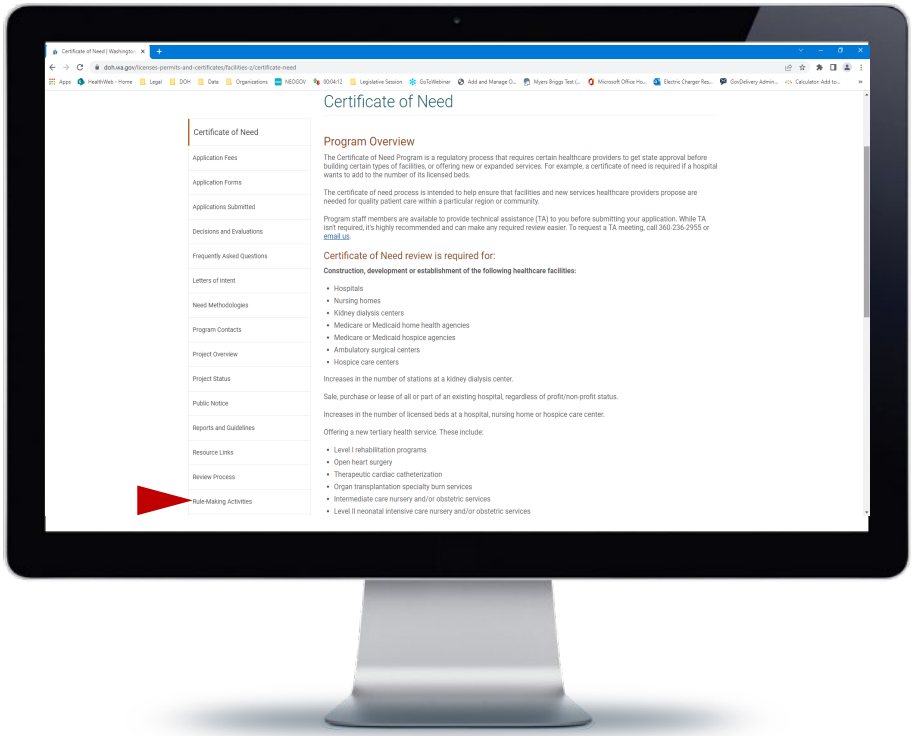
Listserv (GovDelivery)

- June Workshops
- Listening Sessions
- Updates

Rule-Making Activities

- Drafts
- Updates
- Contacts

CNRulemaking@doh.wa.gov



Introductions

John Williams

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Eric Hernandez

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