Harborview Medical Center
Elective PCI Rulemaking
Rules Workshop Presentation and Discussion

DECEMBER 5, 2024

UW Medicine

Harborview's Mission:

To provide healthcare for the most vulnerable residents of King County; to provide and teach exemplary patient care; to provide care for a broad spectrum of patients from throughout the region; and to develop and maintain leading – edge centers of emphasis.

As the only Level I Adult and Pediatric Trauma Center in Washington, Harborview Medical Center provides specialized comprehensive emergency services to patients throughout the region and serves as the disaster preparedness and disaster control hospital for Seattle and King County.

The following groups of patients and programs are given priority for care:

- Persons who are non-English speaking poor
- Persons who are uninsured or underinsured
- Persons who experience domestic violence
- Persons who experience sexual assault
- Persons incarcerated in King County's Jails
- Persons with mental illness, particularly those treated involuntarily
- Persons with substance abuse
- Persons with sexually transmitted diseases
- Persons who require specialized emergency care
- Persons who require trauma care
- Persons who require burn care

Our goal today is to keep, at the forefront, Harborview's mission population and the rule changes we believe are necessary to ensure equitable care delivery.

- We have been actively engaged in the Sub-Committee that has met regularly and support its recommended changes to the methodology and the non-numeric need direction, as well as other select changes.

- There has been consensus that in lieu of tackling planning area definitions, and in recognition that no methodology is perfect, a non-numeric path should be added.

- We also want to reiterate the inter-relationship of proposed rule changes; should one change not be modified or adopted; it does have impacts on the remaining, which will require rework.

Harborview at a Glance

- Largest public safety net hospital in Washington.
- 70% of patient revenue is Medicaid, Medicare and over governmental payers.
- Under hospital services agreement with King County, express mission is to treat every patient who comes to us, regardless of economic, social or legal status.
- Clinical teaching hospital for UW School of Medicine.
- Designated Level I adult and pediatric trauma center and the disaster preparedness and disaster control hospital for King County.
- The tertiary referral site for local FQHC's (NeighborCare, SeaMar, ICHS, HealthPoint). Patients who seek care at Harborview are generally challenged to get care at another provider; due in part to transportation barriers for the mission population and navigation through unfamiliar neighborhoods and hospitals. This results in high rates of no-shows for referred patients.

Harborview has been Pursuing Rule Change For More than 5 years.

- **July 8, 2019** - Petition for Rulemaking submitted to DOH.
- **September 2019** - DOH notifies Harborview that it will open chapter 246-310 WAC, Certificate of Need, to clarify, streamline and modernize the rules including consideration of request to update elective PCI rules.
- **May-October 2022** - DOH holds series of Strategic Listening Sessions to identify changes and to gain input on two “tactical” projects including PCI. Intent was to have rules finalized by 12/31/2022.
- **January 2023** - Harborview sends another request to DOH to commence rulemaking, with no response.
- **January 2024** - Harborview sends another request to DOH. Response received indicating that CR101 was filed on January 16, 2024.
- First rulemaking meeting held in **June 2024**.
- We acknowledge and appreciate the current progress, but note that rulemaking will continue well 2025, meaning applications not likely to be accepted until 2026.

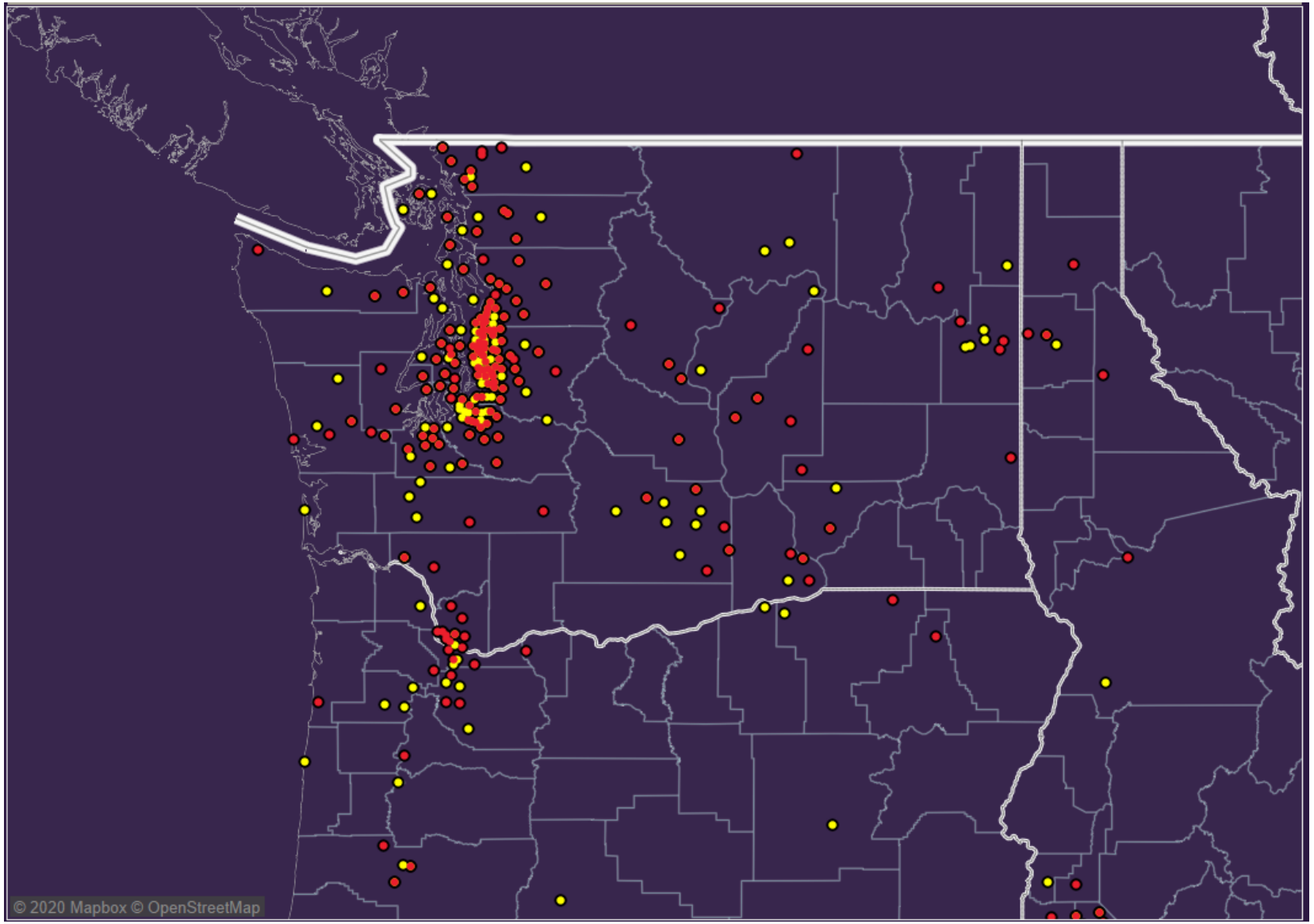
Requested Rule Change was Narrow:

- **Requested Change to WAC 246-310-720 (3) was intended to eliminate a Planning Area definition flaw inherent in the current rules that increases clinical risk, results in duplication, has the potential to impact outcomes, and disproportionately affects Harborview's mission population.**
- **Harborview's proposal was to allow an applicant to be approved absent numeric need, if the applicant;**
  a) Can demonstrate using CHARS, COAP and internal data for the most recent 12-month period for which data is available, that it already manages 200 PCI cases, inclusive of cases actually performed at the applicant hospital, and cases referred to other providers;
  b) Has operated and staffed a cardiac catheterization laboratory 24/7 and performed emergency PCI for at least 10 years; and
  c) Serves a vulnerable population with a rate of at least 40% Medicaid/under or non-insured.

We have previously shared a visual demonstrating the issue with the current Numeric Need methodology.

West King: 2019
UWMC PCI Referrals

- **Yellow = PCI**
- **Red = CTO PCI**
- **Total PCI = Both**

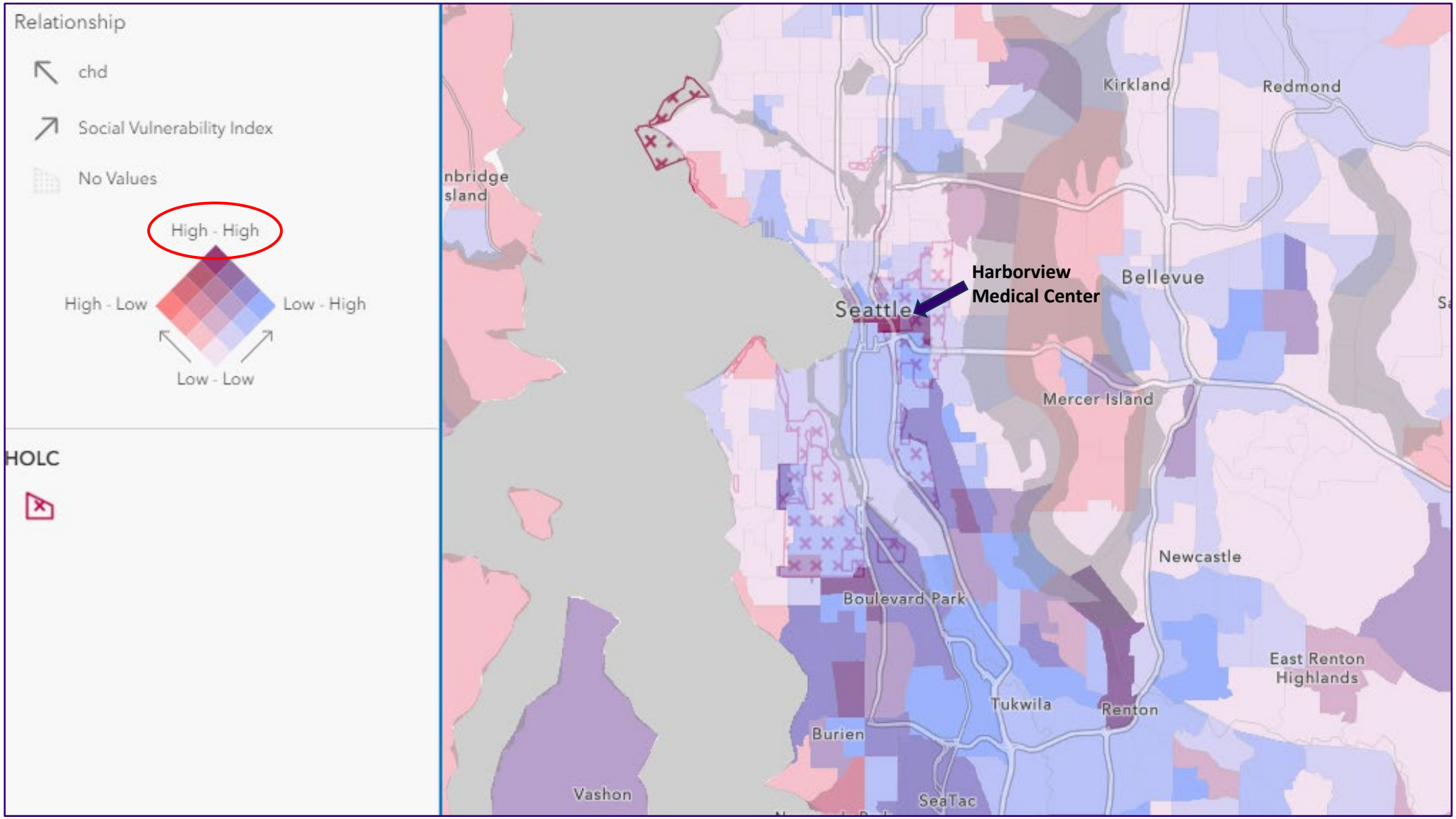


A reminder:

- Harborview's PCI patients are disproportionately minority, including 20% American Indian and 13% Pacific Islander.
- Over past few years, Harborview has referred as many delayed interventions as emergent PCIs. (Delayed Interventions are PCI procedures performed later than the initial PCI or diagnostic catheterization). To date, no shows, are about 16% and deaths are 1.6%.
- Concur with the comments of the COAP medical directors (Drs. Hira and Doll), that the lower volume emergency-only programs in the State should be prioritized in adding elective

As our Community Outreach Clinical Nurse Practitioners demonstrated during their presentation at the August PCI rules meeting, this is an issue of equity for the communities we serve:

Coronary Heart Disease Burden and Social Vulnerability Index



The current draft of the non-numeric path allows the CN Program to approve if:

Draft Non-Numeric Language	Harborview Suggestion
(a) All applicable review criteria and standards with the exception of numeric need have been met;	Given flattening PCI volumes, need to assure that an applicant can achieve 200. Would like to see more elaboration, including our original language, which read: *Can demonstrate using CHARS, COAP and internal data for the most recent 12-month period for which data is available, that it already manages 200 PCI cases, inclusive of cases actually performed at the applicant hospital, and cases referred to other providers* *The 200 language, should also read achieve 200 annually*
(b) The applicant commits to serving Medicare and Medicaid patients	None
(c) Approval under these non-numeric need will not cause existing CN-approved provider(s) to fall below 200 PCIs	None, but makes (a) more critical

Current draft of the non-numeric path, continued. Harborview also recommend limiting this path to hospitals, and exclude other settings:

Draft Non-Numeric Language	Harborview Recommendation
(a) (d) The applicant demonstrates the ability to address at least one of the following non-numeric criteria. Applicants must include empirical data that supports their non-numeric need application. This information must be publicly available and replicable. The non-numeric need criteria are: (a) Demonstration an applicant's request would substantially improve access to communities with documented barriers to access and/or higher disease burdens which result in poorer cardiovascular health outcomes. These communities include low-income and uninsured populations, as well as demographics with higher rates of identifiable risk factors for cardiovascular disease. These measures would be compared to Statewide or National averages as appropriate. (b) Demonstration that an applicant's request would improve access in a PCI Planning Area that lacks a CN-approved elective PCI provider. (c) An existing emergent-only provider has operated for at least three consecutive years and seeks to add elective.	Demonstration of substantial improvement in access in communities with documented barriers and higher disease burdens should top priority. Harborview agrees with 3 years for an existing emergent program but acknowledges that there could be circumstances where there may be lapses. Recommend eliminating word "consecutive" and instead focus on clinical infrastructure and outcomes.

Reiterating our Workshop 1 Request for Acceleration, Adoption and Effective Date Prior to YE 2024 for the Changes Requested.

- Continuation of the current rules means that patients will continue to experience unnecessary delays in care; especially Harborview's mission patients.

- Our petition is now more than 5 years old.

Questions?

Thank You