HARBORVIEW MEDICAL CENTER
UW Medicine | King County

January 4, 2023

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Washington State Department of Health
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Eric Hernandez, Manager – Certificate of Need
Office of Community Health Systems
Washington State Department of Health
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Certificate of Need Rules – Feedback on Percutaneous Coronary Interventions

Dear Mr. Corbridge and Mr. Hernandez,

Three years ago, Harborview Medical Center ("Harborview") petitioned the Washington State Department of Health ("DOH") pursuant to RCW 34.05.330 and chapter 82-05-020 WAC to undertake rulemaking to amend current certificate of need ("CN") rules concerning elective percutaneous coronary interventions ("PCI"). The requested amendment would eliminate a flaw inherent in the current rules that increases clinical risk, results in duplication, has the potential to negatively impact health outcomes, results in higher costs, and disproportionately affects Harborview's mission population—which includes the most vulnerable residents of King County.

With DOH now opening the entire chapter of CN rules, Harborview would like to present its request again as a written comment in response to the CN PCI listening sessions held by DOH. In the listening sessions, DOH has sought feedback on ideas to make the CN rules more equitable. Harborview's petition sought, and continues to seek, to address an issue of inequity. The current language negatively impacts access and continuity of care for vulnerable and traditionally marginalized residents. Because of the limitations of the current rule, Harborview's mission population requiring planned cardiac procedures face delays in treatment. Despite our best efforts, in Fiscal Year 2022 alone, at least 10% of patients did not show up for the scheduled procedure at another hospital. This rate is too high in our vulnerable patients as most are lost to follow up; meaning, we often do not have another chance to intervene before a cardiac event occurs.

We urge DOH to use this rulemaking opportunity to address what we believe is a shared goal, anchored in principles of health equity; to provide the right care to the most vulnerable patients who may

otherwise delay or forgo needed care. As DOH sets priority topics for the upcoming rulemaking sessions, we ask DOH to make PCI the top priority.

Our proposed draft language is attached to this letter as **Attachment A**. We have also included our original petition (**Attachment B**) that includes additional thoughts about how a hospital could demonstrate access and equity issues that impact care for marginalized populations. As advocates for our patients, time is of the essence; we urge prioritization of the PCI inequity issue. The fact that the current inequitable delivery system will continue at least one more year as rulemaking proceeds is concerning.

We appreciate your consideration of our petition. Harborview is prepared to respond to any questions that the Department may have and would be happy to set up a call to discuss if it would be useful.

Sincerely,

Sommer Kleweno Walley, MHA, MA, CCC-SLP
Chief Executive Officer
Harborview Medical Center

Attachment A – Proposed Draft Language
Attachment B – Original Petition

ATTACHMENT A – Proposed Draft Language

The specific rule change would occur at WACs 246-310-720 and 246-310-745:

WAC 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.

(3) The department may grant a certificate of need to new programs within the planning area if:

(a) The state need forecasting methodology does not project unmet volumes sufficient to establish one or more programs; and

(b) The applicant demonstrates that it:

i. Already manages 200 PCI cases, inclusive of cases actually performed at the applicant hospital and cases they refer to other providers;

ii. Has operated and staffed a cardiac catheterization laboratory 24/7 and performed emergency PCI for at least 10 years; and

iii. Serves a vulnerable population with a rate of at least 40% Medicaid/under or non-insured,

WAC 246-310-745- Need Forecasting Methodology

For the purposes of the need forecasting method in this section, the following terms have the following specific meanings:

(1) "Base year" means the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the department's CHARS reports or successor reports.

(2) "Current capacity" means the sum of all PCIs performed on people (aged fifteen years of age and older) by all certificate of need approved adult elective PCI programs, or department grandfathered programs within the planning area. To determine the current capacity for those planning areas where a new program has operated less than three years, the department will measure the volume of that hospital as the greater of:

(a) The actual volume; or

(b) The minimum volume standard for an elective PCI program established in WAC **246-310-720**.

(3) "Forecast year" means the fifth year after the base year.

(4) "Percutaneous coronary interventions" means cases as defined by diagnosis related groups (DRGs) as developed under the Centers for Medicare and Medicaid Services (CMS) contract that describe catheter-based interventions involving the coronary arteries and great arteries of the chest. The department will exclude all pediatric catheter-based therapeutic and diagnostic interventions performed on persons fourteen years of age and younger are excluded. The department will update the list of DRGs administratively to reflect future revisions made by CMS to the DRG to be considered in certificate of need definitions, analyses, and decisions. The DRGs for calendar year 2008 applications will be DRGs reported in 2007, which include DRGs 518, 555, 556, 557 and 558.

(5) "Use rate" or "PCI use rate," equals the number of PCIs performed on the residents of a planning area (aged fifteen years of age and older), per one thousand persons.

(6) "Grandfathered programs" means those hospitals operating a certificate of need approved interventional cardiac catheterization program or heart surgery program prior to the effective date of these rules, that continue to operate a heart surgery program. For hospitals with jointly operated programs, only the hospital where the program's procedures were approved to be performed may be grandfathered.

(7) The data sources for adult elective PCI case volumes include:

(a) The comprehensive hospital abstract reporting system (CHARS) data from the department, office of hospital and patient data;

(b) The department's office of certificate of need survey data as compiled, by planning area, from hospital providers of PCIs to state residents (including patient origin information, i.e., patients' zip codes and a delineation of whether the PCI was performed on an inpatient or outpatient basis); and

(c) Clinical outcomes assessment program (COAP) data from the foundation for health care quality, as provided by the department.

(8) The data source for population estimates and forecasts is the office of financial management medium growth series population trend reports or if not available for the planning area, other population data published by well-recognized demographic firms.

(9) The data used for evaluating applications submitted during the concurrent review cycle must be the most recent year end data as reported by CHARS or the most recent survey data available through the department or COAP data for the appropriate application year. The forecasts for demand and supply will be for five years following the base year. The base year is the latest year that full calendar year data is available from CHARS. In recognition that CHARS does not currently provide outpatient volume statistics but is patient origin-specific and COAP does provide outpatient PCI case volumes by hospitals but is not currently patient origin-specific, the department will make available PCI statistics from its hospital survey data, as necessary, to bridge the current outpatient patient origin-specific data shortfall with CHARS and COAP.

(10) Numeric methodology:

Step 1. Compute each planning area's PCI use rate calculated for persons fifteen years of age and older, including inpatient and outpatient PCI case counts.

(a) Take the total planning area's base year population residents fifteen years of age and older and divide by one thousand.

(b) Divide the total number of PCIs performed on the planning area residents over fifteen years of age by the result of Step 1 (a). This number represents the base year PCI use rate per thousand.

Step 2. Forecasting the demand for PCIs to be performed on the residents of the planning area.

(a) Take the planning area's use rate calculated in Step 1 (b) and multiply by the planning area's corresponding forecast year population of residents over fifteen years of age.

Step 3. Compute the planning area's current capacity.

(a) Identify all inpatient procedures at certificate of need approved hospitals within the planning area using CHARS data;

(b) Identify all outpatient procedures at certificate of need approved hospitals within the planning area using department survey data; or

(c) Calculate the difference between total PCI procedures by certificate of need approved hospitals within the planning area reported to COAP and CHARS. The difference represents outpatient procedures.

(d) Sum the results of (a) and (b) or sum the results of (a) and (c). This total is the planning area's current capacity which is assumed to remain constant over the forecast period.

Step 4. Calculate the net need for additional adult elective PCI procedures by subtracting the calculated capacity in Step 3 from the forecasted demand in Step 2. If the net need for procedures is less than two hundred, the department will not approve a new program, except for programs which may be approved under WAC 246-310-720 (3).

Step 5. If Step 4 is greater than two hundred, calculate the need for additional programs.

(a) Divide the number of projected procedures from Step 4 by two hundred.

(b) Round the results down to identify the number of needed programs. (For example: 375/200 = 1.875 or 1 program.)

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ATTACHMENT B - Original Petition

July 8, 2019

Tami Thompson, Regulatory Affairs Manager
Washington State Department ofHealth
Tami. Thompson@doh.wa .gov

Dear Ms. Thompson:

Pursuant to RCW 34.05.330 and chapter 82-05-020 WAC, Harborview Medical Center respectfully petitions the Washington State Department of Health to undertake rulemaking to amend current certificate of need (CN) rules concerning elective percutaneous coronary interventions. The requested change will eliminate a flaw inherent in the current rules that increases clinical risk, results in duplication, has the potential to impact outcomes, results in higher costs and disproportionately affects Harborview's mission population.

RCW 34.05.330 allows any person to petition a state agency to adopt, repeal, or amend any rule within its authority. Per RCW we understand that the Department of Health will respond to this petition within one business day acknowledging receipt of the petition, after which the Department has 60 days to respond to thepetition.

We appreciate your consideration of this petition, Harborview is prepared to timely respond to any questions that the Department may have.

Sincerely,

Paul Hayes, RN
Executive Director

Administration

Box 359717 325 9th Avenue SEATTLE, WA 98104 206.744.3036 FAX 206.744.8551

UW Medicine

HARBORVIEW MEDICAL CENTER

Petition to Amend Certificate of Need Rules- Elective Percutaneous Coronary Interventions July 8, 2019

1. Name and Address of Petitioners

Harborview Medical Center
325 9th Ave., Seattle, WA 98104
(206) 744.3000
Contact Information:
Sommer K. Kleweno-Walley,
Administrator Patient Care Services
skleweno@uw.edu

2. Name and Address of Agency Responsible for Administering the Rule

Washington State Department of Health, Certificate of Need Program
111 Israel Rd. S.E.
Tumwater, WA 98501
P. O. Box 47852
Olympia, WA 98504-7852

The Department is the state agency authorized and directed to implement the Health Planning and Development Act, chapter 70.38 RCW (the "Act") in the state of Washington. The Department has adopted the rules set forth in chapter 246-310 WAC to assist it in implementing the Act.

3. Rationale for Amendment of the Rule

This petition seeks to eliminate a flaw inherent in the current rules that increases clinical risk, results in duplication, has the potential to impact outcomes, results in higher costs and disproportionately affects Harborview's mission population.

In Washington, any hospital without on-site open-heart surgery is required to secure prior Certificate of Need (CN) approval before performing an elective Percutaneous Coronary Intervention (PCI). PCI is defined in WAC 246-310 as invasive but nonsurgical mechanical

procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries. Harborview does not have CN approval to perform elective PCI and under the current rules is unable to secure CN approval to do so.

Harborview has performed emergency percutaneous coronary interventions (PCI) for more than 15 years. Last year, it performed nearly 130 emergency PCIs and referred another 70 for elective PCI following a diagnostic catheterization. Absent CN approval, Harborview must transfer all patients that are not having an immediate event to other providers. The risk of the transfer has the potential to impact outcomes; it also creates duplication and increases costs. Importantly, Harborview's mission population is disproportionately Medicaid or under/non-insured, which can and does make the timely referral to other providers challenging. Transportation barriers for the mission population and navigation through unfamiliar neighborhoods and hospitals leads to high rates of no-show for those referred to other hospitals.

Because of the structure of the current rules, the "Planning Area" to which WAC assigns Harborview is projected to have a surplus of capacity for the foreseeable future. Any Harborview CN application, under the current rules, would be futile as the Department does not have the latitude to approve a CN application absent numeric need. The current rules also fail to recognize that Harborview has already achieved the minimum volume threshold of 200 cases annually, and that allowing its program to begin treating elective cases would have no demonstrable impact on any other existing hospital.

In addition, Harborview Medical Center (Harborview) provides tertiary and quaternary care for patients from throughout the Pacific Northwest, and is Washington's only designated Level I adult and pediatric trauma center and the disaster preparedness and disaster control hospital for King County. Harborview's mission includes providing care to the most vulnerable residents of King County and to provide and teach exemplary patient care. By virtue of its mission, Harborview is also safety net provider.

This petition seeks to directly address the clinical risk, duplication and higher costs associated with Harborview's inability to perform these procedures. Specifically, this petition requests a simple modification to allow hospitals to be approved regardless of whether need exists in the Planning Area as long as they meet certain criteria. Harborview proposes the following criteria:

1) 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 they refer 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.

4. Proposed Draft Language

The specific rule change would occur at WACs 246-310-720 and WAC 246-310-745:

WAC 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.

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