The Case for an Elective PCI Exception: Accounting for Health Disparities and Community-Specific Access and Availability Factors in CN Rules

DRAFT
May 3, 2017
- Exceptions are Regularly Included in CN Methodologies

- Current Highline Service Area Data Exemplifies Community Factors that Impact Need and Access:
  - Socioeconomic
  - Cardiac volumes, mortality and charges

- Literature Demonstrates that Barriers to Access Exist in Low Income and High Minority Communities

- Providers and Community Leaders Weigh in on Need

- Proposed (Draft) WAC
Virtually every other CN methodology has “exception” language to account for factors beyond the numbers

- Likely because there is general consensus that:
  - Methodologies are not precise enough and data is frequently not publicly available to permit the numeric methodology to be the “be all, end all.”
  - Numbers alone do not tell the story of a community’s need for service.
Virtually every other CN methodology has “exception” language to account for factors beyond the numbers.

- There are 9 tertiary services regulated by CN (including elective PCI):
  - Only 1 other has a prescribed methodology (OHS), and that contain an exception

- There are 6 other services/programs/beds regulated:
  - 4 have a prescribed methodology, and each allows for an exception
  - 1 other (acute beds, NICU) has no WAC methodology, but does include an exception.
  - 1 other (home health) has no WAC methodology.

- These exceptions give the Department the latitude to address access and availability factors in specific communities that impact need for care and patient outcomes.
**WAC 246-310-020: Tertiary Services - Only one methodology is in rule, and it has exception (based on access)**

<table>
<thead>
<tr>
<th>Tertiary Service</th>
<th>Numeric Methodology in Rule?</th>
<th>Exception</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialty burn services</td>
<td>No</td>
<td>NA</td>
</tr>
<tr>
<td>Intermediate care nursery and/or obstetric services level II</td>
<td>No</td>
<td>NA</td>
</tr>
<tr>
<td>Neonatal intensive care nursery and/or obstetric services level III</td>
<td>No</td>
<td>NA</td>
</tr>
<tr>
<td>Transplantation of specific solid organs, including, but not limited to, heart, liver, pancreas, lung, small bowel and kidney and including bone marrow</td>
<td>No</td>
<td>NA</td>
</tr>
<tr>
<td>Kidney dialysis</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Open heart surgery</strong></td>
<td>Yes</td>
<td><strong>Yes</strong></td>
</tr>
<tr>
<td>Elective PCI</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Inpatient physical rehabilitation services level I</td>
<td>No</td>
<td>NA</td>
</tr>
<tr>
<td>Specialized inpatient pediatric services</td>
<td>No</td>
<td>NA</td>
</tr>
</tbody>
</table>
Of the non-tertiary services regulated, nearly every one has an exception

<table>
<thead>
<tr>
<th>Service</th>
<th>Methodology in Rule?</th>
<th>Exception?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Beds</td>
<td>No</td>
<td>Yes, contained in “Criterion 2” in State Health Plan</td>
</tr>
<tr>
<td>Ambulatory Surgery</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Kidney Dialysis</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Home Health</td>
<td>No</td>
<td>NA</td>
</tr>
<tr>
<td>Hospice (Draft)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Nursing Home beds</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Southwest King County’s Case for an Exception
Per CHARS, 76% of Highline’s inpatients reside in the Southwest King Hospital Planning Area.
Some Context on King West

- There are 7 hospitals with PCI in King West, including 5 that are allowed to perform elective PCI.
- Nearly 950,000 population
- Approximately 50% of all PCI cases at these hospitals are generated on residents that reside OUTSIDE of King West.
  - The methodology includes these volumes in the planning area’s capacity, but not in its calculation of need.

<table>
<thead>
<tr>
<th>Hospital</th>
<th>2015 PCI Volumes</th>
<th>% Patients outside of King West</th>
<th>2016 Market Share (Southwest King)</th>
<th>Average Charge (2016) Southwest King Residents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highline</td>
<td>128</td>
<td>17%</td>
<td>34%</td>
<td>$89,109</td>
</tr>
<tr>
<td>Seattle Childrens</td>
<td>53</td>
<td>83%</td>
<td>0%</td>
<td>NA</td>
</tr>
<tr>
<td>Swedish Cherry Hill</td>
<td>967</td>
<td>38%</td>
<td>37%</td>
<td>$118,962</td>
</tr>
<tr>
<td>UW/ Harborview</td>
<td>NA</td>
<td>29%</td>
<td>4%</td>
<td>$113,237</td>
</tr>
<tr>
<td>UW/ Northwest Hospital</td>
<td>230</td>
<td>27%</td>
<td>0%</td>
<td>$118,659</td>
</tr>
<tr>
<td>UW/UWMC</td>
<td>739</td>
<td>73%</td>
<td>6%</td>
<td>$96,000</td>
</tr>
<tr>
<td>Virginia Mason</td>
<td>473</td>
<td>72%</td>
<td>3%</td>
<td>$54,208</td>
</tr>
<tr>
<td>Total</td>
<td>2,590</td>
<td>47%</td>
<td>84%</td>
<td>$99,319</td>
</tr>
</tbody>
</table>

Other Market shares: Valley Medical Center 6%, Overlake: 2%; St. Francis: 2%, SJMC 2%,
Swedish recognized this fact in its CN application requesting a CN for elective PCI.

In its CN application for an elective PCI for its Issaquah Hospital it stated:

*In WAC 246-310-745(5), we calculated a use rate using “the number of PCIs performed on the residents of a planning area [.]” (emphasis added.). It only makes logical sense for us to calculate the capacity available to meet this need based on the number of procedures for Planning Area residents. Otherwise, there will be a shortage of capacity.*

Source: Certificate of Need Evaluation, Swedish Health Services CN Application to Establish Elective PCI Program at Swedish Issaquah, May 2012, p. 9
Socioeconomic factors are contributing to higher mortality and morbidity in South King
Factors such as our race, ethnicity and socioeconomic status should not play a role in how healthy we are or how long we live. Unfortunately, for many of us, they do. In the places where we live, many of us are surrounded by essential ingredients in a healthy life, such as adequate housing and public transportation, quality health care, and safe places to exercise and play. Unfortunately, for many others, these options are either too far away or economically out of reach, creating major obstacles in the pursuit of better health and quality of life.

- Robert Wood Johnson Foundation

A large and compelling body of evidence has accumulated, particularly during the last two decades, that reveals a powerful role for social factors—apart from medical care—in shaping health across a wide range of health indicators, settings, and populations.

The overwhelming weight of evidence demonstrates the powerful effects of socioeconomic and related social factors on health.
DOH has been well aware of the relationship between heart disease and poverty for years (2013 graphic)
Per King County Public Health (KCPH), Burien, North Highline and SeaTac have some of the highest rates of poverty.
Life Expectancy is also significantly lower in South King County.
Lower rates of high school graduation in Southwest King mean less opportunity for family wage jobs and higher poverty.
Per KCPH, South King County Residents Face Significantly More Unmet Health Care Needs Due to Cost

Unmet health care needs due to cost (adults)
King County, 2010-2014 average

- King County: 14%
- Age 18-24: 14%
- 25-44: 17%
- 45-64: 15%
- 65+: 1%
- Male: 13%
- Female: 14%
- AI/AN: 18%
- Asian: 9%
- Black: 22%
- Hispanic: 19%
- Multiple: 19%
- NHPI: 18%
- White: 13%
- Income < $15,000: 39%
- $15,000 to $24,999: 36%
- $25,000 to $34,999: 23%
- $35,000 to $49,999: 12%
- $50,000 to $74,999: 10%
- $75,000+: 1%
- East: 10%
- North: 11%
- Seattle: 14%
- South: 17%
- Washington State: 13%

Source: Behavioral Risk Factor Surveillance System.
Prepared by Public Health - Seattle & King County, APDE, 07/2016.

Confidence interval shows range that includes true value 95% of the time.
Too few cases to protect confidentiality and/or report reliable rates.
Too few cases to meet precision standards, interpret with caution.
Persons of Hispanic ethnicity can be of any race and are included in the racial categories.

Unmet health care needs due to cost (adults)
King County, 2000-2014, three-year rolling averages

Cell phone respondents included beginning in 2009

Trends over time: King County (2000-14: rising); East KC (2000-14: flat); North KC (2000-14: flat); Seattle (2000-14: flat); South KC (2000-14: flat); Washington State (2000-14: rising)
Source: Behavioral Risk Factor Surveillance System.
Prepared by Public Health - Seattle & King County, APDE, 07/2016.
What Counts – Harnessing Data for America’s Communities: Produced more than a dozen multicolored maps of King County – highlighting nearly 400 census tracts, each consisting of about 5,000 residents. Each map features a different measurement – some showed income, others life expectancy, tobacco use or diabetes rates. And tract by tract, each map showed the same pattern – with progressively worse problems across the board in South King County.

The Global to Local Project: Determined that even with some of the best health care in the world, the U.S. also has pockets of the country where health conditions mirror those of developing countries. In fact, Seattle/King County is home to some of the greatest disparity of any American city.

King County – Building Equity & Opportunity: Found that while at a glance, King County is a great place to live, work and play, when you look closer, significant portions of the King County community are being left behind – Southwest King County fairs worse on almost all measures – including education, employment, income, life expectancy and quality of life – than the remainder of King County.

Live United – United Way of King County: Found high poverty rates, communities of color and refugee populations concentrated in South King County coupled with below average rates in several quality of life indicators as well, including education, employment, income and health.
Links to other reports demonstrating Health Inequities in South King

- http://www.whatcountsforamerica.org/truthonamap/
- http://www.kingcounty.gov/elected/executive/~/media/B102A4C8AAE440F1A79BCE76986E80F5.ashx?la=en
Travel times to closest elective PCI providers average nearly 30 minutes assuming access to a personal vehicle and funds to travel

- Travel time to the closest PCI providers from Highline:

<table>
<thead>
<tr>
<th></th>
<th>Valley</th>
<th>Swedish</th>
<th>Virginia Mason</th>
<th>St. Francis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average</td>
<td>22</td>
<td>29</td>
<td>28</td>
<td>28</td>
</tr>
<tr>
<td>Min</td>
<td>20</td>
<td>24</td>
<td>23</td>
<td>25</td>
</tr>
<tr>
<td>Max</td>
<td>30</td>
<td>37</td>
<td>38</td>
<td>35</td>
</tr>
</tbody>
</table>

Source: Google maps, time travel logged every 30 minutes from 8 am to 5pm over three days
CHARS demonstrates higher acute MI Rates, and King County Public Health and OFM both verify higher cardiac mortality in South King
**CHARS Documents that Acute MI Rates are Higher— and Trending Upward in SW King versus Stable in the Rest of King**

**Southwest King County**

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>Total/Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>15+ Population</td>
<td>205,107</td>
<td>207,668</td>
<td>210,315</td>
<td>623,090</td>
</tr>
<tr>
<td>Acute MI Discharges</td>
<td>143</td>
<td>159</td>
<td>240</td>
<td>542</td>
</tr>
<tr>
<td>Acute MI Rate Per 1,000 age 15+</td>
<td>0.697</td>
<td>0.766</td>
<td>1.141</td>
<td>0.870</td>
</tr>
</tbody>
</table>

**King County (less Southwest King), Acute MIs**

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>Total/Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>15+ Population</td>
<td>1,491,597</td>
<td>1,516,404</td>
<td>1,541,995</td>
<td>4,549,996</td>
</tr>
<tr>
<td>Acute MI Discharges</td>
<td>963</td>
<td>1,027</td>
<td>1,007</td>
<td>2,997</td>
</tr>
<tr>
<td>Acute MI Rate Per 1,000 Age 15+</td>
<td>0.646</td>
<td>0.677</td>
<td>0.653</td>
<td>0.659</td>
</tr>
</tbody>
</table>

*Source: WA State CHARS, DRGs, 280-285, Population from Nielsen Claritas*
# South King County Heart Disease Death Rates Exceed those of other areas of King County and the Rest of Washington State

## Heart Disease Death, King County, 2010-2014 Average

<table>
<thead>
<tr>
<th>Category</th>
<th>Rate</th>
<th>Lower CI</th>
<th>Upper CI</th>
<th>Count per Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>King County (all ages)</td>
<td>127.2</td>
<td>125.0</td>
<td>129.5</td>
<td>2528</td>
</tr>
<tr>
<td>Neighborhood Poverty</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>154.2</td>
<td>147.1</td>
<td>161.6</td>
<td>361</td>
</tr>
<tr>
<td>Medium</td>
<td>128.5</td>
<td>125.7</td>
<td>131.4</td>
<td>1685</td>
</tr>
<tr>
<td>Low</td>
<td>106.4</td>
<td>102.0</td>
<td>110.9</td>
<td>458</td>
</tr>
<tr>
<td>Region</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>East</td>
<td>106.3</td>
<td>102.2</td>
<td>110.5</td>
<td>538</td>
</tr>
<tr>
<td>North</td>
<td>124.9</td>
<td>117.1</td>
<td>133.1</td>
<td>207</td>
</tr>
<tr>
<td>Seattle</td>
<td>123.3</td>
<td>119.5</td>
<td>127.3</td>
<td>827</td>
</tr>
<tr>
<td>South</td>
<td>144.7</td>
<td>140.5</td>
<td>149.1</td>
<td>931</td>
</tr>
<tr>
<td>State</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Washington State</td>
<td>142.2</td>
<td>141.0</td>
<td>143.4</td>
<td>10459</td>
</tr>
</tbody>
</table>

**Comparisons:**
- Higher than King County rate (yellow)
- Lower than King County rate (green)

Source: WA State DOH Center For Health Statistics, Death Certificates
Prepared by Public Health – Seattle & King County, APDE, 08/2016
Note: CI is 95% confidence interval
Heart disease deaths by health reporting areas
King County, 2010-2014 average

Note: HRA labels on the map match the chart on the right, listed in alphabetical order.
Source: WA State DOH, Center for Health Statistics, Death Certificates.
Prepared by Public Health - Seattle & King County, APDE, 08/2016.
*Rate = cases per 100,000 population, age-adjusted to the 2000 US population.
South King County Heart Disease Death Rates Exceed those of other areas of King County and the Rest of Washington State
Office of Financial Management also found differences in cardiac mortality in South King legislative districts (2016 study)

- Found a 2.6-fold difference between the state legislative district with the highest coronary artery disease mortality rate and the district with the lowest. SW King includes the 30th and 33rd Districts.
• Literature confirms that it is not uncommon for patients to come into a hospital with pain, but to resist the idea of being transferred to another hospital for an elective procedure:

– The barriers to access to care are not always geographic, measured in miles or mountains, but also exist in the urban environment, and include such intangibles as culture, race, language, poverty, and poor education. These populations are often outside the traditional health care system and fail to obtain access to specialized cardiac services—especially when their trusted, known provider refers to an unknown or distant provider.
One study concluded

- Lower-income patients residing in lower-income neighborhoods were more often female or black, had a higher prevalence of coexistent illness, and were less often admitted to urban hospitals or hospitals that provide CABG and PTCA.

This study also found that people in the highest quintile of income were 74% more likely to receive PCI than individuals in the lowest quintile of income, and that mortality rates were significantly higher in the lowest-income patients.

Another study concluded geographic regions with a high-risk patient population for STEMI and without a nearby PCI capable center would be ideal locations for new growth in PCI-capable hospitals.
The fact that Highline cannot currently provide elective PCI is a deterrent to timely care because the resources in downtown Seattle are simply not available or accessible to a significant number of patients Sea Mar serves.

Mary Bartolo, Deputy Director
Sea Mar Community Health Centers

Other providers of elective PCI are simply perceived as not being available or accessible to many residents.

Colleen Brandt-Schluter,
Human Services Manager
City of SeaTac
Downtown providers are not available or accessible to residents of South King County.

The fact that many services are only available in Seattle is a problem and something that contributes significantly to the health disparities we see. Consequently, the Seattle providers are not available or accessible to residents of South King County.

   Adam Taylor
   Program Director
   GlobalToLocal

Couple the health status indicators with the reduced ability to travel, higher uninsured rates and language barriers and it is evident that despite the State’s assumption that downtown Seattle providers can meet the elective PCI needs of Highline’s service area, the services are simply not available or accessible to many residents.

   Mark Adams, MD
   Past Board member, Puget Sound Health Alliance
   Board Member Cambia Health Solutions (Operates Regence Blue Shield, Oregon Blue Cross Blue Shield, Utah Blue Cross Blue Shield and Idaho Blue Shield)
   Past President of the Washington State Medical Association
   Past Member, American Hospital Association Board of Trustees
The City is increasingly aware that when services are not readily available and accessible at Highline, some citizens are foregoing care due to the cost of travelling downtown and their unfamiliarity with navigating other health care systems. In fact, these “out of area” services are really not available or accessible to our citizens. This lack of care leads to adverse outcomes.

Dan Trimble
Economic Development Manager
City of Burien

All of these health status data support what we at HealthPoint know and experience everyday: the population we serve has a higher overall demand for cardiovascular services and for numerous reasons, has less ability to travel. They are also less trusting of health care providers with whom they do not have an established relationship.... We hear from our community health workers and clinical staff on a too regular basis that patients have chosen to forego care because it is not available locally.

Debra Wilkinson,
Chief Operations Officer
HealthPoint Community Health Center
The delivery system is adversely impacted by Highline’s lack of PCI, and emergency PCI access is increasingly in jeopardy

Key Excerpts from 2012 Senator Keiser Letter to Department of Health:

• ...the rules permanently prohibit the nearest full-service medical center, Highline Medical Center, from even applying for a Certificate of Need to offer elective PCI. This is because the Department, despite concerns and comments, created a new “King West” planning area that to this day has a “surplus” of capacity; no surprise given that this planning area’s “capacity” consists of every PCI procedure performed by all the Seattle hospitals that have elective programs.

• “King West” includes communities truly based in the Southwest King County service area (Burien, Normandy Park, Des Moines, SeaTac and Tukwila) but also includes downtown Seattle, North Seattle and as far east as Mercer Island. Not only is the planning area nonsensical, but many of these Seattle tertiary providers serve patients from a broad geographic area, with as many as 75% of the discharges coming from outside King West, yet the proposed rules include 100% of the historical volume.

• ...my constituents have been denied access to local elective cardiac services, and now our community is also at serious risk of losing access to life-saving emergency services for patients having a heart attack. Highline is beginning to experience increasing difficulties in recruiting and retaining cardiologists and sustaining its emergency program......

• This would be a huge disservice to our community and put some of the most vulnerable patients from one of the most diverse communities in the state at risk.

• Highline and its cardiologists have the infrastructure, expertise and interest to provide elective PCI and needs the ability to preserve its emergency program.
Elective PCI is a fundamental component of a robust and state of the art cardiac program. Its absence is impacting Regional EMS and 24/7 local emergency response.

"Highline's {emergency PCI} service is essential to the region's emergency response ".

Tom Rea, MD, Medical Director
King County's Medic One Program

- Dr. Rea’s email was sent in response to an ED cardiac closure that Highline experienced because of coverage issues (retirement of long-standing cardiologists and inability to recruit new cardiologists—because they are unwilling to work in a setting where they cannot perform elective cases).

- The ability to sustain an emergency program is inextricably linked to our ability to operate an elective program.
Proposed WAC Language Grants the Department the Latitude to Consider a Program Absent Numeric Need when all other Criteria and Quality Standards are Met

- WACs 246-310-210 and 246-310-230 require the Department to consider access, availability, underserved populations and fragmentation in care caused by current delivery systems.
- The Department is “ham-strung” by the current numeric “be all, end-all”
- This 100% reliance on pure numeric methodology is unique to Elective PCI
- The bar is simply too high, and residents in select communities experience worse outcomes; costs are higher as a result.
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) (i) The state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area; and
  
  ——(b) (ii) All existing PCI programs in that planning area are meeting or exceeding the minimum volume standard; OR

  (b) (i) The applicant has demonstrated that health disparities or inequities or a lack of access exists within the zip codes comprising the communities from which 75% of its inpatients reside; and
  
  (ii) All other applicable review criteria and standards have been met.
The exception applies to numeric need only. Applicants still must demonstrate compliance with all other quality standards in WAC 246-310-715, 720, 725, 730, 735, and 740 and other CN review criteria.

WAC 246-310-745 - Need forecasting methodology.

(10) Numeric methodology:
• 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(2)(b).