December 2, 2019

CERTIFIED MAIL # 7016 3010 0001 0575 0440

Dennis Hoover, Senior Director, Cardiovascular Service Line
Virginia Mason Memorial
2811 Tieton Drive
Yakima, Washington 98902

RE: Certificate of Need Application #19-65 – Yakima Valley Memorial Hospital Association

Dear Mr. Hoover:

We have completed review of the Certificate of Need application submitted by Yakima Valley Memorial Hospital Association proposing to establish an adult elective percutaneous coronary intervention program at the Virginia Mason Memorial in Yakima County. Enclosed is a written evaluation of the application.

For the reasons stated in the enclosed decision, the application is consistent with the applicable criteria of the Certificate of Need Program, provided Yakima Valley Memorial Hospital Association agrees to the following in its entirety.

**Project Description:**
This certificate approves the establishment of an adult, elective percutaneous coronary intervention program at Virginia Mason Memorial.

**Conditions:**
1. Approval of the project description as stated above. Yakima Valley Memorial Hospital Association further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.

2. Virginia Mason Memorial will provide charity care in compliance with its charity care policies reviewed and approved by the Department of Health, or any subsequent policies reviewed and approved by the Department of Health. Virginia Mason Memorial will use reasonable efforts to provide charity care in an amount comparable to or exceeding the average amount of charity care provided by hospitals in the Central Region. Currently, this amount is 1.03% gross revenue and 2.74% of adjusted revenue. Virginia Mason Memorial will maintain records of charity care applications received and the dollar amount of charity care discounts granted. The department requires these records to be available upon request.
3. Prior to providing elective percutaneous coronary intervention program at Virginia Mason Memorial, Yakima Valley Memorial Hospital Association will provide a copy of the final Elective PCI Patient Transfer and Surgical Partnering Agreement between Virginia Mason Memorial and Kadlec Regional Medical Center (referenced as KRMC in the agreement) located in Richland, within Benton County. The final agreement shall be consistent with the draft agreement provided in the application.

**Approved Costs:**
There is no capital expenditure associated with this project.

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above project description, conditions, and capital costs for your project. If you accept these in their entirety, your application will be approved and a Certificate of Need sent to you.

If you reject any of the above provisions, your application will be denied. The department will send you a letter denying your application and provide you information about your appeal rights.

Send your written response to the Certificate of Need Program, at one of the following addresses.

**Mailing Address:**
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

**Physical Address:**
Department of Health
Certificate of Need Program
111 Israel Road SE
Tumwater, WA 98501

If you have any questions, or would like to arrange for a meeting to discuss our decision, please contact the Certificate of Need Program at (360) 236-2955.

Sincerely,

[Signature]

Nancy Tyson, Executive Director
Health Facilities and Certificate of Need

Enclosure
EVALUATION DATED DECEMBER 2, 2019, FOR THE TWO CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ESTABLISH AN ADULT, ELECTIVE PERCUTANEOUS CORONARY INTERVENTION PROGRAM IN YAKIMA COUNTY

APPLICANT DESCRIPTIONS

**Astria Health**
The Astria Health system is headquartered in Yakima Valley in Yakima County. Astria Health is the parent non-profit organization of Astria Sunnyside Hospital, Astria Regional Medical Center and Astria Toppenish Hospital along with outpatient Astria Health Centers (14 medical clinics and 24 specialty clinics) located in towns and cities throughout Yakima County and surrounding communities. The chart below shows the name and location of the three Astria hospitals. [source: Astria Health website and April 30, 2019, screening response, Attachment 1]

<table>
<thead>
<tr>
<th>Hospital</th>
<th>City</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Astria Sunnyside Hospital</td>
<td>Sunnyside</td>
<td>Washington</td>
</tr>
<tr>
<td>Astria Regional Medical Center</td>
<td>Yakima</td>
<td>Washington</td>
</tr>
<tr>
<td>Astria Toppenish Hospital</td>
<td>Toppenish</td>
<td>Washington</td>
</tr>
</tbody>
</table>

This application focuses on Astria Sunnyside Hospital listed in the chart above. For this evaluation, the applicant will be referenced as Astria Health. The site for the project is the hospital that will be referenced as Astria Sunnyside Hospital. [source: Application, p1]

**Yakima Valley Memorial Hospital Association**
Effective January 1, 2016, an affiliation of two non-profit entities occurred and the Virginia Mason Health System became the sole member of the Yakima Valley Memorial Hospital Association. The affiliation did not involve a transfer of assets or liabilities. It was not a merger or acquisition and no real estate or other property was bought or sold. Both before and after the affiliation effective date of January 1, 2016, Yakima Valley Memorial Hospital Association and Virginia Mason Health System have remained separate Washington non-profit corporations. The Board of Directors of Yakima Valley Memorial Hospital Association is responsible for the management of Yakima Valley Memorial Hospital Association subject to certain reserved rights of the Virginia Mason Health System, as the sole member. [source: Application, p1]

Virginia Mason Health System owns and operates a variety of healthcare entities in and around King and Yakima counties including two acute care hospitals. The chart below shows the name and location of the two acute care hospitals. [source: Application, p5 and CN historical files]

<table>
<thead>
<tr>
<th>Hospital</th>
<th>City</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virginia Mason Medical Center</td>
<td>Seattle</td>
<td>Washington</td>
</tr>
<tr>
<td>Virginia Mason Memorial</td>
<td>Yakima</td>
<td>Washington</td>
</tr>
</tbody>
</table>

For this evaluation, the applicant is Yakima Valley Memorial Hospital Association and will be referenced as YVMHA. The focus of this project is the hospital known as Virginia Mason Memorial listed in the chart above.
PROJECT DESCRIPTIONS

Astria Health
This project focuses on Astria Sunnyside Hospital located at 1016 Tacoma Avenue in Sunnyside, within Yakima County. The hospital provides healthcare services to the residents of Yakima and Benton counties through a variety of healthcare clinics. The hospital is currently licensed for 38 acute care beds and is designated by the Department of Health as a level IV adult trauma center. Astria Sunnyside Hospital holds a federal Critical Access Designation from Centers for Medicare & Medicaid Services.¹

Under the Critical Access Hospital [CAH] designation, hospitals can have no more than 25 acute care beds in operation. [source: Application, p1 and CN historical files] A CAH may also operate a distinct part rehabilitation and/or psychiatric unit, each with up to ten beds. [source: Department of Health and Human Services Centers for Medicare and Medicaid Services]

On December 15, 2015, Astria Sunnyside Hospital was issued an exemption approval for the replacement of the hospital to a new site in the city of Sunnyside.² On December 27, 2017, CN #1625 was issued to Astria Sunnyside Hospital approving the establishment of a ten-bed psychiatric unit to the hospital at its new site. As of the writing of this evaluation, Astria Sunnyside Hospital remains at its current site of 1016 Tacoma Avenue in Sunnyside and the ten-bed psychiatric unit is not operational. Table 1 below shows the 38 beds broken down by service. [source: DOH hospital licensing files]

<table>
<thead>
<tr>
<th>Bed Type</th>
<th>Current</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical/Surgical</td>
<td>25</td>
</tr>
<tr>
<td>PPS Exempt Psychiatric</td>
<td>0</td>
</tr>
<tr>
<td>Licensed Beds Not In Use</td>
<td>13</td>
</tr>
<tr>
<td>Total Licensed Beds</td>
<td>38</td>
</tr>
</tbody>
</table>

Astria Health submitted this application proposing to establish an adult, elective percutaneous coronary intervention (PCI) program within space at Astria Sunnyside Hospital at its current site. The project would increase the types of services provided at the hospital, but does not propose to increase the total number of acute care beds. [source: Application, p7]

Astria Health states there is no capital expenditure associated with the addition of a PCI program for the following reasons:
- No new equipment is proposed as a result of this project.
- There will be no construction or alterations to the existing space.
- No capital expenditure is required to provide the services.
[source: Application, p8]

¹ A Critical Access Hospital (CAH) is a federal designation under the Rural Hospital Flexibility Program that is administered by the federal Office of Rural Health Policy. A CAH is a small hospital located in rural areas of the state. CAHs are often the central hub of health services in their communities, providing primary care, long-term care, physical and occupational therapy, cardiac rehabilitation and other services in addition to emergency and acute care. Hospital staff provides these services either directly or in partnership with other community providers. A CAH has no more than 25 acute care beds and may add a distinct part ten-bed psychiatric unit and/or a distinct part ten-bed rehabilitation unit.

² Determination of Reviewability #16-12.
Noting that the hospital has previously obtained an exemption approval to relocate Astria Sunnyside Hospital to a new site in Sunnyside, the department requested clarification of where the proposed PCI services would be established. In response, Astria Health provided the following clarification on the location of the proposed services and the cardiac services currently provided at Astria Sunnyside Hospital.

“The replacement hospital has been designed to include a cardiac catheterization laboratory. The timeline for build out of the new hospital has yet to be finalized. Sunnyside has operated a cardiac catheterization laboratory at the current hospital location since [June] 2015. This existing laboratory is the laboratory that will be used to provide elective PCI services upon approval of the CN application.” [source: April 30, 2019, screening response, p1]

Astria Sunnyside Hospital currently provides adult, emergent PCI services to residents of the planning area. If the project is approved, Astria Health states that the adult, elective PCI program would be available upon Certificate of Need approval and estimated approval to be March 2020. [source: Application, p9]

Yakima Valley Memorial Hospital Association
This project focuses on hospital known as Virginia Mason Memorial located at 2811 Tieton Drive in Yakima, within Yakima County [98902]. The hospital is currently licensed for 226 acute care beds and provides a variety of healthcare services to the residents of Yakima County and surrounding communities. Table 2 below shows the 226 beds broken down by service. [source: DOH hospital licensing files]

<table>
<thead>
<tr>
<th>Services Provided</th>
<th>Total Beds</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Medical Surgical</td>
<td>194</td>
</tr>
<tr>
<td>Intermediate Care Nursery - Level II</td>
<td>7</td>
</tr>
<tr>
<td>Neonatal Intensive Care Nursery – Level III</td>
<td>7</td>
</tr>
<tr>
<td>Dedicated Psychiatric</td>
<td>18</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>226</strong></td>
</tr>
</tbody>
</table>

The hospital is currently a Medicare and Medicaid provider and holds a three-year accreditation from the Joint Commission³. [source: DOH hospital licensing files]

YVMHA submitted this application proposing to establish an adult, elective percutaneous coronary intervention (PCI) program within space at Virginia Mason Memorial. The project would increase the types of services provided at the hospital, but does not propose to increase the total number of acute care beds. [source: Application, p9]

YVMHA states there is no capital expenditure associated with the addition of a PCI program and provided the following information to support this position. [source: April 29, 2019, screening response, p6]

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³ The Joint Commission accredits and certifies more than 20,000 health care organizations and programs in the United States. Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization’s commitment to meeting certain performance standards. [source: Joint Commission website]
Virginia Mason Memorial currently provides adult, emergent PCI services to residents of the planning area. If the project is approved, YVMHA states that the adult, elective PCI program would be available upon Certificate of Need approval. YVMHA estimated approval to be January 2020. [source: Application, p11]

**APPLICABILITY OF CERTIFICATE OF NEED LAW**
Both projects are subject to review as the establishment of a new tertiary service not previously provided by the hospital under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(f) and Washington Administrative Code (WAC) 246-310-020(1)(d).

**EVALUATION CRITERIA**
WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction in how the department is to make its determinations. It states:

“Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the department in making the required determinations.

(a) In the use of criteria for making the required determinations, the department shall consider:

(i) The consistency of the proposed project with service or facility standards contained in this chapter;

(ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and

(iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project.”

In the event WAC 246-310 does not contain service or facility standards in sufficient detail to make the required determinations, WAC 246-310-200(2)(b) identifies the types of standards the department may consider in making its required determinations. Specifically WAC 246-310-200(2)(b) states:

“The department may consider any of the following in its use of criteria for making the required determinations:

(i) Nationally recognized standards from professional organizations;

(ii) Standards developed by professional organizations in Washington State;

(iii) Federal Medicare and Medicaid certification requirements;

(iv) State licensing requirements;

(v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and

(vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application.”

To obtain Certificate of Need approval, each applicant must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment). Where applicable, each applicant must demonstrate compliance with the above general criteria by meeting the Adult Elective Percutaneous Coronary
Interventions (PCI) Without On-Site Cardiac Surgery Standards and Forecasting Methodology outlined in WAC 246-310-700 through 755.

**TYPE OF REVIEW**
As directed under WAC 246-310-710, the department accepted these projects under the year 2019 adult, elective PCI Concurrent Review Cycle. The purpose of the concurrent review process is to comparatively analyze and evaluate competing or similar projects to determine which of the projects may best meet the identified need. For PCI projects, concurrent review allows the department to review PCI applications proposing the serve the same PCI planning area [as defined in WAC 246-310-705(5)] simultaneously to reach a decision that serves the best interests of the planning area’s residents.

For this review, both hospitals are located in planning area #4 as defined in WAC 246-310-705(5). The planning area includes the counties of Kittitas and Yakima. It also includes the following specific ZIP codes in east Klickitat County: 98620, 99356, and 99322.

The concurrent review timeline is summarized below.

### APPLICATION CHRONOLOGY

<table>
<thead>
<tr>
<th>Action</th>
<th>Astria Health</th>
<th>Yakima Valley Memorial Hospital Association</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letter of Intent Submitted</td>
<td>January 28, 2019</td>
<td>January 11, 2019</td>
</tr>
<tr>
<td>Application Submitted</td>
<td>February 28, 2019</td>
<td>February 28, 2019</td>
</tr>
<tr>
<td>Department’s pre-review activities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• DOH 1st Screening Letter</td>
<td>March 29, 2019</td>
<td>March 29, 2019</td>
</tr>
<tr>
<td>• Applicant's Responses Received</td>
<td>April 30, 2019</td>
<td>April 29, 2019</td>
</tr>
<tr>
<td>Beginning of Review</td>
<td></td>
<td>May 16, 2019</td>
</tr>
<tr>
<td>End of Public Comment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• No Public Hearing Conducted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Public comments accepted through end</td>
<td></td>
<td></td>
</tr>
<tr>
<td>of public comment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rebuttal Comments Received</td>
<td></td>
<td>August 14, 2019</td>
</tr>
<tr>
<td>Department's Anticipated Decision Date</td>
<td></td>
<td>September 30, 2019</td>
</tr>
<tr>
<td>Department’s Anticipated Decision Date with</td>
<td></td>
<td></td>
</tr>
<tr>
<td>60-day Extension</td>
<td></td>
<td>December 2, 2019</td>
</tr>
<tr>
<td>Department's Actual Decision Date</td>
<td></td>
<td>December 2, 2019</td>
</tr>
</tbody>
</table>

### AFFECTED PERSONS

Washington Administrative Code 246-310-010(2) defines “affected person” as:

“…an “interested person” who:

(a) Is located or resides in the applicant's health service area;
(b) Testified at a public hearing or submitted written evidence; and
(c) Requested in writing to be informed of the department's decision.”

WAC 246-310-010(2) requires an affected person to first meet the definition of an ‘interested person.’

WAC 246-310-010(34) defines “interested person” as:

(a) The applicant;
(b) Health care facilities and health maintenance organizations providing services similar to the services under review and located in the health service area;
(c) Third-party payers reimbursing health care facilities in the health service area;
(d) Any agency establishing rates for health care facilities and health maintenance organizations in the health service area where the proposed project is to be located;
(e) Health care facilities and health maintenance organizations which, in the twelve months prior to receipt of the application, have submitted a letter of intent to provide similar services in the same planning area;
(f) Any person residing within the geographic area to be served by the applicant; and
(g) Any person regularly using health care facilities within the geographic area to be served by the applicant.

During a concurrent review, each applicant is an affected person for the other applications. In addition to each applicant, the following entities requested affected person status.

**Astria Regional Medical Center**
As stated in the application description section of this evaluation, the Astria Health system is headquartered in Yakima Valley in Yakima County. Astria Health is the parent non-profit organization of the following three hospitals: Astria Sunnyside Hospital, Astria Regional Medical Center, and Astria Toppenish Hospital.

Astria Regional Medical Center is an acute care hospital operating in city and county of Yakima located at 110 South 9th Avenue in Yakima [98902]. The hospital is licensed for 214 acute care beds, which includes a number of beds dedicated to a variety of specialized services. The hospital provides open heart surgery, which includes PCI services.4 [source: Astria Health website and ILRS]

Since the hospital is located in Yakima County and provides healthcare services to residents of the county, it meets the interested person criteria outlined in WAC 246-310-010(34) above. Further, Astria Regional Medical Center provided both public comments and rebuttal comments for these projects. Astria Regional Medical Center qualifies as affected person for these PCI projects.

**Kadlec Regional Medical Center [an affiliate of Providence St. Joseph]**
Kadlec Regional Medical Center (Kadlec) is located at 888 Swift Boulevard in Richland [99352], within Benton County. The hospital is licensed for 270 beds, which includes a number of beds dedicated to a variety of specialized services. The hospital provides open heart surgery, which includes PCI services.5 [source: Kadlec website and ILRS]

While Kadlec may provide healthcare services to residents Yakima County, this does not meet the interested person criteria outlined in WAC 246-310-010(34) above. Further, neither Kadlec nor its parent, Providence St. Joseph, provided public comment on this project. As a result, neither Kadlec nor Providence St. Joseph qualifies as an interested person and cannot qualify as an affected person for this project.

In summary, for affected persons during this review, one of the two—Astria Regional Medical Center—qualifies for affected person status. Further, each applicant is an affected person for the other application.

4 Historical records indicate that this hospital began providing open heart surgery services prior to 1978 and before Certificate of Need was required for the services. At that time, the hospital was known as St. Elizabeth Hospital and operated by the Providence Health System.
5 On January 13, 2000, Kadlec Regional Medical Center and Kennewick General Hospital (aka Trios) was issued CN #1199 approving the establishment of a joint open heart surgery program located at Kadlec Regional Medical Center.
SOURCE INFORMATION REVIEWED

- Astria Health’s Certificate of Need application received February 28, 2019
- Astria Health’s first screening responses received April 30, 2019
- Yakima Valley Memorial Hospital Association’s Certificate of Need application received on February 28, 2019
- Yakima Valley Memorial Hospital Association’s first screening responses received on April 29, 2019
- Public comments received by the end of public comment on July 15, 2019
- Astria Health’s rebuttal comments submitted on behalf of Astria Sunnyside Hospital received on or before August 14, 2019
- Astria Health’s rebuttal comments submitted on behalf of Astria Regional Medical Center received on or before August 14, 2019
- Yakima Valley Memorial Hospital Association’s rebuttal comments submitted on behalf of Virginia Mason Memorial received on or before August 14, 2019
- Department of Health’s Hospital and Patient Data Systems’ Comprehensive Hospital Abstract Reporting System data for year 2017
- Department of Health PCI outpatient survey responses for 2017
- Office of Financial Management population estimates released August 2017
- Virginia Mason Memorial DOH Hospital/Finance and Charity Care (HFCC) financial review dated November 27, 2019
- Astria Sunnyside Hospital DOH Hospital/Finance and Charity Care (HFCC) financial review dated November 25, 2019
- Department of Health Integrated Licensing and Regulatory System database [ILRS]
- Compliance history for facilities owned and operated by Astria Health obtained from the Washington State Department of Health – Office of Health Systems Oversight
- Compliance history for facilities owned and operated by Yakima Valley Memorial Hospital Association and Virginia Mason Health System obtained from the Washington State Department of Health – Office of Health Systems Oversight
- DOH Provider Credential Search website: https://www.doh.wa.gov/pcs
- Astria Health’s website at https://www.astria.health
- Virginia Mason Memorial’s website at https://www.yakimamemorial.org
- CMS QCOR Compliance website: https://qcor.cms.gov/index_new.jsp
- COAP (Clinical Outcomes Assessment Program) website at www.coap.org
- Certificate of Need historical files

CONCLUSIONS

Astria Health
For the reasons stated in this evaluation, the application submitted by Astria Health proposing to establish an adult, elective percutaneous coronary intervention program at Astria Sunnyside Hospital is not consistent with applicable review criteria of the Certificate of Need Program and a Certificate of Need is denied.

Yakima Valley Memorial Hospital Association
For the reasons stated in this evaluation, the application submitted by Yakima Valley Memorial Hospital Association proposing to establish an adult, elective percutaneous coronary intervention program at
Virginia Mason Memorial is consistent with applicable review criteria of the Certificate of Need Program, provided the applicant agrees to the following in its entirety.

**Project Description:**
This certificate approves the establishment of an adult, elective percutaneous coronary intervention program at Virginia Mason Memorial.

**Conditions:**
1. Approval of the project description as stated above. Yakima Valley Memorial Hospital Association further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.

2. Virginia Mason Memorial will provide charity care in compliance with its charity care policies reviewed and approved by the Department of Health, or any subsequent policies reviewed and approved by the Department of Health. Virginia Mason Memorial will use reasonable efforts to provide charity care in an amount comparable to or exceeding the average amount of charity care provided by hospitals in the Central Region. Currently, this amount is 1.03% gross revenue and 2.74% of adjusted revenue. Virginia Mason Memorial will maintain records of charity care applications received and the dollar amount of charity care discounts granted. The department requires these records to be available upon request.

3. Prior to providing elective percutaneous coronary intervention program at Virginia Mason Memorial, Yakima Valley Memorial Hospital Association will provide a copy of the final Elective PCI Patient Transfer and Surgical Partnering Agreement between Virginia Mason Memorial and Kadlec Regional Medical Center (referenced as KRMC in the agreement) located in Richland, within Benton County. The final agreement shall be consistent with the draft agreement provided in the application.

**Approved Costs:**
There is no capital expenditure associated with this project.

**CRITERIA DETERMINATIONS**

A. **Need (WAC 246-310-210) Need Forecasting Methodology (WAC 246-310-745), and Standards (WAC 246-310-715(1), (2))**

   Based on the source information reviewed, the department determines that Astria Health does not meet the applicable need criteria in WAC 246-310-210.

   Based on the source information reviewed, the department determines that Yakima Valley Memorial Hospital Association meets the applicable need criteria in WAC 246-310-210.

(1) *The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.*

   WAC 246-310-700 requires the department to evaluate all adult elective PCI applications based on the populations need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The adult, elective PCI specific numeric methodology applied is detailed under WAC 246-310-745. WAC 246-310-210(1) criteria is also identified in WAC 246-310-715(1), and (2).
PCI Methodology WAC 246-310-745

The determination of numeric need for adult, elective PCI programs is performed using the methodology contained in WAC 246-310-745(10). The method is a five-step process of information gathering and mathematical computation. The first step examines historical PCI use rates at the planning area level to determine a base year PCI use rate per 1,000 population. The remaining four steps apply that PCI use rate to future populations in the planning area. The numeric net need for additional PCI programs is the result of subtracting current capacity from projected need. The completed methodology is Appendix A attached to this evaluation.

For PCI programs, Washington State is divided into 14 separate planning areas. Both hospitals are located in Yakima County, identified as PCI planning area #4. The need methodology calculates the need for each planning area. The need methodology discussion in this evaluation is limited to Planning Area #4. This planning area includes the full counties of Kittitas and Yakima, and the following specific ZIP codes in east Klickitat County: 98620, 99356, and 99322.

Astria Health
Astria Health calculated the numeric methodology and provided the department’s year 2018 numeric need methodology posted to its website. The numeric methodology projected a need for one PCI program in the planning area. [source: Application, pp10-12]

Public Comments
None

Rebuttal Comments
None

The department’s review of numeric need for both applicants is below.

Yakima Valley Memorial Hospital Association
YVMHA calculated the numeric methodology and provided the department’s year 2018 numeric need methodology posted to its website. The numeric methodology projected a need for one PCI program in the planning area. [source: Application, pp11-13]

Public Comments
None

Rebuttal Comments
None

Department Evaluation of Numeric Need for Both Projects
For these projects, the department calculated the PCI methodology using two different data sets. One set uses CHARS data for inpatient PCIs and survey responses for outpatient PCIs. The other set uses COAP data, which is reported by each Washington State hospital and identifies the total number of

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6 WAC 246-310-705.
7 COAP is an acronym for Clinical Outcomes Assessment Program, a regional quality collaborative that leverages medical and clinical, administrative, and financial data to establish and drive best practices in cardiac care. One purpose is to support all hospitals and clinicians in achieving the highest levels of patient care and outcomes. COAP operates under the auspices of the Foundation for Health Care Quality (FHCQ), a nationally recognized not-for-profit 501(c)3 corporation which is the sponsor for, and home of, a number of programs addressing patient
PCIs performed, but does not distinguish between inpatient and outpatient procedures. The numeric methodology uses the total number of PCIs in all of its calculations; therefore a separation of inpatient and outpatient PCIs is unnecessary. The methodology using both CHARS and survey response will be referenced as #1; the COAP methodology will be referenced as #2.

The titles for each step are excerpted from WAC 246-310-745.

**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\(^8\) by the result of Step 1 (a). This number represents the base year PCI use rate per thousand.

Specific sections of WAC 246-310-745 defines specific terms used in the methodology. Base year is defined in WAC 246-310-750 as the most recent calendar year for which December 31 data is available as of the first day of the application submission period for the department’s CHARS reports or successor reports. Since these applications were submitted on February 28, 2019, year 2018 data was not yet available. For these projects, base year is 2017.

Using the base year of 2017, the department calculated the use rate as described above. The table below shows both use rates calculated by the department.

<table>
<thead>
<tr>
<th></th>
<th>Department Methodology #1</th>
<th>Department Methodology #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 2017 Population 15+</td>
<td>233,254</td>
<td>233,254</td>
</tr>
<tr>
<td>Divide by 1,000</td>
<td>233.25</td>
<td>233.25</td>
</tr>
<tr>
<td>Year 2017 PCIs</td>
<td>459</td>
<td>499</td>
</tr>
<tr>
<td>Use Rate Calculated</td>
<td>1.97</td>
<td>2.14</td>
</tr>
</tbody>
</table>

As shown in the Step One Table, even though the projected population is the same, when the number of PCI’s counted in the planning area is divided by the population (divided by 1,000), the resulting use rate is slightly different. This resulting use rate is applied throughout the methodology.

**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\(^9\).

In this step, the forecast year is defined as the fifth year after the base year. For this project, the forecast year is 2022. The table below is a summary of step two.

---

\(8\) Residents 15 years of age and older.

\(9\) Residents 15 years of age and older.
As shown in the Step Two Table above, the forecast year populations used are the same in each year. Once the use rate calculated from step 1 is applied, the resulting “projected demand” is slightly different.

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

(a) Identify all inpatient procedures at CON approved hospitals within the planning area using CHARS data;
(b) Identify all outpatient procedures at CON approved hospitals within the planning area using department survey data; or
(c) Calculate the difference between total PCI procedures by CON 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.

In this step, "current capacity" is defined as “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.”

As defined above, the current capacity of planning area #4 the total number of PCIs performed counties of Kittitas and Yakima, plus specific ZIP codes in Klickitat County. There is one provider in the planning area—Astria Yakima Regional Medical Center located in Yakima. The table below shows a comparison of the current capacity.

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Inpatient PCIs (CHARS)</th>
<th>Outpatient PCIs (Survey)</th>
<th>Total</th>
<th>Combined Inpatient &amp; Outpatient (COAP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Astria Regional Medical Center</td>
<td>108</td>
<td>113</td>
<td>221</td>
<td>260</td>
</tr>
</tbody>
</table>

As shown in step three above, both data sources show more than 200 PCIs were performed in the planning area.

**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.
Step 5: If Step 4 is greater than three 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: 575/300 = 1.916 or 1 program.)

For Steps 4 and 5, the department will show the calculations and the results in one table.

<table>
<thead>
<tr>
<th>Department’s Step Four and Step Five Table</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step</td>
</tr>
<tr>
<td>Step 2-Forecasted Demand</td>
</tr>
<tr>
<td>Step 3-Current Capacity</td>
</tr>
<tr>
<td>Net Need in Planning Area</td>
</tr>
<tr>
<td>Divide Net Need by 200</td>
</tr>
<tr>
<td>Round Down</td>
</tr>
</tbody>
</table>

Step 5 shown in the table above shows need for an additional PCI program during this 2019 concurrent review cycle using a base year of 2017 and projecting to year 2022. The department concludes that the numeric methodology demonstrates need for an additional PCI program in planning area #4.

The department concludes this sub-criterion is met for both applicants.

During the review of these projects, the department received public comments regarding availability and accessibility to PCI services in the planning area. Below is a summary of the comments submitted for Astria Health’s project. While all comments were considered during this review, because of the common theme in the comments, below is a representation of the theme under this sub-criterion.

**Public Comments in Support of Astria Health**

For the Astria Health project, many comments were submitted as a form letter, which is restated below.

Form letter received from some representatives of Astria Health and some community members

“I am writing to express my strongest support to Astria Sunnyside Hospital's certificate of need (CN) to establish an elective PCI program. Astria Regional Medical Center is, and has been for decades, the sole provider of elective PCI and cardiac surgery in Yakima, Kittitas, Klickitat and Western Benton Counties. We support the planned, orderly development of a second provider, and note that WAC 246-310-750 states that if two or more applicant hospitals are competing to meet the same forecasted net need, the department shall consider which facility's location provides the most improvement in geographic access. Geographic access means the facility that is located the farthest in statue miles from an existing facility authorized to provide PCI procedures.

The American College of Cardiology, American Heart Association and the Society for Cardiovascular Angiography and Interventions have issued formal recommendations for PCI without surgical back-up. Their most recent guidelines indicate that elective PCI in hospitals without on-site cardiac surgery can be successful and beneficial, provided that appropriate planning for
program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection. Astria Sunnyside undertook program development in 2015 and adheres to rigorous clinical processes as evidenced by its outcomes in COAP and NCDR. Astria Sunnyside also has the staff and other infrastructure in place to perform both primary (emergent) and elective PCI.

Last year Astria Regional Medical Center had more than 40 referrals from Astria Sunnyside for elective cases. A number of patients failed to follow up and have a procedure. The ones that were sent via ambulance had excellent outcomes, but had been subject to delayed treatment, duplicate testing and procedures (including groin punctures and contrast material), and higher costs. Given the proven efficacy of elective PCI, the proven quality of the Astria Sunnyside program, and the improvement to geographic access that will result, it should be given priority in the award of a certificate of need.”

Below is a representation of additional comments submitted in support of the Astria Health project.

Juan Carlos Olivares, Yakima Valley Farm Workers Clinic
“The Yakima Valley Farm Workers Clinic (YVFWC) provides comprehensive medical, dental, behavioral health and social services in select Pacific Northwest communities. In Yakima County, we operate clinics in Toppenish, Yakima, Sunnyside, Grandview and Wapato. Our services are provided without regard to ability to pay, and many of the communities we serve have significant populations of low-income families. Many of our patients face barriers to treatment based on transportation and cost. We serve more than 125,000 patients annually.

Astria Sunnyside Hospital has been a good partner for the YVFWC and shares many of the same values as our organization. As the Chief Executive Officer for YVFWC, I am intimately involved with making sure that the health care needs of our patients are met across all of our service locations. We have a high concentration of clinics within the Yakima Valley and have relied on Astria Sunnyside to provide hospital and specialist services to many of our patients. Despite the efforts of our collective organizations, barriers remain for some Lower Yakima Valley residents needing care. These barriers include, among others, the lack of local services.”

Dawn O’Polka, resident Yakima County
“Astria Regional is a great hospital and currently the sole provider of elective PCI. I support the development of a second provider and believe Astria Sunnyside Hospital is the appropriate location. They sent a large number of referrals from the lower Yakima Valley to Astria Regional in Yakima last year. It is important that patients receive the follow up procedures close to home and an Astria Sunnyside Hospital elective PCI program will facilitate for that.”

Matt Preston, resident of Yakima County
“I am in support of a 2nd provider for Sunnyside Hospital to be able to start an elective PCI Program. To help provide better service for patients in Sunnyside to not have to make patients travel an hour away when it could be done locally.”

Sister Mary Rita Rohde, Board of Directors President of Nuestra Casa in Sunnyside
“Nuestra Casa, a not-for-profit agency established in 2002 in Sunnyside, serves a wide variety of educational needs of adult immigrants who come to the Lower Yakima Valley to do much needed agricultural work Nuestra Casa also serves as a referral service for hundreds of immigrants who often don't understand how various systems work in the U.S. We know first-hand how accessible
health care is for under-served and low-income persons in Sunnyside because of the way Astria Sunnyside makes care personal and welcoming. Whenever immigrants inquire about health issues, we refer them to Astria Sunnyside Hospital because we know the hospital will serve them well.

When we learned that Astria Sunnyside Hospital had applied to establish an elective PCI program we were excited. While Astria Sunnyside can provide treatment for residents actively having a cardiac event, they are required by law to transfer or refer the more elective type patients. We know first-hand the burden and hardship that the inability of Astria Sunnyside to provide this care has had on the Lower Valley. In addition to transportation barriers, many do not trust the "big" providers in Yakima and the Tri-Cities, and others are increasingly cautious about travelling due to increased ICE activity. These individuals often come back to Astria Sunnyside actively having a heart attack and get care emergently. This impacts health, costs, and outcomes and has an impact on families and livelihood.

The demographics of the lower Yakima Valley reveal that much of the current population is low-income, underinsured, possess low literacy skills, and suffer from many chronic illnesses. Approving the Astria Sunnyside application will assure access and address community need. I recommend without reservation that The WA State Department of Health approve Astria Sunnyside's application."

Steve Rowell, Field Operations Manager, CardioSolution

"Cardiosolutions works with hospitals throughout the nation to provide the highest quality comprehensive interventional cardiology services to the patients we serve. We have staffed the catheterization laboratory at Astria Sunnyside since inception in 2015. We can attest to the benefit to the community of the hospital securing the regulatory approval necessary to add elective PCI to its cardiac program.

As you likely know, the incidence and prevalence of cardiac disease and mortality is exceptionally high in Yakima County, and the issues are compounded by poverty, trust and language barriers. Our board-certified interventional cardiologists regularly express frustration related to the hardships placed on patients and families that need to be transferred for an elective PCI. Of the 40+ elective cases transferred or referred in 2018, our cardiologists report that well more than 95% had clinical conditions that would have allowed for excellent outcomes at Astria Sunnyside. While anecdotal, the cardiologists report that a number of patients that were referred did not have an elective case performed out-of-area, and later returned with an active MI and an emergency PCI was performed. ...Astria Sunnyside has done its program development and the rigorous clinical processes are in place, as evidenced by its outcomes in COAP and NCDR. Astria Sunnyside has the necessary staffing and infrastructure to perform PCI. Given the proven efficacy of elective PCI, and the proven quality of the Astria Sunnyside program, the current delivery method is an inefficient and undesirable way of providing needed care. It increases risk and costs and has the very real potential to impact outcomes."

Harlan Halma, MD Swofford & Halma independent primary care clinic in Sunnyside

"It is our experience that too many patients when referred to Yakima or the Tri-Cities for elective care choose to forego that care. Their reasons are numerous, but they most frequently include a lack of transportation, cost (census data shows that nearly one-half of Lower Yakima Valley residents have an income that do not allow them to meet basic needs), and a lack of trust of providers outside of the Lower Valley."
Astria Sunnyside has provided 24/7 emergency PCI since 2015 with very good outcomes. Having the ability to provide elective services locally will support its overall PCI and cardiac program, but most importantly it will directly benefit Lower Valley residents. The data is compelling: The Centers for Disease Control data shows that residents of Yakima County have the highest rates of cardiac death in the State and health behaviors and health status are worse in Yakima County, and especially in the Lower Valley than in the rest of the State.

As our patients continue to age, and as Medicare and other payers demand that we become more responsible for patient outcomes, we know that we need access to more cardiac services locally. Astria Sunnyside serves the same community, and in many instances, the same exact patients as we do. Their commitment to increasing access to elective PCI will improve outcomes, and for this reason we encourage the Department's timely and full approval.”

Cindy Johnson, FACHE, Senior Vice President, Rural Physicians Group

“...Rural Physicians Group provides hospitalist physicians for Sunnyside that are committed to providing excellent patient care in the most cost-effective manner. Our physicians have worked with many patients and families that have received care through Astria's existing emergency PCI program and have been nothing but impressed with the quality of care patients have received in this program and the outcomes that have resulted. This program saves lives for the residents of this community.

Allowing Sunnyside to also provide elective PCI procedures to patients will be of great benefit to patients, families, cardiologists and the entire community. I work with patients and families on a daily basis that consider Sunnyside Hospital "their" hospital and want to receive care here whenever possible. Sunnyside is where they are comfortable, it is close to their families and is their hospital of choice.

Clearly Sunnyside has the capability to perform safely and effectively PCI procedures. They have demonstrated this repeatedly and over time through their emergency PCI program. Allowing patients to also have these elective procedures at Sunnyside will allow the cardiologists to be just that much more efficient, reduce the need for duplicate testing and procedures for patients, and again, result in much more satisfied patients and families.”

Astria Health’s project also received written support from two legislators. The supportive comments are below.

Representative Dan Newhouse, Congress of the United States, House of Representatives

“Astria Sunnyside has provided emergency cardiac services for about five years, but has been prohibited by the Washington Administrative Code from performing elective cases due to the lack of a defined need for a new provider in the region. In late 2018, the Washington State Department of Health published that in 2019 there would be the need for a new program, and Astria Sunnyside quickly indicated its intent to address the need. There is no capital expenditure for the elective program as Astria Sunnyside already has a state-of-the-art catheterization laboratory. With the exception of incremental supplies, there is no additional operational expense. Finally, I am aware that Astria Sunnyside contracts with a national cardiac firm which provides 24/7 staffing and high-quality outcomes.

As you are aware, the health disparities that exist in the region, especially in the Lower Yakima Valley, are reflected in higher rates of heart disease and mortality than in most other areas of the state. From the perspective of my constituents, there are numerous benefits to Astria Sunnyside being
approved to provide elective cases, including the fact that patients in the Lower Valley experience transportation challenges to Yakima or the Tri-Cities. Additionally, patients not actively experiencing a heart attack currently must be sent out of the Lower Valley for elective cases. As a result, EMS incurs time out of area when transporting patients an hour or longer away. This is costly and can potentially affect outcomes.”

Senator Jim Honeyford, Washington State Senate

“I represent Washington's 15th Legislative District, which includes the communities of Grandview, Selah, Sunnyside and Toppenish. I am well aware of the health care needs and concerns of my District's constituents and lend my full support to Astria Sunnyside Hospital's certificate of need application to establish an elective PCI program.

I understand that the Department of Health (Department) has defined that one new provider of elective PCI services in Yakima County is needed. Due in part to the diversity in Yakima County, and especially in the Lower Yakima Valley, data from the Department as well as the Centers for Disease Control show that residents of Yakima County have the highest rates of cardiac death in the State. The same data also shows that the health behaviors that often lead to heart conditions such as smoking and obesity are worse in the County than in much of the rest of the State.

Lower Valley residents experience barriers to access daily. Census data shows that nearly one-half of Lower Yakima Valley residents exist on income levels that cause daily challenges around basic needs, and transportation rises to the top for many. While a fare-free general, public system exists on I-82 between Yakima and Prosser, the service is only available three times per day, Monday-Friday. None of the more outlying communities in the Lower Valley has access to this public transportation, and the three times only nature of the current service, makes it nearly impossible for people to use it for accessing health care. As such, it is not helpful to those needing to travel to Yakima for care.

Astria Sunnyside has proven its ability to step up to address needs and fill gaps. They have operated an emergency PCI program. For a number of years, and last year referred about 40 patients for elective cases. I understand that a number of these patients elected not to travel, or did not have the means to travel to Yakima or the Tri-Cities, and ended up having an emergency procedure weeks or months later. This increases costs, and impacts families and outcomes. More accessible heart care for the Lower Yakima Valley is needed.”

Public Comments in Opposition of Astria Health
Virginia Mason Memorial provided comments related to this sub-criterion that opposes approval of the Astria Health project. The comments are restated below.

Virginia Mason Memorial Public Comments

“An award of the elective PCI CN to Astria Sunnyside would limit patient choice and stifle the beneficial effects of market competition by granting a monopoly on the elective PCI market in the greater Yakima valley to the Astria Health system. The Washington legislature promulgated the policy rationale for the CN Program to promote access to care, patient safety, quality outcomes, costs, and the stability of Washington's cardiac care delivery system. Given these policy directives,

10 The footnote within the Virginia Mason Memorial comments references RCW 70.38.128, which states: “To promote the stability of Washington's cardiac care delivery system, by July 1, 2008, the department of health shall adopt rules establishing criteria for the issuance of a certificate of need under this chapter for the performance of elective percutaneous coronary interventions at hospitals that do not otherwise provide
VMM is the only viable candidate for this CN and will be able to inject patient choice into the Planning Area, avoiding an Astria Health monopoly on elective PCI services.

Astria Regional, operated by the same parent entity as Astria Sunnyside, is currently the only elective PCI provider in the Planning Area. If the CN program grants the CN to Astria Sunnyside, patient access will not be enhanced because patients will not have a choice of hospital provider when seeking elective PCI services. In the absence of a choice of hospital providers, many patients will be forced to seek services outside their primary care provider's system of care, or outside of the Planning Area. Granting the CN to Astria Sunnyside would only have a limiting effect on patient choice for accessing elective PCI services. This is already demonstrated by the number of patients each year who elect to travel outside the planning area to receive elective PCI care, which equates to nearly 17% of the PCIs performed on Planning Area residents.”

“As explained in VMM’s screening responses, VMM is geographically better situated to provide services to the majority of the Planning Area population. In fact, 76% of the Planning Area population is geographically closer to VMM than to Astria Sunnyside.

A common geographic division in Yakima County is to divide the county into two subsections: the Upper Valley and Lower Valley. VMM and Astria Sunnyside are located 37 miles away from each other, with VMM (and Astria Regional) in the Upper Valley and Astria Sunnyside in the Lower Valley. The following two tables illustrate both the population and the 2017 PCI volumes based on the Upper and Lower Valley divisions.”

In addition to the comments above, YVMHA provided two tables showing the ZIP codes of cities located in the Upper Valley and Lower Valley. The table is not recreated in this section of this evaluation because it is included in another section of this document.

Rebuttal Comments from Astria Health

In response to the comments in opposition to this project, both Astria Sunnyside Hospital and Astria Yakima Regional Medical Center provided rebuttal comments. Below are excerpts from the comments.

Astria Sunnyside Hospital rebuttal comments

“Astria Sunnyside has a long and significant commitment to serving the community and an unrelenting focus on ensuring access to the most vulnerable and underserved. The recognition of this commitment was apparent in the more than 60 letters of community support contained in the record. The table below provides a sampling of the organizations, providers and civic leaders that support the Astria Sunnyside application. [Table not included in this evaluation]
As demonstrated by the following excerpts from several of the letters, the quality of Astria Sunnyside’s existing emergency only PCI program and the enhanced local access that will result from CN approval for elective PCI are among the reasons why the application is so highly supported by the community. [Astria Health provided excerpts from the public comments submitted for its application.]

In contrast, VMM arranged for a handful of letters that expressed concern about the Astria Sunnyside application. Almost exclusively, the authors of the letters opposing Astria Sunnyside’s project include representatives of providers directly employed or affiliated with VMM or present or retired cardiologists from the Yakima Heart Center (YHC). YHC is an organization that Yakima Valley Memorial Hospital paid $8 million to establish a Professional Services Agreement (PSA) and Management Services Agreement with. These agreements have resulted in these cardiologists largely changing practice patterns from then Yakima Regional Medical Center to Yakima Valley Memorial Hospital. As recent CHARS data shows, these agreements have also unfortunately resulted in more cardiac patients having to leave the Planning Area to receive treatment at Virginia Mason’s facilities in the Seattle area. Further, while VMM’s public comment put forth a number of conclusory allegations, they provided absolutely no data to substantiate any of them.

We also note that VMM was the organization that petitioned for the PCI rulemaking changes that resulted in the rules that the two PCI Planning Area 4 applications are now being reviewed under. VMM knows full well that Astria Sunnyside prevails when recently enacted WAC 246-310-750 is properly applied. The bottom line is that VMM’s public comment is a poorly veiled attempt to divert attention from the facts that: 1) Astria Sunnyside meets all applicable CN review criteria; and 2) WAC 246-310-750 explicitly gives priority to the project furthest away from the existing provider. In the case of the competing 2019 PCI Planning Area 4 applications, the applicant entitled to priority for improving geographic access is undeniably Astria Sunnyside.”

Only Astria Sunnyside’s project increases access for planning area residents. VMM’s assertion that Astria Sunnyside’s project will limit access and choice is ironic considering their project is the one that proposes an elective PCI program less than two miles from the existing program in the planning area and does nothing to increase access and choice to those underserved planning area patients residing outside the city of Yakima. Review of the public comment confirms the positive impact Astria Sunnyside’s program will have on access, choice, and availability to those most underserved in the planning area. Several of these comments were summarized above.

There also is no “monopoly” on the part of Astria Health, contrary to VMM’s suggestion. The real issue results from the PSA between Yakima Heart Center and VMM and the merger of VMM with Virginia Mason in 2016. This merger has resulted in a more than 76% increase in referrals from Yakima County to Virginia Mason in King County specifically for cardiac surgeries that should be performed locally, as depicted in Table 3:

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virginia Mason Medical Center, Seattle</td>
<td>11</td>
<td>29</td>
<td>45</td>
<td>51</td>
</tr>
</tbody>
</table>

Source: WA State CHARS data; cardiac surgery defined as the following DRGs: 216, 217, 219, 220, 222, 223, 224, 225, 226, 227, 228, 229, 233, 234, 235, 256, 268, 269, 270, 271, 272
As Table 4 shows, this arrangement has also resulted in increases to VMM’s purported emergency-only PCI program and referrals to King County for PCI.

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virginia Mason Medical Center, Seattle</td>
<td>1</td>
<td>9</td>
<td>19</td>
</tr>
</tbody>
</table>

The facts are that only the Astria Sunnyside project will increase local access and address the current barriers faced in the most underserved areas in the planning area. Case in point, travel for health care is a real concern in this relatively rural planning area, and particularly in the communities immediately adjacent to Sunnyside, often referred to as the Lower Yakima Valley. Data shows that 47% of Lower Yakima Valley residents have an income that does not allow them to meet basic needs (compared to 37% statewide). This often means that transportation is a barrier to care. While a fare-free general public system traverses along the main arterial (I-82 corridor) from Yakima to Prosser (with stops in Yakima, Wapato, Toppenish, Zillah, Granger, Sunnyside, Grandview and Prosser) the service is only available three times per day, Monday-Friday. None of the more outlying communities in the Lower Valley have ready access to this public transportation, and the three times per day nature of the current service makes it difficult for people to reliably use it for accessing health care.

Astria Sunnyside’s current Community Health Needs Assessment (CHNA) identifies transportation as a significant issue. According to the CHNA:

> Transportation to obtain healthcare services as well as grocery stores, food banks, and other essential services was noted to be very limited for those residents without a car or those who could not afford gas. One respondent noted “We are rich in healthcare resources – but there is not a way to get there.”

In summary, Astria Sunnyside’s project will improve access and reduce unnecessary transfers and diversions for elective PCIs in Planning Area 4. VMM’s project, on the other hand, would not. VMM’s project would inappropriately concentrate planning area residents’ access to elective PCIs solely in downtown Yakima.”

[Astria’s] Yakima Regional Medical Center rebuttal comments

“A letter from a VMM physician suggests that Astria Regional has had lapses in its ability to accept elective PCI patients. This statement is completely false. I have reviewed records from the time of acquisition of Astria Regional by Astria Health and can state unequivocally that there has been no time when Astria Regional was closed to elective PCI cases.

Another physician, also affiliated with VMM, suggests that Astria Regional’s cardiac surgery program is lacking essential equipment and follow-up care. This claim is also completely false, misleading, an unsubstantiated. The Astria Regional program is fully staffed, equipped, and performing open heart surgery with high quality outcomes.

There were also some vague claims related to confidence in Astria Regional’s program and quality. Again, none of these claims contained any details or were substantiated in any way, so a direct response to this rhetoric is not possible. However, what I can say without a doubt is that our program
is one that our community has and can have the utmost confidence in. The program at Astria Regional is a long-standing and successful program in which all the cardiac providers in the region provide services. The staff at our program have over 230 years of combined experience in the cardiac cath lab, something no other provider in the community or surrounding communities can legitimately claim. This has resulted in many accolades for our program including being the only hospital in Washington to receive the distinguished American Heart Association accreditation for acute cardiac care and to receive the American Heart Association's Mission Lifeline Heart Attack Receiving Center Accreditation. Importantly, Astria Regional was awarded the American College of Cardiology's NCDRACTION Registry Platinum Performance Achievement Award for 2018. This award recognizes Astria Regional's commitment and success in implementing a higher standard of care for heart attack patients and signifies that Astria has reached an aggressive goal of treating these patients to standard levels of care as outlined by the American College of Cardiology/ American Heart Association clinical guidelines and recommendations. Astria Regional is one of only 203 hospitals nationwide to receive the same honor. To receive the ACTION Registry Platinum Performance Achievement Award, Astria Regional demonstrated sustained achievement in the ACTION Registry for eight consecutive quarters and performed at the top level of standards for specific performance measures.”

Department Evaluation

The numeric methodology outlined above objectively addresses the availability and accessibility of existing providers in the planning area by requiring existing hospitals providing PCI services provide a minimum of 200 PCI’s before a new provider can be approved. This standard ensures sufficient PCI volumes for the existing provider, as well as the proposed new provider.

Public comments in support of Astria Health’s project at Astria Sunnyside Hospital express the desire for another PCI provider in the community of Sunnyside and its immediate surrounding areas. Further comments provided by state legislators express the need for a provider that is located in the Lower Yakima Valley.

Information in the Astria Health application, including the public comments, support need for another PCI provider in the planning area under this sub-criterion.

Comments provided in opposition to the Astria Health project assert that approval of the project would limit patient choice to one PCI provider because the existing provider in the planning area—Astria Regional Medical Center—is also an Astria Health facility. Further, comments in opposition state that the majority of the planning area population is located in the Yakima area, rather than lower Yakima Valley. These assertions in opposition conclude that a new provider for the planning area should be located close to the majority of the population that would be using the tertiary services.

In response to this assertion, Astria Health states that there would not be a monopoly of PCI services in the planning area if the Astria Sunnyside Hospital application is approved. Rather, Astria Health contends that a monopoly was created for emergent PCIs with the affiliation between Virginia Mason Medical Center and Yakima Memorial Hospital in year 2016, creating the hospital now known as Virginia Mason Memorial. Tables were provided in the rebuttal comments to demonstrate an increase in PCI activity at Virginia Mason Memorial for years 2017 and 2018, when compared to year 2015 and 2016. A demonstrative table was provided to show the increase in referrals from Virginia Mason Memorial to Virginia Mason Medical Center located in Seattle for planning area patients for year 2017.
The department will not opine on the ‘monopoly’ assertions perceived to be the result of Virginia Mason Memorial’s affiliation with Virginia Mason Hospital. The department will also not opine on the monopoly assertions that focus on Astria Health. These two assertions are not reviewed in this section of the evaluation or under any superiority criteria reviewed in PCI applications.

The department concludes that Astria Health provided sufficient documentation to demonstrate that the existing provider of PCI services may not be available and accessible to meet the projected need in the planning area. This sub-criterion is met for Astria Health’s project.

**Public Comments in Support of Yakima Valley Memorial Hospital Association**
Below is a summary of the comments submitted Virginia Mason Memorial’s project. While all comments were considered during this review, because of the common theme in the comments, below is a representation of the theme under this sub-criterion. For the Virginia Mason Memorial project, some comments were submitted as a form letter, which is restated below.

Form Letter received from representatives of Virginia Mason Memorial

“The Emergency Department at VMM serves more than 80,000 patients annually, making it one of the busiest in the State. VMM’s ED works collaboratively with our two catheterization labs and physicians at Yakima Heart Center to assure that cardiac patients are readily accepted and obtain revascularization with a door-to-balloon time that consistently exceeds best practices. In addition, with a highly skilled and experienced staff-who provide this service on a full time basis, and live in Yakima- VMM performed over 200 emergency PCIs in 2018, and over 2,200 in the past 18 years.

VMM is ready to perform these same services on an elective basis, and are set up to do so without the need for additional staff, capital, or an increase in operating costs. I have no question that VMM will be able to meet the required volume of PCIs and all other quality standards required by Washington State.

Currently, only Astria Regional hospital is able to perform elective PCIs in planning area #4. I believe patients deserve more than one choice, from more than one health system, to receive this service. Recently, Astria Health filed for bankruptcy. As [writer’s title here], it is of utmost concern to me the number of patients who are increasingly anxious and uncomfortable with the thought of being transferred to Astra. Patients deserve to receive comprehensive, consistent care from VMM, whether that service is emergent or elective.

Access is an important consideration in the CofN application. With specialty centers in Ellensburg and Sunnyside, we are able to provide routine cardiovascular services across the planning area. When an elective PCI is needed, we can get patients safely to VMM hospital to perform that service. Cost is also a component of access. Based on publicly reported data, VMM has one of the lowest total charges for PCI procedures in Washington State, significantly lower than both Astria Sunnyside and Astria Regional.

Virginia Mason Memorial has been preparing and planning to deliver this specialized cardiovascular care for more than 10 years. They [We] are ready.”

Below is a representation of additional comments submitted in support of the Virginia Mason Memorial project.
James Sartin, resident of Yakima County
“I am writing this letter to show my support of Virginia Mason Memorial Hospital to establish an elective PCI program that is needed to serve residents in Yakima, Klickitat and Kittitas Counties.

I would encourage you to consider this very strongly so that the general public has the opportunity to go to a hospital of their choice.

If I should have to go to a hospital for heart procedures I will not go to Astria because of past history. Therefore, please consider memorial as an additional hospital for the public.”

Richard Linneweh, Jr. resident of Yakima County
“I am writing in support of the certificate of need application for elective PCI for Virginia Mason Memorial Hospital. As a community member I expect choices when it comes to my medical care. I expect to be able to choose a quality physician, with a high level of training and experience, at an acceptable cost.

Virginia Mason Memorial has been providing PCI services on an emergency basis since 2001. As a result, they have performed this procedure more than 2,200 times over 18 years. They are ready to perform these same services on an elective basis, without the need for additional staff, capital; and, without an increase in operating costs.

Virginia Mason Memorial has a robust cardiac care program in collaboration with their physician partners at Yakima Heart Center. The same interventional cardiologists who perform the emergency PCIs would perform the additional elective cases. All of the staff and physicians who provide this service do so on a full time basis and live in Yakima.”

Jeff Kaplan, MD
“I am writing this letter in support of Virginia Mason Memorial’s application for Certificate of Need #19-65 related to elective PCI. I am a primary care physician who has lived in Yakima for nearly 30 years. The majority of my patients are senior citizens. Over the last 10 years more and more of my patients have expressed a strong preference to receive their inpatient care at Virginia Mason Memorial. As I no longer practice inpatient medicine, this decision is independent of whether I would be involved in their hospital care. It primarily relates to their perception that VMM is where they will receive optimal care by physicians rooted in the community, who will communicate with their primary care provider and work well together as a team. This preference extends to where my patients go when they have chest pain or worsening of their cardiac symptoms. It is exceedingly rare for them to choose a facility other than Virginia Mason Memorial. I also cannot recall any colleague who, in recent years, has not expressed the same preference.”

R. Brian Padilla, MD ED Medical Director, Virginia Mason Memorial Hospital
“I serve as the Emergency Department Medical Director and Attending Physician at Virginia Mason Memorial Hospital (VMM) in Yakima, Washington. I am writing to give my unwavering support to the Certificate of Need for elective PCI application that has been submitted by VMM. I have worked at VMM (formerly Yakima Valley Memorial Hospital) for 18 years. I have served as chief of staff, ED medical director, and was on the board of trustees for many years. I am a board certified emergency medicine physician and a fellow of the American College of Emergency Physicians. I live, work, and play in the Yakima valley. I have a special understanding of the needs of our community.
The Yakima valley is a unique place. Our catchment population exceeds 250,000 people. We have to be very self-sufficient here as access to tertiary care facilities is difficult, expensive, and often unavailable due to inclement weather. Over the years VMM, in partnership with the Yakima Heart Center, has built an outstanding cardiovascular service line. Yakima Heart Center’s cardiologists, NPPs, and technologists that we partner with are outstanding. I’ve entrusted them to care for my family members. The partnership that has been built with Yakima Heart Center evolved into a bustling practice that caters to the needs of our community. VMM has performed over 2,200 PCI procedures in the last 28 years. We are the hospital of choice in our community. Our cardiovascular team certainly has the expertise and capacity to perform elective PCIs. We have 2 busy cath labs and a third is in the works.

I understand that you are considering other facilities for the certificate of need. I applaud your due diligence. Currently only Astria Regional Hospital has the CON for elective PCI. A look at our local newspaper will demonstrate some of the hurdles that Astria Regional is currently facing. Virginia Mason Memorial will be geographically closer to than Astria Sunnyside (another applicant for the CON) to 76% of the planning area population. I mentioned that VMM has a fairly sizable market share. We are the preferred hospital for the majority of patients in our community. Our commitment to the community with programs like Childrens’ Village and Cottage in the Meadow set us apart from our competitors. VMM truly does put the community first.

With only Astria Regional Hospital performing elective PCIs there is a clear and obvious need. I have no doubt that VMM with our Yakima Heart Center partners can meet the demands of our patients. We will undoubtedly meet the quality and volume standards necessary to comply with DOH standards. Given the high quality of our staff, expertise in performing PCI, and commitment to continued excellence through our quality improvement processes, VMM can build a top notch elective PCI program and should be granted the Certificate of Need.”

Douglas Corpron, MD, physician in Yakima County

“I am a third generation Family Physician, all of whom practiced medicine in Yakima and who care a lot about the quality, convenience and cost of health care in our community. I helped to found the first Family Practice Residency program in Yakima in 1975 and which continues and is connected with the Univ. of Washington Dept. of Family Medicine.

I am watching with deep concern as the Astria Hospital system here and in Sunnyside have declared Chapter 11 bankruptcy proceedings. They have never resumed full service medical care (never resumed OB, Medical nor pediatric care) in their Yakima hospital and in their cardiac care floor, they are now staffed by contract nursing and medical staff mostly. Physicians from our Yakima Heart Center continue to provide the most important part of their physician cardiac care.

It is clear to me that awarding Virginia Mason Memorial Hospital their long sought for certificate of need application for elective PCI is an important need for my community. Their physician staff live in Yakima, are well established in our community and the convenience and quality of their care in our city is most important. I understand that studies show that the cost of this care at Virginia Mason Memorial Hospital is one of the lowest in the State and much lower than at the Astria Hospital system in Yakima and Sunnyside.

The Department of Health awarding our Yakima Virginia Mason Memorial this certificate of need for elective PCI is, in my mind, a critical need at this point. Virginia Mason Memorial Hospital has been preparing for this potential for many years, they have the most vigorous and respected cardiac
program in our valley. I and the citizens of my valley will greatly benefit by your approval of this additional hospital to provide elective PCI care in our region.”

William Wheeler, resident of Yakima County
“I wish to support the Virginia Mason Memorial application for the certificate of need for elective PCI. Virginia Mason Memorial (VMM) and the Yakima Heart Center represent the most effective choice for elective PCI in Yakima.

Astria Regional now has this CON and has filed Bankruptcy. The levels of care at VMM is steady, reliable and served with local Coronary experts.

Because of the ever changing status of Astria I, and many of my friends, if in need of elective PCI will leave town and go to Seattle for known professional service. I know this is a serious assessment of the Yakima status, but as a resident of Yakima for 42 years and at 85 years old I would not use Astria. Please look at the VMM emergency PCIs, over 2000, with excellent results over the past 18 years. Most people will think that emergency PCIs are subject to more problems that elective, but if so then VMM’s performance stands out even more. Please act favorably in the VMM application for elective PCI. ”

Barbara Hilman, resident of Yakima County
“I think the town of Yakima needs to have a second PCI. It only makes sense with the large population of the Yakima Valley. Second the heart center is just right across the street. The doctors have a much need of this extra facility.”

Yakima Heart Center Physicians
“The thirteen physician cardiology group at the Yakima Heart Center wholeheartedly supports Virginia Mason Memorial Hospital's (VMM) Certificate of Need APP#19-65 for elective percutaneous coronary intervention (PCI) at VMM. For over 30 years our practice has provided PCI here in Yakima, and since 2001 we have provided 24/7 emergency PCI at both of our local hospitals. Our current three cardiac interventionalists (Drs, Berman, Keshavaprasad, and McLaughlin) have well over 50 years of combined interventional experiences, and far surpass minimum yearly PCI totals suggested by national cardiology guidelines. We fully participate in three state or national cardiac intervention registries for quality assessments, and our results always compare favorably to the benchmarks of all three of these programs (COAP state registry, American College of Cardiology (ACC) national PCI registry, and American Heart, Association (AHA) acute MI national registry).

The excellent cath lab staff (ten cardiovascular techs and seven nurses) at VMM did 1,650 cath lab procedures in 2018, including 225 emergency PCIs. Historically our group has done over 2,200 emergency PCIs at VMM, and provides all the ancillary imaging that is often needed with these PCI patients (nationally accredited echo, nuclear, and vascular ultrasound labs and staff).

Current ACC/ AHA/ ACSI guidelines for percutaneous coronary intervention do not recommend mandatory onsite cardiac surgery for elective procedures. Our long history of high volume and high quality results of PCI at VMM strongly supports this Certificate of Need proposal for elective PCIs at VMM. We would be happy to answer further questions or add further details as need be at any time.”
Robert Williams, MD, community member and physician in Yakima County
“I am writing in support of the certificate of need (CON) application for elective PCI for Virginia Mason Memorial Hospital. As a community member and a physician, I am well aware of the need for quality and experience in the provision of cardiac care.

I believe awarding Virginia Mason Memorial the certificate of need to perform elective percutaneous coronary intervention's (PCI) would expand patient access to quality cardiac care at a time when our aging population needs and expects such access.

In contrast, granting Astria Sunnyside the CON for elective PCI would be a high risk choice, given the Astria Health system currently being in the middle of a bankruptcy proceeding. This casts significant doubt on their future viability. In addition, granting Astria Sunnyside the CON, would put all elective PCI in this region in the hands of this same Astria Health system.

Astria Sunnyside's location is farther away from the majority of the patient population that will need these services compared to Virginia Mason Memorial. Lastly, the experience level of Astria Sunnyside in PCI is minimal compared to Virginia Mason Memorial.

The cardiac care program at Virginia Mason Memorial, combined with the Yakima Heart Center, has an established record of providing high-quality, cardiac care for our community.

In this time of ever increasing costs of healthcare, Virginia Mason Memorial is combatting this issue by having one of the lowest total charges for PCI procedures in Washington State; significantly lower than both Astria Sunnyside and Astria Regional.

I appreciate the opportunity to share my thoughts with you. I would respectfully urge you to grant Virginia Mason Memorial the Certificate of Need for Elective PCI in South Central Washington. As a citizen and long-time physician in this area, I feel that Virginia Mason Memorial is clearly the right choice in this important decision to provide improved access to quality care for the citizens of Washington State.”

Julie Petersen, CDO Kittitas Valley Healthcare
“I am writing in support of Virginia Mason Memorial's Certificate of Need Application #19-65 to provide adult elective percutaneous coronary interventional services.

Kittitas Valley Healthcare and Virginian Mason Memorial have a long standing referral relationship. Both our communities and our providers in Kittitas County appreciate having local access to high quality tertiary care services that are not provided at KVH. Because of our established relationship with Virginia Mason Memorial, we have confidence in the quality of their patient care, the responsiveness of their operations and their communication with our providers.”

Virginia Mason Memorial’s project also received written support from three legislators. The supportive comments are below.

Representative Chris Corry, Washington State House of Representatives
“I am writing in support of the certificate of need application for elective PCI for Virginia Mason Memorial Hospital. As a community member I expect choices when it comes to my medical care. I expect to be able to choose a quality physician, with a high level of training and experience, at an acceptable cost.
Awarding Virginia Mason Memorial the certificate of need to perform elective percutaneous coronary intervention's (PCI) would expand my choices when it comes to health care in the Yakima Valley. Giving the certificate of need to Astria Sunnyside would make Astria Health the only option for this service, taking away my choice of healthcare systems.

The cardiac care program at Virginia Mason Memorial, combined with the Yakima Heart Center, provides me with high-quality cardiac care from physicians who live and work within the Yakima community. I value knowing that my care will be entrusted to this team, the same physicians who currently perform hundreds of emergency PCIs each year and maintain a full-time presence at Virginia Mason Memorial. Knowing I have access to this team of local experts not just in an emergency, but as a pre-emptive measure, makes me feel as if my health care needs are a top priority. Plus, Virginia Mason Memorial is centrally located and allows me and my neighbors to receive services conveniently.

Additionally, I believe that the cost of healthcare can become a barrier for treatment. Virginia Mason Memorial is combatting this issue by having one of the lowest total charges for PCI procedures in Washington State; significantly lower than both Astria Sunnyside and Astria Regional. It is important to me that should I need a procedure of this type, that it not become a financial burden to myself or my family."

Representative Gina Mosbrucker, Washington State House of Representatives

“I am writing in support of Virginia Mason Memorial Hospital's application for a certificate of need to perform adult elective percutaneous coronary interventions (PCI) through the Department of Health. As a State Legislator in the Central Washington area, I know that our communities expect choices when it comes to medical care. We expect to be able to choose a quality physician, with a high level of training and experience, at an acceptable cost.

Awarding Virginia Mason Memorial the certificate of need to perform elective PCIs would expand options it comes to health care in the Yakima Valley. The cardiac care program at Virginia Mason Memorial, combined with the Yakima Heart Center, provides high-quality cardiac care from physicians who currently perform hundreds of emergency PCIs each year and maintain a full-time presence at Virginia Mason Memorial. Virginia Mason Memorial is centrally located and allows our community to receive services conveniently.”

Representative Bruce Chandler, Washington State House of Representatives

“I am writing in support of the certificate of need application for elective PCI for Virginia Mason Memorial Hospital. As a community member I expect choices when it comes to my medical care. I expect to be able to choose a quality physician, with a high level of training and experience, at an acceptable cost.

Awarding Virginia Mason Memorial the certificate of need to perform elective percutaneous coronary intervention's (PCI) would expand my choices when it comes to health care in the Yakima Valley. Giving the certificate of need to Astria Sunnyside would make Astria Health the only option for this service, taking away my choice of healthcare systems.

The cardiac care program at Virginia Mason Memorial, combined with the Yakima Heart Center, provides me with high-quality cardiac care from physicians who live and work within the Yakima community. I value knowing that my care will be entrusted to this team, the same physicians who
currently perform hundreds of emergency PCIs each year and maintain a full-time presence at Virginia Mason Memorial. Knowing I have access to this team of local experts not just in an emergency, but as a pre-emptive measure, makes me feel as if my health care needs are a top priority. Plus, Virginia Mason Memorial is centrally located and allows me and my neighbors to receive services conveniently.

Additionally, I believe that the cost of healthcare can become a barrier for treatment. Virginia Mason Memorial is combating this issue by having one of the lowest total charges for PCI procedures in Washington State; significantly lower than both Astria Sunnyside and Astria Regional. It is important to me that should I need a procedure of this type, that it not become a financial burden to myself or my family.”

Public comments in opposition to the Virginia Mason Memorial project are below.

James Kneller, MD, PhD, cardiologist at Astria Regional Medical Center in Yakima
“I am a cardiologist/electrophysiologist at the Astria Regional Medical Center in Yakima, WA. I am writing to provide my insights into the issue of elective PCI in the Yakima Valley.

Presently the Astria Regional Medical Center in Yakima has the CON for elective PCI in Yakima. This is the only hospital in Yakima with onsite cardiac surgery backup. I am aware that the Virginia Mason Memorial Hospital (VMM) in Yakima (previously the Yakima Valley Memorial Hospital) has applied for the CON for elective PCI multiple times in the past, and this has been consistently declined.

Whenever possible, I believe that elective PCI should be performed at the hospital with onsite cardiac surgery backup. To illustrate the importance of this, I am including a link to an article published just last month titled "Cardiac Arrest, Death During Elective PCI Concerningly Common". (https://www.medscape.com/viewarticle/913869).

In this study of 113,000 elective cases, 330 patients arrested during PCI, or one per 344 procedures. While this number may be statistically small, we must remember that we are discussing patient lives. In Yakima, the Astria Regional hospital and VMM Hospitals are less than one mile apart, and the cardiologists at VMM all have privileges and are routinely present at Astria Regional. In this setting, there remains no need to subject patients to the increased risk of having elective PCI procedures away from site with cardiac surgery. In my opinion, a CON should NOT be awarded to VMM.

As an electrophysiologist, I cannot speak to the PCI needs at Astria Sunnyside. This hospital is certainly more geographically isolated, and it does represent an appreciable hardship for patients to travel to Yakima. In light of this, it does seem more appropriate to offer elective PCI in Sunnyside. I trust my perspective is helpful as you deliberate among the options for elective PCI in the Yakima Valley.”

Rebuttal Comments from Yakima Valley Memorial Hospital Association
The applicant provided rebuttal comments on the access to care issues raised in opposition to its project and the some of the letters of support for Astria Health’s project. The rebuttal comments are below.

“Statistics do not support commentator’s access to care arguments.

The issue of access to care was a repeated concern echoed in the public comments submitted in support of Astria Sunnyside’s application. However, this concern is mainly anecdotal. The statistics
support that for emergent PCIs, the majority of cases were performed at Astria Regional, Virginia Mason Memorial, or Kadlec Regional Medical Center—rather than at Astria Sunnyside. In 2017, Astria Sunnyside only performed 18 PCIs, whereas there were over 101 patients from the Lower Valley that received PCIs, the majority of which were emergent. Geographic access/location does not appear to be a key determinant to patient receipt of care. Many of these patients trusted Virginia Mason Memorial for their emergent care and traveled away from the geographically closer location, Astria Sunnyside, to receive it.

In an effort to better service the residents of the Lower Valley, Virginia Mason Memorial opened our Lower Valley Specialty Center in Sunnyside, in December of 2018. The specialty center is designed to provide current and future Virginia Mason Memorial patients and families access to healthcare services closer to home. The services offered at this specialty center include cardiovascular services, provided by the same physicians from the Yakima Heart Center, who provide services at our hospital and catheterization laboratory.

The majority of the Planning Area needs improved health outcomes

Planning Area 4 has among the lowest education attainment rates and many of the highest rates of health illiteracy, poverty, and unemployment in the State. Yakima County also has higher rates of uninsured individuals and higher mortality rates than Washington State averages. The leading cause of death in Yakima County is major cardiovascular disease, with nearly 7% of adults in Yakima County having cardiovascular disease.

The letters submitted in support of Astria Sunnyside’s applications encourage the CN Program to grant Astria Sunnyside the CN due to the health disparities in the Lower Yakima Valley. Virginia Mason Memorial does not dispute that there are significant health disparities across the Planning Area 4 region as compared with the remainder of the State. Unfortunately, these health disparities exist across a large section of the region and are not limited to only Lower Valley residents.

The Washington Tracking Network, provided by the Washington State Department of Health, identifies 19 indicators to compare communities on environmental and health measures across our state, including Deaths from Cardiovascular Disease (CVD). This data is provided in the form of interactive dashboards and maps (see figure 1 on page 4). Detailed data is found on-line at: https://www.doh.wa.gov/DataandStatisticalReports/EnvironmentalHealth/WashingtonTrackingNetworkWTN

The death from CVD data is rated on a 1 to 10 scale for each US Census tract and identified as “Information by Location” (IBL). A score of 1 indicating low comparable rank for cardiovascular deaths and a score of 10 being the highest rank for cardiovascular deaths. The map shows higher rates of CVD death throughout the Planning Area #4 region, particularly in Yakima County. There are 25 census tracks that have a rank above 8, with half of these at the highest rank of 10.

Both Upper and Lower Valley residents need a stable health care organization to receive cardiovascular services. That organization is Virginia Mason Memorial.

The comments related to the 40 referrals to Astria Regional do not support the need for an Elective PCI Program.

The 18 form letters reference 40 referrals Astria Sunnyside sent to Astria Regional. Noted in each of these letters was that “a number of patients failed to follow up and have a procedure,” with no explanation as to the actual number of patients who failed to follow up, or whether in further analysis
of these patients, an alternative course of treatment or provider was used (for example, if these patients ultimately sought treatment at Kadlec). None of these letters offer evidence to support these comments, and it is questionable how these 18 individuals have personal knowledge of the outcomes for each of these 40 referrals. The next sentence notes the positive results for the patients sent by ambulance – but does not explain why Astria Sunnyside, who currently operates an emergent PCI program, did not perform an emergent PCI instead of transporting these patients via ambulance. If these patients were in need of an elective PCI, then ambulance transport is unnecessary. The fact that Astria Sunnyside referred 40 patients to Astria Regional does not substantiate the need for its elective PCI program.

Further, and more worrisome, is that without these patients Astria Regional may not be able to sustain its 200 case volume threshold. Astria Sunnyside’s patient growth is predicated on keeping those patients that would otherwise receive treatment at Astria Regional, therefore destabilizing an existing program. In comparison, Virginia Mason Memorial projects patient volume based on area population growth and capturing some of the estimated 17% of patients that currently utilize services outside of the Planning Area.

Virginia Mason Memorial remains the only logical candidate for the elective PCI CN. Only Virginia Mason Memorial can establish a viable program without destabilizing the existing Astria Regional program, provide patient choice for all of the residents in the Planning Area, and operate a financially feasible and stable program.”

Department Evaluation
The numeric methodology outlined above objectively addresses the availability and accessibility of existing providers in the planning area by requiring existing hospitals providing PCI services provide a minimum of 200 PCI’s before a new provider can be approved. This standard ensures sufficient PCI volumes for the existing provider, as well as the proposed new provider.

Public comments in support of YVMHA’s project express the desire for another PCI provider in the planning area and surrounding communities and suggest that patient choice of providers is a factor that should be considered in this review. Further comments provided by state legislators express the need for a provider in the planning area and also assert that patient choice for providers should be a deciding factor in this review.

Information in the YVMHA application, including the public comments, support need for another PCI provider in the planning area under this sub-criterion.

Comments provided by an Astria Health physician in opposition to the YVHMA project assert that PCI services should only be provided by a facility with on-site open heart surgery back-up; however, the same physician also asserts that approval of a project at Astria Sunnyside Hospital in Sunnyside would allow for better geographical access for patients requiring PCI procedures. Based on the implementation of the Certificate of Need PCI rules in 2009, the department will not address the topic of whether on-site open heart surgery back-up is necessary for PCI procedures. The Astria Health physician’s assertions in opposition appear to conclude that a new provider for the planning area should be located further from the existing provider.

In its rebuttal responses, YVMHA notes that ‘access to care’ is a repeated concern in the public comments in support of the Astria Health project; but considers the concerns to be anecdotal with no specific data to support the concerns. Providing historical data, YVMHA asserts that the majority
of emergent PCI cases are not receiving the services at Astria Sunnyside Hospital in Sunnyside; rather the emergent services are being obtained at either Virginia Mason Memorial or Astria Regional, both located in Yakima, or Kadlec Medical Center located in Richland within Benton County. YVMHA concludes that geographic access or location of PCI services does not appear to be a key factor for PCI patients in the planning area.

Given that both projects received comments by community members that provided a preference of geographic location for additional PCI services to be in Sunnyside or Yakima, the department will not address the topic of geographic access to care in this section of the evaluation.

Based on the information provided in the application, including both public comments and rebuttal, the department concludes that YVMHA provided sufficient documentation to demonstrate that the existing provider of PCI services may not be available and accessible to meet the projected need in the planning area. This sub-criterion is met for YVMHA’s project.

Further criteria are subject to review under this section of the evaluation. According to General Requirements in WAC 246-310-715, the applicant hospital must submit a detailed analysis regarding the effect that an additional PCI program will have on the University of Washington Medical Center (UWMC) program and how the hospital intends to meet the minimum number of procedures. The criteria and each applicant’s responses are addressed below.

**WAC 246-310-715(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.**

**Astria Health**

“This requirement was written into rule in 2007 when the UWMC Program operated with approximately 300 cases annually, which could have impacted the number of cardiac fellows it was able to train. In 2017, the UWMC Program performed more than 700 cases. Approval of the Sunnyside program will not reduce the volume at the University of Washington Medical Center (UWMC). In 2017, UWMC performed a total of 23 PCIs on residents of PCI Planning Area 4. The patient origin of UWMC’s Planning Area 4 patients is shown in Table 11.” [source: Application, p17]

Astria Health provided a table showing the number of planning area #4 residents that obtained PCI services at UWMC in Seattle for year 2017. The table is not recreated here, but shows a total of 8 inpatient residents and 15 outpatient residents, for a combined total of 23.

“Sunnyside physicians have historically referred PCI patients to the PCI program at Astria Regional. As such, we do not anticipate that UWMC’s volumes from our service area will be impacted, and we do not expect any reduction in cases performed at UWMC based on the commencement of elective services at Sunnyside.

Both Astria and Sunnyside fully recognize and values the resource that an academic tertiary center provides to Washington State and its essential role in the training of new cardiologists. We pledge to support the UWMC, and a letter to the UWMC documenting our data and supporting its program is included in Exhibit 1.” [source: Application, p17 and Exhibit 1]
In its letter to University of Washington Medical Center (UWMC), Astria Health identified the counties and ZIP codes in planning area #4 and provided an analysis of the expected impact on the existing program at UWMC. The letter concluded with an offer to discuss the analysis or provide comments.

Documentation provided in the application demonstrates that UWMC did not submit comments on the Astria Health analysis or provide a response to the letter. [source: April 30, 2019, screening response, p6]

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**
University of Washington Medical Center did not provide comments specific to this application. Information provided in the application states that fewer than 30 patients were referred to University of Washington Medical Center from physicians in planning area #4. Based on the information above, the department concludes that **this sub-criterion is met**.

**Yakima Valley Memorial Hospital Association**
“**In 2017, The University of Washington Medical Center performed 951 PCIs as reported to the COAP PCI registry at the University of Washington Medical Center. Of these, 28 PCIs procedures were performed on Planning Area #4 residents, which is 2.8% of all PCI cases performed at the UW Medical Center. The patient origin from UW's cases in Planning Area #4 are shown in Table 7.**” [source: Application, p18]

The applicant provided a table showing the number of planning area #4 residents that obtained PCI services at UWMC in Seattle for year 2017. The table is not recreated here, but shows a total of 13 inpatient residents and 15 outpatient residents, for a combined total of 28.

“We do not expect cardiology referral patterns to UWMC to noticeably change when an elective PCI program is established at Virginia Mason Memorial. In most cases, inpatient PCIs are typically not elective procedures. Therefore, if we estimate that of the total PCIs performed at the University of Washington from planning area #4, only 13 (1.4 %) might be considered elective. Therefore, we do not expect a noticeable reduction in cases performed at UWMC based upon the commencement of elective PCI services at Virginia Mason Memorial.

*A letter summarizing our analysis of impact of an elective PCI program at Virginia Mason Memorial on the UWMC was sent to Dr. Larry Dean on February 15, 2019. See Exhibit 7.*” [source: Application, p19 and Exhibit 7]

In its letter to University of Washington Medical Center (UWMC), YVMHA identified the counties and ZIP codes in planning area #4 and provided an analysis of the expected impact on the existing UWMC program. The letter concluded with an offer to discuss the analysis or provide comments.

Documentation provided in the application demonstrates that UWMC did not submit comments on the YVMHA analysis or provide a response to the letter.
Public Comments
None

Rebuttal Comments
None

Department Evaluation
University of Washington Medical Center did not provide comments specific to this application. Information provided in the application states that less than 30 patients were referred to University of Washington Medical Center from physicians in planning area #4. Based on the information above, the department concludes that **this sub-criterion is met**.

WAC 246-310-715(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 (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.

Astria Health
“Sunnyside’s estimated volumes for the first three years of expanded operation is (sic) detailed in Table 9.

**Applicant’s Table**

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Source: Applicant.

Our estimates considered the 25 actual emergency PCIs performed in 2018 as well as the 40+ for elective PCI, for a total of 65 PCIs. Our actual year 1 volumes conservatively assume that we will continue to refer some patients for elective PCI. The unmet need in 2022 in the Planning Area is for 279 cases, and we assume that we will capture about 50% of that unmet need. In addition, we have assumed that a percentage of cases currently being done in Yakima and/or the Tri-Cities on Lower Valley residents will return to the Lower Valley and be performed at Sunnyside.

The Department’s numeric need methodology shows that today, there is an unmet need for more than 200 PCIs in Planning Area 4, increasing to approximately 279 by 2022. In 2018, Sunnyside performed or referred 65 cases.

Sunnyside does not have any interventional cardiologists that work only at our hospital. Sunnyside has an agreement with Cardiosolutions for the staffing of our cardiac service 24/7. Two of the interventional cardiologists assigned to Sunnyside (Dr. Ravage and Dr. Zubair), will cover the
elective program and the others (included in Table 5) will continue to perform emergency cases only. ” [source: Application, pp15-16]

Public Comments
Virginia Mason Memorial provided comments specific to WAC 246-310-715(2). The comments are restated below. Virginia Mason Memorial’s footnotes are not repeated in this evaluation; they are part of the comments submitted by Virginia Mason Memorial and considered during this review.

"Astria Sunnyside Cannot Meet the 200 Annual PCI Volume Threshold by its Third Year of Operation.
The elective PCI volume standards ensure that hospitals see enough patients to establish consistent and quality processes and programs. Expert consensus documents published by the SCAI, ACC, and AHA have been key to the establishment of the initial minimum volume standard rules, which were originally set at 300 PCI procedures. In April 2018, the Department adopted the updated 200 annual volume standard and updated the regulatory criteria accordingly. Astria Sunnyside cannot meet the 200 annual PCI volume threshold by its third year of operation.

Astria Sunnyside has operated its catheterization lab for over three years, and in 2018 only performed 25 emergent PCI cases. To meet the 200 volume standard, Astria Sunnyside would need to achieve an unprecedented 800% increase in procedures over three years. This is simply not attainable, especially without impacting existing PCI programs.

Astria Sunnyside projects some of its volume increase by pulling PCI cases from their health system partner, Astria Regional. This could impact, and perhaps even threaten, the incumbent elective PCI program’s volume, potentially enough to drop it below the 200 annual volume standard required in WAC 246-310-720(b). Oddly, Astria Sunnyside’s own screening responses were inconsistent about the types of PCI patients referred to Astria Regional. In response to Question 10, Astria Sunnyside states that it expects a "return of 35 of the 40 cases that were referred by Sunnyside for elective PCI in 2018." However, in response to Question 15, Astria Sunnyside noted that it "referred at least 40 patients for PCI. Most of these patients were transferred via ambulance." Typically elective PCI patients do not travel via ambulance because they are not emergent patients. Further, if Astria Sunnyside was capable of performing the emergent PCI procedures, why did they not provide these services directly?

Based upon available 2017 COAP data from the Department, there were 493 total PCIs performed for Planning Area 4 patients. Astria Regional performed 260 total elective and emergent PCIs. VMM performed 195 emergent PCIs. Astria Sunnyside would need to capture all 37 remaining PCI procedures as well as pull significant volume away from both VMM and Astria Regional to increase its program to the minimum 200 PCIs, including a significant volume of emergent PCIs, which is unlikely given its lack of geographic proximity to the majority of the planning area population. The ability for Astria Sunnyside to shift this volume is doubtful, and will have an adverse effect on its sister hospital Astria Regional, threatening Astria Regional’s maintenance of the minimum volume threshold of 200 cases.

Another unsubstantiated assumption is that additional volume growth would come from outside PCI Planning Area 4. The only planning area adjacent to Astria Sunnyside is PCI Planning Area 2 (Benton, Columbia, Franklin, Garfield and Walla Walla counties). There is only one town, Prosser (with a population of about 13,000), which is closer to Astria Sunnyside than to the predominant PCI provider in Planning Area 2 - Kadlec Regional Medical Center (KRMC). In 2017, there were
only 11 PCIs reported in CHARS and the DOH Survey for Prosser residents. All but two received their PCI at KRMC, and the remaining two were performed at VMM and Virginia Mason Medical Center respectively. The Benton County COAP data lists the 24 PCIs that were reported for all of Benton County in 2017, which includes the Prosser zip code. It shows that there was only 1 PCI performed at Astria Regional for the entire county, with no cases at Astria Sunnyside. The COAP Data also shows that 10 of 24 cases from Benton County were performed at the University of Washington. It is improbable that a critical access hospital could shift any PCI volume from larger, more established PCI programs -especially the University of Washington- whose volume must not be impacted by Department rule. Reliance on cases from outside the planning area is not supported by the data.

Astria Sunnyside stated in its application that "the unmet need in 2022 in the Planning Area is for 279 cases, and we assume that we will capture 50% of that unmet need." Astria Sunnyside does not provide any data to support the assumption that they "will capture 50% of the unmet need." It is questionable that Astria Sunnyside, a critical access hospital which (1) is geographically farther away from the population and (2) does not have the established resources of a full hospital, will be able to achieve this claim.

In conclusion, the SCAI/ACCF/AHA consensus document of 2014 has stated that there is an association between volume and quality and that this volume threshold appears to be at 200 cases per year for a facility. The CN Program's current volume threshold was not arbitrarily established, they are based on ensuring quality outcomes and patient safety. The CN Program cannot, with any level of confidence, determine that Astria Sunnyside can even come close to this important patient safety threshold.”

“Astria Sunnyside is Geographically Further than the Majority of the Patient Population
As explained in VMM's screening responses, VMM is geographically better situated to provide services to the majority of the Planning Area population. In fact, 76% of the Planning Area population is geographically closer to VMM than to Astria Sunnyside.

A common geographic division in Yakima County is to divide the county into two subsections: the Upper Valley and Lower Valley. VMM and Astria Sunnyside are located 37 miles away from each other, with VMM (and Astria Regional) in the Upper Valley and Astria Sunnyside in the Lower Valley. The following two tables illustrate both the population and the 2017 PCI volumes based on the Upper and Lower Valley divisions:
In order to successfully meet the 200 PCI volume threshold, Astria Sunnyside needs to capture all of the PCI volume from the Lower Valley as well as nearly 100 cases from a population that resides closer to VMM and Astria Regional. Not only is it unlikely that Astria Sunnyside would be able to capture this volume, but even if it was successful, it would hurt the elective PCI volume of Astria Regional.

Out of total PCIIs performed in Planning Area 4 in 2017, approximately 100 cases were performed on patients residing geographically closer to Astria Sunnyside. Of those 101 cases, the majority (73 cases) were likely emergent PCI procedures (based on the statewide percentage of emergent PCIs - 72%). However, in 2017, Astria Sunnyside only performed 18 PCI cases. Even of those patients who are geographically closer, Astria Sunnyside was only able to capture less than 25% of the emergent cases performed.
Astria Sunnyside also assumes that patients will return to the Lower Valley for elective PCI care. We question the validity of this assumption. Many of the patients leaving Planning Area 4 seek elective PCI services at large tertiary medical centers in Seattle (namely University of Washington, Swedish Health Services and Virginia Mason). These patients are already electing not to receive services at Astria Regional, which is closer than Seattle-based hospitals. We question the likelihood that a critical access hospital has the ability to attract these patients away from established tertiary medical centers.”

Rebuttal Comments
In response to the concerns raised by YVMHA regarding the projected volumes at Astria Sunnyside Hospital, Astria Health provided the following rebuttal comments. [source: August 14, 2019, rebuttal comments, pp12-13]

“While VMM suggests that Astria Sunnyside is not capable of meeting the 200 minimum volume, Astria Sunnyside’s screening response describes in detail the specific assumptions used in our volume projections. These assumptions and projections are reasonable and ensure the program will meet the 200 minimum volume by the end of the third full year of operation. These assumptions are again summarized below:

- The volumes during the first year (2020, 9 months) represents the 25 actual emergency PCIs performed in 2018 as well as a return of 35 of the 40 cases that were referred by Sunnyside for elective PCI in 2018, typically to Astria Regional Medical Center, for a total of 60 PCIs. Projected year 1 volumes conservatively assume no growth over 2018.
- Per the methodology, the unmet need in the planning area in 2021 is interpolated to be 274 cases. Sunnyside’s actual 2018 patient origin per CHARS indicates that 8% of our total patients reside outside of PCI Planning Area 4. Because PCI is a regional service, in year 2, it was assumed that 10% would come from outside of the Planning Area (14 cases). It also assumed that another 10% (14 cases) will come from PCIs currently being performed in Yakima, the Tri-Cities or elsewhere on Lower Valley residents that will return to the Lower Valley and be performed at Sunnyside. Note: the “return” of cases that are being performed elsewhere is not part of the unmet need of 274; these patients are currently receiving a PCI but are travelling outside of the Lower Valley to do so.
- This means that of the estimated year two 140 cases, 14 will be from outside of the Planning Area, and 14 will be on PCI patients returning to the Lower Valley, leaving 112 from the planning area’s unmet need. The math is as follows:
  112 net new Planning Area cases projected for Sunnyside/274 cases of unmet need
  = 40.9% market share of unmet need
- In year 3, similar assumptions were made, but we increased the number of patients from out of area choosing to have a PCI at Sunnyside from 10% to 15%. Again, we assumed that 10% of our volume will come from Lower Valley residents returning to the Lower Valley for their PCI: From the estimated year three 205 cases, 20.5 will reside outside of the Planning Area, and 30.75 will be on PCI patients returning to the Lower Valley, leaving 154 from the planning area’s unmet need. The math is as follows:
  154 net new Planning Area cases projected for Sunnyside/279 cases of unmet need
  = 55.2% market share of unmet need

These assumptions are sound and reasonable, while also resulting in increased access for vulnerable and underserved populations in the planning area. VMM’s concerns about taking market share from Astria Regional Medical Center are unfounded and, in any event, are concerns that would exist with VMM’s proposal as well.”
**Department Evaluation**

Stated in WAC 246-310-700, PCI is a tertiary health service as listed in WAC 246-310-020. Tertiary health service is defined in WAC 246-310-010(58) below.

"Tertiary health service" means a specialized service meeting complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care."

This standard requires an applicant to substantiate its projected PCI volumes for the first three years of operation. The intent of this standard is two-fold:

1) to ensure that the project hospital can meet the minimum volume standard of 200 PCIs by the end of the third year of operation; and
2) to ensure that the physicians associated with the project hospital can meet the minimum volume standard of 50 PCIs by the end of the third year of operation.

When the required minimum volume standards are coupled with the numeric need methodology that requires a minimum net need for 200 PCI’s before a new provider can be approved, the result is the intent that new providers should not rely on capturing patients from existing providers. This means that a new provider would not assume significant changes in referral patterns for PCI patients—either elective or emergent.

Astria Health clarified in its screening responses that one factor used as a basis for its projections for year one volumes is the historical number of emergent PCIs performed at Astria Sunnyside Hospital. This number represents 25 PCIs performed in 2018. Another factor relied on by Astria Health is the 35 cases it referred to Astria Regional Medical Center in Yakima for year 2018. Astria Health states it does not have access to historical data showing the number of cases it transferred to any providers for years 2016 and 2017 because its PCI database does not collect this information. Its application relies on 2018 data for cases transferred to Astria Regional Medical Center. These two factors [25 + 35] represent the 60 projected PCIs for year one at Astria Sunnyside Hospital and are based on 2018 data. The assumptions for year one can be substantiated and considered reasonable.

For year two (2021), Astria Health projects 140 PCI cases would be performed at Astria Sunnyside Hospital. Astria Health uses the unmet need in the planning area of 274 cases as a basis for part of its projected number of cases using the calculation below.

\[
112 \text{ new patients} = 40.9\% \text{ market share of the unmet need of 274}
\]

Astria Health does not provide the rationale for its projected market share of 40.9%. The 112 patients cannot be substantiated by data provided in the application, screening responses, or rebuttal documents. The department cannot conclude that the resulting number of projected patients in year two based on the market share percentage is reliable.

Astria Health also uses Astria Sunnyside Hospital’s patient origin data that demonstrates 8% of its patients reside outside of the PCI planning area #4 that includes Kittitas and Yakima counties, plus three specific ZIP codes for east Klickitat County. Because PCI is a regional service, for year two, Astria Heath assumes this percentage will increase to 10%, which represents 14 patients.
To substantiate this assumption, the department reviewed the most recent three years patient discharge and patient day data reported by Astria Sunnyside Hospital to the Department of Health’s hospital data collection office (CHARS). Each of the three years is shown in Table 3 below.

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PCI Planning Area</strong></td>
<td>2,177</td>
<td>2,224</td>
<td>1,161</td>
</tr>
<tr>
<td><strong>Outside Planning Area</strong></td>
<td>199</td>
<td>184</td>
<td>95</td>
</tr>
<tr>
<td><strong>Patient Discharges</strong></td>
<td>6,435</td>
<td>6,734</td>
<td>3,460</td>
</tr>
<tr>
<td><strong>Patient Days</strong></td>
<td>503</td>
<td>508</td>
<td>267</td>
</tr>
</tbody>
</table>

As shown in the table above, neither patient discharge nor patient day data for year 2018 substantiates Astria Health’s assumption that 8.0% of its patients reside outside of the PCI planning area. The table also does not support any increase that was assumed by Astria Health. It is noted in the table above that the 2018 patient discharge and patient day data is approximately one half of the previous two years. This represents a decrease in both patients and patient days for the most recent year available.

Table 4 below shows the three year average of the patient discharges and patient days for Astria Sunnyside Hospital.

<table>
<thead>
<tr>
<th></th>
<th>3 Year Average</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Discharges</strong></td>
<td><strong>Patient Days</strong></td>
</tr>
<tr>
<td><strong>PCI Planning Area</strong></td>
<td>1,854</td>
</tr>
<tr>
<td><strong>Outside Planning Area</strong></td>
<td>159</td>
</tr>
</tbody>
</table>

While Table 4 above may be used to support the assumption that 8.0% of Astria Sunnyside Hospital’s patients reside outside of the PCI planning area, as noted in the previous table, there is no historical indication of an increase in this percentage. As a result, the assumption that this percentage will increase to 10% for year two cannot be substantiated.

Astria Health also provided the following assumption for its projected number of cases in year two. [source: August 14, 2019, rebuttal comments, p3]

“We also assumed that another 10% (14 cases) will come from PCIs currently being performed in Yakima, the Tri-Cities or elsewhere on Lower Valley residents that will return to the Lower Valley and be performed at Sunnyside. Note: the “return” of cases that are being performed elsewhere is not part of the unmet need of 274; these patients are currently receiving a PCI but are travelling outside of the Lower Valley to do so.”

The assumption above expects to change referral patterns for planning area patients and capture patients from the existing providers. This approach, while initially seems reasonable, is not a reliable
factor that can be used for a new PCI program. There are numerous reasons that a patient would choose to obtain elective PCI services from a specific provider, and geographic access is not always the deciding factor for patients or families. Astria Health did not provide any other supportive documentation or data to substantiate that it would or could capture these patients. Further, as stated above, Astria Health does not have any historical data for years 2016 and 2017 to show that these patients were referred to the existing providers by Astria Sunnyside Hospital. Rather, Astria Health assumes that these patients with a ‘Lower Yakima Valley’ ZIP code would choose to obtain PCI services at Astria Sunnyside Hospital. This assumption cannot be substantiated with data from Astria Health and cannot be considered reliable.

In summary, for year two, Astria Health’s projected number of cases of $112 + 14 + 14 = 140$ cannot be substantiated.

For year three (2022), Astria Health projects 205 PCI cases at Astria Sunnyside Hospital. Astria Health uses the unmet need in the planning area of 279 cases as a basis for part of its projected number of cases using the calculation below.

$$154 \text{ new patients} = 55.2\% \text{ market share of the unmet need of 279}$$

For year two, the department concluded that Astria Health could not substantiate its projected market share. Since the year three market share simply relies on an increase from year two, the department also cannot conclude this number is reliable.

Astria Health also assumed 10% of its patients would return from the Lower Yakima Valley to Astria Sunnyside Hospital, which equates to 31 patients (30.75). Astria Health assumed 15% of its patients would come from out of area, resulting in 21 (20.5).

For year two, the department concluded that Astria Health could not substantiate the two percentages used. Since year three is simply an increase in percentage from year two, the department also cannot conclude these numbers are reliable.

In conclusion, Astria Health provided reasonable assumptions for its projection in year one, which counts 25 emergent cases in 2018 and adds 35 cases referred to its sister hospital, Yakima Regional Medical Center. For years two and three, Astria Health did not provide data to substantiate its market share or percentages of PCI patients it projected to capture or recapture. Year two and three projections cannot be substantiated and do not demonstrate that the hospital would meet this standard in years two or three.

Specific to the number of PCIs performed by each of the physicians, Astria Health provided the table showing that the two physicians associated with CardioSolutions performed more than the minimum volume required (50) in each of the historical years (2016 through 2018). Given that these physicians are currently meeting this standard without approval of the PCI program at Astria Sunnyside Hospital, the department concludes that the volume standard for the physicians can be met.

Based on the information provided above and the documentation provided in the application, the department concludes that this sub-criterion is not met.
Yakima Valley Memorial Hospital Association

"Memorial’s anticipated volume during the first three years of expanded operations is detailed in Table 3.

Applicant’s Table

Table 3
Virginia Mason Memorial Hospital
Projected PCI Volumes

<table>
<thead>
<tr>
<th>Year</th>
<th>Total PCIs</th>
<th>Net PCI increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>255</td>
<td>30</td>
</tr>
<tr>
<td>Year 2</td>
<td>265</td>
<td>40</td>
</tr>
<tr>
<td>Year 3</td>
<td>275</td>
<td>50</td>
</tr>
</tbody>
</table>

Virginia Mason Memorial employed a straightforward methodology to develop these conservative volume projections, which include:

- Use of current and future total planning area PCI volumes
- Use of actual historical baseline emergent PCI volume trends for Memorial
- Incremental annual growth projections for elective and emergent PCI volumes
- Known demand for an alternative provider within Planning Area #4

Virginia Mason Memorial’s emergent PCI program has shown consistent and steady growth over the past several years. It has already surpassed the minimum volume threshold, performing 225 emergent PCIs in 2018. Table 4 shows the most recent 3-year volumes and growth percentages:

Applicant’s Table

Table 4
Virginia Mason Memorial

<table>
<thead>
<tr>
<th>Year</th>
<th>PCI cases</th>
<th>% Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>178</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>194</td>
<td>9.0%</td>
</tr>
<tr>
<td>2018</td>
<td>225</td>
<td>16.0%</td>
</tr>
</tbody>
</table>

As described previously, Memorial is already a provider for emergent PCI care. We are committed to providing both emergent and elective care commensurate with our new role as a comprehensive PCI provider.

Using the Department's PCI needs forecast methodology and the update to minimum volume threshold, Virginia Mason Memorial has already achieved a volume significantly greater than 200+ cases annually. Given the demonstrated growth of Memorial's emergent PCI program, the projected growth in the planning area, the existing level of out-migration, and the reasonableness of our market assumptions, we are very confident that we can sustain a minimum annual volume of greater than 200 total PCI cases.
There are three interventional cardiologists who provide 24/7 coverage for PCIs performed at Virginia Mason Memorial. (See Table 5). Each cardiologist provides equivalent cath lab coverage (about 122 days/year per provider) and thus have similar annual PCI case volumes. Each interventional cardiologist has current annual volumes meeting the 50 case volume threshold with our existing emergent PCI services (Table 5). In addition to the case volume performed at Virginia Mason Memorial, these same interventional cardiologists are the primary providers at Astria Regional. While the application specifies "only at the applicant hospital", it is noted that each performs a similar, if not higher, volume of additional PCI procedures at Astria Regional, which helps ensure proficiency associated with high volume providers.

### Applicant's Table

<table>
<thead>
<tr>
<th>Location: Virginia Mason Memorial</th>
<th>Name</th>
<th>WA License #</th>
<th>2016 PCI Cases</th>
<th>2017 PCI Cases</th>
<th>2018 PCI Cases</th>
<th>3 Yr. Average</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mark Berman</td>
<td>MD 00032484</td>
<td>50</td>
<td>56</td>
<td>64</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td>Bharat Kesavaprasad</td>
<td>MD 60281565</td>
<td>65</td>
<td>63</td>
<td>75</td>
<td>68</td>
</tr>
<tr>
<td></td>
<td>R Thomas McLaughlin</td>
<td>MD 00031045</td>
<td>63</td>
<td>75</td>
<td>94</td>
<td>77</td>
</tr>
</tbody>
</table>

(source: Application, pp16-18)

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**

YVMHA clarified in the application that the basis for its projection is the historical and current numbers of emergent PCIs performed at the Virginia Mason Memorial. For year 2018, this number is 225 and is greater than the 200 minimum volume standard referenced above. This project assumes that emergent patients would continue to obtain PCI services at the hospital and the majority of patients choosing elective PCI would no longer be referred; instead would obtain PCI services at Virginia Mason Memorial. This approach of projecting the number of PCI's performed at the hospital can be substantiated and is both reliable and reasonable.

Specific to the number of PCIs performed by each of the physicians, YVMHA provided the table showing that each of the three physicians already perform more than the minimum volume required (50) at the hospital in each of the historical years (2016 through 2018). Again, this approach of projecting the number of PCI’s to be performed by each of the three physicians is both reliable and reasonable.

Based on the information provided above and the documentation provided in the application, the department concludes that **this sub-criterion is met**.

**2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.**
To evaluate this sub-criterion, the department evaluates an applicant’s admission policies, willingness to serve Medicare and Medicaid patients, and willingness to serve patients that cannot afford to pay for services.

The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and assurances regarding access to treatment. The admission policy must also include language to ensure all residents of the planning area would have access to the proposed services. This is accomplished by providing an admission policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

Medicare certification is a measure of an applicant’s willingness to serve the elderly. With limited exceptions, Medicare is coverage for individuals age 65 and over. It is also recognized that women live longer than men and therefore more likely to be on Medicare longer.

Medicaid certification is a measure of an applicant’s willingness to serve low income persons and may include individuals with disabilities.

Charity care shows a willingness of a provider to provide services to individuals who do not have private insurance, do not qualify for Medicare, do not qualify for Medicaid, or are underinsured. With the passage of the Affordable Care Act in 2010, the amount of charity care decreased over time. However, with recent federal legislative changes affecting the ACA, it is uncertain whether this trend will continue.

**Astria Health**

Astria Health provided copies of the following policies currently used at Astria Sunnyside Hospital.

- Patient Rights and Responsibilities and Responsibilities Policy and Procedure – updated February 2018
- Financial Assistance Policy and Procedure (Charity Care Policy) – updated April 2019

The above polices are also posted to the Department of Health website along with the following policies:

- End of Life Policy – updated July 2012
- Non-Discrimination Policy – updated March 2014
- Nurse Staffing Policy – updated January 2019
- Hospital Reproductive Health Services (provided) – updated October 2019

Astria Sunnyside Hospital is currently Medicare and Medicaid certified. Astria Health provided its current source of revenues by payer for Astria Sunnyside Hospital as a whole and for the cardiac catheterization services currently provided at the hospital. Astria Health also provided the projected sources of revenues if this project is approved. The information is provided in the table below. **[source: April 30, 2019, screening response, p2]**
Department’s Table 5

Astria Sunnyside Hospital Current and Projected Percentages of Revenue

<table>
<thead>
<tr>
<th>Revenue Source</th>
<th>Current Hospital-Wide</th>
<th>Current Cardiac Cost Center</th>
<th>Project Hospital-Wide With Elective PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare</td>
<td>35.8%</td>
<td>71.3%</td>
<td>36.0%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>35.7%</td>
<td>17.9%</td>
<td>35.7%</td>
</tr>
<tr>
<td>Self Pay (no insurance)</td>
<td>3.6%</td>
<td>0.5%</td>
<td>3.5%</td>
</tr>
<tr>
<td>HMO/PPO/Commercial</td>
<td>20.9%</td>
<td>9.8%</td>
<td>20.8%</td>
</tr>
<tr>
<td>Other</td>
<td>4.0%</td>
<td>0.5%</td>
<td>4.0%</td>
</tr>
<tr>
<td>Total</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

In addition to the policies and payer mix information, Astria Health provided the following information related to access to healthcare services provided by Astria Sunnyside Hospital. [source: Application, p18]

“Sunnyside is committed to providing health care services to all individuals based on need; we prohibit discrimination on the basis of income, race, ethnicity, sex, or handicap.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation

Astria Sunnyside Hospital is a longtime provider of healthcare services to the residents of Yakima County and surrounding areas. Healthcare services are stated to be available to low-income, racial and ethnic minorities, handicapped and other underserved groups. [source: Application, p18]

The Patient Rights and Responsibilities Policy and Procedure (Admission Policy) provided in the application has been effective since Astria Health was created in October 2017. [source: Astria Health website at www.astria.health/about-us/history] Prior to Astria Health’s creation, Astria Sunnyside Hospital operated with similar policies for admission that included the required access to care and nondiscrimination language found in the current policies. [source: CN historical files]

The Admission Policy describes the process Astria Sunnyside Hospital uses to admit a patient and outlines rights and responsibilities for both Astria Sunnyside Hospital and the patient. Included in the policy is the following non-discrimination language.

“Each patient has the right to impartial access to treatment, regardless of race, religion, sex, sexual orientation, ethnicity, age or handicap.”

Also within the Patient Rights and Responsibilities Policy and Procedure is references to the related policies listed below:

- Patient Visitation Policy
- Patient Visitation Rights
- Informed Consent Policy and Procedure
- Advance Directives
- Patient complaints and Grievance Policy and Procedure
- Restraint and Seclusion Policy and Procedure
Astria Sunnyside Hospital currently provides services to both Medicare and Medicaid patients. Astria Health does not anticipate substantial changes in Medicare or Medicaid percentages resulting in approval of this project. Astria Sunnyside Hospital’s current combined Medicare and Medicaid revenues are approximately 71.5% of total revenues. If this project is approved, the hospital’s combined Medicare and Medicaid revenues are expected to be 71.7% of total revenues. Financial data provided in the application also shows both Medicare and Medicaid revenues.

The Financial Assistance Policy and Procedure (Charity Care Policy) provided in the application has been reviewed and approved by the Department of Health's Hospital Charity Care and Financial Data Program (HCCFDP). The policy outlines the process one would use to obtain financial assistance or charity care and includes the following non-discrimination language.

“No patient/resident that meets these requirements shall be denied uncompensated health care based upon race, creed, color, sex, national origin, sexual orientation, disability, age, or source of income.”

The Financial Assistance Policy and Procedure was approved in February 2019. This is the same policy posted to the department’s website for Astria Sunnyside Hospital. The pro forma financial documents provided in the application include a charity care 'line item' as a deduction of revenue.

Based on the information above, the department concludes that the policies provided in the application demonstrate adequate access to care, with no discrimination, for Astria Sunnyside Hospital.

For hospital projects, the department must review the applying hospital’s historical charity care percentages and determine if the hospital has historically been providing adequate charity care to the residents of the planning area. Given that both Astria Health and YVMHA are located in Yakima County, this review will be completed concurrently below.

Yakima Valley Memorial Hospital Association

The applicant provided copies of the following policies currently used at Virginia Mason Memorial. [source: Application, Exhibits 8, 9, & 10]

- Admitting Patents/Bed Placement (Admission Policy) – reviewed April 2017
- Financial Assistance (Charity Care Policy) – reviewed September 2018
- Community Service Policy

With the exception of the Community Service Policy, the above polices are also posted to the Department of Health website along with the following policies:

- End of Life Policy – updated March 2014
- Non-Discrimination Policy – updated March 2014
- Nurse Staffing Policy – updated December 2018
- Reproductive Health Policy – updated March 2014
- Hospital Reproductive Health Services (provided) – updated September 2019

Virginia Mason Memorial is currently Medicare and Medicaid certified. YVMHA provided its current source of revenues by payer for the hospital as a whole and for the cardiac catheterization services currently provided at the hospital. YVMHA also provided the projected sources of revenues.

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11 Revised Code of Washington 70.38.115(2)(k).
if this project is approved. The information is provided in the table below. [source: April 29, 2019, screening response, p2]

<table>
<thead>
<tr>
<th>Revenue Source</th>
<th>Current Hospital-Wide</th>
<th>Current Cardiac Cost Center</th>
<th>Project Hospital-Wide With Elective PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare</td>
<td>47.6%</td>
<td>64.8%</td>
<td>47.6%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>24.4%</td>
<td>13.4%</td>
<td>24.4%</td>
</tr>
<tr>
<td>Private Payers</td>
<td>1.7%</td>
<td>1.2%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Other Insurance (HMO)</td>
<td>26.4%</td>
<td>20.6%</td>
<td>26.4%</td>
</tr>
<tr>
<td><strong>Total</strong>*</td>
<td><strong>100.0%</strong></td>
<td><strong>100.0%</strong></td>
<td><strong>100.0%</strong></td>
</tr>
</tbody>
</table>

* = Numbers may not add due to rounding

In addition to the policies and payer mix information, YVMHA provided the following information related to access to healthcare services provided by Virginia Mason Memorial. [source: Application, p19]

“Memorial is committed to providing healthcare services to all individuals; we prohibit discrimination of any kind or on the basis of on the basis of income, race, ethnicity, sex or disability. Memorial also recognizes and acts upon the need to provide health care services to individuals of limited financial resources. For hospital charity care reporting purposes, the Department divides Washington State into five regions. Memorial is located in the Central Washington region. The 2017 charity care average for Central Washington is 1.10% of gross revenue and 3.03% of net revenue. The percentage of charity care for Memorial is 1.26% of gross revenue and 3.73% of net revenue, above the Central Washington Region average. Memorial is committed to continuing to provide charity care at a level consistent with the regional average.”

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**
Virginia Mason Memorial is a longtime provider of healthcare services to the residents of Yakima County and surrounding areas. Healthcare services are stated to be available to low-income, racial and ethnic minorities, handicapped and other underserved groups. [source: Application, p19]

The Admitting Patients/Bed Placement policy (Admission Policy) provided in the application is currently in use at the hospital. The Admission Policy describes the process Virginia Mason Memorial uses to admit a patient and provides the procedures used for admission. Included in the policy is the following non-discrimination language.

“VMM will not deny admission to any patient due to race, color, religion, gender, sexual orientation, financial class or national origin. Patients shall be admitted upon referral and placed under the care of a physician who shall be a member of the medical staff or has temporary privileges according to the medical staff bylaws.”
Virginia Mason Memorial currently provides services to both Medicare and Medicaid patients. YVMHA does not anticipate any changes in Medicare or Medicaid percentages resulting in approval of this project. Virginia Mason Memorial’s current and projected combined Medicare and Medicaid revenues are approximately 72.0% of total revenues. Financial data provided in the application also shows both Medicare and Medicaid revenues.

The Financial Assistance Policy (Charity Care Policy) provided in the application has been reviewed and approved by the Department of Health's Hospital Charity Care and Financial Data Program (HCCFDP). The policy outlines the process one would use to obtain financial assistance or charity care and includes the following non-discrimination language. “Financial Assistance shall be available and without discrimination as to race, color, creed, national origin, religion, sex, sexual orientation, disability, age, source of income, or any other class protected by federal or Washington state law.”

The policy was approved in October 2018. This is the same policy posted to the department’s website for Virginia Mason Memorial. The pro forma financial documents provided in the application include a charity care 'line item' as a deduction of revenue.

Based on the information above, the department concludes that the policies provided in the application demonstrate adequate access to care, with no discrimination, for Virginia Mason Memorial.

Charity Care Percentage Requirement for Both Hospitals
For charity care reporting purposes, Washington State is divided into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. Both Astria Sunnyside Hospital and Virginia Mason Memorial are located in Yakima County, within the Central Region. Currently there are 21 hospitals operating within the region. This charity care review focuses on data reported by each of the Central Region hospitals for years 2016, 2017, and 2018.

The charity care data is required to be reported to the Hospital Charity Care and Financial Data Program (HCCFDP) as part of its year-end reporting no later than 180 days after the end of the hospital’s fiscal year. For years 2016 and 2017, all 21 hospitals in the region reported charity care data. For year 2018, the three Astria Health hospitals did not report. Given that the Astria hospitals represent three of the four hospitals in Yakima County, the absence of their 2018 charity care data makes evaluating overall charity care provided in Yakima County impossible.

Table 7 below compares the three-year historical average of charity care provided by the 21 hospitals currently operating in the Central Region and Virginia Mason Memorial’s historical charity care percentages for years 2016-2018.

For Astria Sunnyside Hospital, the table compares historical percentages only for years 2016 and 2017. The table below also compares the projected percentage of charity care. [source: Astria Health April 30, 2019 screening response, Attachment 3, YVMHA April 29, 2019, screening response, Exhibit 4, and HCCFDP 2016-2018 charity care summaries]
**Department’s Table 7**

**Charity Care Percentage Comparisons**

<table>
<thead>
<tr>
<th></th>
<th>Percentage of Total Revenue</th>
<th>Percentage of Adjusted Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Region Historical 3-Year Average(^{12})</td>
<td>1.03%</td>
<td>2.74%</td>
</tr>
<tr>
<td>Astria Sunnyside Hospital Historical 2-Year Average</td>
<td>1.00%</td>
<td>3.48%</td>
</tr>
<tr>
<td>Astria Sunnyside Hospital Projected Average</td>
<td>2.07%</td>
<td>7.31%</td>
</tr>
<tr>
<td>Virginia Mason Memorial Historical 3-Year Average</td>
<td>1.08%</td>
<td>2.46%</td>
</tr>
<tr>
<td>Virginia Mason Memorial Projected Average</td>
<td>1.66%</td>
<td>5.92%</td>
</tr>
</tbody>
</table>

**Astria Sunnyside Hospital Charity Care Review Conclusion**

For Astria Health, the table above shows the two-year historical average. Astria Sunnyside Hospital has been providing charity care below the total regional average and above the adjusted regional averages. For this project, Astria Health projects that Astria Sunnyside Hospital would increase its charity care to percentages above the regional average for both total and adjusted revenues.

In past hospital CN applications, the department has been attaching a charity care condition to the approvals, based, in part, on the fluctuation of charity care percentages since the passage of the Affordable Care Act in March 2010. Additionally, the department would typically attach a charity care condition on a hospital project that is proposing a new service, including a tertiary service.

If the Astria Health project is approved, the department would attach a condition requiring the applicant to agree to the following charity care condition for Astria Sunnyside Hospital.

Astria Sunnyside Hospital will provide charity care in compliance with its charity care policies reviewed and approved by the Department of Health, or any subsequent policies reviewed and approved by the Department of Health. Astria Sunnyside Hospital will use reasonable efforts to provide charity care in an amount comparable to or exceeding the average amount of charity care provided by hospitals in the Central Region. Currently, this amount is 1.03% gross revenue and 2.74% of adjusted revenue. Astria Sunnyside Hospital will maintain records of charity care applications received and the dollar amount of charity care discounts granted. The department requires these records to be available upon request.

Based on the information provided in the application and with Astria Health’s agreement to the condition, the department concludes **this sub-criterion is met for the Astria Sunnyside Hospital project.**

**Virginia Mason Memorial Charity Care Review Conclusion**

For Virginia Mason Memorial, the table shows the hospital’s three-year historical average is above the regional average for gross revenues and below for adjusted revenues. For this project, YVMHA projects that Virginia Mason Memorial would provide charity care above the regional average for both total and adjusted revenues.

In past hospital CN applications, the department has been attaching a charity care condition to the approvals, based, in part, on the fluctuation of charity care percentages since the passage of the

\(^{12}\) As explained above, the 2018 data for the region does not include the three Astria Health hospitals because of their failure to report.
Affordable Care Act in March 2010. Additionally, the department would typically attach a charity care condition on a hospital project that is proposing a new service, including a tertiary service.

For these reasons and the review of the historical charity care percentages for Virginia Mason Memorial, if this project is approved, the department would attach a condition that requires the applicant to agree to the following charity care condition for Virginia Mason Memorial.

Virginia Mason Memorial will provide charity care in compliance with its charity care policies reviewed and approved by the Department of Health, or any subsequent policies reviewed and approved by the Department of Health. Virginia Mason Memorial will use reasonable efforts to provide charity care in an amount comparable to or exceeding the average amount of charity care provided by hospitals in the Central Region. Currently, this amount is 1.03% gross revenue and 2.74% of adjusted revenue. Virginia Mason Memorial will maintain records of charity care applications received and the dollar amount of charity care discounts granted. The department requires these records to be available upon request.

Based on the information provided in the application and with YVMHA’s agreement to the condition, the department concludes this sub-criterion is met for the Virginia Mason Memorial project.

(3) The applicant has substantiated any of the following special needs and circumstances the proposed project is to serve.

(a) The special needs and circumstances of entities such as medical and other health professions schools, multidisciplinary clinics and specialty centers providing a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.
(b) The special needs and circumstances of biomedical and behavioral research projects designed to meet a national need and for which local conditions offer special advantages.
(c) The special needs and circumstances of osteopathic hospitals and non-allopathic services.

Department Evaluation
This sub-criterion is not applicable to these applications.

(4) The project will not have an adverse effect on health professional schools and training programs. The assessment of the conformance of a project with this criterion shall include consideration of:

(a) The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided.
(b) If proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools serving the area will have access to the services for training purposes.

Department Evaluation
This sub-criterion is not applicable to these applications.

(5) The project is needed to meet the special needs and circumstances of enrolled members or reasonably anticipated new members of a health maintenance organization or proposed health maintenance organization and the services proposed are not available from nonhealth maintenance organization providers or other health maintenance organizations in a reasonable and cost-effective
manner consistent with the basic method of operation of the health maintenance organization or proposed health maintenance organization.

Department Evaluation
This sub-criterion is not applicable to these applications.

B. Financial Feasibility (WAC 246-310-220)
Based on the source information reviewed, the department determines that Astria Health does not meet the applicable financial feasibility criteria in WAC 246-310-220.

Based on the source information reviewed, the department determines that Yakima Valley Memorial Hospital Association meets the applicable financial feasibility criteria in WAC 246-310-220.

(1) The immediate and long-range capital and operating costs of the project can be met.
WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that direct what the operating revenues and expenses should be for a project of this type and size. Therefore, using its experience and expertise the department evaluates if the applicant’s pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

Astria Health
Astria Health provided the following assumptions to project adult, elective PCI volumes, patient mix, and payer mix at Astria Sunnyside Hospital. [source: Application, p19 and April 30, 2019, screening response, pp3-4]

"PCI Project" Assumptions:
1. Volume: As noted in earlier sections of this application, Sunnyside assumed: 60 PCIs in the first 12 months, 140 cases in year 2, and 205 cases in year 3.
2. Patient mix: Sunnyside assumed that the PCI cases would be 60% inpatient, and 40% outpatient.
3. Payor mix: The actual Sunnyside cardiac catheterization lab payor mix.

As noted on page 15 of the CN application, the volumes during the first year (2020, 9 months) represents the 25 actual emergency PCIs performed in 2018 as well as a return of 35 of the 40 cases that were referred by Sunnyside for elective PCI in 2018, typically to Astria Regional, for a total of 60 PCIs. Our projected year 1 volumes conservatively assume no growth over 2018.

Per the methodology, the unmet need in the planning area in 2021 is interpolated to be 274 cases. In addition, Sunnyside’s actual 2018 patient origin per CHARS indicates that 8% of our total patients reside outside of PCI Planning Area 4. Because PCI is a regional service, in year 2, we assumed that 10% would come from outside of the Planning Area (14 cases). We also assumed that another 10% (14 cases) will come from PCIs currently being performed in Yakima, the Tri-Cities or elsewhere on Lower Valley residents that will return to the Lower Valley and be performed at Sunnyside. Note: the “return” of cases that are being performed elsewhere is not part of the unmet need of 274; these patients are currently receiving a PCI but are travelling outside of the Lower Valley to do so.
This means that of our estimated year two 140 cases, 14 will be from outside of the Planning Area, and 14 will be on PCI patients returning to the Lower Valley, leaving 112 from the planning area’s unmet need. The math is as follows:

112 net new Planning Area cases projected for Sunnyside/274 cases of unmet need

\[= 40.9\% \text{ market share of unmet need}\]

In year 3, we made similar assumptions, but we increased the number of patients from out of area choosing to have a PCI at Sunnyside from 10% to 15%. Again, we assumed that 10% of our volume will come from Lower Valley residents returning to the Lower Valley for their PCI. As such, from our estimated year three 205 cases, 20.5 will reside outside of the Planning Area, and 30.75 will be on PCI patients returning to the Lower Valley, leaving 154 from the planning area’s unmet need. The math is as follows:

154 net new Planning Area cases projected for Sunnyside/279 cases of unmet need

\[= 55.2\% \text{ market share of unmet need}\]

The assumption regarding mix of inpatient/outpatient matches the actual experience at our sister organization, Astria Regional Medical Center.

Since year 1 is a partial year, we have added a fourth year to the pro forma (calendar year 2023). Volume in 2023 was held flat at 2022 levels.”

Astria Health assumed a project start date of March 1, 2020. Astria Sunnyside Hospital’s utilization and payer mix projections are shown in Tables 8 and 9 below beginning in calendar year 2020 through calendar year 2023.

**Department’s Table 8**

<table>
<thead>
<tr>
<th>Adult, Elective PCI for Years 2020 through 2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Volume</td>
</tr>
<tr>
<td>Patient Mix</td>
</tr>
</tbody>
</table>

**Department’s Table 9**

<table>
<thead>
<tr>
<th>Revenue Source</th>
<th>Current and Projected Cardiac Cost Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare</td>
<td>71.3%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>17.9%</td>
</tr>
<tr>
<td>Self Pay (no insurance)</td>
<td>0.5%</td>
</tr>
<tr>
<td>HMO/PPO/Commercial</td>
<td>9.8%</td>
</tr>
<tr>
<td>Other</td>
<td>0.5%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100.0%</strong></td>
</tr>
</tbody>
</table>

The assumptions Astria Health used to project revenue, expenses, and net income for Astria Sunnyside Hospital’s adult, elective PCI cost center for calendar years 2020 through 2023 are below. [source: Application, p19 and April 30, 2019, screening response, pp8-9]

**Revenues and Expenses**

“Baseline financial charges and expenses are based on actual at Sunnyside held constant.

a. Charges per case
b. Expenses per case

c. Charges, expenses, and reimbursements per case by payor type (Medicare, Medicaid, commercial, etc.) and patient type (inpatient, outpatient)

Reimbursement rate is based on actual at Sunnyside.”

PCI Cost Center Expense Line Item Explanations

- The only reason that the dollar amount of the deductions from revenue were estimated lower than original in the PCI Project Specific Only pro forma financial statement included in the application filing is because the columns labelled “Projected Year 1, Projected Year 2 and Projected Year 3” were incremental revenue and expense only.
- For the CN Program’s reference, the total cath lab revenue and expenses can be obtained by adding 2019 information to the incremental revenue and expenses for each subsequent year (2020-2023). Sunnyside has done this, and has included an aggregated PCI cost center pro forma in Attachment 3. As depicted in the aggregated cost center, deductions from revenue are not lower than actual.
- The only reason that the dollar amount of the Year 1 is lower than current Year 2019 is because the PCI Project Specific Only pro forma financial statement included in the application filing is because the columns labelled “Projected Year 1, Projected Year 2 and Projected Year 3” were incremental revenue and expense only.
- In year 1, only 35 additional cases were assumed. In years 2 and 3, incremental cases are 105 and 180, respectively.
- For the CN Program’s reference, the total cath lab revenue and expenses can be obtained by adding 2019 information to the incremental revenue and expenses for each subsequent year (2020-2023). Sunnyside has done this, and has included an aggregated PCI cost center pro forma in Attachment 3. As depicted in the aggregated cost center, deductions from revenue are not lower than actual.
- As stated above, in the PCI Project Specific Only pro forma financial statements included in the application filing, only incremental revenue and expense were included. Sunnyside already staffs the cath lab 24/7. The net addition of cases associated with the elective PCI program is relatively small. If one assumes that 100% of the elective PCI cases occur on a work day, the increase per day can be quantified as follows:
  - Year 1: 35 cases/9 months/work days = 195 days = 0.2 additional cases per day
  - Year 2-105 additional cases/260 days = 0.4 additional cases per day
  - Year 3 and 4-180 additional cases/260 = 0.7 additional cases per day
This incremental volume requires no additional staffing.
- Purchased services-other includes non-medical or maintenance contracted related purchased services such as therapy or cleaning.
- Other direct expenses include such items as: dues, travel, education, freight, and repairs.”

Based on the assumptions above, Astria Health provided the following revenue and expense statement for Astria Sunnyside Hospital’s adult, elective PCI cost center. The statement shows calendar years 2020 through 2023. [source: April 30, 2019, screening response, Attachment 3]
Department’s Table 10
Astria Sunnyside Hospital Adult, Elective PCI Cost Center
Projections for Calendar Years 2020 through 2023

<table>
<thead>
<tr>
<th></th>
<th>CY 2020</th>
<th>CY 2021</th>
<th>CY 2022</th>
<th>CY 2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Revenue</td>
<td>$990,859</td>
<td>$1,055,916</td>
<td>$1,108,775</td>
<td>$1,108,775</td>
</tr>
<tr>
<td>Total Expenses</td>
<td>$1,004,245</td>
<td>$1,019,724</td>
<td>$1,032,300</td>
<td>$1,032,300</td>
</tr>
<tr>
<td>Net Profit / (Loss)</td>
<td>([$13,386])</td>
<td>$36,192</td>
<td>$76,475</td>
<td>$76,475</td>
</tr>
</tbody>
</table>

Net revenue includes both inpatient and outpatient PCI revenue, minus any deductions for contractual allowances, bad debt, and charity care. Given that Astria Sunnyside Hospital already operates a cardiac cost center, total expenses include all incremental expenses specific to the addition of PCI services.

Astria Health also provided its revenue by payer source for the hospital and the PCI cost center, which is shown in the table below.

Department’s Table 11
Astria Sunnyside Hospital
Current and Projected Percentages of Revenue

<table>
<thead>
<tr>
<th>Revenue Source</th>
<th>Current Hospital-Wide</th>
<th>Project Hospital-Wide With Elective PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare</td>
<td>35.8%</td>
<td>36.0%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>35.7%</td>
<td>35.7%</td>
</tr>
<tr>
<td>Self Pay (no insurance)</td>
<td>3.6%</td>
<td>3.5%</td>
</tr>
<tr>
<td>HMO/PPO/Commercial</td>
<td>20.9%</td>
<td>20.8%</td>
</tr>
<tr>
<td>Other</td>
<td>4.0%</td>
<td>4.0%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100.0%</strong></td>
<td><strong>100.0%</strong></td>
</tr>
</tbody>
</table>

In addition to providing the adult, elective PCI cost center revenue and expense statement, Astria Health also provided a projected revenue and expense statement for Astria Sunnyside Hospital as a whole with the PCI program. The statement below shows calendar year 2019 (current) and projection years 2020 through 2023. [source: April 30, 2019, screening response, Attachment 3]

Department’s Table 12
Astria Sunnyside Hospital with Adult, Elective PCI Service
Projections for Current Year FY 2019 and Calendar Years 2020 through 2023

<table>
<thead>
<tr>
<th></th>
<th>CY 2019</th>
<th>CY 2020</th>
<th>CY 2021</th>
<th>CY 2022</th>
<th>CY 2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Revenue</td>
<td>$104,156,584</td>
<td>$104,205,376</td>
<td>$104,270,433</td>
<td>$104,323,292</td>
<td>$104,323,292</td>
</tr>
<tr>
<td>Total Expenses</td>
<td>$97,454,632</td>
<td>$97,465,213</td>
<td>$97,479,322</td>
<td>$97,490,784</td>
<td>$97,490,784</td>
</tr>
<tr>
<td>Net Profit / (Loss)</td>
<td>$6,614,072</td>
<td>$6,652,283</td>
<td>$6,703,231</td>
<td>$6,744,628</td>
<td>$6,744,628</td>
</tr>
</tbody>
</table>

Net revenue includes both inpatient and outpatient revenue for the entire hospital, minus any deductions for contractual allowances, bad debt, and charity care. Total expenses include all expenses for the hospital, including purchased services, professional fees, staff wages and benefits, management fees, and allocated costs. Management fees and allocated costs are determined using the formula below. [source: April 30, 2019, screening response Appendix 1, 2016 & 2017 Audited Financial Statement, p8]
“During 2017, Regional Health doing business as Astria Health (Astria Health) was formed as the parent company of the Association. Astria Health also acquired hospitals and clinics in Yakima and Toppenish, Washington, in 2017. Many of the startup costs for Astria Health and costs related to the acquisitions in 2017 were funded by the Association and are reported as due from related parties in the consolidated statements of financial position.

The Association pays 1 percent of gross revenue as a management fee to Astria Health under a management agreement. The agreement provides for certain management and administrative services. The agreement has no specific termination date. In addition, a percentage of all Astria Health corporate expenses are allocated to the Association. For the year ended December 31, 2017, the Association recognized $2,635,193 of corporate expenses allocated to the Association and $303,282 of management fees from Astria Health. These expenses are all included in purchased services on the consolidated statements of operations and changes in net assets.”

Public Comments
Virginia Mason Memorial provided comments specific to WAC 246-310-220(1). The comments are restated below. Within the public comments below is a number of relevant footnotes. While the footnotes are not repeated in this evaluation, they are part of the comments submitted by Virginia Mason Memorial and considered during this review.

“Astria Sunnyside is not Capable of Successfully Operating an Elective PCI Program
Astria's Bankruptcy is a Clear Red Flag of its Financial Instability. Astria Health's present (and future) financial stability is, at best, questionable. Standing testament to this fact is the recent decision by Astria Regional (Yakima) and Astria Sunnyside to file voluntary petitions for relief under Chapter 11 of the United States Bankruptcy Code. Moreover, notwithstanding Astria's widely-circulated stated rationale for the filings (appearing in various media reports, and in its sworn bankruptcy pleadings)-namely, that the bankruptcy filings were necessitated by an acute liquidity crunch due to the failure of a third-party billing agent to timely process Astria's payor claims - its own sworn bankruptcy schedules suggest a more obvious, troubling explanation: Astria and its subsidiaries are teetering on the brink of insolvency, if not already there.

By way of brief summary, Astria Health and its subsidiaries were subject to approximately $71.7 Million of debt, repayment of which was secured in part by (1) all personal property and certain real property of Astria Sunnyside, (2) accounts receivable of Astria Regional and Astria Toppenish, and (3) all other personal property of Astria Regional and Astria Toppenish. At the time of the bankruptcy filing, Astria Health was not able to meet basic obligations such as payroll, nor was it able "to meet its other obligations critical to the maintenance of safe facilities and the delivery of effective acute care services for its patients.

Indeed, the Bankruptcy Court has already approved Astria Health's incurrence of post-petition, debtor-in-possession financing of $36 Million, of which approximately $28 Million was needed to immediately refinance various pre-petition secured obligations, leaving only $8 Million for payment of ongoing administrative expenses related to bankruptcy and ongoing working capital needs. Astria Health's financial history also suggests that, even with its new infusion of $8 Million from the post-petition financing, it will likely continue to be undercapitalized on a going forward basis without a substantial increase in revenue.

Approximately $35 Million of pre-petition secured debt was not refinanced by this new credit facility, leaving such debt presently due and owing. Moreover, pursuant to the terms of the post-petition
credit facility, Astria Health must file a Chapter 11 plan of reorganization within 120 days of the petition date (May 6, 2019), or within 180 days of the petition to effectuate said plan or obtain court approval of an alternative transaction acceptable to the lender (presumably a sale of all or some of Astria Health's assets and/or subsidiaries). Given Astria Health's historical and ongoing cash-flow problems, meeting these deadlines would appear to be optimistic at best.

These sentiments were evident at the Bankruptcy Court's hearing on June 13, 2019 regarding Astria Health's motions to approve use of cash collateral and for final approval of its post-petition financing. While the Court ultimately approved both motions, it noted for the record that "administrative insolvency is a very real concern in this case," and that there "are reasons to be concerned by [Astria's] prospects." By its own admission at said hearing, Astria Health (through the testimony of Michael Lane) admitted that its collections were improving, but had not yet stabilized, and that Astria Regional continues to lose money.

At present, Astria Health's ability to reorganize and successfully emerge from bankruptcy protection with the financial wherewithal to service its debts, while at the same time provide quality medical care to its patient population and commence a new elective PCI program, is unlikely.

Astria Cannot Pay its Current Vendors and Physicians
Building a new program in light of its current financial situation is irresponsible and infeasible. Astria Sunnyside depends on contract services to operate and, specifically for its PCI Program, uses a third-party physician organization - CardioSolution. This very vendor on which its application depends has filed a claim in the bankruptcy court for $139,247, due to Astria Sunnyside's failure to pay pursuant to the contract. The annual cost of this 24/7 /365 interventional program is listed at $1.4 million annually. This is a very high cost burden for a fledgling program. Considering that Astria Sunnyside is already failing to pay CardioSolution, how can it guarantee that it will have the staff to operate an elective (or even an emergent) PCI program?

CardioSolution is one of many vendors that Astria Sunnyside has failed to pay. In fact, as reported by the Yakima Herald, many suppliers and vendors are afraid that they will not be paid and have subsequently discontinued to provide products and services to Astria Sunnyside.

Astria Sunnyside's Application Fails to Meet the Financial Feasibility Requirements
Following our review of Astria Sunnyside's financial statements, we believe there are serious flaws in the application, namely under-reporting expenses and actual program costs. Additionally, gross and net revenue per case report dramatic reductions over the 3 year projection period. Specifically, the "PCI Project Specific - Incremental Only" financial statement does not reflect the true operational costs associated with operating a PCI program. Our conclusions are based on the following examples:

- **Staffing Costs.** Astria Sunnyside reports that there are 6 FTEs at the cardiac cath lab. The total salary and wages expenses appears low, considering the number of staff for the program. Astria Sunnyside's screening response reports current salary and wages at $83,240, this calculates to $13,873/FTE. Additionally, benefits are calculated at only 7.5% of wages. However, this appears to be much lower than typical benefit packages which are at about 20-25% of wages. The Salary and Wages expense line item appears to be significantly under reported.
- **Supply Costs.** Astria Sunnyside's supply costs appear unreasonably low considering the cost of supplies to perform PCIs. The average cost for a single drug eluting PCI stent is about $950. Plus, there are numerous other supplies, such as PCI balloons, guidewires, closure devises, procedure packs, medications, and additional supplies that are used to complete a PCI case. A
more realistic cost of these supplies, for just a basic single vessel PCI is approximately $2,300 per case (see table below). Astria Sunnyside's supply costs on a per case basis in fact is just $253 per case in year 2022. This is unreasonably low considering the basic supply costs themselves, as well as supply costs projected by other PCI applicants. Approximate projections for supply costs for pending CN applications are as follows: (a) VMM = $4,347.57/case, (b) Swedish Issaquah = $3,728/case, and (c) Trios Health = $4,718/case. We note that Astria Sunnyside stated in its Screening Responses that the major supplies for PCI are included in the Sunnyside's central supply cost center; however, maintaining this information outside of the PCI Specific pro formas does not allow the CN Program to determine if the costs are accurate as compared to other CN applications and actual supply costs.

<table>
<thead>
<tr>
<th>PCI Supply Item</th>
<th>Quantity</th>
<th>Invoice Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cath Lab angio pack</td>
<td>1</td>
<td>$75.83</td>
</tr>
<tr>
<td>Diagnostic wire</td>
<td>1</td>
<td>$7.00</td>
</tr>
<tr>
<td>Diagnostic catheters</td>
<td>3</td>
<td>$9.60</td>
</tr>
<tr>
<td>Contrast Dye</td>
<td>1</td>
<td>$12.80</td>
</tr>
<tr>
<td>Access sheath</td>
<td>2</td>
<td>$8.00</td>
</tr>
<tr>
<td>PCI wire</td>
<td>1</td>
<td>$80.00</td>
</tr>
<tr>
<td>Inflation kit</td>
<td>1</td>
<td>$44.00</td>
</tr>
<tr>
<td>Injection supplies</td>
<td>1</td>
<td>$37.50</td>
</tr>
<tr>
<td>Guide cath</td>
<td>1</td>
<td>$45.00</td>
</tr>
<tr>
<td>Dilation Balloon</td>
<td>2</td>
<td>$110.00</td>
</tr>
<tr>
<td>DES Stent</td>
<td>1</td>
<td>$950.00</td>
</tr>
<tr>
<td>IVUS Catheter</td>
<td>1</td>
<td>$725.00</td>
</tr>
<tr>
<td>Closure device</td>
<td>1</td>
<td>$210.00</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>17</strong></td>
<td><strong>$2,314.73</strong></td>
</tr>
</tbody>
</table>

- Decrease in Total Operating Expenses. Astria Health's total operating expenses are reported to be $39,705/case in 2019 for 25 cases. In year three (2022), the total operating expense is dramatically reduced to only $5,036/case. This is implausible; nor is there any explanation for this significant decrease.

- Revenue Projections. Astria Sunnyside also misstates its revenue projections. In the current year (2019), the "Total Patient Services Revenue" equates to $110,269 per case, based upon 25 cases. In Projected Year 2022, the calculated Patient Services Revenue is reduced by over 630% to only $17,460 per case, based upon their proposed volume of 205 cases. Likewise, the "Net Patient Service Revenue" decreases from $37,683/case to $5,409/case in 2022. Astria Sunnyside fails to provide an explanation of its revenue projections or why it believes it will have such a significant decrease on a per case basis.

VMM encourages the CN Program to thoroughly investigate Astria Sunnyside's financial pro formas. Astria Sunnyside failed to provide a detailed list of its assumptions and explanations supporting these financial projections, nor are the financial projections consistent with other pending CN applications. However, regardless of the reliability of Astria Sunnyside's pro formas, the pending bankruptcy eliminates any belief in the ability of Astria Sunnyside to actually operate its existing hospital and services, let alone a new elective PCI program.
VMM is also concerned with Astria Health's long-term financial viability, impacting their ability to provide consistent services to patients. Due to supplier payment issues, even the inventory of necessary supplies at the Astria Sunnyside cardiac catheterization labs have been negatively impacted, resulting in potential care concerns.

Rebuttal Comments
In response to the financial issues raised in public comment, Astria Health provided the following rebuttal comments. During this review, the department noted that a portion of Astria Health’s rebuttal comments includes new comments on the financial feasibility of Virginia Mason Memorial’s project. These new comments are not included below and cannot be considered in this review.

Astria’s solvency is not a factor in this analysis. In fact, federal law prohibits discriminating against Astria Health because of its bankruptcy filing. VMM attempt to use a recent Chapter 11 reorganization filing by Astria Sunnyside’s parent, Astria Health, as evidence that Astria Sunnyside is not financially stable and reliable is a misguided attempt to get Astria Sunnyside disqualified prior to application of the geographic access criterion in WAC 246-310-750 because VMM knows that Astria Sunnyside’s proposal prevails under that criterion. Not only is VMM’s attempt misguided and inaccurate, but it is requesting the Department to partake in blanket discrimination prohibited by federal law. Please refer to Attachment 1 to this rebuttal document, a letter from Samuel R. Maizel with Dentons US LLP, and Attachment 2, a letter from Michael R. Lane, Astria Health’s Chief Restructuring Officer, with specific and detailed responses to the allegations put forth by VMM.

The bottom line is that VMM’s allegations about the Astria bankruptcy are unsupported by the public information in the marketplace and, worse, VMM is asking the Department to violate federal law by discriminating against Astria Health because of its bankruptcy filing.

In a nutshell, rather than provide a forthright approach to the situation, VMM has boldly declared that Astria and its subsidiaries are insolvent. This is simply not true. As set forth in the original application and elsewhere in the response, Astria and its subsidiaries are indeed in a bankruptcy reorganization. However, that filing is NOT due to operational deficiencies. Rather, it is due to the actions of a 3rd party vendor that over-promoted and over-promised the abilities of their product to collect Astria’s revenues. Stated differently, this isn’t a situation where a company simply spends more than it makes, for several years, in a hopeless spiral. Rather, Astria is a stable system plagued by a vendor that has significantly underperformed. Despite VMM’s baseless allegations, Astria was not, in fact, on the verge of missing payroll prior to filing bankruptcy. Debtor in possession (DIP) financing was arranged to pay off two pre-petition lenders that were not cooperative with or supportive of Astria restructuring. Additional funds were provided in the DIP financing to provide a cushion of liquidity.

Specifically, as to Astria Sunnyside, it is a very strong hospital with significant positive EBIDA margins compared to the most profitable hospitals across the U.S., and it has consistently performed as such over the last 6 years. Astria Sunnyside is running at a projected annual $15+ million EBITDA margin for the 7 months ended July 31, 2019, and any discussion of it being insolvent is simply untrue. Moreover, the bankruptcy filing provides optics into the performance of Astria Sunnyside, and VMM knows or should know that any claims of insolvency are unsupported following a review of the filed material.
The recitation of bankruptcy “facts” is similarly inaccurate. The Debtors collectively borrowed $36 million, of which $20.5 million retired existing secured claims. After paying over $1 million in loan fees and costs, the Debtors continue to have significant free cash available for operations. Current cash in the bank is in excess of $15 million. While VMM (wrongly) guesses at cash needs and paints a dire picture, the truth is that Astria Sunnyside is generating positive EBITDA and the system has in excess of $15 million in cash which demonstrates, despite a bankruptcy filing and the related costs, Astria has not utilized the excess funds borrowed, further supporting our argument above that we have a cash cushion. Moreover, due to the failure of the vendor to collect accounts receivable, the uncollected cash still exists and represents over $30 million in additional value to the Astria system. In short, the facts simply don’t support the wildly inaccurate arguments posited by VMM.

Worse, and as is clearly demonstrated in Attachment 1, attempting to cast Astria Health’s efforts to ensure the survival of its services for the community as a negative and use it as a reason for denial in this process is not only inappropriate, but actually is prodding the Department to violate federal law by discriminating against Astria Health because of its bankruptcy filing. As explained in Attachment 1, Section 525(a) of the Bankruptcy Code is an anti-discrimination provision that provides, in pertinent part: “[A] governmental unit may not deny, revoke, suspend, or refuse to renew a license, permit, charter, franchise, or other similar grant to, condition such a grant to, discriminate with respect to such a grant against, …, a person that is or has been a debtor under” the Bankruptcy Code. This provision prohibits the State of Washington, for example, from discriminating against a debtor for, among other things, exercising its constitutional right to avail itself of bankruptcy protection. This statute represents Congress’s intent that governmental entities are forbidden from treating companies that file bankruptcy differently or unfairly. What VMM has asked the Department to do is to violate federal law by discriminating against Astria Health and Astria Sunnyside because of its bankruptcy filing. The Department should disregard VMM’s highly inappropriate efforts to prejudice the Department’s decision in this matter by urging the Department to unlawfully discriminate against a company that is exercising its constitutional rights.

Astria Sunnyside’s cardiac staffing partner, Cardiosolutions, is committed to continued staffing of the expanded PCI service.

VMM also attempts to use the recent Chapter 11 reorganization filing to suggest that Astria Sunnyside’s relationship with Cardiosolutions is at risk. This, again, is completely inaccurate. Astria Sunnyside has had a long and positive working relationship with Cardiosolutions that will continue with this elective PCI program. A letter from Cardiosolutions’ Field Operations Manager, Steve Rowell, is included as Attachment 3 to this rebuttal document, which demonstrates Cardiosolutions ongoing support for Astria Sunnyside and their continuing commitment to partner with Astria Sunnyside to provide interventional cardiology staffing support to ensure a quality, accessible elective PCI program for the planning area.

Salaries and wages are more than sufficient to support a high-quality program.

VMM erroneously claims the total salary and wages expense line item for Astria Sunnyside’s catheterization lab appears low. The total salary and wages expense line item does not include all of the staffing costs as some of the cath lab staff are contracted staff. The contracted staff expense is contained in the professional fees line item. The total salary and wages expense line item relates only to 1.0 FTE of the total staffing of 6.0 FTEs. Also, as noted in Astria Sunnyside’s screening response, no incremental staffing or expense is needed for the additional elective PCI cases. Astria Sunnyside’s assumption is no different than VMM’s, which also assumed no increase in staffing by adding elective PCI.
No costs are omitted or understated.
VMM suggests that Astria Sunnyside has omitted costs from the pro forma. As stated on page 8 of Astria Sunnyside’s screening response, consistent with application guidelines, Astria Sunnyside provided only the incremental revenue and expenses associated with the elective PCI project specific cost center. The exact guidance included in the Program’s CN application states...

In addition, the financial forms included with the application guidelines, request a revenue and expense statement titled: “PCI Project Specific Only”.

Consistent with other PCI applicants, Astria Sunnyside’s project specific PCI cost center included the incremental revenues and expenses associated with the establishment of an elective PCI program. In previous PCI applications, several other applicants also submitted incremental project specific cost center information.

Astria Sunnyside’s PCI cost center is consistent with application guidelines and long-standing practice. However, in response to the Department’s screening questions, Astria Sunnyside previously provided as Attachment 3 to the April 2019 screening response a consolidated PCI cost center pro forma.

VMM also argues that Astria Sunnyside’s supply costs seem low. As noted on page 4 of Astria Sunnyside’s screening response, supplies are included in the central supply cost center, which are ‘rolled up’ into the total hospital pro forma. And, because the CN forms only require a PCI specific cost center pro forma, Astria Sunnyside appropriately did not include any other cost center specific pro formas. However, Astria Sunnyside did assume additional costs associated with the elective PCI program. While Astria Sunnyside has begun to recognize efficiencies, including better pricing for supplies as a result of the affiliation with Astria Toppenish and Astria Yakima Regional Medical Center, no additional efficiencies beyond the 2019 budget were assumed. As noted in the 2019 budget contained in the screening response at Attachment 3, supplies were expected to be about 2% less in total than 2018. To be conservative, Astria Sunnyside did not assume any additional efficiencies (although we expect another 2-3% further reduction), and simply held 2019 supplies flat throughout the projection period.

Operating expenses and patient services revenue demonstrate a strong and financially viable program.
VMM erroneously claims Astria Sunnyside’s operating expense assumption per case and net patient revenue per case are questionable. As noted in Astria Sunnyside’s screening response, and consistent with application guidelines, the project specific only statement appropriately includes only the incremental expenses and incremental revenue associated with the elective PCI project. This is consistent with the PCI application guidelines which require applicants to provide a PCI Project Specific Only pro forma.

For the record, Astria Sunnyside notes that the baseline 2018 and 2019 include all operating costs and revenue associated with the cath lab (which also includes interventional radiology associated revenue and expenses).”

Department Evaluation
To evaluate this sub-criterion, the department first reviewed the assumptions used by Astria Health to determine the projected number of patient volumes and patient mix for the PCI program at Astria Sunnyside Hospital. In the need section of this evaluation under WAC 246-310-715(1), the
The department concluded that the projected patient volumes for years two and three could not be substantiated.

The foundation for the projected PCI cost center revenue and expenses is the projected patient volumes discussed above. If the patient volumes are not considered reliable, the projected revenues and expenses for both the PCI cost center and the hospital with PCI services also cannot be considered reliable.

For this sub-criterion, the Department of Health’s Hospital Charity Care and Financial Data Program (HCCFDP) provides a review for hospital project. The review includes pro forma financial statements submitted in the application, including screening responses and rebuttal documents, and historical data report to the data collection office within the Department of Health. Once the information is reviewed, staff from HCCFDP provides a written analysis of the project for the financial feasibility and cost containment criteria (WAC 246-310-220 and WAC 246-310-240, respectively). After reviewing this project, staff from HCCFDP provided the following analysis. [source: November 22, 2019, HCCFDP analysis, pp2-3]

"Financial Viability
This program typically uses financial reports submitted under WAC 246-454 to verify or corroborate financial data provided by hospital applicants. The department collects two sets of financial data that may be used for that purpose – the year-end financial reports and the quarterly financial reports. Year-end reports are due 120 days after the hospital’s fiscal year end (with a possible 60 day extension, for a total of 180 days), and quarterly reports are due 45 days after the end of each quarter. This program generally uses the newest data available when it writes its evaluation.

Astria’s hospitals operate on a January to December fiscal year. The Astria hospitals’ year-end reports are due on April 30 each year, with an optional extension until June 30. When this application was screened in March 2019, the most recent year-end financial reports due to the agency were for FY 2017. Astria submitted FY 2017 year end reports for each of its hospitals after the allowable extension period. Astria Sunnyside’s 2017 report was not submitted until March 5, 2019 – more than 8 months past the extension date. The fiscal-year 2018 reports were due April 30, 2019. Astria requested extended due dates for each of its hospitals, but has not submitted any of the reports at the time of this evaluation. Each report is currently more than four months past due.

Astria Sunnyside has not submitted any quarterly reports since before January 2015. Astria has not submitted quarterly reports for Toppenish or Regional hospitals since it purchased them in 2017.

To support the projections in this application, Astria provided audited financial reports for Sunnyside hospital for the 2015, 2016, and 2017, and updated pro-forma income statement and balance sheet values for 2018. Astria did not provide any financial information for the parent organization. Without any 2018 financial data for Sunnyside or the other Astria facilities, I sought corroborating information elsewhere.

Astria filed a voluntary petition for relief under Chapter 11 of the US Bankruptcy code on May 6, 2019. The bankruptcy case includes 13 entities – Astria and 12 related/organizations – including each of the three Astria hospitals. Among the various items filed with that court as part of Astria’s restructuring process are monthly income statement and balance sheets for the organization as a whole and each of the other Astria entities. The current docket includes reports for May through October 2019.
In each of the months for which reports are available, Sunnyside has returned positive net income, for a total of about $6.6 million. The Astria organization as a whole has accumulated a net loss of $10.7 million in the same six-month period. The two other Astria hospitals have demonstrated less financial success than Sunnyside – Astria Regional showed net losses each month, and Astria Toppenish reported losses in three of the six months.

I reviewed the Sunnyside income statements and balance sheets provided to the US Bankruptcy court and concluded that they are reasonably consistent with the 2018 financial data and projected financial performance for 2019 that Sunnyside provided in its initial application and screening responses. From that review, I find Sunnyside’s financial projections to be reasonable.

You will note that I have concluded that this project appears to be financially feasible, contingent on a demonstration of need for the proposed PCI project. This conclusion is tempered by concerns about the financial health of the overall organization. The bankruptcy process is intended to allow an organization to restructure its debts and, hopefully, emerge as a healthy entity. My conclusion about financial feasibility is based on the fact that this project has no capital cost and on the apparent financial health of Astria Sunnyside Hospital alone. The continuing financial losses of the greater Astria organization are of concern. A project requiring capital expenditure, or projecting operating losses in the future would necessitate greater scrutiny of the parent organization and its ability to fund a project than this application does. Based on the limited information available to me about the current financial performance of the greater Astria Health organization, a more costly or less profitable project might not be found financially feasible.”

The HCCFDP evaluation provides a financial ratio analysis that assesses the financial position of an applicant, both historically and prospectively. The financial ratios typically analyzed are 1) long-term debt to equity; 2) current assets to current liabilities; 3) assets financed by liabilities; 4) total operating expense to total operating revenue; and 5) debt service coverage. Historical and projected balance sheet data is used in the analysis.

Given the lack of reporting data for Astria Sunnyside Hospital, the financial ratio analysis relies on 2017 data and compares it to 2018 statewide data. Staff from HCCFDP concluded that the hospital, with the PCI program, is projected to breakeven at the end of the third year of operation and has the reserves to sustain the PCI program. However, as stated above, the ratio analysis relies on 2017 data submitted in March 2019. Year 2018 data has not been submitted by Astria Health. The department concludes that an accurate comparison cannot be completed for the Astria Health project.

Astria Health filed Chapter 11 Bankruptcy for Astria Health on May 6, 2019. During the public comment portion of this review, entities expressed concerns regarding the financial health of Astria Health and its associated hospitals, including Astria Sunnyside Hospital. In response to the concerns, in its rebuttal documents, Astria Health asserts that its solvency is not a factor in this analysis. The department disagrees with this statement. The financial health of the applicant, regardless of whether the applicant is a health system or one healthcare entity, is one factor in a Certificate of Need review.

In its rebuttal documents, Astria Health did not provide any historical financial information for Astria Health to dispute the concerns raised regarding the Chapter 11 filing. Based on the date of the Chapter 11 filing, Astria Health could have provided information regarding the filing and the financial health of Astria Health during this review as shown below.
With the assertions during public comment, providing the financial information for demonstrative purposes would have been acceptable. Without any other information to review for Astria Health, staff from HCCFDP relied on financial statement included in the Chapter 11 Bankruptcy filing. These financial statements show a bleak financial history for Astria Health.

Astria Health asserts that federal law prohibits discriminating against Astria Health because of its bankruptcy filing and cites section 525(a) of the Bankruptcy Code, Chapter 11. The specific section referenced by the applicant does not allow discrimination solely because “such bankrupt or debtor is or has been a debtor under this title or a bankrupt or debtor under the Bankruptcy Act, …”

The department does not conclude that the Astria Health project is not financially feasible solely because of the Chapter 11 Bankruptcy filing; rather, the department concludes that the project does not meet the financial feasibility criteria for the following reasons.

- The projected PCI patient volumes for years two and three could not be substantiated.
- The projected revenues for the PCI cost center cannot be substantiated without reliable patient volumes.
- The projected revenues for Astria Sunnyside Hospital as a whole cannot be substantiated without reliable patient volumes.
- Because of Astria Health’s poor data reporting compliance, HCCFDP cannot provide a reliable financial review for Astria Sunnyside Hospital’s project.
- The only financial health review for Astria Health that could be conducted was based on Chapter 11 Bankruptcy filing documents. The applicant may assert that the documents are not a fair representation of the financial health of Astria Health, however no other financial statements for Astria Health were provided by the applicant during this review.

For the reasons outlined above, the department concludes that the immediate and long-range operating costs of the project cannot be evaluated. This sub-criterion is not met.

Yakima Valley Memorial Hospital Association

YVMHA provided the following assumptions to project adult, elective PCI volumes, patient mix, and payer mix Virginia Mason Memorial. [source: Application, p17, p20, and April 29, 2019, screening response, p3]

PCI Volume and Utilization Assumptions:

a. The additional PCI volume of 30 cases in year one and an additional 10 cases for years 2 and 3 results is a total cath lab case volume increase of 1.8% in year one (30 cases/1,654 total of all CCL case types in 2018), and then an incremental year two and three increase of about 0.6%. These are small increases and are within the capabilities of existing operations.

b. Current cath lab utilization is about 58% of available time. The impact of this modest additional case volume can be easily accommodated by existing staff and existing facilities. Virginia Mason Memorial employed a straightforward methodology to develop these conservative volume projections, which include:

- Use of current and future total planning area PCI volumes.
- Use of actual historical baseline emergent PCI volume trends for Memorial.
• Incremental annual growth projections for elective and emergent PCI volumes.
• Known demand for an alternative provider within Planning Area #4.

The financial proformas have been revised and resubmitted as Exhibit 4. This includes the “PCI Only” proforma that includes the financial data for Virginia Mason Memorial’s entire PCI program, both elective and emergent. It is reflective of the existing (2018) 225 emergent PCIs as Inpatient and the incremental growth of elective PCIs as Outpatient over the 3 year implementation period.

An explanation of Out-Patient elective PCIs is as follows:
Elective PCIs are performed most often as outpatient procedures. In the PCI only pro forma, it is the incremental additional elective PCIs that are outpatient. The existing volume of emergent PCIs will continue to be mainly inpatient. The CMS criteria for an inpatient stay requires an anticipated two (2) midnight stay or medical necessity requiring inpatient hospitalization such as severity of illness and co-morbidities. As elective PCI, a patient is otherwise medically stable and would not typically meet these inpatient criteria.

As illustrated in the DOH needs methodology using CHARS and the DOH survey, there were 158 outpatient PCIs identifies in the DOH survey for Planning Area 4. This is 34.9% (158/453) of the total planning area PCI using the CHARS/DOH survey data. This consistent with the 2017 COAP data showing a statewide outpatient PCI percentage of 35%. (see figure 1).

Elective PCI procedures (Non-Acute for COAP) are not currently performed at Virginia Mason Memorial, which is reflected in our current outpatient cases being less than 2% of all emergent (NSTEMI & STEMI) PCI cases. Virginia Mason Memorial projects that case volume growth will be predominately outpatient as reflected in the financial proforma.

Applicant’s Figure 1 as referenced above.

![COAP 2017 PCI OutPatient Status by PCI Category](image)

YVMHA assumed a project start date of January 1, 2020. Virginia Mason Memorial’s utilization and payer mix projections are shown in Tables 13 and 14 below beginning in calendar year 2020 through calendar year 2022.
Department’s Table 13  
Virginia Mason Memorial  
Adult, Elective PCI for Years 2020 through 2022

<table>
<thead>
<tr>
<th></th>
<th>CY 2020</th>
<th>CY 2021</th>
<th>CY 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Volume</td>
<td>255</td>
<td>265</td>
<td>275</td>
</tr>
<tr>
<td>Patient Mix&lt;sup&gt;13&lt;/sup&gt;</td>
<td>Inpatient 88% Outpatient 12%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Department’s Table 14  
Adult, Elective PCI Payer Mix

<table>
<thead>
<tr>
<th>Revenue Source</th>
<th>Current and Projected Cardiac Cost Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare</td>
<td>64.8%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>13.4%</td>
</tr>
<tr>
<td>Private Payers</td>
<td>1.2%</td>
</tr>
<tr>
<td>Other Insurance (HMO)</td>
<td>20.6%</td>
</tr>
<tr>
<td>*<em>Total</em></td>
<td><strong>100.0%</strong></td>
</tr>
</tbody>
</table>

The assumptions YVMHA used to project revenue, expenses, and net income for Virginia Mason Memorial’s adult, elective PCI cost center for calendar years 2020 through 2022 are below. [source: Application, pp20-21 and April 29, 2019, screening response, pp2-3]

Revenues and Expenses
“The financial pro forma for ‘PCI only’ uses current rates for the emergent PCI procedures in the following categories: deductions, bad debt, and charity care. Because we do not perform elective PCI procedures, we have modeled the elective PCI cases using the same rates. The financial pro forma for ‘Hospital without PCI uses current rates for the hospital overall. These rates are as follows and are held constant for the three year period.”

Applicant’s Table Recreated

<table>
<thead>
<tr>
<th></th>
<th>PCI Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bad Debt</td>
<td>0.57%</td>
</tr>
<tr>
<td>Contractual Adjustments</td>
<td>58.5%</td>
</tr>
<tr>
<td>Charity Care</td>
<td>2.0%</td>
</tr>
</tbody>
</table>

- No additional staffing will be needed for the additional 1.8% of cases. We will rely on staff productivity and efficiency gains to cover any additional cases.
- The existing two cardiac cath labs have the space and availability to accommodate any additional case volume. No construction will be needed for the elective PCI program.
- No additional equipment and technology will be needed for the elective PCI program. There is a wide array of equipment available that is currently used to provide care to the emergency PCI program. Memorial currently has the appropriate equipment for elective PCI procedures due to its existing emergent PCI services.
- Financial assumptions used to complete the financial statements are as follows: To see the full impact of the PCI program on the hospital financials, we are keeping the hospital only projections flat for each year of the new program.

<sup>13</sup> The applicant did not provide its specific patient mix by percentage; the department calculated the patient mix using current and projected volumes for year one (2020).
PCI Specific Statement of Operations

- **Deductions from Revenue:**
  - Deductions from Revenue PCI Specific worksheet reflects the incremental change due to the incremental volume projected each year.
  - Charity Care for the PCI program was projected using actual hospital rates for FY 2018, charity care as a percentage of gross revenue.
  - Bad Debt for the PCI program was projected using actual hospital rates for FY 2018, bad debt as a percentage of gross revenue.

- **Operating Expenses:**
  - Salaries and Benefits are not projected to increase due to the additional incremental volume. The department is currently staffed appropriately and can handle the additional volume.
  - Supplies are based on our current per case experience.
  - Purchased Services are primarily made up of linen.
  - Rentals and Leases are primarily made up of equipment rental as well as equipment repair and maintenance.
  - License and Taxes are expected to remain at zero for the program. Our current service utilization is predominately Medicare and Medicaid, neither of which result in B&O taxes.
  - Interest should not change, as no additional leases, financing, or capital expenditures are necessary for expansion of the program.
  - Other Direct Expense is zero, as direct expenses are primarily included in Supplies or included in other categories listed above.
  - Allocated Expense is zero. The additional cases will not require additional overhead. Currently the organization does not allocate indirect expenses to individual departments.

Based on the assumptions above, YVMHA provided the following revenue and expense statement for Virginia Mason Memorial’s adult, elective PCI cost center. The statement shows calendar years 2019 (current year) through projection years one through three (2020 – 2022). [source: April 29, 2019, screening response, Exhibit 4]

<table>
<thead>
<tr>
<th>Department’s Table 15</th>
<th>Virginia Mason Memorial Adult, Elective PCI Cost Center</th>
<th>Calendar Years 2019 through 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CY 2019</td>
<td>CY 2020</td>
</tr>
<tr>
<td>Net Revenue</td>
<td>$5,324,295</td>
<td>$5,707,088</td>
</tr>
<tr>
<td>Total Expenses</td>
<td>$1,474,601</td>
<td>$1,614,254</td>
</tr>
<tr>
<td>Net Profit / (Loss)</td>
<td>$3,849,694</td>
<td>$4,092,834</td>
</tr>
</tbody>
</table>

Net revenue includes both inpatient and outpatient PCI revenue, minus any deductions for contractual allowances, bad debt, and charity care. Given that Virginia Mason Memorial already operates a cardiac cost center, total expenses include all incremental expenses specific to the addition of PCI services.

YVMHA also provided its revenue by payer source for the hospital and the PCI cost center, which is shown in the table below.
Department’s Table 16
Virginia Mason Memorial
Current and Projected Percentages of Revenue

<table>
<thead>
<tr>
<th>Revenue Source</th>
<th>Current Hospital-Wide</th>
<th>Project Hospital-Wide With Elective PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare</td>
<td>47.6%</td>
<td>47.6%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>24.4%</td>
<td>24.4%</td>
</tr>
<tr>
<td>Private Payers</td>
<td>1.7%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Other Insurance (HMO)</td>
<td>26.4%</td>
<td>26.4%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100.0%</strong></td>
<td><strong>100.0%</strong></td>
</tr>
</tbody>
</table>

* = Numbers may not add due to rounding

In addition to providing the adult, elective PCI cost center revenue and expense statement, YVMHA also provided a projected revenue and expense statement for Virginia Mason Memorial as a whole with the PCI program. The statement below shows calendar year 2019 (current) and projection years 2020 through 2022. [source: April 29, 2019, screening response, Exhibit 4]

Department’s Table 17
Virginia Mason Memorial with Adult, Elective PCI Service
Projections for Current Year FY 2019 and Calendar Years 2020 through 2022

<table>
<thead>
<tr>
<th></th>
<th>CY 2019</th>
<th>CY 2020</th>
<th>CY 2021</th>
<th>CY 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Revenue</td>
<td>$512,986,020</td>
<td>$513,368,544</td>
<td>$513,496,052</td>
<td>$513,623,560</td>
</tr>
<tr>
<td>Total Expenses</td>
<td>$508,491,024</td>
<td>$508,630,677</td>
<td>$508,677,904</td>
<td>$508,725,131</td>
</tr>
<tr>
<td><strong>Net Profit / (Loss)</strong></td>
<td><strong>$4,494,996</strong></td>
<td><strong>$4,737,867</strong></td>
<td><strong>$4,818,148</strong></td>
<td><strong>$4,898,429</strong></td>
</tr>
</tbody>
</table>

Net revenue includes both inpatient and outpatient revenue for the entire hospital, minus any deductions for contractual allowances, bad debt, and charity care. For this statement summary, the department also included any non-operating revenue in the net revenue section. Total expenses include all expenses for the hospital, including purchased services, professional fees, staff wages and benefits. Allocated costs and management costs are not identified in the hospital wide statement because the applicant, YVMHA, is responsible for the management of the hospital. [source: Application, p4]

Public Comments
None

Rebuttal Comments
None

Department Evaluation
To evaluate this sub-criterion, the department first reviewed the assumptions used by YVMHA to determine the projected number of patient volumes and patient mix for the PCI program at Virginia Mason Memorial. In the need section of this evaluation under WAC 246-310-715(1), the department concluded that the projected patient volumes for years one through three could be substantiated. Further the projected inpatient and outpatient PCI mix and the PCI payer mix is also based on Virginia Mason Memorial’s 2018 data. Based on the above information, the department can substantiate YVMHA’s assumptions and concludes they are reasonable.
For its projected PCI cost center revenue and expenses, YVMHA also based its projections on actual experience at Virginia Mason Memorial. If this project is approved, YVMHA expects the elective PCI services would be available in January 2020. For this reason, YVMHA provided its patient days and discharge projections beginning with current year 2019 through projection year 2022, which is year three of the project. The projected revenue and expense statement for Virginia Mason Memorial’s PCI cost center shows revenues covering expenses for all years shown.

YVMHA also provided the current and projected revenue and expense statement for Virginia Mason Memorial as a whole, with the PCI program. That statement also showed revenues covering expenses for years 2019 through 2022.

To assist in the evaluation of this sub-criterion, the Department of Health’s Hospital Charity Care and Financial Data Program (HCCFDP) reviewed the pro forma financial statements submitted by YVMHA for Virginia Mason Memorial. To determine whether the hospital would meet its immediate and long range capital costs, HCCFDP reviewed the December 2018 balance sheet for both YVMHA and Virginia Mason Memorial. The information for YVMHA is shown in Table 18 below and the balance sheet for Virginia Mason Memorial is shown in Table 19. [source: HCCFDP analysis, p2]

### Department’s Table 18
**Yakima Valley Memorial Hospital Association Balance Sheet for Year 2018**

<table>
<thead>
<tr>
<th>Assets</th>
<th>Liabilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Assets</td>
<td>$ 91,805,239</td>
</tr>
<tr>
<td>Board Designated Assets</td>
<td>$ 60,132,394</td>
</tr>
<tr>
<td>Property/Plant/Equipment</td>
<td>$ 205,034,662</td>
</tr>
<tr>
<td>Other Assets</td>
<td>$ 5,542,148</td>
</tr>
<tr>
<td><strong>Total Assets</strong></td>
<td><strong>$ 362,512,443</strong></td>
</tr>
</tbody>
</table>

### Department’s Table 19
**Virginia Mason Memorial Balance Sheet for Year 2018**

<table>
<thead>
<tr>
<th>Assets</th>
<th>Liabilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Assets</td>
<td>$ 103,626,140</td>
</tr>
<tr>
<td>Board Designated Assets</td>
<td>$ 47,551,913</td>
</tr>
<tr>
<td>Property/Plant/Equipment</td>
<td>$ 204,958,485</td>
</tr>
<tr>
<td>Other Assets</td>
<td>$ 1,771,608</td>
</tr>
<tr>
<td><strong>Total Assets</strong></td>
<td><strong>$ 357,908,146</strong></td>
</tr>
</tbody>
</table>

For hospital projects, HCCFDP provides a financial ratio analysis assesses the financial position of an applicant, both historically and prospectively. The financial ratios typically analyzed are 1) long-term debt to equity; 2) current assets to current liabilities; 3) assets financed by liabilities; 4) total operating expense to total operating revenue; and 5) debt service coverage. Historical and projected balance sheet data is used in the analysis. YVMHA’s 2017 balance sheet and Virginia Mason Memorial’s 2018 balance sheets were both used to review applicable ratios and pro forma financial information.

Table 20 compares statewide data for historical year 2018, YVMHA’s historical data for year 2018, historical year 2018 for Virginia Mason Memorial, and projection years 2020 through 2022 for Virginia Mason Memorial with the PCI program. [source: HCCFDP analysis, p3]
### Department’s Table 20

**Current and Projected Debt Ratios**

<table>
<thead>
<tr>
<th>Category</th>
<th>Trend*</th>
<th>State 2018</th>
<th>YVMHA 2018</th>
<th>VMM 2018</th>
<th>VMM 2020</th>
<th>VMM 2021</th>
<th>VMM 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Term Debt to Equity</td>
<td>B</td>
<td>0.457</td>
<td>0.201</td>
<td>0.205</td>
<td>0.145</td>
<td>0.141</td>
<td>0.138</td>
</tr>
<tr>
<td>Current Assets/Current Liabilities</td>
<td>A</td>
<td>2.699</td>
<td>1.180</td>
<td>1.335</td>
<td>1.106</td>
<td>1.257</td>
<td>0.313</td>
</tr>
<tr>
<td>Assets Funded by Liabilities</td>
<td>B</td>
<td>0.396</td>
<td>0.336</td>
<td>0.340</td>
<td>0.351</td>
<td>0.331</td>
<td>0.326</td>
</tr>
<tr>
<td>Operating Expense/Operating Revenue</td>
<td>B</td>
<td>0.976</td>
<td>1.024</td>
<td>1.012</td>
<td>0.998</td>
<td>0.997</td>
<td>0.997</td>
</tr>
<tr>
<td>Debt Service Coverage</td>
<td>A</td>
<td>5.031</td>
<td>1.262</td>
<td>1.300</td>
<td>3.946</td>
<td>9.275</td>
<td>9.244</td>
</tr>
</tbody>
</table>

**Definitions:**

<table>
<thead>
<tr>
<th>Category</th>
<th>Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Term Debt to Equity</td>
<td>Long Term Debt/Equity</td>
</tr>
<tr>
<td>Current Assets/Current Liabilities</td>
<td>Current Assets/Current Liabilities</td>
</tr>
<tr>
<td>Assets Funded by Liabilities</td>
<td>Current Liabilities + Long term Debt/Assets</td>
</tr>
<tr>
<td>Operating Expense/Operating Revenue</td>
<td>Operating expenses / operating revenue</td>
</tr>
<tr>
<td>Debt Service Coverage</td>
<td>Net Profit+Dep and Interest Exp/Current Mat. LTD and Interest Exp</td>
</tr>
</tbody>
</table>

* A is better if above the ratio; and B is better if below the ratio.

After reviewing the financial ratios above, staff from HCCFDP provided the following statements. [source: HCCFDP analysis, p2]

“**CON year 3, (third full year following addition of elective PCI services) fiscal year end ratios for VMMH are either within or nearly within preferred range of the 2018 State average. Each ratio except current assets to current liabilities (current ratio) is either within the average range or nearly so and trending toward the statewide average in the future. The current ratio measures an entity’s ability to pay short term liabilities with liquid assets or assets that can easily be turned into cash. A ratio above one indicates that there are sufficient current assets to satisfy the current liabilities. While VMMH’s current ratio is lower than the statewide average, it is above one and may simply be indicative of management practices such as maintaining lower inventory levels than the industry average or maintaining some current assets in the board-designated asset category, which is not used in the current ratio.”

HCCFDP also provided a financial analysis of the revenue and expense statement for the PCI program. The statement shows revenue covering expenses in all three years of the project. HCCFDP provided the following analysis of the statement. [source: HCCFDP analysis, pp3-4]

“In reviewing PCI procedures in the 2018 Comprehensive Hospital Abstract Reporting System (CHARS) there is variation among hospitals in the billed charges based on the healthcare common procedure coding system (HCPCS). I also reviewed the 0481 Cardiac Catheterization Lab cost center in 2018 CHARS and there is variation among hospitals in this category also. The financial database does not have a cost center that is exclusive to cardiac catheterization. Contingent upon a demonstration of need, this project should not result in an unreasonable impact on the costs and charges for health services. This criterion is satisfied.”

In the ‘need’ section of this evaluation, the department concluded that need for an additional PCI program was demonstrated. The assumptions used as a basis for the financial projections are considered reasonable and reliable. The HCCFDP financial analysis also concludes a sound financial health for both YVMHA and Virginia Mason Memorial.

For those reasons, the department concludes that the immediate and long-range operating costs of the project are reliable. **This sub-criterion is met.**
(2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

WAC 246-310 does not contain specific WAC 246-310-220(2) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what an unreasonable impact on costs and charges would be for a project of this type and size. Therefore, using its experience and expertise the department compared the proposed project’s costs with those previously considered by the department.

Department Evaluation for Astria Health
There are no costs associated with this project. This sub-criterion is not applicable to this project.

Department Evaluation for Yakima Valley Memorial Hospital Association
There are no costs associated with this project. This sub-criterion is not applicable to this project.

(3) The project can be appropriately financed.

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project’s source of financing to those previously considered by the department.

Department Evaluation for Astria Health
There are no costs associated with this project. This sub-criterion is not applicable to this project.

Department Evaluation for Yakima Valley Memorial Hospital Association
There are no costs associated with this project. This sub-criterion is not applicable to this project.

C. Structure and Process (Quality) of Care (WAC 246-310-230), General (PCI Program) Requirements (WAC 246-310-715(3), (4), and (5); Physician Volume Standards (WAC 246-310-725; Staffing Requirements (WAC 246-310-730); Partnering Agreements (WAC 246-310-735) and Quality Assurance (WAC 246-310-740)

Based on the source information reviewed, the department determines that Astria Health does not meet the applicable structure and process of care criteria in WAC 246-310-230 and associated standards.

Based on the source information reviewed, the department determines that Yakima Valley Memorial Hospital Association meets the applicable structure and process of care criteria in WAC 246-310-230 and associated standards.

(1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

For adult, elective PCI projects, specific WAC 246-310-230(1) criteria is identified in WAC 246-310-715(3), (4) and (5); WAC 246-310-725; and WAC 246-310-730 (1) and (2).

WAC 246-310-715(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.

**Astria Health**
In response to this sub-criterion, Astria Health provided the following statements. [source: Application, p24]

“Sunnyside has the necessary staffing infrastructure in place to perform PCI. We currently operate our medical cardiology and diagnostic and therapeutic catheterization programs with a highly-qualified, trained, and experienced team of nurses, and catheterization laboratory technicians. These same individuals will staff the elective PCI program.”

<table>
<thead>
<tr>
<th>FTE by Type</th>
<th>CY 2019 Current</th>
<th>CY 2020 Increase</th>
<th>CY 2021 Increase</th>
<th>CY 2022 Increase</th>
<th>CY 2023 Increase</th>
<th>Total FTEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technologists FTEs</td>
<td>3.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Nursing FTEs</td>
<td>2.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Management FTEs</td>
<td>1.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Total FTEs</strong></td>
<td><strong>6.0</strong></td>
<td><strong>0.0</strong></td>
<td><strong>0.0</strong></td>
<td><strong>0.0</strong></td>
<td><strong>0.0</strong></td>
<td><strong>6.0</strong></td>
</tr>
</tbody>
</table>

In addition to the table above, Astria Health provided the following statements related to this sub-criterion. [source: April 30, 2019, screening response, p5]

“A description of the current FTEs included in the table are provided below:

- Technologist – cardiovascular invasive specialists
- Nurses – registered nurses, Bachelor of Science in Nursing
- Management – Registered Nurse, Master’s Degree in Nursing

Physicians are not included in the FTE table because they are contracted, not employed.

Sunnyside staffs the catheterization laboratory at core staffing levels per shift. In addition to emergency PCI, the lab also performs diagnostic catheterization. The increase from our current volumes to the year three 205 cases is less than 0.7 patients per day. This relatively small incremental volume can be accommodated with current staffing.”

**Public Comments**
None

**Rebuttal Comments**
None

**Department Evaluation**
This section of the evaluation focuses on the staffing of the proposed project. As stated in the project description section of this evaluation, Astria Sunnyside Hospital is currently licensed for 38 acute care beds and holds a critical access hospital designation. The addition of adult, elective PCI program does not require the addition of acute care beds, but could require an increase in staff appropriate to the program. Given that Astria Sunnyside Hospital currently operates a cardiac catheterization lab, the addition of PCI to the hospital does not require additional staff.
Information provided in the application demonstrates that Astria Sunnyside Hospital is a well-established provider of healthcare services in Sunnyside and Yakima County. With no addition of FTEs required, the department concludes this sub-criterion is met.

**Yakima Valley Memorial Hospital Association**

In response to this sub-criterion, YVMHA provided the following statements. [source: Application, p33]

“Virginia Mason Memorial operates two (2) cardiac catheterization labs which provide services for three (3) distinct groups or types of procedures, they are: 1) Interventional Cardiology Procedures (PCIs and Diagnostic Heart Caths), 2) Peripheral Vascular (non-cardiac procedures) and 3) Cardiac Electrophysiology (pacemakers, implanted defibrillators, and cardiac mapping and ablation). These procedures are performed in the two existing cardiac cath labs and are operated with an integrated staffing model which supports all three programs. Pertinent to this application, the interventional cardiology services account for nearly 42% of the total procedures, PCIs account for 14.1% of all procedures, and diagnostic heart catheterizations without PCI (coronary angiograms) make up 27.7% of all procedures. Peripheral Vascular cases account for 28% of all procedures and Cardiac EP for 29% of procedures. For the purposes of this section of the application, only the elective interventional cardiology PCI program will be considered in the content provided.

In year 1, after the approval of an elective PCI program, we project an increase of 30 PCI procedures. While this is an increase of 13% in total PCI procedures, it equates to modest 1.8% increase in the total cath lab procedures and represents an average increase of about one (1) additional PCI case per week. In year 2 and 3, the total increase from current for PCI cases is projected to be 40 cases and 50 cases respectively. The impact of this number of PCI cases would be less than 1 an additional cases per week in year 2 and year 3. This is within the overall staffing capabilities of the existing staff. Table 8 illustrates that no staffing increase are projected for this elective PCI program.”

**Department’s Table 22**

**Virginia Mason Memorial**

**Current and Proposed FTEs for Cardiac Catheterization Cost Center**

<table>
<thead>
<tr>
<th>FTE by Type</th>
<th>CY 2019 Current</th>
<th>CY 2020 Increase</th>
<th>CY 2021 Increase</th>
<th>CY 2022 Increase</th>
<th>Total FTEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technologists FTEs</td>
<td>9.3</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>9.3</td>
</tr>
<tr>
<td>Nursing FTEs</td>
<td>6.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>6.0</td>
</tr>
<tr>
<td>Nurse Manager (all programs)</td>
<td>1.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Scheduler (all programs)</td>
<td>1.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Total FTEs</strong></td>
<td><strong>17.3</strong></td>
<td><strong>0.0</strong></td>
<td><strong>0.0</strong></td>
<td><strong>0.0</strong></td>
<td><strong>17.3</strong></td>
</tr>
</tbody>
</table>

**Public Comments**

None

**Rebuttal Comments**

None
**Department Evaluation**

This section of the evaluation focuses on the staffing of the proposed project. As stated in the project description section of this evaluation, Virginia Mason Memorial is currently licensed for 226 acute care beds and provides a variety of health care services. The addition of adult, elective PCI program does not require the addition of acute care beds, but could require an increase in staff appropriate to the program. Given that Virginia Mason Memorial currently operates a cardiac catheterization lab, the addition of PCI to the hospital does not require additional staff.

Information provided in the application demonstrates that Virginia Mason Memorial is a well-established provider of healthcare services in Yakima and surrounding communities within Yakima County. With no addition of FTEs required, the department concludes **this sub-criterion is met**.

*WAC 246-310-715(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.*

**Astria Health**

To demonstrate compliance with this sub-criterion, Astria Health provided the following information and specific line drawings of the catheterization labs at related to the infrastructure of Astra Sunnyside Hospital. Astria Health also noted that the current and proposed line drawings are identical because there are no alterations required to implement the proposed project. [source: Application, p8 and April 30, 2019, screening response, Attachment 2]

“There will be no construction or alternations to the existing space.”

The line drawings provided show the location of the existing catheterization laboratory and the existing three operating rooms.

**Public Comments**
None

**Rebuttal Comments**
None

**Department Evaluation**

Documentation provided demonstrates that catheterization laboratory staff and equipment meet the standards outlined in WAC 246-310-730(2). **This sub-criterion is met.**

**Yakima Valley Memorial Hospital Association**

To demonstrate compliance with this sub-criterion, YVMHA provided the following information and specific line drawings of the catheterization labs at related to the infrastructure of Virginia Mason Memorial. YVMHA also noted that the current and proposed line drawings are identical because there are no alterations required to implement the proposed project. The applicant provided the following description of the location of the cardiac catheterization labs within the hospital. [source: Application, pp6-7 and April 29, 2019, screening response, p1]

“The existing two cardiac cath labs are located on the first floor of the main hospital adjacent to the surgery department and the clinical laboratory.”
The line drawings provided show the location of the existing catheterization laboratory and the existing two operating rooms.

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Documentation provided demonstrates that catheterization laboratory staff and equipment meet the standards outlined in WAC 246-310-730(2). **This sub-criterion is met.**

WAC 246-310-715(5) Be prepared and staffed to perform emergent PCIs twenty-four hours per day, seven days per week in addition to the scheduled PCIs.

**Astria Health**
In response to this sub-criterion, Astria Health provided the following statements. [source: Application, pp23-24]

“Sunnyside’s PCI program is already staffed to perform emergency PCIs twenty-four hours per day, seven days per week. Sunnyside provides on-site staffing of the cath lab from 7:30 a.m. – 4:00 p.m. Monday through Friday. A call team covers after hours and on weekends. On-call staff are required to be in-house within 30 minutes of call. Table 13 identifies Sunnyside’s staffing plan detailing the twenty-four-hour coverage.”

**Applicant’s Table**

<table>
<thead>
<tr>
<th>Table 13</th>
<th>Sunnyside Current Cardiac Catheterization Lab Staffing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hours</td>
<td>Staffing</td>
</tr>
<tr>
<td>0730 to 1700 Monday- Friday</td>
<td>2 RNs/3 Techs</td>
</tr>
<tr>
<td>On-Call 1700-0730 Monday-Friday 24 hours Saturday and Sunday</td>
<td>1 RN/ 2 Techs or 2 RNs/1 Tech  Depending on shift</td>
</tr>
</tbody>
</table>

Source: Applicant.

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Based on the documentation provided, the department concludes that all identified staff will be available 24/7 and will be appropriately trained as required by the standards. **This sub-criterion is met.**
Yakima Valley Memorial Hospital Association
In response to this sub-criterion, YVMHA provided the following statements. [source: Application, pp23-24]

“Virginia Mason Memorial is already staffed to perform emergent PCIs twenty-four hours per day, seven days per week. Memorial has three cardiac teams that provide on-site staffing of the two (2) cath labs from 6:00 a.m. to 5:30 p.m. Monday through Friday. A call team provides coverage after hours and on weekends. The on-call staff must be on the premises within 30 minutes of being contacted. Table 10 identifies Memorial’s current staffing plan which details this twenty-four hour coverage schedule. This coverage model will remain in place with the addition of an elective program. Memorial has three interventional cardiologists from the Yakima Heart Center that currently provide 24/7 coverage. The addition of elective PCI procedures will not result in any change in this coverage.”

<table>
<thead>
<tr>
<th>Hours</th>
<th>Virginia Mason Memorial Cardiac Cath Lab Staffing for Interventional Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>0600 to 1630 Monday-Friday</td>
<td>1 FTE Registered Nurse</td>
</tr>
<tr>
<td>0700 to 1730 Monday-Friday</td>
<td>2 FTE Technician</td>
</tr>
<tr>
<td>1730-0700 Monday-Friday</td>
<td>2 FTE Registered Nurse</td>
</tr>
<tr>
<td>24 hours Saturday and Sunday</td>
<td>4 FTE Technician</td>
</tr>
<tr>
<td></td>
<td>1 FTE Scheduler</td>
</tr>
</tbody>
</table>

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Based on the documentation provided, the department concludes that all identified staff will be available 24/7 and will be appropriately trained as required by the standards. This sub-criterion is met.

WAC 246-310-725 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.

Astria Health
In response to this sub-criterion, Astria Health provided the following information. [source: Application, p26]

“Only Dr. Zubair and Dr. Ravage will provide elective PCI during the start-up of the PCI program. Each of these providers performed more than 50 cases per year over the last three years. The documentation to support these cases includes a letter of attestation from Cardiosolutions, which is included as Exhibit 5. The numbers in the attestation are summarized in Table 15.”
**Applicant’s Table 15 Recreated**

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imran Zubair, MD</td>
<td>111</td>
<td>5</td>
<td>59</td>
</tr>
<tr>
<td>Christopher Ravage, MD</td>
<td>67</td>
<td>72</td>
<td>70</td>
</tr>
</tbody>
</table>

Astria Health provided the following clarification in a footnote. [source: Application, p26, footnote 2]

“At some point, CardioSolutions may identify another interventional cardiologist that meets all ACC, SCAI and Washington State CN requirements for elective only programs. Should that occur, Sunnyside will give advance notice to the Program.”

**Public Comments**

None

**Rebuttal Comments**

None

**Department Evaluation**

This standard requires documentation of historical volumes for the physicians that would perform PCI procedures at the applying hospital. Based on the information above and documents provided in the application, the department concludes that this sub-criterion is met.

**Yakima Valley Memorial Hospital Association**

In response to this sub-criterion, YVMHA provided the following information. [source: Application, p35]

“Affidavit attesting to this requirement signed by Dr. David Krueger, Medical Director of the Yakima Heart Center. (Exhibit 12).”

The letter referenced in Exhibit 12 of the application identifies the total number of PCI cases for years 2016 through 2018. The table included with the letter is below.

** Applicant's Table **

<table>
<thead>
<tr>
<th>Name</th>
<th>WA License #</th>
<th>2016 PCI Cases</th>
<th>2017 PCI Cases</th>
<th>2018 PCI Cases</th>
<th>3 Yr. Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mark Berman</td>
<td>MD 00032484</td>
<td>50</td>
<td>56</td>
<td>64</td>
<td>57</td>
</tr>
<tr>
<td>Bharat Keshavaprasad</td>
<td>MD 60281565</td>
<td>65</td>
<td>63</td>
<td>75</td>
<td>68</td>
</tr>
<tr>
<td>R. Thomas McLaughlin</td>
<td>MD 00031045</td>
<td>63</td>
<td>75</td>
<td>94</td>
<td>77</td>
</tr>
</tbody>
</table>

Public Comments

None

Rebuttal Comments

None

**Department Evaluation**

This standard requires documentation of historical volumes for the physicians that would perform PCI procedures at the applying hospital. Based on the information above and documents provided in the application, the department concludes that this sub-criterion is met.
WAC-246-310-730(1)  Employ a sufficient number of properly credentialed physicians so that both emergent and elective PCIs can be performed\textsuperscript{14}

\textbf{Astria Health}

Astria Health provided the following information for this sub-criterion. [source: Application, pp25-26] “As noted in Table 5, Sunnyside’s interventional cardiology program is staffed by Cardiosolutions and has been since late 2014. This group will continue to provide staffing as we commence the elective service. At this time, Dr. Zubair will cover the elective PCI program, with Dr. Ravage providing back-up. Until volumes exceed 200 total cases, the other interventional cardiologist will cover the Program 24/7 and will perform emergent only cases.

Sunnyside’s providers are in place and have been providing services since late 2014. These providers are under contract, not employed.”

\textbf{Public Comments}
None

\textbf{Rebuttal Comments}
None

\textbf{Department Evaluation}

Documentation provided by Astria Health demonstrated Astria Sunnyside Hospital will employ a sufficient number of cardiologists to meet its projected number of PCIs. \textbf{This sub-criterion is met.}

\textbf{Yakima Valley Memorial Hospital Association}

In response to this requirement, YVMHA provided Table 12 showing each of the cardiologist on Virginia Mason Memorial’s active medical staff. The table is below. [source: Application, p36]

\textbf{Applicant’s Table}

\begin{tabular}{|c|c|c|c|}
\hline
Physician & WA Dept of Health License # & Board Certification & Credentialled for PCIs \\
\hline
Mark S. Barman, MD & MD0002464 & ABIM - Cardiovascular Disease & Yes \\
Ralph Thomas McLaughlin, MD & MD00031045 & ABIM - Interventional Cardiology & Yes \\
Bhuvanesh Prasad, MD & MD00281365 & ABIM - Cardiovascular Disease & Yes \\
Dilip K. Salvesen, MD & MD00239988 & ABIM - Internal Medicine & No \\
Erik A Monick, MD & MD0071444 & ABIM - Cardiovascular Disease & No \\
Robert Ordiz & MD00034960 & ABIM - Internal Medicine & No \\
Adarsh Bhardwaj, MD & MD00432791 & ABIM - Cardiovascular Disease & No \\
Jesse P Coxe MD & MD00269345 & ABIM - Internal Medicine & No \\
Mohan Ashok Kumar, MD & MD00500125 & ABIM - Cardiovascular Disease & No \\
Rajesh Mottla, MD & MD00733483 & ABIM - Internal Medicine & No \\
Duc Gia Pham MD & MD00047997 & ABIM - Cardiovascular Disease & No \\
\hline
\end{tabular}

\textsuperscript{14} The term "employ" is interpreted to mean traditional employment relationships and traditional privileging practices that formally allow physicians to practice in a hospital.
YVMHA clarified the specific physicians credentialed to perform PCI if this project is approved. [source: April 29, 2019, screening response, p6]

“Only the three cardiologists below are currently credentialed to perform PCIs for this project:”

- Mark S. Berman, MD  License # MD0032484
- Ralph Thomas McLaughlin, MD  License # MD00031045
- Bharat Keshavapradad, MD  License # MD60281565

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**

Documentation provided by YVMHA demonstrated Virginia Mason Memorial will employ a sufficient number of cardiologists to meet its projected number of PCIs. **This sub-criterion is met.**

WAC 246-310-730(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

**Astria Health**

Astria Health provided the following description and qualification detail for the FTEs referenced in its FTE table. [source: Application, p25 and April 30, 2019, screening response, p45]

“A description of the current FTEs included in the table are provided below:

- Technologist – cardiovascular invasive specialists
- Nurses – registered nurses, Bachelor of Science in Nursing
- Management – Registered Nurse, Master’s Degree in Nursing

“Sunnyside’s existing cath lab nursing staff has current experience and demonstrated competencies working in an interventional laboratory. All nursing staff have coronary care, critical care, or equivalent experience. We are also planning to begin rotating through Astria Regional, our sister hospital and a tertiary provider.

The job descriptions and competencies are included as Exhibit 4. Any nursing staff assigned to the cath lab will be required to demonstrate competencies in PCI related technologies.

Sunnyside’s current cath lab nurses are all advanced cardiac life support (ACLS) certified and have demonstrated balloon pump placement and management competency. ACLS certification ensures that training in performing endotracheal intubation and ventilator management has occurred. In addition, all nursing staff has completed training and certification in conscious sedation. That said, Sunnyside does not rely on the cath lab staff to perform these procedures in an emergent in-lab situation. Rather, the protocol requires that 24/7 in-house emergency room physicians, hospitalists and respiratory therapists be stat called to immediately respond to a respiratory code.
If a patient requires ventilator management during transfer, our cath lab nurses and/or respiratory therapists will be available to accompany patients during transfer.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Documentation provided demonstrated that catheterization laboratory staff meets the standards outlined in WAC 246-310-730(2). This sub-criterion is met.

For the entire sub-criterion of 246-310-230(1), the department concludes that if there is need for the additional PCI services in the planning area, the Astria Health application meets the sub-criterion.

Yakima Valley Memorial Hospital Association
YVMHA provided the following description and qualification detail for the FTEs referenced in its FTE table. [source: Application, 25]
“Our existing cath lab staff is experienced and competent in working in an interventional laboratory. The nurses, RTs and RCIS all demonstrate competency in operating PCI-related technologies and equipment on a daily, ongoing basis. The nursing staff all have coronary care unit experience or equivalent. As a comprehensive acute care facility, Memorial also has high quality post-procedure care units that are staffed with qualified nurses with direct experience and competencies in coronary care. (See Exhibit 11 for staff competencies)

All of Memorial's cath lab nurses are certified and have demonstrated balloon pump and Impella® placement and management competency. Advanced Cardiac Life Support certification ensures that training in performing endotracheal intubation and ventilation management has occurred. In addition, all nursing staff have completed training and certification in conscious sedation. However, Memorial does not routinely rely on the cath lab staff to perform these emergency procedures in a non-emergency in lab situation. Rather, our protocol requires that we stat-call our 24/7 in-house board certified emergency room physicians and respiratory therapists to immediately respond to a respiratory code in the cath lab.

If a patient needs ventilator management during transfer, our cath lab nurses and/or respiratory therapists are available to accompany the patient during the transfer.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Documentation provided demonstrated that catheterization laboratory staff meets the standards outlined in WAC 246-310-730(2). This sub-criterion is met.
For the entire sub-criterion of 246-310-230(1), the department concludes that if there is need for the additional PCI services in the planning area, the YVMHA application meets the sub-criterion.

(2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.

Both Astria Sunnyside Hospital and Virginia Mason Memorial are currently operating hospitals and have long-established and well-functioning relationships with health and social service providers in the area. For PCI projects, specific WAC 246-310-230(2) criteria is identified in WAC 246-310-735(1)-(13). Each of the two hospitals will be reviewed separately under this sub-criterion and standards.

Many sections of this sub-criterion require documentation from an applicant to demonstrate compliance with the standard. In this section, the department will first identify the documents provided by each applicant, then reference those documents in specific areas throughout the sub-criterion.

**Astria Health**

Documents provided by Astria Health include:
- Executed PCI Partnering Agreement between Astria Sunnyside Hospital and Astria Regional Medical Center, located in Yakima. [source: April 30, 2019, screening response, Attachment 4]
- Executed Agreement for Ambulance Transport Services between Astria Sunnyside Hospital Association and the City of Sunnyside, with February 27, 2019, addendum. [source: Application, Exhibit 7]
- (Patient) Informed Consent for Catheterization/Coronary Angiogram [source: Application, Exhibit 8]
- Quality Improvement Plan [source: Application, Exhibit 9]

**Yakima Valley Memorial Hospital Association**

Documents provided by YVMHA include:
- Draft Elective PCI Patient Transfer and Surgical Partnering Agreement between Virginia Mason Memorial and Kadlec Regional Medical Center (referenced as KRMC in the agreement) located in Richland, within Benton County. [source: April 29, 2019, screening response, Exhibit 10]
- Transport Agreement Advance Life Systems between Advanced Life Systems (ALS) and Virginia Mason Memorial [source: Application, Exhibit 14]
- (Patient) Informed Consent for Virginia Mason Memorial [source: Application, Exhibit 15]
- Elective and Emergency PCI Quality Assurance and Improvement Plan Scope of Services, Virginia Mason Memorial [source: Application, Exhibit 16]

WAC 246-310-735(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.
Astria Health
Page 1 of the PCI Partnering Agreement includes a recital, which is quoted below.

A. Percutaneous coronary interventions ("PCI") are invasive but nonsurgical mechanical procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries. These interventions include, but are not limited to, the following:
   (a) Bare and drug-eluting stent implantation;
   (b) Percutaneous transluminal coronary angioplasty (PTCA);
   (c) Cutting balloon atherectomy;
   (d) Rotational atherectomy;
   (e) Directional atherectomy;
   (f) Excimer laser angioplasty; and
   (g) Extractional thrombectomy.

B. Sunnyside is, upon receipt of a Certificate of Need, instituting a program for the provision of adult elective PCIs at its facilities (the "Program") as allowed by Washington Administrative Code ("WAC") Ch. 246-310.

C. Regional is qualified and allowed to provide on-site cardiac surgery, including open-heart surgery.

D. Sunnyside and Regional desire to facilitate the care and timely transfer of Sunnyside Program patients to Regional in the case of a patient complication during or following PCI services.

E. Sunnyside and Regional desire to ensure ongoing coordination and quality review of all appropriate elements and aspects of Sunnyside's Program.”

Pages 1 and 2 of the PCI Partnering Agreement state:
“Sunnyside and Regional will coordinate on the availability of cardiac surgical teams and operating rooms at Regional so that for all hours that elective PCIs are being performed at Sunnyside, Regional is available to provide cardiac surgery. Regional is not required to maintain an available surgical suite twenty-four hours a day, seven days a week. Prior to emergency transport, Sunnyside will contact Regional to ensure operating room availability. Regional will accept and admit all Program patients transferred by Sunnyside upon the determination of need for transfer as substantiated by the patient's physician and upon operating room availability. Regional shall also make available its diagnostic and therapeutic services as ordered by the patient's attending physician.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Astria Health provided an executed PCI Partnering Agreement to meet many of the PCI standards and many of the standards in this evaluation rely on the executed agreement. Specific to this sub-criterion, the executed PCI Partnering Agreement submitted by Astria Health demonstrated compliance with this standard. This sub-criterion is met.

Yakima Valley Memorial Hospital Association
Section 1 on page 1 of the draft Elective PCI Patient Transfer and Surgical Partnering Agreement includes the following information.
“On-Site Cardiac Surgery Hospital.”
KRMC shall serve as Transferring Facility's back-up cardiac surgery hospital, providing cardiac surgery during all hours that elective PCIs are being performed at Transferring Facility. In furtherance thereof:

a. KRMC and the Transferring Facility shall:
   i. Coordinate availability of surgical teams and operating rooms;
   ii. Participate in at least two annual timed emergency transportation drills and report outcomes to the Transferring Facility's quality assurance program; and
   iii. Participate in joint quarterly conferences in which a significant number of preoperative and postoperative cases, including all transport cases, are reviewed.

b. KRMC shall report peak volume periods to Transferring Facility and assist Transferring Facility in securing alternate back-up surgical services when necessary.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
YVMHA provided a draft Elective PCI Patient Transfer and Surgical Partnering Agreement to meet many of the PCI standards. If this project is approved, the department would attach a condition requiring YVMHA to submit a copy of the executed Elective PCI Patient Transfer and Surgical Partnering Agreement. The executed agreement must be consistent with the draft agreement provided in the application that was reviewed by the Certificate of Need Program. While many of the standards in this evaluation rely on the draft agreement, this condition will not be repeated throughout this evaluation.

Specific to this sub-criterion, the draft Elective PCI Patient Transfer and Surgical Partnering Agreement submitted by YVMHA demonstrated compliance with this standard. This sub-criterion is met.

WAC 246-310-735(2) Assurance the backup surgical hospital can provide cardiac surgery during all hours that elective PCIs are being performed at the applicant hospital.

Astria Health
Pages 1 and 2 of the PCI Partnering Agreement states:

“Sunnyside and Regional will coordinate on the availability of cardiac surgical teams and operating rooms at Regional so that for all hours that elective PCIs are being performed at Sunnyside, Regional is available to provide cardiac surgery. Regional is not required to maintain an available surgical suite twenty-four hours a day, seven days a week. Prior to emergency transport, Sunnyside will contact Regional to ensure operating room availability. Regional will accept and admit all Program patients transferred by Sunnyside upon the determination of need for transfer as substantiated by the patient's physician and upon operating room availability. Regional shall also make available its diagnostic and therapeutic services as ordered by the patient's attending physician.”

Public Comments
None
Department Evaluation
The executed PCI Partnering Agreement submitted by Astria Health demonstrated compliance with this standard. **This sub-criterion is met.**

Yakima Valley Memorial Hospital Association
Page 1 of the draft Elective PCI Patient Transfer and Surgical Partnering Agreement states:

*KRMC shall serve as Transferring Facility's back-up cardiac surgery hospital, providing cardiac surgery during all hours that elective PCIs are being performed at Transferring Facility. In furtherance thereof:
  a. KRMC and the Transferring Facility shall:
     i. Coordinate availability of surgical teams and operating rooms;...”*

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Specific to this sub-criterion, the draft Elective PCI Patient Transfer and Surgical Partnering Agreement submitted by YVMHA demonstrated compliance with this standard. **This sub-criterion is met.**

WAC 246-310-735(3) Transfer of all clinical data, including images and videos, with the patient to the backup surgical hospital.

Astria Health
Page 2 of the PCI Partnering Agreement states:

“The Sunnyside physicians performing the elective PCI shall communicate to Regional’s cardiac surgeon(s) about the clinical reasons for the urgent transfer and advising of the patient’s clinical condition. Sunnyside will transfer with each patient, either at the time of transfer or as soon thereafter as possible, all of the patient’s clinical data, including images and videos, together with any other essential identifying and administrative information.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
The executed PCI Partnering Agreement submitted by Astria Health demonstrated compliance with this standard. **This sub-criterion is met.**
Yakima Valley Memorial Hospital Association
Page 1 of the draft Elective PCI Patient Transfer and Surgical Partnering Agreement states:
“Clinical Data and Transfer Memorandum.
Transferring Facility will transfer all clinical data, including images and videos, with the patient to KRMC.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
The draft Elective PCI Patient Transfer and Surgical Partnering Agreement submitted by YVMHA demonstrated compliance with this standard. This sub-criterion is met.

WAC 246-310-735(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.

Astria Health
Page 2 of the PCI Partnering Agreement states:
“The Sunnyside physicians performing the elective PCI shall communicate to Regional’s cardiac surgeon(s) about the clinical reasons for the urgent transfer and advising of the patient’s clinical condition. Sunnyside will transfer with each patient, either at the time of transfer or as soon thereafter as possible, all of the patient’s clinical data, including images and videos, together with any other essential identifying and administrative information.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
The executed PCI Partnering Agreement submitted by Astria Health demonstrated compliance with this standard. This sub-criterion is met.

Yakima Valley Memorial Hospital Association
Page 1 of the draft Elective PCI Patient Transfer and Surgical Partnering Agreement states:
“Acceptance of Patients.
The physician at the Transferring Facility shall immediately notify the cardiac surgeon(s) at KRMC regarding the clinical reasons for urgent transfer and the patient's clinical condition. The transferring physician and the receiving physician shall cover and jointly determine the patient's appropriateness for transfer. KRMC shall accept, as promptly as possible, all patients who are appropriately referred for transfer under the terms of this Agreement. Even at peak volumes, all patients will be accepted, triaged, and stabilized as appropriate.”
**Department Evaluation**
The draft Elective PCI Patient Transfer and Surgical Partnering Agreement submitted by YVMHA demonstrated compliance with this standard. **This sub-criterion is met.**

*WAC 246-310-735(5) Acceptance of all referred patients by the backup surgical hospital.*

**Astria Health**
Page 1 of the PCI Partnering Agreement states:
“Sunnyside and Regional will coordinate on the availability of cardiac surgical teams and operating rooms at Regional so that for all hours that elective PCIs are being performed at Sunnyside, Regional is available to provide cardiac surgery. Regional is not required to maintain an available surgical suite twenty-four hours a day, seven days a week. Prior to emergency transport, Sunnyside will contact Regional to ensure operating room availability. Regional will accept and admit all Program patients transferred by Sunnyside upon the determination of need for transfer as substantiated by the patient’s physician and upon operating room availability. Regional shall also make available its diagnostic and therapeutic services as ordered by the patient’s attending physician.”

**Department Evaluation**
The executed PCI Partnering Agreement submitted by Astria Health demonstrated compliance with this standard. **This sub-criterion is met.**

**Yakima Valley Memorial Hospital Association**
Page 1 of the draft Elective PCI Patient Transfer and Surgical Partnering Agreement states:
“Acceptance of Patients.
The physician at the Transferring Facility shall immediately notify the cardiac surgeon(s) at KRMC regarding the clinical reasons for urgent transfer and the patient's clinical condition. The transferring physician and the receiving physician shall cover and jointly determine the patient's appropriateness for transfer. KRMC shall accept, as promptly as possible, all patients who are appropriately referred for transfer under the terms of this Agreement. Even at peak volumes, all patients will be accepted, triaged, and stabilized as appropriate.”

**Department Evaluation**
The draft Elective PCI Patient Transfer and Surgical Partnering Agreement submitted by YVMHA demonstrated compliance with this standard. **This sub-criterion is met.**
Department Evaluation
The draft Elective PCI Patient Transfer and Surgical Partnering Agreement submitted by YVMHA demonstrated compliance with this standard. This sub-criterion is met.

WAC 246-310-735(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.

Astria Health
Page 2 of the PCI Partnering Agreement states:
“Sunnyside has or will have, as part of the Program, an agreement with an emergency transport provider which will timely, expeditiously, appropriately and safely transport and care for Program patients who require transfer to Regional. Total transport time from the decision to transfer the patient with an elective PCI complication at Sunnyside to arrival in Regional’s operating room will be less than one hundred twenty minutes. Sunnyside will be responsible for ensuring emergency transport staff are 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). Sunnyside will ensure that emergency transportation begins within twenty minutes of the initial identification of a complication requiring transport to Regional. Sunnyside shall be responsible for the transfer of the patient’s personal effects to Regional, which shall accept and handle the same in accordance with its standard policies and procedures.”

Astria Health also provided the following information related to this standard. [source: April 30, 2019, screening response, pp13-14]

“Sunnyside also maintains an emergency transport agreement with the City of Sunnyside Fire Department. An addendum to this agreement was included in the CN application under Exhibit 7. The specific language consistent with the requirement listed above can be found in Addendum No. 1 of this agreement on page 86 of the application. It reads:
1. The City of Sunnyside Fire Department will expeditiously transport patients who experience complications during elective PCIs that require transfer to a backup hospital with on-site cardiac surgery, with a total transport time of less than one hundred twenty minutes.
2. The City of Sunnyside Fire Department will have the necessary qualifications to transfer Elective PCI patients with complications, including, but not limited to, being ACLS (advanced cardiac life support) certified and that have the skills, experience and equipment to monitor and treat the patient en route. Sunnyside will also provide ACLS certified staff that has the skills, experience and equipment to monitor and treat the patient en route and to manage an intra-aortic balloon pump (IABP), which Sunnyside will provide during transport. The City of Sunnyside Fire Department will transport Sunnyside’s staff back to the Sunnyside in a timely manner.
3. The City of Sunnyside Fire Department will participate in at least two annual timed emergency transportation drills with the Sunnyside and a hospital providing on-site cardiac surgery. The Sunnyside will report outcomes of those drills to its quality assurance program.”

Public Comments
None

Rebuttal Comments
None
**Department Evaluation**
The executed PCI Partnering Agreement submitted by Astria Health demonstrated compliance with this standard. The applicant also provided an executed Agreement for Ambulance Transport Services that demonstrated compliance with this standard. **This sub-criterion is met.**

**Yakima Valley Memorial Hospital Association**
Page 2 of the draft Elective PCI Patient Transfer and Surgical Partnering Agreement states:

“**Transportation of Patient**
Transferring Facility shall arrange for transportation of the patient to KRMC in accordance with the following:

a) Transferring Facility will have a signed transportation agreement that provides for expeditious transport by land or air for all patients who experience complications during elective PCIs that require transfer to KRMC.
b) Transferring Facility will ensure that emergency transportation will begin within twenty minutes of the initial identification of a complication.
c) Transferring Facility will document the transportation time from the decision to transfer the patient with an elective PCI complication to arrival in the operating room of KRMC and will ensure that transportation time is less than one hundred and twenty minutes.

Transferring Facility will provide staff for the emergency transport that are advanced cardiac life support (ACLS) certified and have the skills, experience, and equipment necessary to monitor and treat the patient en route and to manage an intra-aortic balloon pump (IABP) if in use.”

**Public Comments**
None

**Rebuttal Comments**
None

**Department Evaluation**
The draft Elective PCI Patient Transfer and Surgical Partnering Agreement submitted by YVMHA demonstrated compliance with this standard. **This sub-criterion is met.**

**WAC 246-310-735(7) Emergency transportation beginning within twenty minutes of the initial identification of a complication.**

**Astria Health**
Page 2 of the PCI Partnering Agreement states:

“Sunnyside has or will have, as part of the Program, an agreement with an emergency transport provider which will timely, expeditiously, appropriately and safely transport and care for Program patients who require transfer to Regional. Total transport time from the decision to transfer the patient with an elective PCI complication at Sunnyside to arrival in Regional’s operating room will be less than one hundred twenty minutes. Sunnyside will be responsible for ensuring emergency transport staff are 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). **Sunnyside will ensure that emergency transportation begins within twenty minutes of the initial identification of a complication** requiring transport to Regional. Sunnyside shall be responsible for the transfer of the patient’s personal effects to Regional, which shall accept and handle the same in accordance with its standard policies and procedures.”
Astria Health also provided the following information related to this standard. [source: April 30, 2019, screening response, pp13-15]

“The Sunnyside Quality Improvement Plan included with the CN in Exhibit 9 included language ensuring compliance with this standard. The language is included on page 93. It reads:
• The safe transportation of PCI patients experiencing complications to a partnering open-heart hospital including:
  o Maintaining a signed transportation agreement with a vendor who will expeditiously transport patients who experience complications during elective PCIs.
  o Ensuring that transport staff are advanced cardiac life support certified.
  o Providing the equipment and staff with the skills and experience to monitor and treat the patient en route and to manage an intra-aortic balloon pump (IABP).
  o Initiation of emergency transportation within twenty minutes of the initial identification of a complication.
  o Ensuring that the time from the decision to transfer the patient with an elective PCI complication to arrival in the operating room at the partner surgical hospital will be less than one hundred twenty minutes.
  o Documentation of transport time for all elective PCI patients needing emergency transport. These transport times are collected by Sunnyside staff that are part of the emergency transport team and reported to the Cardiology and Medical QI Committees as needed.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
The executed PCI Partnering Agreement submitted by Astria Health demonstrated compliance with this standard. The applicant also provided an executed Agreement for Ambulance Transport Services that demonstrated compliance with this standard. The Quality Improvement Plan provided in the application also demonstrated compliance with this standard. This sub-criterion is met.

Yakima Valley Memorial Hospital Association
Page 2 of the draft Elective PCI Patient Transfer and Surgical Partnering Agreement states:

“Transportation of Patient
Transferring Facility shall arrange for transportation of the patient to KRMC in accordance with the following:

a) Transferring Facility will have a signed transportation agreement that provides for expeditious transport by land or air for all patients who experience complications during elective PCIs that require transfer to KRMC.

b) Transferring Facility will ensure that emergency transportation will begin within twenty minutes of the initial identification of a complication.

c) Transferring Facility will document the transportation time from the decision to transfer the patient with an elective PCI complication to arrival in the operating room of KRMC and will ensure that transportation time is less than one hundred and twenty minutes.

Transferring Facility will provide staff for the emergency transport that are advanced cardiac life support (ACLS) certified and have the skills, experience, and equipment necessary to monitor and treat the patient en route and to manage an intra-aortic balloon pump (IABP) if in use.”
YVMHA also provided the Advanced Life System Transport Agreement, with Schedule A that includes the following language in Section 4. Noted that throughout this agreement the term ‘customer’ is used. For this agreement, the customer is Virginia Mason Memorial, not the PCI patient.

“ALS will dispatch emergency transportation immediately upon notification of a need for transport by Customers. ALS will use best efforts to respond within twenty (20) minutes. Emergent transports for Customer will have priority over other non-emergency patients, such as scheduled transports, in the local area. The transport will be done by:

a. The first preference will be to send a CCT ambulance staffed with ALS CCT level personnel to transport patients.
b. In the event that a CCT ambulance is not available within a reasonable timeframe, a Basic Life Support ambulance and ALS BLS staffed crew will be dispatched with the care being maintained by Customer CCT level staff during transport to the backup hospital.
c. In either case (CCT ambulance or BLS ambulance), Customer will send ACLS certified and experienced staff to monitor the patients and equipment in order to specifically manage patients with an intra-aortic balloon pump.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
The draft Elective PCI Patient Transfer and Surgical Partnering Agreement submitted by YVMHA demonstrated compliance with this standard. YVMHA also provided two separate transfer agreement. One agreement, entitled Transport Agreement Advance Life Systems between Advanced Life Systems (ALS) and Virginia Mason Memorial and the second agreement is a Schedule A associated with the initial agreement. Information provided in the two transfer agreements demonstrated compliance with this standard. This sub-criterion is met.

WAC 246-310-735(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).

Astria Health
Page 2 of the PCI Partnering Agreement states:

“Sunnyside has or will have, as part of the Program, an agreement with an emergency transport provider which will timely, expeditiously, appropriately and safely transport and care for Program patients who require transfer to Regional. Total transport time from the decision to transfer the patient with an elective PCI complication at Sunnyside to arrival in Regional’s operating room will be less than one hundred twenty minutes. Sunnyside will be responsible for ensuring emergency transport staff are 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). Sunnyside will ensure that emergency transportation begins within twenty minutes of the initial identification of a complication requiring transport to Regional. Sunnyside shall be responsible for the transfer of the patient’s personal effects to Regional, which shall accept and handle the same in accordance with its standard policies and procedures.
Astria Health also provided the following information related to this standard. [source: April 30, 2019, screening response, p15]

“The emergency transport agreement addendum with the City of Sunnyside Fire Department included in Exhibit 7 in the original CN also ensures compliance with this standard and reads: The City of Sunnyside Fire Department will have the necessary qualifications to transfer Elective PCI patients with complications, including, but not limited to, being ACLS (advanced cardiac life support) certified and that have the skills, experience and equipment to monitor and treat the patient en route. Sunnyside will also provide ACLS certified staff that has the skills, experience and equipment to monitor and treat the patient en route and to manage an intraaortic balloon pump (IABP), which Sunnyside will provide during transport. The City of Sunnyside Fire Department will transport Sunnyside’s staff back to the Sunnyside in a timely manner.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
The executed PCI Partnering Agreement submitted by Astria Health demonstrated compliance with this standard. The applicant also provided an executed Agreement for Ambulance Transport Services that demonstrated compliance with this standard. This sub-criterion is met.

Yakima Valley Memorial Hospital Association
Page 2 of the draft Elective PCI Patient Transfer and Surgical Partnering Agreement states:

“Transportation of Patient
Transferring Facility shall arrange for transportation of the patient to KRMC in accordance with the following:

a) Transferring Facility will have a signed transportation agreement that provides for expeditious transport by land or air for all patients who experience complications during elective PCIs that require transfer to KRMC.

b) Transferring Facility will ensure that emergency transportation will begin within twenty minutes of the initial identification of a complication.

c) Transferring Facility will document the transportation time from the decision to transfer the patient with an elective PCI complication to arrival in the operating room of KRMC and will ensure that transportation time is less than one hundred and twenty minutes.

Transferring Facility will provide staff for the emergency transport that are advanced cardiac life support (ACLS) certified and have the skills, experience, and equipment necessary to monitor and treat the patient en route and to manage an intra-aortic balloon pump (IABP) if in use.”

YVMHA also provided the Advanced Life System Transport Agreement, with Schedule A that includes the following language in Section 4.

“ALS will dispatch emergency transportation immediately upon notification of a need for transport by Customers. ALS will use best efforts to respond within twenty (20) minutes. Emergent transports for Customer will have priority over other non-emergency patients, such as scheduled transports, in the local area. The transport will be done by:
a. The first preference will be to send a CCT ambulance staffed with ALS CCT level personnel to transport patients.
b. In the event that a CCT ambulance is not available within a reasonable timeframe, a Basic Life Support ambulance and ALS BLS staffed crew will be dispatched with the care being maintained by Customer CCT level staff during transport to the backup hospital.
c. In either case (CCT ambulance or BLS ambulance), Customer will send ACLS certified and experienced staff to monitor the patients and equipment in order to specifically manage patients with an intra-aortic balloon pump.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
YVMHA provided two separate transfer agreement. One agreement, entitled Transport Agreement Advance Life Systems between Advanced Life Systems (ALS) and Virginia Mason Memorial and the second agreement is a Schedule A associated with the initial agreement. Information provided in the two transfer agreements demonstrated compliance with this standard. This sub-criterion is met.

WAC 246-310-735(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.

Astria Health
Page 2 of the PCI Partnering Agreement states:
“Sunnyside has or will have, as part of the Program, an agreement with an emergency transport provider which will timely, expeditiously, appropriately and safely transport and care for Program patients who require transfer to Regional. Total transport time from the decision to transfer the patient with an elective PCI complication at Sunnyside to arrival in Regional’s operating room will be less than one hundred twenty minutes. Sunnyside will be responsible for ensuring emergency transport staff are 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). Sunnyside will ensure that emergency transportation begins within twenty minutes of the initial identification of a complication requiring transport to Regional. Sunnyside shall be responsible for the transfer of the patient’s personal effects to Regional, which shall accept and handle the same in accordance with its standard policies and procedures.”

Astria Health also provides the following information related to this standard. [source: April 30, 2019, screening response, p16]

“The Sunnyside Quality Improvement Plan included with the CN in Exhibit 9 also included language ensuring compliance with this standard. The language is included on page 93. It reads:
4. Emergency Transport Process
• The safe transportation of PCI patients experiencing complications to a partnering open-heart hospital including:
  o Maintaining a signed transportation agreement with a vendor who will expeditiously transport patients who experience complications during elective PCIs.
o Ensuring that transport staff are advanced cardiac life support certified.

o Providing the equipment and staff with the skills and experience to monitor and treat the patient en route and to manage an intra-aortic balloon pump (IABP).

o Initiation of emergency transportation within twenty minutes of the initial identification of a complication.

o Ensuring that the time from the decision to transfer the patient with an elective PCI complication to arrival in the operating room at the partner surgical hospital will be less than one hundred twenty minutes.

o Documentation of transport time for all elective PCI patients needing emergency transport. These transport times are collected by Sunnyside staff that are part of the emergency transport team and reported to the Cardiology and Medical QI Committees as needed.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation

The executed PCI Partnering Agreement submitted by Astria Health demonstrated compliance with this standard. The Quality Improvement Plan provide by the applicant also demonstrated compliance with this standard. This sub-criterion is met.

Yakima Valley Memorial Hospital Association

Page 2 of the draft Elective PCI Patient Transfer and Surgical Partnering Agreement states:

“Transportation of Patient

Transferring Facility shall arrange for transportation of the patient to KRMC in accordance with the following:

a) Transferring Facility will have a signed transportation agreement that provides for expeditious transport by land or air for all patients who experience complications during elective PCIs that require transfer to KRMC.

b) Transferring Facility will ensure that emergency transportation will begin within twenty minutes of the initial identification of a complication.

c) Transferring Facility will document the transportation time from the decision to transfer the patient with an elective PCI complication to arrival in the operating room of KRMC and will ensure that transportation time is less than one hundred and twenty minutes.

Transferring Facility will provide staff for the emergency transport that are advanced cardiac life support (ACLS) certified and have the skills, experience, and equipment necessary to monitor and treat the patient en route and to manage an intra-aortic balloon pump (IABP) if in use.”

YVMHA also provided the Advanced Life System Transport Agreement, with Schedule A that includes the following language in Section 5.

“ALS and Customer will agree to total patient transportation time - from notification of the need to transport to arrival in the operating room at a backup hospital with on-site cardiac surgery - of 120 minutes or less.”

Public Comments
None
Rebuttal Comments
None

Department Evaluation
YVMHA provided two separate transfer agreements. One agreement, titled “Transport Agreement Advance Life Systems between Advanced Life Systems (ALS) and Virginia Mason Memorial” and the second agreement is a Schedule A associated with the initial agreement. Information provided in the two transfer agreements demonstrated compliance with this standard. This sub-criterion is met.

WAC 246-310-735(10) At least two annual timed emergency transportation drills with outcomes reported to the hospital's quality assurance program.

Astria Health
Page 2 of the PCI Partnering Agreement states:
“Sunnyside, its emergency transport provider and Regional will conduct at least two timed emergency transportation drills annually and Sunnyside will report the outcomes of those drills to Sunnyside’s quality assurance program. Sunnyside will have a policy and be responsible for documenting the transportation time from the decision to transfer the patient with an elective PCI complication to arrival in Regional’s operating room, which, as stated above, shall be less than one hundred twenty minutes.”

Astria Health also provided the following information related to this standard. [source: April 30, 2019, screening response, p17]
“The emergency transport agreement addendum with the City of Sunnyside Fire Department included in Exhibit 7 in the original CN also ensures compliance with this standard and reads: The City of Sunnyside Fire Department will participate in at least two annual timed emergency transportation drills with the Sunnyside and a hospital providing on-site cardiac surgery. The Sunnyside will report outcomes of those drills to its quality assurance program.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
The executed PCI Partnering Agreement submitted by Astria Health demonstrated compliance with this standard. The applicant also provided an executed Agreement for Ambulance Transport Services that demonstrated compliance with this standard. This sub-criterion is met.

Yakima Valley Memorial Hospital Association
Section 1 on page 1 of the draft Elective PCI Patient Transfer and Surgical Partnering Agreement includes the following information.
“On-Site Cardiac Surgery Hospital.
KRMC shall serve as Transferring Facility's back-up cardiac surgery hospital, providing cardiac surgery during all hours that elective PCIs are being performed at Transferring Facility. In furtherance thereof:
a. KRMC and the Transferring Facility shall:
   i. Coordinate availability of surgical teams and operating rooms;
   ii. Participate in at least two annual timed emergency transportation drills and report outcomes to the Transferring Facility’s quality assurance program; and
   iii. Participate in joint quarterly conferences in which a significant number of preoperative and postoperative cases, including all transport cases, are reviewed.

b. KRMC shall report peak volume periods to Transferring Facility and assist Transferring Facility in securing alternate back-up surgical services when necessary."

YVMHA also provided the Advanced Life System Transport Agreement, with Schedule A that includes the following language in Section 6.

“ALS will participate in at least two annual timed emergency transportation drills with Customer and two (2) annual time emergency drills with Customer to ensure the timelines referenced within this agreement continue to be met.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
YVMHA provided two separate transfer agreements. One agreement, entitled Transport Agreement Advance Life Systems between Advanced Life Systems (ALS) and Virginia Mason Memorial and the second agreement is a Schedule A associated with the initial agreement. Information provided in the two transfer agreements demonstrated compliance with this standard. This sub-criterion is met.

WAC 246-310-735(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.

Astria Health
Page 2 of the PCI Partnering Agreement states:

“Sunnyside will properly inform Program patients that (a) the PCI is being performed without all possible on-site surgery backup, (b) describing that transfer to Regional may be necessary, and (c) the risks related to transfer and urgent surgery at Regional. Sunnyside will obtain the advance written consent of Program patients for and to such transfer and urgent surgery at Regional should such transfer and urgent surgery be necessary.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
The executed PCI Partnering Agreement submitted by Astria Health demonstrated compliance with this standard. **This sub-criterion is met.**

**Yakima Valley Memorial Hospital Association**

Pages 1 and 2 of the Percutaneous Coronary Intervention (PCI) Informed Consent provide the following information.

“Washington State law guarantees that you have both the right and the obligation to make decisions regarding your health care. Your physician can provide you with the necessary information and advice, but as a member of the health care team, you must participate in the decision making process. This form will acknowledge your consent to treatment recommended by your physician.

For PCI Balloon/Stenting there is generally less than 1% risk of heart attack, death, or need for emergency transfer to another hospital for open heart surgery. Open heart surgery is not available at Yakima Valley Memorial Hospital.

Should emergency transfer to an open heart surgery hospital be needed, I will be transferred to Kadlec Regional Medical Center in Richland, Washington or another hospital that offers open heart surgery. Yakima Valley Memorial Hospital has an established agreement with Advanced Life Systems of Yakima (ALS) a qualified emergency transport agency that will ensure a total transportation time of less than 120 minutes, which is the ideal standard. I understand that a transport team will be en route with me that include staff certified in advance cardiac life support who have the skills, experience, and equipment to monitor and treat me and to manage an intra-aortic balloon pump. Yakima Valley Memorial Hospital will immediately notify both Kadlec Regional Medical Center and ALS in the rare case a complication should arise. Emergency transport occurs in less than 3 out of 1,000 cases.”

**Public Comments**
None

**Rebuttal Comments**
None

**Department Evaluation**

YVMHA provided a (Patient) Informed Consent for Virginia Mason Memorial in the application. Information provided in document demonstrated compliance with this standard. **This sub-criterion is met.**

WAC 246-310-735(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.**

**Astria Health**

Page 2 of the PCI Partnering Agreement states:

“Representatives of Sunnyside and Regional shall conference at least quarterly to review and discuss all or a significant number of preoperative and post-operative cases (including all transport cases).”

**Public Comments**
None
**Department Evaluation**
The executed PCI Partnering Agreement submitted by Astria Health demonstrated compliance with this standard. **This sub-criterion is met.**

**Yakima Valley Memorial Hospital Association**
Section 1 on page 1 of the draft Elective PCI Patient Transfer and Surgical Partnering Agreement includes the following information.

**“On-Site Cardiac Surgery Hospital.”**
KRMC shall serve as Transferring Facility's back-up cardiac surgery hospital, providing cardiac surgery during all hours that elective PCIs are being performed at Transferring Facility. In furtherance thereof:

a. KRMC and the Transferring Facility shall:
   i. Coordinate availability of surgical teams and operating rooms;
   ii. Participate in at least two annual timed emergency transportation drills and report outcomes to the Transferring Facility's quality assurance program; and
   iii. Participate in joint quarterly conferences in which a significant number of preoperative and postoperative cases, including all transport cases, are reviewed.

b. KRMC shall report peak volume periods to Transferring Facility and assist Transferring Facility in securing alternate back-up surgical services when necessary."

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**
The draft Elective PCI Patient Transfer and Surgical Partnering Agreement submitted by YVMHA demonstrated compliance with this standard. **This sub-criterion is met.**

**WAC 246-310-735(13) Addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.).**

**Astria Health**
Page 2 of the PCI Partnering Agreement states:

“Sunnyside and Regional shall prepare and adopt a policy for addressing peak volume periods of Regional that may impact the ability of Regional to provide potentially-necessary surgical backup for elective PCIs performed at Sunnyside. Such policy may include temporary staff increases and/or agreements with other facilities having appropriate permission to perform backup cardiac surgery.”

Public Comments
None

Rebuttal Comments
None
**Department Evaluation**
The executed PCI Partnering Agreement submitted by Astria Health demonstrated compliance with this standard. **This sub-criterion is met.**

**Yakima Valley Memorial Hospital Association**
Section 1 on page 1 of the draft Elective PCI Patient Transfer and Surgical Partnering Agreement includes the following information.

**“On-Site Cardiac Surgery Hospital.”**
KRMC shall serve as Transferring Facility's back-up cardiac surgery hospital, providing cardiac surgery during all hours that elective PCIs are being performed at Transferring Facility. In furtherance thereof:

a. KRMC and the Transferring Facility shall:
   i. Coordinate availability of surgical teams and operating rooms;
   ii. Participate in at least two annual timed emergency transportation drills and report outcomes to the Transferring Facility's quality assurance program; and
   iii. Participate in joint quarterly conferences in which a significant number of preoperative and postoperative cases, including all transport cases, are reviewed.

b. KRMC shall report peak volume periods to Transferring Facility and assist Transferring Facility in securing alternate back-up surgical services when necessary.”

**Public Comments**
None

**Rebuttal Comments**
None

**Department Evaluation**
The draft Elective PCI Patient Transfer and Surgical Partnering Agreement submitted by YVMHA demonstrated compliance with this standard. **This sub-criterion is met.**

**Summarized Conclusion for Astria Sunnyside Hospital for WAC 246-310-230(2)**
For the entire sub-criterion of 246-310-230(2), the department concludes that if there is need for the additional PCI services in the planning area, approval of this project would not negatively affect existing healthcare relationships within the planning area. All documents associated submitted under this sub-criterion and standards are in final / executed format. As a result, if this project is approved, the department would not attach conditions requiring Astria Health to provide final or executed agreements. **This sub-criterion is met for the Astria Health project.**

**Summarized Conclusion for Virginia Mason Memorial for WAC 246-310-230(2)**
For the entire sub-criterion of 246-310-230(2), the department concludes that if there is need for the additional PCI services in the planning area, approval of this project would not negatively affect existing healthcare relationships within the planning area. Provided that YVMHA agrees to conditions related to the draft agreements provided in the application, **this sub-criterion is met for the YVMHA project.**
(3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.

WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant’s history in meeting these standards at other facilities owned or operated by the applicant.

As part of this review, the department must also conclude that the proposed services provided by an applicant would be provided in a manner that ensures safe and adequate care to the public. To accomplish this task, the department reviews the quality of care compliance history for all Washington State and out-of-state healthcare facilities owned, operated, or managed by an applicant, its parent company, or its subsidiaries.

**Astria Health**

In response to this sub-criterion, Astria Health provided the following statements. [source: Application, p31]

“Neither Astria nor Sunnyside, nor any physician identified in this application has had any sanctions or notifications related to the above items referenced in (a)-(f).”

**Public Comments**

None

**Rebuttal Comments**

None

**Department Evaluation**

Astria Health, the applicant for this project, operates three acute care hospitals and two in home service agencies in Washington State. Astria Health does not own or operate any out-of-state facilities. The Washington State facilities are listed below.

<table>
<thead>
<tr>
<th>Name of Facility</th>
<th>Type of Facility</th>
<th>State Credential Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Astria Sunnyside Hospital</td>
<td>Acute Care Hospital</td>
<td>HAC.FS.00000198</td>
</tr>
<tr>
<td></td>
<td>Critical Access Hospital Designation</td>
<td></td>
</tr>
<tr>
<td>Astria Toppenish Hospital</td>
<td>Acute Care Hospital</td>
<td>HAC.FS.60790220</td>
</tr>
<tr>
<td>Astria Regional Medical Center</td>
<td>Acute Care Hospital</td>
<td>HAC.FS.60790591</td>
</tr>
<tr>
<td>Atria Home Health</td>
<td>Home Health Agency</td>
<td>IHS.FS.60097245</td>
</tr>
<tr>
<td>Sunnyside Home Health</td>
<td>Home Health Agency</td>
<td>IHS.FS.60724314</td>
</tr>
</tbody>
</table>

The department reviewed the survey history of the healthcare facilities listed above using the Center for Medicare and Medicaid Services Quality, Certification & Oversight Reports (QCOR) website and Washington State Department of Health internal database known as ILRS.

Three healthcare facilities—Astria Toppenish Hospital, Astria Regional Medical Center, and Atria Home Health—became part of the Astria Health system on October 17, 2017, following the change

15 WAC 246-310-230(5).
of ownership to Regional Health on September 1, 2017. For these three facilities, the department focused on years 2018 and 2019 during the Astria Health ownership.

For Astria Sunnyside Hospital and Sunnyside Home Health, these two healthcare became part of the Astria Health system on October 17, 2017, without undergoing a change of ownership. For these two healthcare facilities, the department focused on years 2015 through 2019.

### Survey Focus Years 2017, 2018, and 2019

<table>
<thead>
<tr>
<th>Month/Year Surveyed</th>
<th>Facility Name</th>
<th>Type of Survey</th>
<th>Citations Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 2019</td>
<td>Astria Toppenish Hospital</td>
<td>Standard Health</td>
<td>Standard Citations Issued No Follow Up Visits</td>
</tr>
<tr>
<td>No Surveys for years 2017-2019</td>
<td>Astria Regional Medical Center</td>
<td>Most recent survey 2017 for Joint Commission Accreditation</td>
<td></td>
</tr>
<tr>
<td>No Surveys for years 2017-2019</td>
<td>Astria Home Health</td>
<td>Most recent CHAP survey 2016 No citations listed</td>
<td></td>
</tr>
</tbody>
</table>

As shown in the table above, the only hospital with a recent survey is Astria Toppenish Hospital. The survey resulted in standard citations with no follow up visits required. The department did not identify facility closures or decertification.

### Survey Focus Years 2015, 2016, 2017, 2018, and 2019

<table>
<thead>
<tr>
<th>Month/Year Surveyed</th>
<th>Facility Name</th>
<th>Type of Survey</th>
<th>Citations Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2015, March 2018, September 2019</td>
<td>Astria Sunnyside Hospital</td>
<td>Complaint &amp; Standard</td>
<td>Standard &amp; Condition Citations Issued</td>
</tr>
<tr>
<td>September 2017</td>
<td>Sunnyside Home Health</td>
<td>Standard Health</td>
<td>No Deficiencies No Follow Up Visits</td>
</tr>
</tbody>
</table>

As shown in the table above, the only hospital with a recent survey is Astria Sunnyside Hospital. The facility was cited for one condition survey in March 2018 that required a follow up visit in June 2018; the facility was cited for two conditions in April 2015 that required a follow up visit in May 2015. The department did not identify facility closures or decertification. Currently the facility is operating in compliance with state and federal requirements.

In addition to the facilities identified above, Astria Health also provide the name and credential numbers for each of the staff currently associated with its emergent PCI services. Astria Health does not anticipate a staff increase if this project is approved. The department reviewed the credential history for each of the current staff shown in the table below.

### Department’s Table 23

<table>
<thead>
<tr>
<th>L.Name</th>
<th>F Name</th>
<th>MName</th>
<th>Credential #</th>
<th>Status</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zubair</td>
<td>Imran</td>
<td>NMI</td>
<td>MD00028404</td>
<td>Active</td>
<td>Cardiologist - Primary</td>
</tr>
<tr>
<td>Raven</td>
<td>Christopher</td>
<td>K.</td>
<td>MD00032069</td>
<td>Active</td>
<td>Cardiologist-Backup</td>
</tr>
<tr>
<td>Adan</td>
<td>John</td>
<td>NMI</td>
<td>MD60540307</td>
<td>Active</td>
<td></td>
</tr>
<tr>
<td>Becker</td>
<td>Michael</td>
<td>David</td>
<td>MD60556181</td>
<td>Active</td>
<td></td>
</tr>
<tr>
<td>Perry</td>
<td>John</td>
<td>Joseph</td>
<td>MD60421229</td>
<td>Active</td>
<td></td>
</tr>
<tr>
<td>Rowe</td>
<td>William</td>
<td>Westel</td>
<td>MD00025511</td>
<td>Active</td>
<td></td>
</tr>
<tr>
<td>Sachdev</td>
<td>Sumeet</td>
<td>NMI</td>
<td>MD60789987</td>
<td>Active</td>
<td></td>
</tr>
<tr>
<td>Schmidt</td>
<td>James</td>
<td>Edward</td>
<td>MD60450543</td>
<td>Active</td>
<td></td>
</tr>
</tbody>
</table>
Using data from the Washington State Department of Health Office of Customer Service, the department found that all staff, shown in the table above are compliant with state licensure and there are no enforcement actions on any of the staff licenses.

Given the compliance history of the facilities own or operated by the applicant, the department concludes there is reasonable assurance the proposed PCI services would be operated in conformance with applicable state and federal licensing and certification requirements. Based on the information reviewed, the department concludes this sub criterion is met.

Yakima Valley Memorial Hospital Association

In response to this sub-criterion, YVMHA provided the following statement. [source: Application, p39]

“Neither Virginia Mason Memorial (owner/operator), nor any physician identified in this application, has any issues with the above items referenced in 4. a-f.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation

YVMHA, the applicant for this project, operates one acute care hospital, Virginia Mason Memorial and one home health and hospice agency, and one hospice care center. All are located in Yakima County. Additionally, the affiliated Virginia Mason Health System operates an acute care hospital and four ambulatory surgical facilities (ASF). All of these healthcare facilities are located in King County. Neither YVMHA nor Virginia Mason Health System own or operate any out-of-state facilities. The Washington State facilities are listed below.

<table>
<thead>
<tr>
<th>Name of Facility</th>
<th>Type of Facility</th>
<th>State Credential Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virginia Mason Hospital</td>
<td>Acute Care Hospital</td>
<td>HAC.FS.00000010</td>
</tr>
<tr>
<td>Virginia Mason Memorial</td>
<td>Acute Care Hospital</td>
<td>HAC.FS.00000058</td>
</tr>
<tr>
<td>Virginia Mason Bellevue ASF</td>
<td>Ambulatory Surgical Facility</td>
<td>ASF.FS.60101657</td>
</tr>
<tr>
<td>Virginia Mason Issaquah ASF</td>
<td>Ambulatory Surgical Facility</td>
<td>ASF.FS.60101658</td>
</tr>
<tr>
<td>Virginia Mason Lynnwood ASF</td>
<td>Ambulatory Surgical Facility</td>
<td>ASF.FS.60101659</td>
</tr>
<tr>
<td>Memorial Home Care Services</td>
<td>Home Health Agency, Hospice Agency, Hospice Care Center</td>
<td>IHS.FS.00000343</td>
</tr>
</tbody>
</table>

The department reviewed the survey history of the healthcare facilities listed above using the Center for Medicare and Medicaid Services Quality, Certification & Oversight Reports (QCOR) website and Washington State Department of Health internal database known as ILRS.
Three healthcare facilities—Virginia Mason Memorial and Memorial Home Care Services—became part of the Virginia Mason Health System on January 1, 2016. For these two facilities, the department focused on years 2016 through 2019 during the Virginia Mason Health System ownership.

The Virginia Mason Hospital and the three ASFs located in King County were created under the Virginia Mason Health System. For these four healthcare facilities, the department focused on years 2015 through 2019.

<table>
<thead>
<tr>
<th>Month/Year Surveyed</th>
<th>Facility Name</th>
<th>Type of Survey</th>
<th>Citations Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 2016, August 2017, June 2019</td>
<td>Virginia Mason Memorial</td>
<td>Complaint &amp; Standard</td>
<td>Standard &amp; Condition Citations Issued</td>
</tr>
<tr>
<td>November 2017, June 2018</td>
<td>Memorial Home Care-surveys include hospice, home health, &amp; hospice care center</td>
<td>Standard</td>
<td>Standard Citations Issued No Follow Up Visits</td>
</tr>
</tbody>
</table>

The August 2017 survey resulted in conditions citations issued and required a follow up survey in November 2017. The department did not identify facility closures or decertification. Currently both healthcare facilities are operating in compliance with state and federal requirements.

<table>
<thead>
<tr>
<th>Month/Year Surveyed</th>
<th>Facility Name</th>
<th>Type of Survey</th>
<th>Citations Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2015, May 2016, September 2016, July 2019, September 2019</td>
<td>Virginia Mason Hospital</td>
<td>Complaint</td>
<td>Standard Citations Issued No Follow Up Visits</td>
</tr>
<tr>
<td>June 2019</td>
<td>Virginia Mason Bellevue ASF</td>
<td>Standard</td>
<td>Standard Citations Issued No Follow Up Visits</td>
</tr>
<tr>
<td>March 2016</td>
<td>Virginia Mason Issaquah ASF</td>
<td>Standard</td>
<td>Standard Citations Issued No Follow Up Visits</td>
</tr>
<tr>
<td>June 2017</td>
<td>Virginia Mason Lynnwood ASF</td>
<td>Standard</td>
<td>Standard Citations Issued No Follow Up Visits</td>
</tr>
</tbody>
</table>

As noted in the table above, Virginia Mason Hospital underwent four complaint surveys. Each of the four resulted in standard citations and three of the four complaint surveys were substantiated. No follow up visits were required. The department did not identify facility closures or decertification. Currently the hospital is operating in compliance with state and federal requirements.

The three surgery centers associated with the Virginia Mason Health System have each had one survey resulting in conditions issued, with no follow up visits required. The department did not identify facility closures or decertification. Currently the three ASFs are operating in compliance with state and federal requirements.

In addition to the facilities identified above, YVMHA also provide the name and credential numbers for each of the staff currently associated with the emergent PCI services at Virginia Mason Memorial. YVMHA does not anticipate a staff increase if this project is approved. The department reviewed the credential history for each of the current staff shown in the table below.
Using data from the Washington State Department of Health Office of Customer Service, the department found that all staff, shown in the table above are compliant with state licensure and there are no enforcement actions on any of the staff licenses.

Given the compliance history of the facilities own or operated by the applicant, the department concludes there is reasonable assurance the proposed PCI services would be operated in conformance with applicable state and federal licensing and certification requirements. Based on the information reviewed, the department concludes this sub criterion is met.

In addition to the general quality of care sub-criterion above, WAC 246-310-740(1)-(4) identify specific quality assurance/quality improvements requirements for adult, elective PCI programs.

WAC 246-310-740(1) A process for ongoing review of the outcomes of adult elective PCI’s. Outcomes must be benchmarked against state or national quality of care indicators for elective PCIs.

Astria Health
In response to the four standards in this section, Astria Health provided the following information.

[A source: April 30, 2019, screening response, pp18-19]

“Sunnyside’s PCI Program Quality Assurance and Improvement Plan included in Exhibit 9 of the original CN application complies with all of the WAC requirements listed below, is overseen by a PCI QA/QI committee and will

- Provide for a process for ongoing review of the outcomes for adult PCIs.
o Provide a system of patient selection that will result in outcomes that are equal to or better than benchmark standards.

o Provide for a process of formalized review of pre and post-operative patient care with our partner surgical backup hospital for all patients transferred for surgical intervention.

o Provide a process for reporting elective PCI information to the Washington State Department or an entity designated by the Washington State Department of Health.

o Document, assess and improve the emergency transport processes and timeframes.

For reader ease, Sunnyside has re-stated each WAC requirement and then listed the location of the specific language and included the verbatim language from the Plan that complies with that section.”

Specific to standard #1 above, Astria Health provided the following statements.

PCI Program Quality Assurance and Improvement Plan, pg. 92, #1:
Ongoing Outcome Review & Reporting Information

o The tracking, documentation and reporting out of PCI outcomes to the Washington State Clinical Outcomes Assessment Program (COAP). This information will be sent electronically on a quarterly basis.

o The ongoing review of Sunnyside’s outcome data as compared to the statewide benchmarks. Sunnyside will utilize benchmarks established by the Clinical Outcomes Assessment Program (COAP).

o The review of bi-annual emergency transport drill outcomes.

o The development and implementation of any action plans that may be necessary to resolve any identified outcome issues or to improve performance. Action plans will have accountabilities and timelines well defined with progress reported at each committee meeting. Traditional Plan-Do-Check-Act quality improvement methods will be utilized to improve outcomes and processes.

o The review and response of all requests made by the Department of Health of outcome information. Requests will be handled by the Cardiac Services/Cath Lab Manager with a response to Department of Health or its designee no later than 30 days of the request.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Astria Health provided a Quality Improvement Plan to meet many of the PCI standards. Specific to this sub-criterion, the Quality Improvement Plan demonstrated compliance with this standard. This sub-criterion is met.

Yakima Valley Memorial Hospital Association
The Virginia Mason Memorial Hospital Elective and Emergent PCI Quality Assurance and Improvement Plan provided information related to the four standards under WAC 246-310-740. The entire document is restated below.
“PURPOSE
The purpose of the plan is:
1. Provide for a process for ongoing review of the quality and outcomes for adult elective and emergent PCIs.
2. Provide a system of patient selection that will result in outcomes that are equal to or better than benchmark standards.
3. Provide for a process of formalized review of pre and post-operative patient care with partner surgical backup hospital(s) including all patients transferred for surgical intervention.
4. Provide a process for reporting elective PCI information to the Washington State Department of Health or entity designated by the Washington State Department of Health.
5. Document, assess and improve the emergency transport processes and timeframes.”

POLICYPROCEDURE
Virginia Mason Memorial Hospital has an established Cardiac Quality team (committee) that will oversee all QA/PI activities as they relate to the Elective PCI Program. This will include a process of formalized case review for all preoperative and post-operative elective PCI cases including those that involve patient transfers. Specifically, the committee:

• Meets quarterly
• Reports to Cardiac, Pulmonary and Critical Care (CPCC) committee where selected cases are reviewed in a peer protected environment.
• Is comprised of the following participants:
  • Cath Lab Manager/Supervisor (Chair)
  • Cath Lab Medical Director
  • Emergency Department Medical Director
  • Cardiovascular Service Line Senior Director
  • Critical Care Senior Director
  • Representatives from the partner surgical hospital(s)
  • Critical Care Manager
  • Performance Improvement representative
  • Pharmacy representatives
  • Local emergency services representatives
  • Plus designated staff as committee deems appropriate
• The Cardiac Quality Committee will be part of the hospital's Performance Improvement Program and will abide by all relevant standards.
• Quality and Performance issues identified at Cardiac Quality will be addressed at that level unless further discussion is needed in a peer protected environment. In that case, these will be forwarded to the Cardiac, Pulmonary & Critical Care Quality Assurance/Performance Improvement Committee for review.
• Approved recommendations will be forwarded for inclusion in the hospital's Performance Improvement Programs. Additional actions will adhere to Memorial's Quality, Peer Review and Medical Executive processes.
• The Cardiac Quality Committee and its work will be protected by Washington State Statute RCW 70.41.200.

Elective PCI case submission will be included in the WA State Clinical Outcomes Assessment Program (COAP). Outcomes will be benchmarked against the statewide outcome data and included in the case review meetings and presented quarterly to the Cardiac Quality Committee including recommendations on how to resolve any identified problems.
Specific benchmarks will be consistent with Level I and Level II indicators consistent with those of COAP-PCI.

**Level I Indicators**
- In-Hospital Mortality
- Median door to Balloon Time

**Level II Indicators**
- Appropriate use
- Bleeding events within 72 hours
- Post-Procedure CVA
- Vascular Complications
- Unplanned CABG

Cardiologists will use the Society for Cardiovascular Angiography and Interventions (SCAI) guidelines for patient, lesion and case selection to determine which patients are suitable candidates for elective PCI.

Memorial will ensure the safe transportation of elective PCI patients experiencing emergency complications to Kadlec Medical Center, or other appropriate receiving hospital based upon patient stability including:
- Maintaining a signed transportation agreement with a vendor who will expeditiously transport patients who experience complications during elective PCIs.
- Ensuring that transport staff are advanced cardiac life support certified.
- Providing the equipment and staff with the skills and experience to monitor and treat the patient en route to include Intra-aortic balloon pump (IABP) and/or similar technology such as Impella®.
- Initiation of emergency transportation within twenty minutes of the initial identification of a complication.
- Ensuring that the time from the decision to transfer the patient with an elective PCI complication to arrival in the operating room at the partner surgical hospital will be less than one hundred twenty minutes.
- Documentation of transport time for all elective PCI patients needing emergency transport. These transport times will be presented to the Cardiac Quality Committee for further review.

**REPORTING PROCESS**
The Cardiac Quality Committee will report in writing all findings, data and performance improvement activities from all the QA/PI activities contained in this plan. The report will be forwarded to the Department of Health or the Department's designee as requested.”

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**
YVMHA provided a document entitled Elective and Emergency PCI Quality Assurance and Improvement Plan Scope of Services Virginia Mason Memorial intended to meet many of the PCI standards. Specific to this sub-criterion, the document demonstrated compliance with this standard. **This sub-criterion is met.**
WAC 246-310-740(2) A system for patient selection that results in outcomes that are equal to or better than the benchmark standards in the applicant's plan

**Astria Health**

“PCI Program Quality Assurance and Improvement Plan, pg. 93, #2: Patient Selection

- The utilization of the Society for Cardiac Angiography (SCAI) guidelines for patient, lesion and case selection to determine which patients are suitable candidates for elective PCI at Sunnyside.
  - All elective cases are reviewed by the Cath Lab Medical Director for compliance with SCAI guidelines.”

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**

The Quality Improvement Plan demonstrated compliance with this standard. This sub-criterion is met.

**Yakima Valley Memorial Hospital Association**

The Virginia Mason Memorial Hospital Elective and Emergent PCI Quality Assurance and Improvement Plan provided information related to the four standards under WAC 246-310-740. The entire document was restated under (1) above. Specific sections of the document that relate to WAC 246-310-7240(2) are restated below.

**PURPOSE**

The purpose of the plan is:
1. Provide for a process for ongoing review of the quality and outcomes for adult elective and emergent PCIs.
2. Provide a system of patient selection that will result in outcomes that are equal to or better than benchmark standards.
3. Provide for a process of formalized review of pre and post-operative patient care with partner surgical backup hospital(s) including all patients transferred for surgical intervention.
4. Provide a process for reporting elective PCI information to the Washington State Department of Health or entity designated by the Washington State Department of Health.
5. Document, assess and improve the emergency transport processes and timeframes.”

**POLICY/PROCEDURE**

Elective PCI case submission will be included in the WA State Clinical Outcomes Assessment Program (COAP). Outcomes will be benchmarked against the statewide outcome data and included in the case review meetings and presented quarterly to the Cardiac Quality Committee including recommendations on how to resolve any identified problems.

Specific benchmarks will be consistent with Level I and Level II indicators consistent with those of COAP-PCI.
Level I Indicators
- In-Hospital Mortality
- Median door to Balloon Time

Level II Indicators
- Appropriate use
- Bleeding events within 72 hours
- Post-Procedure CVA
- Vascular Complications
- Unplanned CABG

Cardiologists will use the Society for Cardiovascular Angiography and Interventions (SCAI) guidelines for patient, lesion and case selection to determine which patients are suitable candidates for elective PCI.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
The Elective and Emergency PCI Quality Assurance and Improvement Plan Scope of Services Virginia Mason Memorial demonstrated compliance with this standard. This sub-criterion is met.

WAC 246-310-740(3) A process for formalized case reviews with partnering surgical backup hospital(s) of preoperative and post-operative elective PCI cases, including all transferred cases

Astria Health
“PCI Program Quality Assurance and Improvement Plan, pg. 93, #3:
Formalized Case Review
- The establishment and implementation of case review meetings with our partnering open-heart surgery hospital to include both pre- and post-operative elective PCI cases, including all transferred cases. Case review meetings specifics are as follows:
  - Frequency: Quarterly
  - Participants: Sunnyside’s Elective PCI QA/QI Committee and partnering open heart surgery hospital’s counterparts
  - Case selection:
    - All transferred cases will be reviewed by the Cath Lab Medical Director with areas of process improvements identified and discussed in formal case review.
    - A random selection of Elective PCI cases will be reviewed by the Cath Lab Medical Director for patient selection, procedural performance and outcomes with a summary of findings presented and discussed in formal case review.
    - All major complications will be reviewed by the Cath lab Medical Director with areas of process improvements identified and discussed in formal case review. Findings of major complications will also be shared with Sunnyside’s Cardiology and Medical QI Committees.
  - Case Review Documentation:
    - All areas for improvement along with action steps, communication plan, goals, accountabilities and timelines will be documented in the minutes.
• The status of action items will be reviewed quarterly until results exceed established goals.
• Reporting: A summary of case review results, recommendations and resolutions will be reported to Sunnyside’s Cardiology and Medical QI Committees and to Sunnyside’s Medical Executive Committee.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
The Quality Improvement Plan demonstrated compliance with this standard. This sub-criterion is met.

Yakima Valley Memorial Hospital Association
The Virginia Mason Memorial Hospital Elective and Emergent PCI Quality Assurance and Improvement Plan provided information related to the four standards under WAC 246-310-740. The entire document was restated under (1) above. Specific sections of the document that relate to WAC 246-310-7240(3) are restated below.

“PURPOSE
The purpose of the plan is:
1. Provide for a process for ongoing review of the quality and outcomes for adult elective and emergent PCIs.
2. Provide a system of patient selection that will result in outcomes that are equal to or better than benchmark standards.
3. Provide for a process of formalized review of pre and post-operative patient care with partner surgical backup hospital(s) including all patients transferred for surgical intervention.
4. Provide a process for reporting elective PCI information to the Washington State Department of Health or entity designated by the Washington State Department of Health.
5. Document, assess and improve the emergency transport processes and timeframes.”

POLICY /PROCEDURE
Memorial will ensure the safe transportation of elective PCI patients experiencing emergency complications to Kadlec Medical Center, or other appropriate receiving hospital based upon patient stability including:
• Maintaining a signed transportation agreement with a vendor who will expeditiously transport patients who experience complications during elective PCIs.
• Ensuring that transport staff are advanced cardiac life support certified.
• Providing the equipment and staff with the skills and experience to monitor and treat the patient en route to include Intra-aortic balloon pump (IABP) and/or similar technology such as Impella®.
• Initiation of emergency transportation within twenty minutes of the initial identification of a complication.
• Ensuring that the time from the decision to transfer the patient with an elective PCI complication to arrival in the operating room at the partner surgical hospital will be less than one hundred twenty minutes.
• Documentation of transport time for all elective PCI patients needing emergency transport. These transport times will be presented to the Cardiac Quality Committee for further review.”

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**
The Elective and Emergency PCI Quality Assurance and Improvement Plan Scope of Services Virginia Mason Memorial demonstrated compliance with this standard. **This sub-criterion is met.**

WAC 246-310-740(4) A description of the hospital's cardiac catheterization laboratory and elective PCI quality assurance reporting processes for information requested by the department or the department's designee. The department of health does not intend to require duplicative reporting of information.

**Astria Health**
“PCI Program Quality Assurance and Improvement Plan, pg. 92, #1:
Ongoing Outcome Review & Reporting Information
  o The tracking, documentation and reporting out of PCI outcomes to the Washington State Clinical Outcomes Assessment Program (COAP). This information will be sent electronically on a quarterly basis.
  o The ongoing review of Sunnyside’s outcome data as compared to the statewide benchmarks. Sunnyside will utilize benchmarks established by the Clinical Outcomes Assessment Program (COAP).
  o The review of bi-annual emergency transport drill outcomes.
  o The development and implementation of any action plans that may be necessary to resolve any identified outcome issues or to improve performance. Action plans will have accountabilities and timelines well defined with progress reported at each committee meeting. Traditional Plan-Do-Check-Act quality improvement methods will be utilized to improve outcomes and processes.
  o The review and response of all requests made by the Department of Health of outcome information. Requests will be handled by the Cardiac Services/Cath Lab Manager with a response to Department of Health or its designee no later than 30 days of the request.”

Public Comments
None

Rebuttal Comments
None

**Department Evaluation**
The Quality Improvement Plan demonstrated compliance with this standard. **This sub-criterion is met.**
**Yakima Valley Memorial Hospital Association**  
The Virginia Mason Memorial Hospital Elective and Emergent PCI Quality Assurance and Improvement Plan provided information related to the four standards under WAC 246-310-740. The entire document was restated under (1) above. Specific sections of the document that relate to WAC 246-310-7240(4) are restated below.

**“PURPOSE”**
The purpose of the plan is:
1. Provide for a process for ongoing review of the quality and outcomes for adult elective and emergent PCIs.
2. Provide a system of patient selection that will result in outcomes that are equal to or better than benchmark standards.
3. Provide for a process of formalized review of pre and post-operative patient care with partner surgical backup hospital(s) including all patients transferred for surgical intervention.
4. Provide a process for reporting elective PCI information to the Washington State Department of Health or entity designated by the Washington State Department of Health.
5. Document, assess and improve the emergency transport processes and timeframes.”

**POLICY/PROCEDURE**
Virginia Mason Memorial Hospital has an established Cardiac Quality team (committee) that will oversee all QA/PI activities as they relate to the Elective PCI Program. This will include a process of formalized case review for all preoperative and post-operative elective PCI cases including those that involve patient transfers. Specifically, the committee:

- Meets quarterly
- Reports to Cardiac, Pulmonary and Critical Care (CPCC) committee where selected cases are reviewed in a peer protected environment.
- Is comprised of the following participants:
  - Cath Lab Manager/Supervisor (Chair)
  - Cath Lab Medical Director
  - Emergency Department Medical Director
  - Cardiovascular Service Line Senior Director
  - Critical Care Senior Director
  - Representatives from the partner surgical hospital(s)
  - Critical Care Manager
  - Performance Improvement representative
  - Pharmacy representatives
  - Local emergency services representatives
  - Plus designated staff as committee deems appropriate
- The Cardiac Quality Committee will be part of the hospital’s Performance Improvement Program and will abide by all relevant standards.
- Quality and Performance issues identified at Cardiac Quality will be addressed at that level unless further discussion is needed in a peer protected environment. In that case, these will be forwarded to the Cardiac, Pulmonary & Critical Care Quality Assurance/Performance Improvement Committee for review.
- Approved recommendations will be forwarded for inclusion in the hospital’s Performance Improvement Programs. Additional actions will adhere to Memorial's Quality, Peer Review and Medical Executive processes.
- The Cardiac Quality Committee and its work will be protected by Washington State Statute RCW 70.41.200.
REPORTING PROCESS
The Cardiac Quality Committee will report in writing all findings, data and performance improvement activities from all the QA/PI activities contained in this plan. The report will be forwarded to the Department of Health or the Department's designee as requested.”

Public Comments
None

Rebuttal Comments
None

Department Evaluation
The Elective and Emergency PCI Quality Assurance and Improvement Plan Scope of Services Virginia Mason Memorial demonstrated compliance with this standard. This sub-criterion is met.

(4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.
WAC 246-310 does not contain specific WAC 246-310-230(4) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how to measure unwarranted fragmentation of services or what types of relationships with a services area’s existing health care system should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

Astria Health
In response to this sub-criterion, Astria Health provided the following statements. [source; Application, p27]
“Sunnyside has established a partnership agreement with our sister hospital, Astria Regional, which provides a full range of interventional and cardiac surgical services. This agreement is included as Exhibit 6.”

Public Comments
The department received comments in support of this project that focus on this sub-criterion. The comments are restated below.

Martin Casey, Manager, City of Sunnyside
“Last year Astria Regional Medical Center had more than 40 referrals from Astria Sunnyside for elective cases. A number of patients failed to follow up and have a procedure. The ones that were sent via ambulance had excellent outcomes, but had been subject to delayed treatment, duplicate testing and procedures (including groin punctures and contrast material), and higher costs.

Sunnyside Fire Chief Ken Anderson has emphasized to me a number of benefits from bringing this PCI program to the lower Yakima Valley, including more efficient use of our EMT ambulance resources and significantly improved access to care. Given the proven efficacy of elective PCI, the proven quality of the Astria Sunnyside program, and the improvement to geographic access that will result, it should be given priority in the award of a certificate of need.”
Ken Anderson, Fire Chief, City of Sunnyside

“The City of Sunnyside owns and operates the Sunnyside Fire Department and its EMS division, which is the primary provider of ambulance services, including advanced life support, in the Sunnyside area. We have approximately 20 firefighters that are cross-trained as paramedics/EMS. We operate three ambulances each equipped with up-to-date 12-lead capable cardiac heart monitors that also measure blood pressure, oxygen saturation, and carbon dioxide outputs. We provide our service 24/7, 365 days per year.

Sunnyside EMS relies on Astria Sunnyside, our partner, to receive a range of patients with acute medical illness. When Astria Sunnyside is unable to provide an advanced service like elective coronary intervention, we are required to divert or transfer the patient (typically after exam in the ED and/or cauterization laboratory of Astria Sunnyside) to the next geographically available appropriate hospital, which is in Yakima or the Tri-Cities. Such diversion is not ideal for the patient as it delays treatment and typically places the patient further from home and family and potentially outside their local system of medical care.

Moreover, it places one-third of our ambulance capacity out of area for hours. For this reason, Sunnyside EMS cannot always guarantee to respond to a request to transfer the patient timely, or if we are out-of-area, it carries the risk of not being able to respond timely to the next local emergency. We are most at risk during fire season.

From an EMS perspective, additional travel away from the assigned paramedic service area can lead to subsequent delays and gaps in EMS and in the case of Sunnyside EMS, in fire response. From an operational and clinical perspective, the ideal system, and because it is staffed and equipped to do so, would be to have Astria Sunnyside able to provide full-spectrum interventional cardiology.

For the reasons outlined in this letter, Sunnyside EMS is in full support of the CN application of Astria Sunnyside to add an elective component to their current emergency PCI program. With elective PCI services available at Astria Sunnyside Hospital, our patients would receive care in conformance with American Heart Association guidelines and industry best practices to ultimately improve patient outcomes and save more lives. As such, I strongly urge the Department to approve ASH's elective PCI program.”

Rebuttal Comments
None

Department Evaluation
This evaluation considers the letters of support provided for projects. It also considers the need assessment and rules related to the establishment of a new adult, elective PCI program within a planning area. Astria Health also provided documentation to demonstrate compliance with the patient transfer standards within the PCI rules.

As stated in this evaluation, Astria Health could not substantiate its projected PCI volumes for Astria Sunnyside Hospital under WAC 246-310-210(1) resulting in a fail under the sub-criterion. Because the projected volumes could not be substantiated, Astria Health’s application also failed to meet the financial feasibility sub-criterion under WAC 246-310-220(1). Additional rationale for the projects failure to meet the sub-criterion in WAC 246-310-220(1) are outlined in that section of this evaluation. For those reasons, the department concludes that approval of the Astria Health project
may result in unwarranted fragmentation of PCI services in the planning area. **This sub-criterion is not met.**

**Yakima Valley Memorial Hospital Association**  
In response to this sub-criterion, YVMHA provided a copy of the draft Elective PCI Patient Transfer and Surgical Partnering Agreement Draft Virginia Mason Memorial and Kadlec Regional Medical Center. [source; April 29, 2019, screening response, Exhibit 10]

**Public Comments**  
None

**Rebuttal Comments**  
None

**Department Evaluation**  
This evaluation considers the letters of support provided for projects. It also considers the need assessment and rules related to the establishment of a new adult, elective PCI program within the planning area. YVMHA also provided documentation to demonstrate compliance with the patient transfer standards within the PCI rules.

For these reasons, the department concludes that approval of this project would not result in unwarranted fragmentation of PCI services in the planning area. **This sub-criterion is met.**

(5) **There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.**

**Department Evaluation for Astria Health**  
This sub-criterion is addressed in sub-section (3) above and **is met.**

**Department Evaluation for Yakima Valley Memorial Hospital Association**  
This sub-criterion is addressed in sub-section (3) above and **is met.**

**D. Cost Containment (WAC 246-310-240)**  
Based on the source information reviewed, the department determines that Astria Health does not meet the applicable need criteria in WAC 246-310-240.

Based on the source information reviewed, the department determines that Yakima Valley Memorial Hospital Association meets the applicable need criteria in WAC 246-310-240.

(1) **Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.**  
To determine if a proposed project is the best alternative, in terms of cost, efficiency, or effectiveness, the department takes a multi-step approach. First the department determines if the application has met the other criteria of WAC 246-310-210 thru 230. If the project has failed to meet one or more of these criteria then the project cannot be considered to be the best alternative in terms of cost, efficiency, or effectiveness as a result the application would fail this sub-criterion.

If the project has met the applicable criteria in WAC 246-310-210 through 230 criteria, the department then assesses the other options considered by the applicant. If the department determines
the proposed project is better or equal to other options considered by the applicant and the department has not identified any other better options, this criterion is determined to be met unless there are multiple applications.

If there are multiple applications, the department’s assessment is to apply any service or facility superiority or tiebreaker criteria contained in WAC 246-310-750.

**Astria Health**

Astria Health states that the following two options were considered: continue an emergency only program or submit a CN application requesting approval of an elective service to complement the emergency program. Astria Heath provided the following rationale for rejecting the option to continue an emergency program only. [source: Application, p32]

“There are numerous benefits to seeking CN approval: staff and providers will increase volumes, assuring competency and the additional volume will improve efficiency and cost. There is no impact on hospital space, and patients in the lower Yakima Valley that experience, daily, transportation challenges to Yakima or the Tri-Cities will have the burden lifted. The improvement in geographic access and distribution of services is both significant and real in our community. Because Sunnyside already has the staffing, including qualified cardiologists, no disadvantages were identified.”

Astria Health states that the elective PCI program will promote staff efficiency and productivity and provided the following information to support this assertion. [source: Application, p32]

“Being able to perform elective PCI will support our already highly trained and competent cath lab staff in performing more cases which will assure skills while also realizing productivity increases and operating efficiencies.

In addition, our emergency department and cath lab staff now spend time each month preparing patients that are not actively experiencing a cardiac event for transfer to Astria Regional or the Tri-Cities. The region’s EMS staff incur time away from their service bases when transporting patients an hour or longer away. This is not costly and can potentially affect outcomes.”

Astria Health states that the elective PCI program will promote system efficiency and provided the following information to support this assertion. [source: Application, p33]

“The current delivery system is inefficient. Transporting patients that have had a diagnostic catheterization for a PCI procedure dramatically increases costs (often an ambulance ride, two groin punctures, two procedures, etc.) and can affect patient outcomes. The efficiencies that will be realized will be significant for patients, for the hospitals and cardiologists, for payers and for the health of the community.”

**Public Comments**

None

**Rebuttal Comments**

None

**Department Evaluation for Astria Health**

For this project, Astria Health did not meet the applicable review criteria under WAC 246-310-210, 220, and 230. Therefore, the department concludes this sub-criterion is not met.
The department will not evaluate the Astria Health project under the remaining cost containment sub-criterion below.

**Yakima Valley Memorial Hospital Association**

YVMHA provides the following statements under this sub-criterion. [source: Application, pp40-41]

“There are no other options considered. Virginia Mason Memorial has advocated and worked diligently for more than a decade to ensure that we deliver quality cardiovascular services consistent with other emergent and elective PCI programs in Washington. During the past 2 years, Memorial has worked cooperatively with the Department's staff to revise and update the PCI volume standards to reflect best practice evidence as provided by the SCAI/ACC/AHA Consensus document 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Back-up (JACC vol. 63, No 23, 2014).

Based upon the application of the elective PCI needs forecast methodology and the inclusion of numerous PCI data sets, it is clear that there is an unmet need for elective PCI in Planning Area #4. Given Virginia Mason Memorial's strong community preference, demonstrated quality outcomes, and the ability to provide this service at no additional incremental costs, we enthusiastically submit this Certificate of Need application for Adult Elective Percutaneous Coronary Interventional Services.

**Advantages**

In 2018, Virginia Mason Memorial operated the second busiest emergency department in Washington State, and performed 225 emergent PCI procedures. This is an increase in emergent PCIs of almost 16% from the previous year. This growth is due to quality outcomes for our patients and a dedicated team of staff and physicians who consistently demonstrate a high level of commitment and service to our community.

The Yakima community deserves choice for where they have an elective PCI. In fact, the data indicates that over 85 PCI procedures are performed outside of Planning Area #4, in large part due to the lack of choice.

**Disadvantages**

We believe there are no disadvantages to approving Virginia Mason Memorial's CN application.

**Impact on operating costs of the hospital**

As evidenced in the content of the application, we do not anticipate any additional capital or incremental operating costs associated with the approval of this application.

**Impact on staffing**

The existing hospital staff and interventional cardiologists will provide elective PCI services. Adding an elective PCI program will enhance the skills, teamwork, and efficiency of our existing cardiac team. There are no additional staffing requirements associated from any incremental increase in volume.

**Impact on costs to the patient**

Approving this application has many cost benefits to the patient:

- Repeat or out of network cases associated with elective PCI services occur when Virginia Mason Memorial is unable to perform a necessary and appropriate elective PCI during or after a
diagnostic heart catheterization. The patient must have a repeat procedure performed elsewhere. This raises the cost to patients and may potentially put them at risk for additional adverse events.

- As demonstrated in the first two quarters of 2018 CHARS data. Virginia Mason Memorial is the third lowest cost provider in Washington. (See Exhibit 17) Key hospital charge data points are:
  - Average WA hospital charge for interventional cardiac per case, which includes PCI is $85,104.
  - Virginia Mason Memorial average interventional cardiac case charge is $62,376, which is $22,728 less than the Washington State average (73% of state average). More importantly, many of these cases are for emergent PCI, which are exclusively inpatient cases with longer lengths of stay and associated costs. Even considering these factors, the costs to the patient at Memorial is considerably less than the state average.
  - Astria Regional Medical Center average charge is $124,852 per case, the highest of any acute care hospital in Washington State, and 200% ($62,476) higher than Virginia Mason Memorial and 147% higher than the Washington State average.
  - Astria Sunnyside’s average charge is $81,239, which is 130% ($18,863) higher than that of Virginia Mason Memorial.

**Impact on Physical Hospital Space**
No additional hospital expansion required for elective PCI.

**Reason for rejecting each option**
The alternative of not granting Memorial an elective PCI certificate of need is not a true option as it will continue to lead to continued outmigration and will not service the Planning Area #4 patient population.”

YVMHA states that the elective PCI program will promote staff efficiency and productivity and provided the following information to support this assertion. [source: Application, p41]

“As stated previously, the additional case volume increases in the cath lab will not require additional staff. Performing the additional cases with the same staff will require a focus on increasing efficiency (continuous improvement in turnaround times) and effective staffing and productivity, without compromising the quality and safety for patients.”

YVMHA states that the elective PCI program will promote system efficiency and provided the following information to support this assertion. [source: Application, p41]

“An elective PCI program will reduce unnecessary duplication of services, unnecessary transfers to other facilities, continuity of care for patients, and integration of clinical care and medical records. Further, the cardiologists who perform all cardiology services for Virginia Mason Memorial will be the same cardiologists who will perform elective PCI services. Thus, there will be no need to bring in different providers or staff to care for patients needing these services. Cardiologists will be able to make comprehensive decisions and provide the necessary care for patients in the same setting with the same staff, equipment and resources. Further, the medical records pertaining to the elective PCI program will be integrated into the hospital EHR directly and will not have to be transferred from a different facility, enabling system efficiencies and better patient care. “

**Public Comments**
None

**Rebuttal Comments**
None
Department Evaluation for Yakima Valley Memorial Hospital Association

The department did not identify any alternative that was superior in terms of cost, efficiency, or effectiveness that is available or practicable. Taking into account the results of the numeric need methodology, YVMHA provided information within the application and supplemental documents that its project is reasonable and the best available option for the planning area and surrounding communities. **This sub-criterion is met.**

(2) *In the case of a project involving construction:*

(a) **The costs, scope, and methods of construction and energy conservation are reasonable;**

(b) **The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.**

Department Evaluation for Yakima Valley Memorial Hospital Association

There are no costs associated with this project. This sub-criterion is not applicable to this project.

(3) **The project will involve appropriate improvements or innovations in the financing and delivery of health services which foster cost containment and which promote quality assurance and cost effectiveness.**

Department Evaluation for Yakima Valley Memorial Hospital Association

This sub-criterion is evaluated in conjunction with WAC 246-310-240(1) above and is considered met.
## Updated 2018-2019 Percutaneous Coronary Intervention Numeric Need Methodology

### Using COAP data

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<th>Planning Area</th>
<th>County</th>
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<th>2017 PCI Pop./1000 (1a)</th>
<th>2017 PCIs (COAP ONLY)</th>
<th>WA pts in Oregon</th>
<th>Total PSA PCIs</th>
<th>2017 Use Rate (1b)</th>
<th>2022 15+ Pop</th>
<th>2022 PCI Pop./1000 (1a)</th>
<th>2022 Use Rate</th>
<th>2022 Projected Demand (2a)</th>
<th>Current PCI Capacity (3d)</th>
<th>2022 Projected Net Need (4)</th>
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Source: County Age Pop. Projections OFM August 2017
Sub County Pop Claritas 2017-2022
COAP data for 2017
PCI Inpatient Oregon Data for 2017
## Department of Health

**Updated 2018-2019 Percutaneous Coronary Intervention Numeric Need Methodology**

**Using COAP data**

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Source: County/Age Pop. Projections OFM August 2017
Sub county Pop Claritas 2017-2023
COAP data for 2017
PCI Inpatient Oregon Data for 2017
# Department of Health

## Updated 2018-2019 Percutaneous Coronary Intervention Numeric Need Methodology

Using CHARS and DOH survey data

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<th>2017 PCI Pop./1000 (1a)</th>
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<th>2017 Outpatient PCIs SURVEY</th>
<th>WA pts in Oregon</th>
<th>Total PSA PCIs</th>
<th>2017 Use Rate (1b)</th>
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<th>2022 PCI Pop./1000 (1a)</th>
<th>2022 Use Rate</th>
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<th>Current PCI Capacity (3a)</th>
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Source: County_Age.Pop. Projections OPM August 2017
Sub county Pop. Claritas 2017-2022
PCI Outpatient 2017 Data Survey
Washington + Oregon Inpatient Data for 2017
### Department of Health

**Updated 2018-2019 Percutaneous Coronary Intervention Numeric Need Methodology**

*Using CHARS and DOH survey data*

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Source: County_Age Pop. Projections OFM August 2017
Sub county Pop Clusters 2017-2022
PCI Outpatient 2017 Data Survey
Washington + Oregon Inpatient Data for 2017