STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

February 6, 2020

CERTIFIED MAIL # 7019 1640 0000 8194 1106

John Solheim, CEO
RCCH Trios Health, LLC dba Trios Health
3810 Plaza Way
Kennewick, WA 99338

RE: CN Application #19-64

We have completed review of the Certificate of Need application submitted by Trios Health proposing to establish an elective percutaneous coronary intervention (PCI) program. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the department has concluded that the project is not consistent with the Certificate of Need review criteria identified below, and a Certificate of Need is denied.

Washington Administrative Code 246-310-210	Need
Washington Administrative Code 246-310-220	Financial Feasibility
Washington Administrative Code 246-310-230	Structure and Process of Care
Washington Administrative Code 246-310-240	Cost Containment

This decision may be appealed. The two appeal options are listed below.

Appeal Option 1:
You or any person with standing may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington Administrative Code 246-310-560. A reconsideration request must be received within 28 calendar days from the date of the decision 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

Appeal Option 2:
You or any person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610. A request for an adjudicative proceeding must be received within the 28 days at one of the following addresses:

Mailing Address:	Physical Address
Department of Health	Department of Health
Adjudicative Service Unit	Adjudicative Service Unit
Mail Stop 47879	111 Israel Road SE
Olympia, WA 98504-7879	Tumwater, WA 98501

If you have any questions, please contact the Certificate of Need Program at (360) 236-2955.

Sincerely,

Nancy Tyson, Executive Director
Health Facilities and Certificate of Need

Enclosure

EVALUATION DATED FEBRUARY 6, 2020 FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY RCCH TRIOS HEALTH, LLC PROPOSING TO ESTABLISH A PERCUTANEOUS CORONARY INTERVENTION PROGRAM AT TRIOS HELTH, WITHIN BENTON COUNTY.

APPLICANT DESCRIPTION

The applicant for this project is RCCH Trios Health LLC. RCCH Trios Health, LLC is owned 100% by RCCH - UW Medicine Healthcare Holdings, LLC. RCCH - UW Medicine Healthcare Holdings, LLC is owned 96% by RCCH Northwest, LLC and 4% by the University of Washington, through its unincorporated division. RCCH Northwest LLC is 100% owned by RCCH Healthcare Partners, which has since merged with LifePoint Health and now does business as such. For this project, though RCCH Trios Health is the applicant, the parent is LifePoint Health. For reader ease, the applicant will be referred to as "Trios Health" or simply "Trios," whereas the parent will referred to as LifePoint Health. [source: Application, pdf5]

LifePoint Health, through its subsidiaries, owns or leases and operates general acute care hospitals and other related health care organizations in the United States. This includes four hospitals in Washington State, including Trios Health, Lourdes Medical Center, Lourdes Counseling Center, and Capital Medical Center. [source: LifePoint Health website, CN historical files]

PROJECT DESCRIPTION

This project focuses on Trios Health, located in Kennewick. The hospital has been in operation since 1952 and provides a variety of healthcare services to the residents of Benton and Franklin Counties and the surrounding communities. As of the writing of this evaluation, Trios Health is licensed for a total of 111 beds. The hospital includes two inpatient campuses, which are identified below. [source: Application, pdf11, CN historical files]

Hospital Campus Name	Location	# of Licensed Beds
Trios Southridge Hospital	3810 Plaza Way, Kennewick/99338	74
Trios Women's & Children's Hospital	900 South Auburn Street, Kennewick/99336	37

As of the writing of this evaluation, Trios Health provides a variety of general medical surgical services, including intensive care, emergency services, and a Level II intermediate care nursery. The hospital is currently a Medicare and Medicaid certified hospital. [sources: ILRS, and CN historical files]

Trios Health submitted this application proposing to establish an adult, elective percutaneous coronary intervention (PCI) program within existing space at the Southridge campus. The project would increase the types of services provided at Trios Health, but does not propose to increase the total number of acute care beds. [source: Application, pdf11]

There is no estimated capital expenditure, as Trios Health already operates cardiac catheterization labs for emergent PCIs.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This application is subject to review as the addition of a tertiary service under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(f) and Washington Administrative Code (WAC) 246-310-020(1)(d)(i)(G).

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, the 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, the 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 this project 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.

Trios Health is located in planning area #2 as defined in WAC 246-310-705(5). The planning area includes the following counties: Benton, Columbia, Franklin, Garfield, and Walla Walla. In the context of a PCI review, the planning area is frequently referred to as the "PSA."

During the year 2019 PCI concurrent review, no other application was submitted proposing to establish a PCI program in this planning area. As a result, the department reviewed this project under a regular review schedule as allowed under WAC 246-310-710(3). The review timeline is summarized on the following page.

APPLICATION CHRONOLOGY

Action	Trios Health
Letter of Intent Submitted	January 30, 2019
Application Submitted	February 28, 2019
Department's pre-review activities • DOH 1st Screening Letter • Applicant's Responses Received • DOH 2nd Screening Letter • Applicant's Responses Received	 March 29, 2019 June 21, 2019 July 18, 2019 October 18, 2019
Beginning of Review	November 1, 2019
End of Public Comment/No Public Hearing Conducted • Public comments accepted through end of public comment	December 9, 2019
Rebuttal Comments Received	December 23, 2019
Department's Anticipated Decision Date	February 6, 2020
Department's Actual Decision Date with 30-day Extension[1]	February 6, 2020

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.

[1] 30-day extension letter sent on September 25, 2019.

During the review of this project, two entities qualified for affected person status – Providence St Mary Medical Center and Kadlec Regional Medical Center. Both providers are located in PSA #2. Kadlec Regional Medical Center is currently a PCI provider. Like Trios Health, Providence St Mary Medical Center currently provides PCI on an emergent basis only. Both submitted comments and requested to be informed of the department's decision.

SOURCE INFORMATION REVIEWED

- Trios Health's Certificate of Need application received February 28, 2019
- Trios Health's screening responses
- Public comments received by the close of business on December 9, 2019
- Rebuttal comments received by close of business on December 23, 2019
- Hospital/Finance and Charity Care (HFCC) Financial Review
- Department of Health Integrated Licensing and Regulatory System database [ILRS]
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Office of Customer Service
- Trios Health website at trioshealth.org
- Washington Courts website at www.courts.wa.gov
- Certificate of Need historical files

CONCLUSIONS

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

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that Trios Health **did not meet** 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.[2] Trios Health is located in Kennewick, within Benton County, identified as PCI planning area #2. The need methodology calculates the need for each planning area. The need methodology discussion in this evaluation is limited to Planning Area #2.

Trios Health

Trios Health applied the five-step numeric need methodology for the PCI planning area #2, but did not provide their entire methodology. Trios provided the following information:

As published by the CN Program in February 2018, WAC 246-310-745's numeric methodology estimates need for 182 additional PCIs in the Planning Area in 2022 (the projection year). Trios is well aware that the Program's current methodology is short of the 200-case requirement. However, Trios Health has identified a number of areas in which the methodology is missing data. Specifically:

1) *There is no count of cases, and no attempt (to date) to secure data on Planning Area 2 residents that underwent PCI in the border states of Idaho and Oregon. In the Oregon inpatient database, we identified at least 5 cases, and in addition, our sister hospital, St. Joseph in Lewiston, has, to date, identified 8 cases that it performed in 2017 on Planning Area 2 residents.*

2) *Walla Walla General Hospital closed on July 24, 2017. It reported no outpatient data for 2016 or 2017, no inpatient PCI cases beyond Q1 2017 in CHARS and no data to COAP in 2016 or 2017. However, we have confirmed that it continued performing PCI well into 2017.*

[2] WAC 246-310-705.

While we are still confirming, we anticipate that at least 20 cases were underreported in 2017.

Based on the above, Trios Health is confident that the real unmet need in 2022 is in excess of 200. We will work with the Program to secure provide verifiable data. [source: Application pdf15]

WAC 246-310-720 provides the following guidance for approval of a new program, which includes minimum volume standards for hospitals with an elective PCI program as well as the requirement that numeric need be demonstrated. It states:

"(1) Hospitals with an elective PCI program must perform a minimum of three hundred adult PCIs per year by the end of the third year of operation and each year thereafter.
(2) The department shall only grant a certificate of need to new programs within the identified planning area if:
(a) The state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area; and
(b) All existing PCI programs in that planning area are meeting or exceeding the minimum volume standard."

The department's published numeric need methodology did not show need for an additional PCI program in PSA #2. For this reason, during the review of this project, the department asked questions about Trios Health' approach to the numeric methodology. Below is a restatement of the exchange between the department and Trios Health. [source: Certificate of Need Screening 1, Screening 1 Response pdf2-5]

Certificate of Need Program Question
[WAC 246-310-720(2) restated]
Note the "state need forecasting methodology" referenced in rule was published on the Department of Health website in February 2019. This is the methodology that will be used in the 2019 concurrent review cycle.

Though all approved programs in the planning area meet the minimum volume standard, there is no numeric need in the planning area. The rule does not include any provisions for an exception to this standard. Please confirm your understanding of this section of rule. Contact me if you would like to discuss your options.

Trios Health Screening Response
The Department of Health (Department) has determined that the existing Planning Area providers of PCI meet the requirement of (b). In terms of sub-criterion (a), and with due respect, the methodology posted to the Department's website in February of 2019 is incomplete and inaccurate. The posted information is missing inpatient data on Planning Area residents that receive care in neighboring states. Historically, the Department has sought and used both inpatient and outpatient data from contiguous states. To assist the Department and to assure the record is complete, Trios is providing:

1) The Oregon Association of Hospitals and Health Systems' raw data for PCI Planning Area #2 residents who had an inpatient PCI in an Oregon hospital in 2017 (MSDRGs 246-251) is included as Attachment 4.

2) Attachment 5 includes a letter from LifePoint Health documenting the outpatient cases for Walla Walla General Hospital from January 1, 2017 through its July 2017 closing. We are providing this data because Walla Walla General Hospital failed to submit an outpatient survey for the seven months it was operational in 2017. This data is provided from the Trilliant database, which is accurate at the 95% confidence level. In addition to the Walla Walla General Hospital data, this letter also provides outpatient and inpatient data for Oregon hospitals serving PCI Planning Area #2 residents.

3) Attachment 6 includes inpatient and outpatient PCI data using the Department of Health's form for St. Joseph Medical Center in Lewiston, Idaho. The data provided by St. Joseph Medical Center details inpatient and outpatient PCI volumes for PCI Planning Area #2 residents that occurred at the hospital in 2017.

The Department's current unwillingness to collect available and publicly reportable data on residents of PCI Planning Area #2 that reside in Washington but travel to Idaho and/or Oregon for care is unreasonable, arbitrary and capricious. It is also inconsistent with WAC 246-310-745 and the Department's past practice and precedent.

During the course of the review, the department was able to secure access to the Oregon Inpatient Database, and updated the methodology to include these publically accessible volumes.

Public Comments

During the review of this project, the department received one letter with additional documentation from Trios Health and several letters of opposition from representatives of Providence St Mary Medical Center and Kadlec Regional Medical Center. The majority of the information in these letters of opposition focus on this sub-criterion. Below are applicable excerpts of the letters:

Rob Watilo, Chief Strategy Office – Kadlec Regional Medical Center and Providence St Mary Medical Center

1. There is no need for Trios' proposed new elective PCI program under the PCI need forecasting methodology.

In order for its application to be approved, Trios must demonstrate that its proposal satisfies need subcriterion 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." With respect to new adult elective PCI programs, satisfaction of this requirement is determined solely by application of the PCI need forecasting methodology, which is set forth in WAC 246-310-745(10). As discussed below, the Department's need calculation for PCI Planning Area 2 shows that there is no need for Trios' proposed program.

a. The need for Trios' proposed PCI program is determined by applying the PCI need forecasting methodology.

Under the PCI need forecasting methodology, a new PCI program cannot be approved unless the projected need for adult elective PCI procedures in a PCI Planning Area meets or exceeds the 200-procedure minimum volume standard established by the Department. The regulation states: "If the net need for procedures is less than two hundred, the Department will not approve a new program."

It is important to note that the methodology does not provide for any exceptions to the need calculation made under the methodology. As noted above, the regulation unequivocally states that "the Department will not approve a new program" if the net need for PCI procedures is less than

200. This also is made clear in other PCI CN regulations: "The Department shall only grant a certificate of need to new programs within the identified planning area if: (a) The state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area." Accordingly, the need calculation alone determines whether a PCI CN application satisfies need subcriterion 1. ***There are no exceptions to this requirement.*** [emphasis in original]

The Department annually calculates the need in each PCI Planning Area in advance of the coming year's PCI concurrent review cycle. Thus, in January of 2019, the Department issued the "2018-2019 Percutaneous Coronary Intervention Numeric Need Methodology." However, the January need calculation was superseded by the "Corrected 2018-2019 Percutaneous Coronary Intervention Numeric Need Methodology" ("Corrected Need Methodology"), which was issued by the Department in February of 2019. In its application, Trios relied upon the Corrected Need Methodology. In its first set of screening questions on Trios' application, the Department confirmed that the Corrected Need Methodology would be used in its evaluation of the application: "Note the 'state need forecasting methodology' referenced in rule was published on the Department website in February 2019. This is the methodology that will be used in the 2019 concurrent review cycle."

<u>b. The PCI need forecasting methodology establishes that there is no need for Trios' proposed new adult elective PCI program.</u>
The February 2019 Corrected Need Methodology establishes that there is no need for a new adult elective PCI program in Planning Area 2. The need calculation shows a "2022 Projected Net Need" of only 182 adult PCI procedures in the Planning Area, which is less than the 200-procedure minimum volume standard." The "Projected Need I 200" is only 0.91. Therefore, there is no need for Trios' proposed new PCI program under the PCI need forecasting methodology.

As noted above, Kadlec objects to the Department "updating" the 2018-2019 PCI need calculation by adding Oregon data during the pendency of the 2019 PCI CN application review cycle. Thus, we respectfully request the Department not to use the October 3, 2019 Updated Need Methodology in determining whether there is a need for Trios' proposed new PCI program. However, even if the Department elects to use the Updated Need Methodology, there is still no need for Trios' proposed program. The "updated" need calculation shows a "2022 Projected Net Need" of only 188 adult PCI procedures in Planning Area 2, which is less than the 200-procedure minimum volume standard. The "Projected Need/ 200" is only 0.94.

Therefore, under both the Corrected Need Methodology and the Updated Need Methodology, the PCI need forecasting methodology establishes that there is no need for a new adult elective PCI program in PCI Planning Area 2. The need methodology alone determines whether there is a need for a proposed PCI program. Because there is no need for Trios' proposed program under the methodology, Trios' CN application cannot satisfy need subcriterion 1. Accordingly, the application must be denied.

<u>2. Trios cannot circumvent the result of the PCI need forecasting methodology by offering supplemental data in an attempt to alter the need calculation in its favor.</u>
In its application, Trios acknowledges that there is no need for its proposed program under the PCI need forecasting methodology: "Trios is well aware that the Program's current methodology is short of the 200-case requirement." Faced with this inescapable conclusion, Trios makes the claim that it "has identified a number of areas in which the methodology is missing data." However, the supplemental data offered by Trios cannot be considered by the Department because it has not been

obtained from the three permissible data sources identified in the PCI need forecasting methodology regulation.

a. The PCI need calculation is based upon three specified data sources.
Trios argues that (1) data relating to PCI Planning Area 2 residents who obtained PCI procedures in Oregon or Idaho hospitals and (2) data relating to PCI procedures performed at the now-closed Walla Walla General Hospital should be used by the Department to supplement the data contained in the Department's 2018-2019 PCI need calculation. Trios hopes that this supplemental data will increase the unmet need for PCI procedures above the 200-procedure minimum volume requirement. However, the data proffered by Trios cannot be used to alter the Department's need calculation because it does not fall within the three data sources identified in the PCI need forecasting methodology regulation.

The regulation states:

> *The data sources for adult elective PCI case volumes include:*
> *(a) The comprehensive hospital abstract reporting system (CHARS) data from the Department, office of hospital and patient data;*
> *(b) The Department's office of certificate of need survey data as compiled, by planning area, from hospital providers of PCIs to state residents (including patient origin information, i.e., patients' zip codes and a delineation of whether the PCI was performed on an inpatient or outpatient basis); and*
> *(c) Clinical Outcomes Assessment Program (COAP) data from the Foundation for Health Care Quality, as provided by the Department.*

Thus, the regulation does not permit an applicant to supplement the three data sources with its own information: data from the enumerated sources is the only data that may be used by the Department to apply the need forecasting methodology.

b. The supplemental data offered by Trios cannot be used to recalculate PCI need.
Trios is asking the Department to use data beyond the three authorized sources in order to change the outcome of the Department's PCI need calculation. As noted above, in its application, Trios makes assertions regarding "missing" data relating to (1) Planning Area 2 residents obtaining PCI procedures in Oregon or Idaho hospitals and (2) PCI procedures performed at Walla Walla General Hospital. But, in the application, Trios fails to provide documentation supporting the data. Instead, it states: "We will work with the Program to secure provide [sic] verifiable data." Trios provided additional information regarding supplemental data in its responses to the Department's screening questions. However, Trios has not provided "verifiable data" from any of the three permitted data sources.

In its June 21, 2019, responses to the Department's first set of application screening questions, Trios attempted to provide source support for its supplemental data. First, Trios offered purported "raw data" relating to Planning Area 2 residents who "had an inpatient PCI in an Oregon hospital in 2017."28 The data was not obtained from any of the three authorized data sources. 29 Second, Trios offered data purporting to show the number of PCI procedures performed at Walla Walla General Hospital in 2017. Again, the data was not obtained from a permitted data source.

Finally, Trios provided a "2018 Annual Outpatient Percutaneous Coronary Intervention (PCI) Survey" form filled out by a representative of St. Joseph Regional Medical Center ("St. Joseph")

(Lewiston, Idaho), Trios' "sister hospital." The form purports to show the number of inpatient and outpatient PCI procedures performed on patients residing in Zip Code 99347 (Garfield County) in 2017. Importantly, however, the form appears to differ from the Department's standard PCI survey form. The purpose of the Department's survey form is to report only outpatient PCI procedures performed at hospitals. Therefore, the third page of the standard form contains two tables with two columns. The titles for the columns are the same in both tables: "Patient Zip Code" and "Number of Outpatient PCIs." In contrast, the St. Joseph survey form provided by Trios differs from the standard form: in the table on the right, the word "Outpatient" has been replaced by the word "Inpatient," even though the form is titled "2018 Annual Outpatient Percutaneous Coronary Intervention (PCI) Survey." This raises questions as to ·whether the form has been altered, and, if so, by whom.

Accordingly, none of the supplemental data submitted by Trios to the Department falls within the three permitted data sources identified in WAC 246-310-745(7). The data relating to procedures performed on PCI Planning Area 2 residents (1) in Oregon or (2) at Walla Walla General Hospital is not CHARS data, PCI survey data, or COAP data. The data relating to PCI procedures performed on PCI Planning Area 2 residents at St. Joseph in Idaho is neither CHARS data nor COAP data. Trios has attempted to portray the data as PCI survey data. However, as discussed above, there are significant questions as to the reliability of the survey form, both as to its form and content. Thus, it cannot be concluded that the St. Joseph information is, in fact, PCI survey data.

Therefore, the data offered by Trios cannot, under the regulation, be used by the Department to recalculate need in PCI Planning Area 2. The Department's 2018-2019 PCI need calculation governs the Department's determination of whether there is a need for Trios' proposed new program. That calculation indisputably establishes that there is no need for Trios' program.

3. It appears Trios overcounted its 2017 PCI volumes. Correcting the overcounting significantly reduces the projected 2022 PCI procedure need in PCI Planning Area 2. This further confirms that there is no need for Trios' proposed new PCI program.

As discussed in detail below, it appears that Trios overcounted its 2017 PCI procedure volumes. The error appears to be attributable to an overcounting of 2017 outpatient PCI procedures, as reported in Trios' 2018 PCI Survey form. This procedure volume error is, in turn, reflected in the Department's 2018-2019 PCI need calculation. Correction of the error significantly reduces the projected 2022 PCI procedure need in PCI Planning Area 2. This further confirms that there is no need in the Planning Area for Trios' proposed new program.

In a screening question submitted to Trios, the Department noted that the 2017 PCI procedure volumes reported in Trios' CN application "were a significant departure from historical trends." We agree with this assessment and believe the 2017 PCI procedure volumes provided by Trios are likely inaccurate. Analysis of the information provided by Trios suggests it is likely that Trios incorrectly reported both 2017 inpatient and outpatient PCI procedures in its 2018 PCI Survey form, which was supposed to contain only outpatient procedure data.

The inaccurate reporting results in overestimates of (1) PCI procedure need in PCI Planning Area 2 and (2) projected future PCI procedure volumes for Trios' proposed program.

As the first step in evaluating the accuracy of Trios' reported 2017 PCI procedure volumes, Table 1 and Figure 1 show Trios' reported PCI procedures by care setting (inpatient and outpatient) between 2015 and 2018.

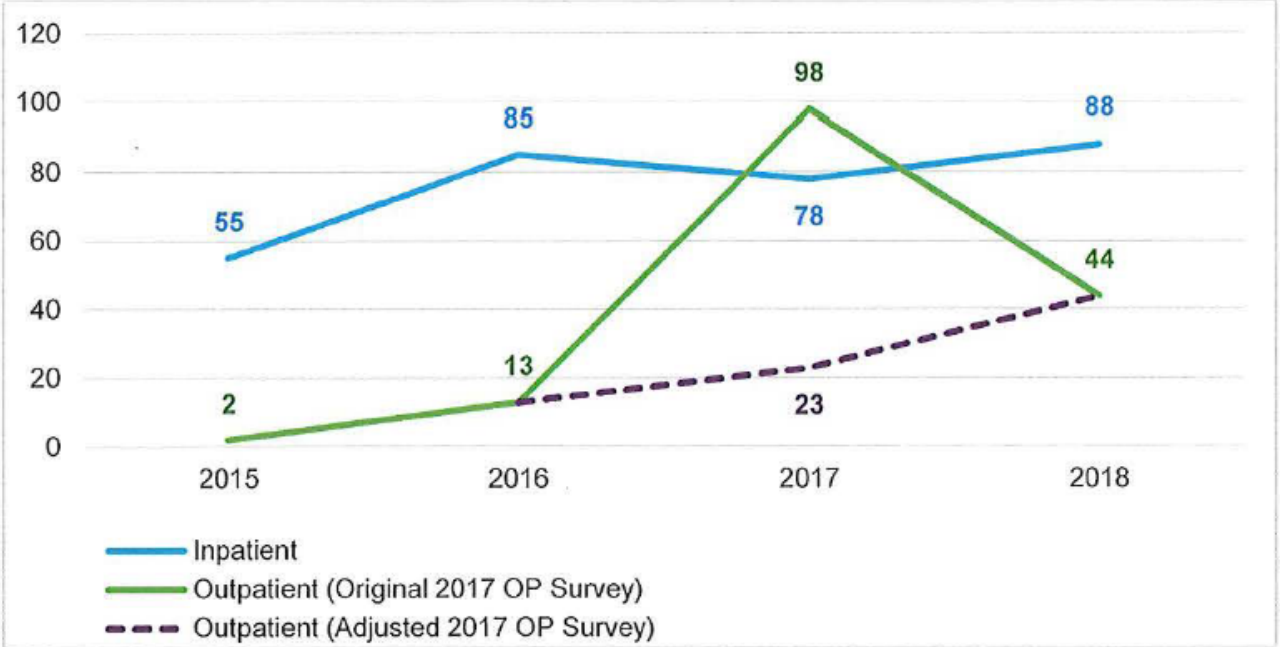
Public Comment Table

Table 1: Trios Health PCI Volumes by Care Setting, 2015 to 2018

	Inpatient (1)	Outpatient (2)	Total (3)
2015	55	2	57
2016	85	13	98
2017	78	98	176
2018	88	44	132
Source:	CHARS 2015 to 2018	Column (3) - Column (1)	CN 19-64, Table 3 & First Screening Responses, Table 3

Public Comment Figure

Figure 1: Trios Health PCI Volumes By Care Setting, 2015 to 2018



Sources: CHARS inpatient counts derived from 2015-2018 CHARS inpatient data. Outpatient cases are inferred from the total PCI counts provided in Trios' CN application (CN 19-64) and First Screening Responses. See Attachment 3 and discussion below for adjusted outpatient survey estimates.

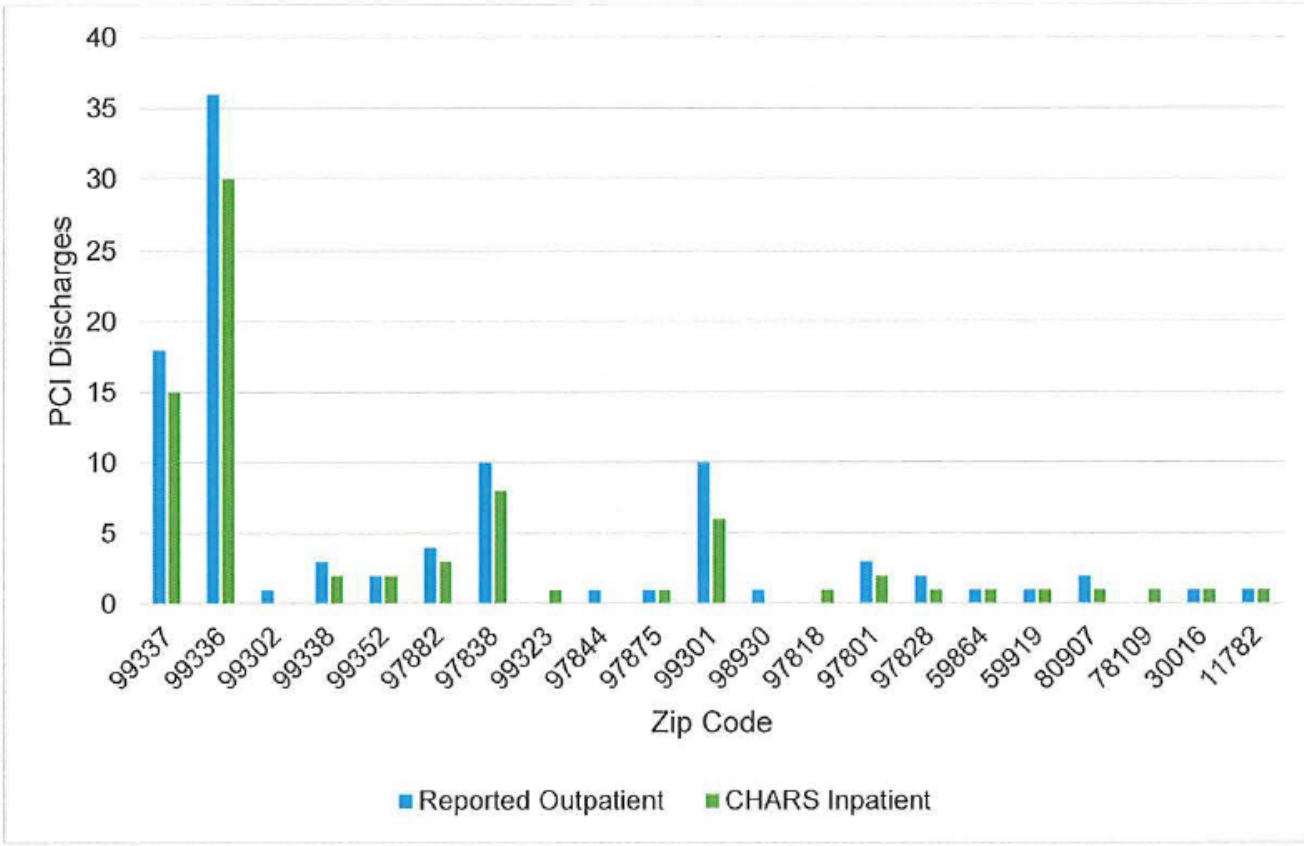
The inpatient PCI procedure data was obtained from CHARS inpatient discharge data, and the outpatient PCI procedure data was obtained from information provided by Trios in its application and First Screening Responses. Immediately evident is the nearly two-fold increase in PCI procedures at Trios between 2016 and 2017. This large increase is not consistent with the change between 2015 and 2016, nor is it consistent with the number of PCI procedures reported in 2018, which is 25% less than the procedure volume in 2017. Furthermore, the number of inpatient PCI procedures at Trios has remained relatively constant (an annual average of approximately 83 procedures in the period from 2016 through 2018). In sharp contrast, the number of outpatient PCI

procedures performed at Trios ostensibly increased over 650% between 2016 and 2017, then fell by approximately 55% between 2017 and 2018.

The reported increase in outpatient PCI procedures performed at Trios between 2016 and 2017 is not realistic, and it appears to be caused by a conflation of 2017 inpatient and outpatient PCI procedures in Trios' 2018 PCI Survey form. This conclusion is confirmed through a comparison of 2017 outpatient PCI procedures by patient zip code (as reported by Trios in its 2018 PCI Survey form) with Trios' 2017 CHARS inpatient data. This comparison is set forth in Figure 2 below.

Public Comment Figure

Figure 2: Trios 2017 Outpatient Survey Reported PCI Volumes Versus 2017 CHARS Inpatient Volumes



Sources: CHARS Inpatient counts derived from 2017 CHARS inpatient data. Reported Outpatient counts taken from Trios Health 2018 Annual PCI Survey.

Figure 2 shows that there is a close correspondence between the ostensible number of outpatient PCI procedures reported by Trios in its 2018 PCI Survey form and the number of inpatient PCI procedures reported in CHARS data. With the exception of three Zip Codes, Trios reported a greater number of outpatient procedures than inpatient procedures, and, overall, reported outpatient volume as greater than inpatient volume by 20 cases in 2017. This is despite the fact that Trios currently does not have an elective PCI program and treats all PCI patients as "inpatients."

Further evidence raising questions about the accuracy of Trios' reporting of 2017 outpatient PCI procedures is the reported provision of inpatient and outpatient PCI procedures to out-of state

residents. CHARS data for 2017 indicates that inpatient PCI procedures were provided to two individuals from Montana (Zip Codes 59864 and 59919), one individual from Colorado (Zip Code 80907), one individual from Texas (Zip Code 78109), one individual from Georgia (Zip Code 30016), and one individual from New York (Zip Code 11782). Accepting the accuracy of Trios' reported data requires the conclusion that the same number of outpatient procedures were also provided to individuals originating from identical Zip Codes in Montana, Georgia, and New York, and that two outpatient PCI procedures were provided to persons originating from identical Zip Codes in Colorado, as reported in Trios' 2018 PCI Survey form. This pattern of utilization is extremely unlikely.

A Zip Code comparison between Trios' 2017 inpatient PCI procedures as reported in CHARS and its ostensible 2017 outpatient procedures as reported in Trios' 2018 PCI Survey form appears in Attachment 3 hereto. The table in Attachment 3 shows the Zip Code correspondences discussed above and demonstrates the likelihood of double-counting by Trios with respect to its 2017 PCI procedure volumes. In addition, Attachment 3 contains calculations showing the appropriate adjustments to the 2017 data in Trios' 2018 PCI Survey form in order to correct for the apparent double-counting.

Overall, it is estimated that Trios likely performed only 23 outpatient PCI procedures in 2017, not 98. Thus, it is estimated that Trios' 2018 PCI Survey form likely double-counted 75 outpatient PCI procedures for 2017. Of those procedures, it is estimated that 55 of the 75 double-counted procedures related to residents of Zip Codes in PCI Planning Area 2. Accordingly, the 2022 Projected Net Need for PCI procedures in the Planning Area must be revised to remove the 55 procedures for 2017 that were apparently double-counted due to the inaccurate 2018 PCI Survey form.42 Table 2 demonstrates the 2022 Projected Net Need for PCI procedures in the Planning Area is only 151 procedures, which is well below the 200-procedure minimum volume need threshold, even if Trios' proposed supplemental data for 2017 is (solely for the sake of argument) included in the count of PCI procedures.

Public Comment Table

Table 2: Estimated Net Need for PCI Planning Area #2

Data Source	# of Cases
Net Need Per DOH 2/2019 Published Methodology	182
Net Need Per DOH 10/3/2019 Published Methodology (after addition of Oregon inpatient data – net need increased by 6)	188
St. Joseph Hospital Lewiston PCI survey submittal (inpatient and outpatient)	6
Walla Walla General Hospital Outpatient Cases	6
Oregon Outpatient Cases	3
Additional Oregon Inpatient Cases (included in June 2019 screening submittal, Attachment 5 which identified 9 inpatient cases in Oregon or 3 more than identified by DOH in the October 3, 2019 methodology).	3
Total	**206**
Adjustment to remove double counting between Trios CHARS Inpatient and Survey response	-55
Total (Revised)	**151**

Source: Second Screening Responses, p. 3. See Attachment 3 for methodology used to estimate "Adjustment".

Accordingly, the correction of Trios' overcounting of its 2017 PCI procedure volumes further confirms that there is no need under the PCI need forecasting methodology for Trios' proposed new adult elective PCI program. Thus, Trios' CN application cannot satisfy need subcriterion 1, and it must be denied.

Susan Blackburn, Chief Executive – Providence St Mary Medical Center

I respectfully ask the Department of Health deny the application based on the following: when examining the PCI need methodology provided by the DOH, no need is shown in the planning area. From my understanding the laws and regulations that govern this process plainly state that the Department of Health shall only approve a PCI program when need is shown. Absent need, the Trios application must be denied.

Additionally, the Department's announcement on October 3rd, 2019 to include Oregon inpatient data during an open concurrent cycle negatively impacts other programs in the planning area. Oregon data was not included in the need calculation methodology for the 2019 concurrent review cycle. The Department's standard practice is to issue annual PCI need calculations prior to commencement of the PCI review cycle. By modifying the need calculation during an open concurrent review cycle, but not allow other applications to be filed based on the new calculation, the ability to expand access to care and consider geographic distribution of services in the planning area is removed. If the Department intends to include Oregon data in the calculation, it should do so as part of the need calculation for the 2019-2020 PCI calculation, in advance of the 2020 PCI CN application review process.

Susan Kreid, Member and Past Chair – Kadlec Regional Medical Center Board of Directors

I am opposed to granting Trios Health a certificate of need (application #19-64) to establish a new elective PCI program in Benton County at this time. I have been told that the method the Department

of Health uses to determine the need for a PCI program indicates that there is actually no need for an additional elective PCI program in this area. Therefore, I believe that approval by the Department would result in unjustified duplication of services.

Kirk Harper, Chief Operating Officer/Chief Nursing Officer – Kadlec Regional Medical Center
After reviewing the pertinent details, I strongly oppose the project and request that the Department of Health (DOH) deny the application. Based on the 2019 need projections provided by the DOH, there is insufficient need to approve a new PCI program in the community. From my understanding, the guiding regulations are well-defined and, when need for a program is not shown, the DOH shall not approve a PCI program. In following these guidelines and, since need is not demonstrated, the DOH must deny the Trios PCI application.

While I support improving access to health care services, if the DOH were to approve the Trios elective PCI program it would result in a clear duplication of services simply because there Is no need shown for another PCI program in the Planning Area. In fact, when examining the PCI procedure growth projections provided by Trios, the annual growth rate exceeds the population-driven increases and consequently Trios must rely on taking market share away from existing elective PCI providers in order to achieve their stated growth rates.

Larry Jecha, MD, MPH
I am a retired physician who has had a career in public health serving as the Health Officer of Benton/Franklin County Health District for over 20 years and a member of the Kadlec Board for 8 years. Population Health is becoming more important as we make decisions on certificate of need process.

I feel the Trios Health certificate of need application [#19-64] to establish a new elective PCI program in Benton County, Washington is not in the best interests of our community. Adding an additional elective PCI program when there is no proven need or benefit, it dilutes the effectiveness for this program for the whole region. Our community has just completed a Community Needs Assessment and adding this program does not meet any of those needs.

Denying this certificate, would be the most appropriate action.

Rebuttal Comments
Trios provided combined rebuttal that responds to both Providence and Kadlec's comments:

*"**Numeric Need Exists for a Second Provider***
Providence suggests that numeric need does not exist. When all cases are appropriately counted, the forecasting methodology found in WAC 246-310-705, establishes the need for a second provider in PCI Planning Area 2.

As documented in Table 1 and Attachment 5 and 6 of Trios' public comment, just conservatively accounting for all PCI cases documented and publicly available in CHARS and the Oregon Inpatient database, the net need is for 205 cases. Over and above the 205 documented net need in our public comment, we included in Table 1 additional cases that should be included and serve to further increase the need.

a. The Department failed to issue PCI projections in a timely manner.

Providence's view is that potential applicants for a CN related to percutaneous coronary intervention (PCI) services were prejudiced by the Department's decision to incorporate Oregon data into its 2019 methodology after review had begun. Providence contends that the Department should have waited to include the data until the 2020 application cycle. But inclusion of the data in the 2019 methodology did not actually impact potential applicants in the way described by Providence. Letters of intent for the 2019 cycle were due in January 2019, before the Department issued its first methodology on February 8, 2019. Providence's statement in its public comment on page 4 that the Department issued its methodology in January 2019 is simply incorrect. Additionally, Providence is incorrect in stating the that the Department has released a methodology annually; in fact, the 2019 methodology is the first methodology released by the Department since the methodology using 2013 data was produced.

Thus, all interested hospitals had to decide whether to apply for a PCI CN before they knew whether the Department would include Oregon data in its methodology. Trios opted to submit a letter of intent in anticipation that the Department would include Oregon data and accept attested data from adjacent Idaho State, consistent with the Department's past practice and as required by the rules, but Trios had no assurances this would occur.

Providence observes that the Department typically issues need calculations for each planning area before the concurrent review cycle starts. Even so, this is not explicitly required by the rules; rather it has been the Department's practice to do so, which also makes good common sense. Nevertheless, nothing in the rules prevents the Department from updating its methodology after the initial publication. Had the Department not updated the 2019 methodology to include Oregon data, the methodology would have remained incomplete and inaccurate as to the PCI use rate in Planning Area 2. The Department appropriately, although incompletely, incorporated Oregon data into its 2019 calculation as soon as the data became available.

It is also worth noting that Trios ***did include*** *appropriate Oregon inpatient and outpatient data in the need methodology that it prepared and submitted as part of its application.*

The Department's late inclusion of the Oregon data in its version of the need methodology for 2019 did not prejudice any party in the 2019 application concurrent review cycle because any interested applicant was forced to file a letter of intent prior to the Department publishing its 2019 methodology on February 8, 2019. Furthermore, Trios, and any other applicant in the 2019 concurrent review cycle, would be unreasonably prejudiced as a matter of fact had the Department failed to include Oregon data when the need methodology requires that data to be included in order to produce any meaningful results.

b. Data is not restricted to the three sources suggested by Providence. The inclusion of rightful data does not prejudice any party.

Providence asserts, incorrectly that WAC 246-310-745 limits the data that the Department can use in calculating need under the methodology. The assertion is incorrect as a matter of law, as well as unreasonable and arbitrary and capricious as a matter of policy.

First, while WAC 246-310-745(7) does list the CHARS, COAP and survey data, it does so by first stating: "The data sources for adult elective PCI case volumes include . . . ." It does not say that the data sources are limited to CHARS, COAP and survey data. Therefore, there is nothing precluding the Department from using additional data sources, especially where the data at issue is needed to

perform an accurate need forecast for the PSA at issue and is not otherwise available in the listed data sources.

Second, prior to the Department running this 2018 version of the PCI methodology, the Department ***had*** *used Oregon data in all prior versions of the methodology, including both inpatient data from HCUP and, during those years when responses were sought by the Department, outpatient data from a survey taken by the Department of Oregon hospitals. Please see Attachment 1 for examples of the Department's PCI methodologies from 2009, 2010, 2011 and 2012-2013.*

The 2008 methodology using 2007 data is the first time (we believe) that the Department ran the methodology under WAC 246-310-745 which was newly adopted at the time. We can tell that the Department used Oregon data for two reasons: (1) the use rate for PSA 5 (i.e., Clark County) is similar to the use rate for the rest of the state (and if the data was excluded it would be 30% or so lower like the current methodology); and (2) footnote 2 on page 2 specifically references Oregon HCUP data. We also have attached the 2011 methodology that has the same footnote showing that it used 2010 Oregon data. Finally, we have attached the 2012-2013 methodology which has a similar footnote saying that it used 2011 Oregon data. That is the last version of the methodology that we are aware of that the Department ran and published. It is also our understanding that as for Oregon outpatient data, Bob Russell, the individual running the methodology, surveyed the Oregon providers in the same way the Department surveys Washington providers.

We also note that in the 2009 PCI methodology, the footnotes indicate that in performing the calculations the Department used 2009 CHARS and Department survey data but 2008 HCUP data. Third, the Department has used out of state data for hospital bed need calculations as well as pediatric open-heart surgery applications, among others. This is clearly demonstrated in the Department's own March 2002 Evaluation approving Legacy Health's establishment of a hospital in Clark County, Legacy Salmon Creek.

> *"The inclusion of Oregon data is important to this methodology because Washington residents spent approximately 55,000 patient days in Oregon hospitals in 2000. This represents about 2.75% of all patient days for Washington residents. Clark County residents alone comprise over 60% of these patient days. Approximately 31.65% of all patient days for Clark County residents were spent in Oregon hospitals.* ***An accurate representation of bed need for Clark County residents would not be possible without inclusion of Oregon data****.*
>
> *Department of Health Certificate of Need Program Evaluations for Legacy Health System and Southwest Washington Medical Center, March 2015, p. 11, emphasis added.*

Therefore, there is no regulatory limitation on the data that the Department can and should consider in establishing need. In fact, in order to properly affect the policy goals of the CN Statute and Regulations, the Department, by its own admission, must consider sufficient data to perform an accurate version of the methodology.

In a Planning Area as unique as PCI Planning Area 2, which borders two other states—Oregon and Idaho, and from which available data demonstrates that a number of residents from the Planning Area travel to these adjacent states for services, especially tertiary services, it is incumbent to collect sufficient data to perform a full and accurate calculation of need.

c. The signed, attested data form from St. Joseph Regional Medical Center in Lewiston, Idaho is necessary data and should be counted.

St. Joseph Regional Medical Center (SJRMC) is a tertiary care hospital located in Lewiston, Idaho, approximately 3 miles from the Washington/Idaho border. There is no CHARS equivalent database in Idaho, and the Program did not send a survey to SJRMC or any other hospital in Idaho. To our knowledge it did not attempt, by any means, to collect information from Idaho hospitals regarding Washington residents seeking PCI care in their facility.

The survey form submitted by SJRMC is the same exact survey form sent by all Washington providers—the only exception is that SJRMC also identified inpatient cases (since Idaho does not have an inpatient data base). The form doesn't typically include inpatient procedures because this information is available in Washington and Oregon through the inpatient databases. No similar inpatient database exists for Idaho. To ensure that all of SJRMC's cases were included, the form was modified to list both inpatient and outpatient cases. This form was signed with the same attestation as other PCI survey forms submitted by a Washington or Oregon hospital.

Interestingly, Providence questioned the data provided by SJRMC, in part because it included data for Garfield County residents (see footnote 34, p. 8 of Kadlec's public comment). As Garfield County is included in PCI Planning Area 2, these volumes are appropriately counted.

3. LifePoint believes the 2017 PCI volumes reported by Trios represent a true and accurate count of cases. Even in the unlikely case that the out-of-state "double-counting" cited by Providence is correct, net need for a second provider is still demonstrated.

Providence argues that Trios' 2017 PCI survey volumes are overstated. First and foremost, as the CN Program is aware, the outpatient PCI survey requires that respondents attest to the information provided, and Trios did so. To the best of our knowledge, and in recognition of the fact that Kennewick Public Hospital District, the prior owner/operator of Trios was experiencing significant financial pressure, and workforce restructuring throughout 2017, we used all available records, and reverified, before submitting our survey.

Providence's argument is that they believe that there is duplication of six out-of-state cases, and then they conclude that this duplication "significantly reduces the projected need"—but only after it inflates these cases and suggests that a total of 75 cases performed at Trios were duplicated. Because Providence provided no data or direction to support their conclusion of 75 duplicated cases, we can only focus our response on the six out of state cases cited.

Trios importantly reminds the Program that out of state or out of area patients served by Trios or any other hospital, for that matter, has no impact on the use rate. It also has no impact on capacity when the out of state or out of area patients are served by an emergency only PCI provider. ***In other words, there is no impact on net need associated with the inclusion or exclusion of these six cases****. Providence's argument is without merit. These six cases on out of state patients had no impact on the net need identified in the DOH 10/3/2019 published Methodology.*

Specifically, and per Step 2 of the PCI methodology, the ***use rate*** *calculation is based on the planning area* ***residents*** *inpatient and outpatient PCIs (in the CN Program's October 2019 methodology this number was 598). That number is then divided by the 2017 15+ population/1,000. Out of state and out-of-area are specifically excluded. There is no place in this step to include out of state patients.*

*Secondly, the count of **capacity** for the planning area, includes only CN approved elective PCI providers. Therefore, any volume, including any of area or out of state persons served by Trios are not included in capacity. In other words, whether Trios provided services to one person from outside of PCI Planning Area #2 or 100, this number does not and did not impact the PCI published methodology."*

Department Evaluation

For this project, 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[3], which is reported by each Washington State hospital and identifies the total number of 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.

This portion of the evaluation will describe, in summary, the calculations the department made at each step of the methodology and the assumptions and adjustments, if any, made in that process. This section will also include a discussion of any differences between the applicant's and the department's numeric methodologies. For the department's methodology, the discussion below will address the results of each data set used. 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[4] 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 this application was submitted on February 28, 2019, year 2018 data was not yet available. For this project, base year is 2017.

Using the base year of 2017, the department calculated the use rate as described above. The table below identifies the use rates calculated by both the department. Trios Health did not provide a

[3] 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 safety, variability, outcomes and quality in various medical and surgical services. All hospitals in Washington State that provide adult cardiac surgery and/or percutaneous coronary interventions (PCI) participate in COAP, producing a rigorous database that allows the State to identify areas for quality improvement and collaborate on improvement efforts.

[4] Residents 15 years of age and older.

complete unique methodology, and instead only offered adjustments to the Department's methodology.

Department's Table 1
Department's Step One

	Department Methodology #1	Department Methodology #2
Year 2017 Population 15+	273,620	273,620
Divide by 1,000	273.62	273.62
Year 2017 PCIs	598	115
Use Rate Calculated	2.19	0.42

As shown in the Step One Table above, the 2017 population of residents 15 years and older is same, as the data source is the same. The significant difference in the table is the year 2017 PCIs, which when divided by the population results in a use rate. Since the calculated use rate is multiplied by the projected population step two below, any differences in the use rate are carried throughout the methodology. Trios Health did not report to COAP their 2017 data, making this methodology less reliable.

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.[5]

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.

Department's Table 2
Department's Step Two

	Department Methodology #1	Department Methodology #2
Forecast Year Population	295,936	295,936
Divide by 1,000	295.9	295.9
Use Rate (calculated from step 1)	2.19	0.42
Projected Demand for Planning Area Residents	188	124

As shown in the Step Two Table above, the forecast year populations are the same. However, once the use rate calculated from step 1 is applied, the resulting 'projected demand' is very 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.

[5] Residents 15 years of age and older.

(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 #9 the total number of PCIs performed at Kadlec Regional Medical Center. The table below shows the current capacity by facility. Note that the sum of CHARS and Survey data does not always equal the total reported by COAP. This could be due to a variety of factors, though the total of CHARS and Survey data is *generally* consistent with the COAP figures, with some exceptions.

Department's Table 3
Department's Step Three
Current Capacity by Hospital

Hospital	Inpatient PCIs (CHARS)	Outpatient PCIs (Survey)	Total	Combined Inpatient & Outpatient (COAP)
Kadlec Regional Medical Center	276	183	**459**	**678**

The number of PCIs performed by the hospitals above are added together and the sum represents the current capacity in the planning area as defined in the numeric methodology.

Step 4: Calculate the net need for additional adult elective PCI procedures by subtracting the calculated capacity in Step 3 from the forecasted demand in Step 2. If the net need for procedures is less than two hundred, the department will not approve a new program.

Step 5: If Step 4 is greater than two hundred, calculate the need for additional programs.
(a) Divide the number of projected procedures from Step 4 by two hundred.
(b) Round the results down to identify the number of needed programs. (For example: 375/200 = 1.875 or 1 program.)

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

Department's Table 4
Department's Steps Four and Five

	Step	Department Methodology #1	Department Methodology #2
Step 2-Forecasted Demand	4	647	124
Step 3-Current Capacity	4	459	678
Net Need in Planning Area	4	188	-554
Divide Net Need by 200	5	0.94	-2.27
Round Down	5	0	0

Step 5 shown in the table above shows the department projects need for no additional PCI programs during this 2019 concurrent review cycle using a base year of 2017 and projecting to year 2022.

As acknowledged by the applicant, WAC 246-310-720(2) provides the following guidance for the addition of a new PCI program in a planning area. It states:

(2) The department shall only grant a certificate of need to new programs within the identified planning area if:
(a) The state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area; and
(b) All existing PCI programs in that planning area are meeting or exceeding the minimum volume standard."

The existing providers volumes for the 2019 review cycle, which satisfies (2)(b). However, even with the inclusion of Oregon inpatient data and outpatient surveys sent and received by the department, there is not sufficient numeric need to justify an additional program. As a result, no applicant for this planning area can satisfy (2)(a). This fact was pointed out by both Providence and Kadlec in their public comments. Kadlec is a PCI provider in the planning area and qualifies as an affected person.

Trios requested that the following data sources also be included. The associated volumes with these data sources was provided in screening. They are not consistent with department practice, explained below:

Department's Table 5
Data Source Exclusion Summary

Data Source	Reason for Exclusion
St Joseph Medical Center-Idaho	Trios surveyed their sister hospital in Idaho using an altered DOH survey form. The department does not survey Idaho hospitals – because the State of Idaho does not maintain an inpatient database, there is no verifiable data source for Idaho facilities. Inclusion of a survey that was not distributed by the department is not an acceptable data source.
LifePoint Health Letter included in Screening 1 Response, Attachment 5	LifePoint Health provided a letter with a table of PCI volumes at various hospitals, both in and out of state. LifePoint Health is not a representative of these entities, and department has no mechanism for verifying these volumes.

Applicants relied on three data sources in the methodology to develop and submit their applications by the last working day in February. Following the department's survey, the PCI survey responses are made available to the public.

To accept novel data sources that could not have been publically available prior to the concurrent review cycle changes the process and removes the element of transparency, fairness, and predictability in a Certificate of Need review. Inclusion of the Oregon inpatient data is important,

but as demonstrated in the updated numeric need methodology published in October 2019, inclusion of this data does not change the outcome in Step 5.

WAC 246-310-720(2) has two components, both of which must be met based on a plain read of this rule. Regardless of the factors identified by Trios, the Certificate of Need program is not in a position to violate its own rules to approve a new program if both components are not met. Providence and Kadlec both identified that the department does not have a mechanism for approving an additional elective PCI program under these circumstances.

Furthermore, there is case law supporting the department's interpretation of WAC 246-310-720(2). In Swedish Health v. The Department of Health[6] the Court of Appeals upheld the department's action in denying a Certificate of Need to a hospital in a planning area where one of the two required components in WAC 246-310-720(2) was not met.. Relevant excerpts from the Opinion are below:

"…if the Department were to grant a certificate of need to Swedish, despite the plain language of its regulation that specifies minimum volume standards for existing PCI programs, it is fair to assume prejudice to those existing programs. Otherwise, minimum volume levels of existing programs would be irrelevant to forecasting need." [source: Swedish v. Department of Health p12]

"Swedish points to the Department's regulations for certificates of need for different procedures or services. Swedish argues that these regulations "contain[] numerous exceptions, exemptions, and caveats which allow for[the] approval of various types of projects which may not otherwise satisfy applicable criteria." But the fact that those other regulations contain exemptions is not material to the issues before us.

The PCI regulations lack such language, indicating that their standards are mandatory and not subject to exemption. We reject the argument that the fact that other certificates of need may be granted without meeting all the identified criteria establishes that PCI certificates of need can also be granted without meeting the governing criteria." [source: Swedish v. Department of Health pp13-14]

"Swedish appears to argue that the Department failed to decide whether the special circumstances that Swedish cites merited issuance of a certificate of need, despite the failure to meet an essential criterion for issuance. Because the regulation clearly requires fulfillment of the minimum volume criterion, and it is undisputed that this criterion is not met in this case, the Department did not need to decide whether the special circumstances advanced by Swedish merited issuance of a certificate of need. Swedish's arguments to the contrary are unpersuasive for the reasons we explained earlier in this opinion." [source: Swedish v. Department of Health pp15-16]

"Moreover, even assuming the Department could have issued an order inconsistent with its rules, nothing indicates that it was required to consider doing so before denying Swedish's application. Thus, the Department did not fail to decide all issues requiring resolution." [source: Swedish v. Department of Health p16]

"In sum, the Department did not erroneously interpret or apply the law when it denied Swedish's application for a certificate of need." [source: Swedish v. Department of Health p15]

[6] Swedish Health Servs. v. Dep't of Health, 189 Wn. App. 911, 358 P.3d 1243, 2015 Wash. App. LEXIS 2088, 189 Wn. App. 911, 358 P.3d 1243, 2015 Wash. App. LEXIS 2088

Trios' rebuttal comments continue to argue for use of data sources not available to the public. While the department does not entirely agree with Kadlec and Providence's position that the three data sources outlined in WAC are the only appropriate data source, the department does agree that inclusion of data that was not available or accessible to the department in its preparation of the methodology or the public at large is inappropriate. Oregon inpatient data was included as soon as it was available to the department, and it did not impact the outcome.

WAC 246-310-720 is mandatory, not permissive. The numeric methodology is a population and utilization-based assessment used to determine the projected need for PCI services in a planning area. Based solely on the numeric methodology applied by the department using appropriate and accessible data sources, need for an additional PCI program in PSA #2 is not demonstrated.

For the reasons above under WAC 246-310-720, the department concludes that the department cannot approve a new PCI program in planning area #2. **This sub-criterion is not met**.

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 (UWMC) program and how the hospital intends to meet the minimum number of procedures. The criteria and 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.

Trios Health

"The University of Washington, through its unincorporated division, UW Medicine is a minority owner of RCCH Trios Health, LLC and we work closely and collaboratively with the UWMC. According to the Program's data, in 2017, UWMC performed a total of 10 PCIs on residents of PCI Planning Area 2, equating to a 1.7% share of the all PCIs from the area…

Trios Health fully recognizes and values the resource that an academic tertiary center provides to Washington State and its essential role in the training of new cardiologists. We fully support the UWMC, and we have been in correspondence with UW Medicine and they acknowledge the data." [source: Application pdf18-19]

Trios provided documentation of their correspondence with UWMC. [source: Screening 1, Attachment 10]

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 Trios expects to have little to no impact on the UWMC program if approved. UWMC's reports to the department and COAP indicate their program has consistently exceeded the minimum volume of 200 PCIs per year.

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.

Trios Health

Trios Health provided a table showing the projected number of PCIs it expects to perform through the first three years of the proposed program. The table below summarized the information provided by the applicant. [source: Application, pdf17]

Applicant's Table

Year	Total
Year 1	220
Year 2	240
Year 3	260

Source: Applicant.

Trios' assumptions supporting the volume projections are below. [source: Application pdf29-30, Screening 1 response pdf4-5]

"Using the actual 2017 Trios volumes as a baseline (176 cases), Trios assumed the following:
1) The service will become operational on May 1, 2020.
2) We expect to be performing 220 cases by the end of 2020, an increase of 25% over actual 2017. The rationale is based on the number of cases that we have been referring out because of a lack of an elective PCI program. As noted in the CN application, Trios referred 39 patients to other providers in 2017 because we did not have approval to perform elective cases. The assumption in 2020 is that the vast majority of these cases (35 of 39) would be performed at Trios. In addition, to the ability to retain these cases, a growth of 5% over 2017 PCIs (9 incremental cases), for a total of 220 cases in 2020 has been assumed.
3) In 2021 and 2022, Trios assumed an increase of 20 cases annually. The growth to 240 cases in Year 2 and 260 cases in Year 3 is intended to reflect the expected addition of a new interventional cardiologist and increased outreach to inform the Benton/Franklin region and NE Oregon of the new capacity at Trios. No additional growth in volumes was assumed in 2023 (the third full year of operation)."

A discussion regarding physician volumes was also included. [source: Application pdf30]

"No cardiologist will work exclusively at Trios Health. Trios Health's agreement with CardioSolutions for the staffing of our cardiac service. To staff the service 24/7, CardioSolutions has a number of cardiologists that staff Trios Health. The interventionalist that will initially be the sole provider of elective cases the 50 annual PCI volume requirement."

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health clarified in the application that a large percentage of patients expected to be served by their proposed PCI program would be patients currently being served in an emergent capacity.

Trios identified that the physicians who would perform PCI at Trios are one and the same with the current CardioSolutions physicians, and therefore foresee no issue with meeting the minimum volume standards. The screening response included a letter from CardioSolutions attesting to physicians' past volumes. For these reasons, 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 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 under insured.[7]

[7] WAC 246-453-010(4)

Trios Health

Trios provided copies of the following policies currently in used at the hospital. [source: Application Exhibit 1]

- Admission Policy
- Charity Care Policy

Trios is currently Medicare and Medicaid certified. Trios provided its current source of revenues by payer for the existing PCI volumes. Trios did not anticipate it would change with the project. Trios also provided the current and projected sources of revenue by payer for the hospital as a whole – these are not expected to change as a result of the project, as the PCI program does not have a payer mix consistent with the hospital as a whole. The payer mixes are shown below. [source: Application pdf12]

Department's Table 6
Payer Mix

Revenue Source	Entire Hospital	PCI Program
Medicare	46.7%	57.6%
Medicaid	21.7%	11.9%
Private Self Pay	2.6%	4.2%
Commercial	23.2%	22.8%
HMO/PPO	1.9%	1.3%
Other	3.9%	2.2%
Total	**100.00%**	**100.00%**

In addition to the policies and payer mix information, Trios provided the following information related to uncompensated care provided by Trios. [source: Application, pdf34-35]

"For hospital charity care reporting purposes, the Department divides Washington State into five regions. Trios Health is located in the Central Washington Region. According to 2015-2017 charity care data produced by the Department (the latest data available), the three-year charity care average for the Region was 0.96% of gross revenue and 2.51% of adjusted revenue. During the same time frame, Trios Health's charity care, under prior ownership, was 0.50% and 1.50%, respectively. The percentage of charity care included in the pro forma is consistent with the three-year Central Washington regional average of 0.96% of total revenue.

Trios Health understands that a condition is likely to be placed on our CN award requiring that we use reasonable efforts to meet the regional average. We are amenable to such a condition." [source: Application pdf19-20]

Public Comments

The department received letters that referenced this sub-criterion, excerpts of which are captured below:

Reza Kaleel, Chief Executive – Kadlec Regional Medical Center

An additional concern for our community is the issue of charity care provided by Trios. In the original CN application, Trios states that it will provide charity care "consistent with the three-year Central Washington regional average of 0.96% of total revenue" (p 15, Trios PCI CN application, dated 2/28/ 19). At Kadlec, we consider the provision of charity care as pa1t of our commitment to our community, and we take this commitment ve1y seriously. Charity care provides vital suppo1t in

keeping our communities healthy and supporting those who may otherwise not have access to healthcare. Given the importance that each health care entity fairly contribute to the community via the provision of charity care, we request that DOH assess Trios' track record and continue to monitor and ensure that Trios provides charity care at rate consistent with the Central Washington average.

Robert Watilo, Chief Strategy Officer, Kadlec Regional Medical Center and Providence St Mary Medical Center

The history of Trios' parent organization in the State of Washington raises significant concerns about Trios' ability to provide "adequate access" to all residents of the community, especially those who are financially vulnerable or in need of charity care.

In order for its application to be approved, Trios must satisfy need subcriterion 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." In evaluating whether Trios' application satisfies this requirement, the Department must consider not only Trios' own commitment to meeting the subcriterion, but the history of Trios' parent and related organizations with respect to recognizing and addressing the goals embodied in the subcriterion. Trios' ultimate parent organization is RCCH HealthCare Partners ("RCCH"). RCCH also owns Capital Medical Center ("Capital") in Olympia.46 Accordingly, the history of RCCH's operation of Capital is relevant to an evaluation of Trios' ability to meet need subcriterion 2. That history raises serious concerns about Trios' ability to serve all residents in PCI Planning Area 2, especially those who are financially vulnerable and in need of charity care.

On September 21, 2017, the Attorney General of Washington filed a Complaint for Injunctive and Other Relief under the Consumer Protection Act ("Complaint") against Capital. The Complaint alleges:

> *1.2 Capital undermined the purpose of the Charity Care Act, RCW 70.170, and violated the Washington Consumer Protection Act, RCW 19.86, when it pressured thousands of its low-income patients to pay for their treatment upfront and prevented them from accessing charity care from at least 2012 until 2016.*

The Complaint further alleges:

> *1.11 Capital's practices deceived low-income patients about their liability for medical expenses, misled patients about their payment and financial assistance options, and unfairly prevented them from accessing care. Without information about and access to charity care, Capital's low-income patients paid for medical expenses they should not have been responsible for, took on medical credit cards, incurred medical debts, and deferred medical care.*
>
> *1.12 These practices caused Capital to provide charity care at one of the lowest rates in the Southwest Washington Region and the State of Washington. In 2014 Southwest Washington Region hospitals provided an average of 5.93 percent of their adjusted revenue in charity care. In contrast, Capital provided just 0.37 percent of its adjusted revenue in charity care that year. This trend continued in 2015, when Southwest Washington Region hospitals provided an average of 3.18 percent of their adjusted revenue in charity care and Capital provided only 0.44 percent. In both years, Capital provided the lowest rate of charity care in the Southwest Washington Region and in the State of Washington.*

Kadlec recognizes that the Attorney General's Complaint contains allegations. We also recognize RCCH and Capital are contesting those allegations. However, we presume the Attorney General commenced the action only after conducting an extensive investigation, as is supported by the evidence presented in the Complaint. Accordingly, we believe it is appropriate for the Department to take the Attorney General's action (and RCCH's and Capital's responses to the action) into account when evaluating whether Trios has the ability to satisfy need subcriterion 2.

The Attorney General's action is not the first time that concerns have been raised about Capital's charity care practices. In November 2009, the Department issued CN #1410 to Capital, authorizing it to establish an adult elective PCI program. The Department approved Capital's CN application subject to three conditions, which Capital accepted. One of the conditions provides:

> *Capital Medical Center will provide charity care in compliance with the charity care policies reviewed and approved by the Department of Health. Capital Medical Center will use reasonable efforts to provide charity care in an amount comparable to or exceeding the regional average amount of charity care provided by hospitals in the Southwest Washington Region. Currently, this amount is 2. 7 4% of gross revenue and 6.16% of adjusted revenue. Capital Medical Center will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies.*

Providence Health & Services-Washington d/b/a Providence St. Peter Hospital ("PSPH") commenced an adjudicative proceeding challenging the issuance of CN #1410 to Capital. The Department, Capital, and PSPH agreed to a settlement, pursuant to which Capital retained its CN. As part of the settlement, Capital agreed to "fulfill its ongoing obligations to provide charity care by using reasonable efforts to provide an amount of charity care comparable to or exceeding a percentage of the regional average amount of charity care provided by hospitals in the Southwest Washington Region. The Stipulation and Agreed Order implementing the settlement states: "Capital recognizes that its failure to meet the requirements of this stipulation and agreed order constitute cause for suspension or revocation of CN #1410."

Capital failed to comply with the charity care commitments made by it in the Stipulation and Agreed Order. Therefore, on September 19, 2014, the Department issued a "Notice of Suspension of CN #1410" to Capital. The Notice states:

> *[The charity care] data indicates that from 2010 to 2012 Capital failed to make reasonable efforts to meet the charity care requirements of the Agreed Order. Under Paragraph 8 of the Agreed Order, this failure is grounds for the Department to suspend or revoke CN #1410. Accordingly, the Department hereby suspends CN #1410.*

On October 17, 2014, Capital requested an adjudicative proceeding to contest the suspension, which, ultimately, led to the Health Law Judge approving a revised Stipulation for Dismissal that set forth new settlement terms. The settlement included the following provisions:

> *5. CMG [Capital] will provide not less than the charity care average by June 2017 for the proceeding [sic] 12 months, and each June thereafter, for all hospitals in Thurston, Mason, Grays Harbor, and*
> *Lewis Counties.*

6. By September 1 of each year, if CMG has failed to meet the requirement in Paragraph 5, CMG will pay an amount calculated by the formula in Attachment 2 to this Stipulation to one or more local organizations that provides medical care to indigent persons. The organizations must be unaffiliated with CMG in terms of ownership or governance and be approved by the Department. The Department will consult with Providence St. Peter Hospital prior to approving a recipient organization.

In subsequent years, Capital has failed to meet the charity care requirement set forth in Paragraph 5. Thus, for the reporting periods from June 2016 through May 2017 and from June 2017 through May 2018, the Department required Capital to make payments to local charitable organizations in accordance with Paragraph 6. It is our understanding that the Department is currently in the process of evaluating whether Capital has met the charity care requirement for the period from June 2018 through May 2019.

The Attorney General's legal action and the Department's suspension of CN #1410 raise troubling questions about RCCH's and Capital's commitment to providing charity care and to serving low-income members of the community. Given RCCH's ownership of Trios, the history of Capital's charity care issues is something that the Department must take into account when assessing Trios' ability to satisfy need subcriterion 2.

Rebuttal Comments

Trios Health provided the following rebuttal to Kadlec and Providence's comments:

Providence attacks the commitment of Trios to serve all residents in the community and its commitment to charity care based on the ongoing litigation at Capital Medical Center ("CMC"). These attacks are misdirected, used to tarnish the applicant, and fail to appreciate the history of RCCH/LifePoint's operations in Washington. These are similar arguments made by Kadlec to contest RCCH/LifePoint's applications concerning the acquisition Trios Hospital, Lourdes Medical Center and Lourdes Counseling Center.

RCCH/LifePoint feels compelled to respond to these concerns related to CMC, even though the concerns have no applicability to this pending Application and were previously addressed in various rebuttal comments related to the RCCH Trios Hospital acquisition CN application and the RCCH Lourdes application.

Regarding the CMC lawsuit, in 2016, the Washington State Attorney General ("AG") began an investigation into CMC's charity care program, policies and procedures. RCCH and CMC cooperated with the AG in the investigation. CMC and RCCH had a good faith belief that they were on the path to a settlement that might have included a corrective action plan for alleged violations of the state charity care law, as well as monetary penalties. Independently, during 2016, CMC reviewed all of its charity care policies and procedures and made changes necessary to bring CMC's policies and practices into conformity with the AG's interpretation of the charity care law. Despite these good faith efforts on the part of CMC and the AG, the AG chose to file a lawsuit, alleging violations of the state Consumer Protection Act (CPA) based on failure to follow the AG's interpretation of the charity care law. The alleged violations in the lawsuit involve conduct from 2012 until 2016.

The matter is on-going, and RCCH and the AG remain in active settlement discussions. CMC intends to defend the matter vigorously. In the interim, CMC and RCCH will continue to monitor their

practices to ensure they are performing their obligations, at a minimum, in compliance with state law. RCCH is committed to providing charity care to patients in all communities served by RCCH, and to do so in a manner that conforms with best practices as well as Washington State law.

The focus solely on the lawsuit with the AG ignores the innovation, high quality care, and commitment to the community provided by CMC. Located in Olympia, CMC has a history of serving state employees, including through the Health Care Authority's innovative value-based accountable care product, UMP+ for the UW Medicine Accountable Care Network. Since CMC and UW Medicine ACN began working together, the quality of care delivered at CMC has been continuously improving. For example, CMC is a four-star Medicare hospital, the first hospital in the South Sound to earn a Gold Seal of Approval® for hip replacement, knee replacement and spine surgery from The Joint Commission, recipient of the 2017 WSHA Award for Quality and the BlueCross/Blue Shield Blue Distinction Center+ hospital for Knee & Hip Replacement and Spine.

In addition, access to care within the community has steadily grown, including bringing additional primary care to the community through a collaboration between CMC and the UW Neighborhood Clinics. The materials submitted by Kadlec describing charity care ignores the consistent, high quality delivery of care in support of community needs that CMC provides. They also fail to recognize that as a tax paying, for-profit entity, RCCH Trios Health, LLC provides millions of dollars in public benefit in the form of property taxes, B&O taxes, Federal Income Tax, and sales and use taxes to the greater Tri-Cities community.

Finally, we note that Providence itself was recently sued over charity care issues: Hofstader v. Emergency Physicians Services, P.S., Providence Holy Family Hospital and Providence Health and Services (Case No. 2:18-cv-00062-SMG ED WA) and appears to be close to settling that class action lawsuit.

Department Evaluation

Trios Health has been providing healthcare services to the residents of Benton and Franklin County through its hospitals and medical clinics for many years. RCCH assumed ownership of Trios in 2018. Healthcare services are stated to be available to low-income, racial and ethnic minorities, handicapped and other underserved groups. [source: Application Exhibit 1, Trios Health website]

The Admission Policy describes the process Trios uses to admit a patient and outlines rights and responsibilities for both Trios and the patient. It is the current, approved policy in place.

Trios currently provides services to both Medicare and Medicaid patients. Trios does not anticipate any significant changes in Medicare or Medicaid percentages resulting in approval of this project.

Trios Health's current Medicare revenues are approximately 47% of total revenues, likewise, Medicaid revenues are currently approximately 22%. Other revenues are expected to remain the same as well. Financial data provided in the application also shows both Medicare and Medicaid revenues.

The Charity Care Policy provided in the application has been reviewed and approved by the Department of Health's Hospital Financial/Charity Care Program (HFCCP). The policy outlines the process one would use to obtain financial assistance or charity care. The pro forma financial documents provided in the application include a charity care 'line item' as a deduction of revenue.

Providence and Kadlec raised questions regarding whether Trios has met their obligations regarding charity care – this will be discussed in the following section.

Charity Care Percentage Requirement

For charity care reporting purposes, Washington State is divided into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. Trios proposes to establish a PCI program in Kennewick located in the Central Region. Currently there are 21 hospitals operating within the region. Of the 21 hospitals, some did not report charity care data for years reviewed.[8]

Table 7 on the following page compares the three-year historical average of charity care provided by the hospitals currently operating in the Central Region, and Trios Health's historical charity care percentages for years 2015-2017. The table also compares the projected percentage of charity care. [source: Application and HFCCP 2015-2017 charity care summaries]

Department's Table 7
Charity Care Percentage Comparisons

	Percentage of Total Revenue	Percentage of Adjusted Revenue
Central Region Historical 3-Year Average	0.95%	2.54%
Trios Health's 3-Year Average	0.55%	1.50%
Trios Health's Projected Average	0.96%	--

As noted in Table 7 above, the three-year historical average shows Trios has been providing charity care below both the total and adjusted regional averages. For this project, Trios projects that the hospital would provide charity care slightly exceeding the regional average for total revenues and adjusted revenues. The pro forma demonstrate that Trios expects to provide charity care within the PCI program at a rate consistent with the rest of the hospital.

Trios has been providing health care services at their campuses campus for several years. Charity care is health care provided through the hospital at no cost or reduced cost to low income patients. Charity care is a state-mandated and partially state-funded program that allows uninsured or underinsured people to receive inpatient and outpatient care at a reduced cost. Only people who meet certain income and asset criteria are eligible to receive charity care.

Providence and Kadlec provided some discussion of the performance at Capital Medial Center – another Washington State Hospital operated by RCCH. They provided information suggesting they doubted Trios' ability to meet the regional average based on past performance at Capital Medical Center. Since Trios was purchased by RCCH in 2018, the department does not have sufficient information to conclude that Trios is unable to meet its obligation.

If this project were to be approved, Trios would be required to agree to the charity care condition stated below.

> Trios 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. Trios will use reasonable efforts to provide charity care in an

[8] For year 2017, Astria/Sunnyside did not report; for year 2015, Wenatchee Valley Hospital, Quincey Valley Hospital, and Astria/Sunnyside did not report.

amount comparable to or exceeding the amount of charity care identified in the application or average amount of charity care provided by hospitals in the Central Region. Currently, this amount is 0.95% gross revenue and 2.54% of adjusted revenue. Trios 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 Trios' agreement to the condition, the department concludes t**his sub-criterion is met.**

(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.

Department Evaluation
This sub-criterion is not applicable to this application.

(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.

Department Evaluation
This sub-criterion is not applicable to this application.

(c) The special needs and circumstances of osteopathic hospitals and non-allopathic services.

Department Evaluation
This sub-criterion is not applicable to this application.

(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.

Department Evaluation
This sub-criterion is not applicable to this application.

(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 this application.

(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 this application.

B. Financial Feasibility (WAC 246-310-220)
Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that Trios **did not meet** 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 directs 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.

Trios Health
Trios provided the following assumptions to determine the projected number of PCIs during the projection period. [source: Screening 1 pdf4-5]

"Using the actual 2017 Trios volumes as a baseline (176 cases), Trios assumed the following:
1) The service will become operational on May 1, 2020.
2) We expect to be performing 220 cases by the end of 2020, an increase of 25% over actual 2017. The rationale is based on the number of cases that we have been referring out because of a lack of an elective PCI program. As noted in the CN application, Trios referred 39 patients to other providers in 2017 because we did not have approval to perform elective cases. The assumption in 2020 is that the vast majority of these cases (35 of 39) would be performed at Trios. In addition, to the ability to retain these cases, a growth of 5% over 2017 PCIs (9 incremental cases), for a total of 220 cases in 2020 has been assumed.
3) In 2021 and 2022, Trios assumed an increase of 20 cases annually. The growth to 240 cases in Year 2 and 260 cases in Year 3 is intended to reflect the expected addition of a new interventional cardiologist and increased outreach to inform the Benton/Franklin region and NE Oregon of the new capacity at Trios. No additional growth in volumes was assumed in 2023 (the third full year of operation)."

Using the assumptions stated above, Trios projected the number of PCIs with the addition of an elective program. The projections shown below begins with calendar year 2020. [source: Screening 1 Response pdf8]

Applicant's Table

2020-2023 PCI Volumes: Inpatient and Outpatient

Year	Inpatient	Outpatient	Total
2020	26	14	40
2021	39	21	60
2022	52	28	80
2023	52	28	80

Source: Applicant

The assumptions Trios used to project revenue, expenses, and net income for the PCI cost center are below. [source: Screening 1 Response pdf8-9]

Revenues:

- *The incremental gross revenue per case was assumed to be $91,242. This is a weighted average for inpatient and outpatient.*
- *Deductions from revenue were based on the current cath lab experience.*

Expenses:

- *The only incremental expenses are for supplies (assumed to be $4,718 per case) and the management fee (assumed to be 2% of net revenue).*
- *No additional staffing is required for the incremental volumes.*

Based on the assumptions above, Trios provided the following revenue and expense statement for the hospital with and without the project. The "with" scenario is shown below. [source: Screening Response 1, Exhibit 9]

Department's Table 8
Trios WITH Project

	2020	2021	2022	2023
Net Revenue	$149,128,285	$153,704,589	$158,392,731	$162,619,940
Total Expenses	$152,591,223	$154,897,769	$157,512,518	$160,074,888
Net Profit / (Loss)	**($3,462,938)**	**($1,193,180)**	**$880,213**	**$2,545,052**

The 'Net Revenue' line item is gross inpatient and outpatient hospital revenue, plus any non-operating revenue. The 'Total Expenses' line item includes all expenses related to hospital operations, including all staff salaries/wages and allocated costs.

Public Comments

Rob Watilo, Chief Strategy Office – Kadlec Regional Medical Center and Providence St Mary Medical Center

1. Trios' pro forma financial statements are not reliable due to key errors and omissions. Therefore, Trios' application does not satisfy financial feasibility subcriterion 1.

In order for its application to be approved, Trios must demonstrate that its proposal satisfies financial feasibility subcriterion 1: "The immediate and long-range capital and operating costs of the project can be met." As discussed below, there are significant issues relating to the pro forma

financial statements and supporting financial information submitted by Trios. Accordingly, the financial statements are not reliable, and Trios' proposal does not satisfy subcriterion 1.

a. Trios' utilization projections are highly questionable, thereby raising significant concerns regarding the validity and reliability of its pro forma financial statements.

The reliability of Trios' pro forma financial statements is contingent upon the reliability of its utilization projections for inpatient and outpatient PCI procedures. If those projections are unreliable, then Trios' financial projections are, in turn, unreliable. As discussed below, there are critical flaws in Trios' PCI procedure volume projections.

There are serious defects in the method used by Trios to project its future procedure volumes. In Table 2 of its Second Screening Responses, Trios estimates that its inpatient PCI procedure volume will increase from 88 procedures in 2018 to 169 procedures in 2022. It appears Trios' projection method consists of forecasting total PCI procedures (inpatient and outpatient) using 2017 as the base year, and apportioning inpatient and outpatient procedures according to the 2018 inpatient and outpatient procedure mix. This arbitrary application of statistics from different years results in utilization projections that are simultaneously inconsistent with the 2018 PCI procedure volumes and with the 2017 procedure mix.

The problematic nature of this method is evident when looking at Trios' projected inpatient PCI procedure volume growth. Between 2018 and 2022, Trios projects a 23% average annual growth in inpatient procedures (a total volume growth of nearly 100% over the projection period). This far exceeds any population-driven increases in future planning area need, and, thus, relies upon Trios capturing a significantly larger market share of the PCI procedures performed in the planning area to the detriment of existing PCI programs. Furthermore, Trios' inpatient procedure volumes were 85 in 2016, 78 in 2017, and 88 in 2018. Therefore, its projected growth in inpatient procedures is not consistent with its historical inpatient volumes.

The second, and greater, problem with Trios' PCI procedure volume forecast is the fact that Trios bases its utilization projections on its reported 2017 PCI procedure volumes. However, as discussed in detail in Section II.A.3 above, Trios' reported 2017 PCI procedure volumes likely include significant double-counting of outpatient procedures: we estimate that 75 procedures were likely double-counted. Thus, Trios' base year of 2017 should have had a volume of 101 PCI procedures (176 minus 75), which is similar to the number of procedures reported in 2016 (98).

Trios projects that it will provide 220 PCI procedures in 2020. Using the ostensible 176 PCI procedures performed in 2017 as a "baseline," Trios posits that it will add 35 procedures purportedly referred to other hospitals, yielding a total of 211 procedures (176 plus 35). Trios then states: "In addition to the ability to retain these [35] cases, a growth of 5% over 2017 PCIs (9 incremental cases), for a total of 220 cases in 2020 has been assumed."

However, as noted above, Trios' 2017 PCI procedure volume was likely only 101 procedures, which is only 46% of the 2020 projected volume of 220 procedures. Even adding the 35 procedures that were purportedly referred to other hospitals, the adjusted projected volume of 136 PCI procedures (101 plus 35) is still only 62% of the projected 2020 volume of 220 procedures: 84 procedures short of the projected 2020 volume. Therefore, Trios would somehow have to add 84 procedures to reach its 2020 volume forecast. This is unrealistically high. Where will the procedures come from? In sum, Trios' utilization projections are not supported by its historical volume of PCI procedures, and, as discussed in detail in Section I1.A.3 above, are likely based upon inaccurate procedure volume data.

The accuracy of Trios' pro forma financial statements is dependent upon the accuracy of Trios' utilization projections. Those utilization projections are flawed. Thus, the application fails to establish that "the immediate and long-range capital and operating costs of the project can be met."

b. The 2% annual management fee included in Trios' pro forma Statement of Revenue & Expense constitutes corporate allocations. Trios has not identified, or provided the assumptions for, the specific corporate overhead components included in the fee. Therefore, the Department cannot evaluate whether the fee reasonably and accurately allocates corporate overhead.
According to Trios, "[t]he hospital's corporate overhead is charged as a management fee. This management fee is fixed at 2% of net revenue for the hospital." Thus, Trios is using the annual management fee as a surrogate for the allocation of corporate overhead.

However, in the absence of further information, there is no way of knowing whether Trios' 2% annual management fee accurately reflects the actual cost of corporate overhead that is attributable to the operation of the PCI program. In order to reduce this type of uncertainty and to enable it to evaluate whether overhead cost allocations are accurately reflected in an applicant's pro forma financial statements, it is the Department's standard practice to require applicants who use corporate allocations to identify, and provide the assumptions for, the allocations.

To our knowledge, Trios has not provided the Department with a description of the specific components included in its allocation of corporate overhead. Instead, as noted above, it simply states: "The hospital's corporate overhead is charged as a management fee. This management fee is fixed at 2% of net revenue for the hospital." Nor has Trios provided the Department with an explanation of the assumptions behind the adoption of a flat 2% annual management fee as a surrogate for the allocation of corporate overhead.

Therefore, the Department has no way of evaluating the reasonableness of the annual allocation "fee," and whether it is an accurate reflection of the actual amount of corporate overhead consumed by the PCI program. There is no way of knowing whether the management fee (i.e., the corporate allocation) understates or overstates the true cost of corporate overhead attributable to the PCI program. This uncertainty renders Trios' pro forma financial statements unreliable since the Department cannot determine whether the statements include the full cost of the proposed program."

Rebuttal Comments
Trios provided the following rebuttal:

"Trios' pro formas are reliable. There are no errors or omissions. The pro formas were prepared in a manner consistent with CN guidelines, and consistent with those of other applicants that have been awarded Certificates of Need.

a. Volume projections are reliable.
Providence argues that Trios' proposal fails the financial feasibility criteria in WAC because they are contingent upon the reliability of our utilization projections for inpatient and outpatient procedures. As documented in earlier sections of this document, Trios is standing by the reported and attested 2017 volumes. These volumes formed the basis for our utilization projections.
Furthermore, Trios has demonstrated that there is sufficient need for an additional PCI program in PCI Planning Area #2. With 176 cases in 2017 and more than 130 cases in 2018, we expect no difficulty in achieving 200 cases annually. Trios is located in the portion of Planning Area #2 which

is experiencing some of the fastest growth in the State. In fact, Kadlec relied on the same population growth rates in its recent acute care bed need application in which it was awarded additional acute care beds.

Trios is confident that it will be able to achieve its immediate and long-range capital and operating costs. In fact, as noted in the application and screening responses, the establishment of an elective PCI program requires no capital and only incremental operating costs. Trios' overall financial position will be improved with the additional volume and revenue associated with the elective PCI program.

b. The management fee and corporate overhead allocations are correct.
Providence's comments related to the management fee and corporate allocation appear to be a direct response to the issues raised by RCCH's CMC, Olympia in response to the clear exclusion of corporate overhead allocations in the recent Providence St. Peter Hospital acute care bed expansion application. In that application, RCCH pointed out that the financials contained in the CN application were inconsistent with the Department of Health's year end reports. Specifically, the CN financials contained no overhead allocations yet $100million in overhead had been included in the DOH year end report. The Department agreed with RCCH. In contrast, the baseline used by Trios in the 2nd screening response are consistent with its 2017 year end report.

As was described in Trios Screening Response 1, Trios does not allocate corporate overhead as s separate cost center. LifePoint's corporate overhead is charged as a management fee and this management fee is fixed at 2% of net revenue. This explanation must have been acceptable to the CN Program because no further questions were asked in the 2nd screening.

Providence seems to question Trios' lack of corporate overhead because it is different from its own overhead allocation methodology. In fact, in the Kadlec CN application for additional acute care beds, system overhead represented 17.6% of net revenue. LifePoint is simply under a different business model and does not believe in burdening its hospitals with that level of corporate overhead.

Part of the difference is also explained by the fact that a high percentage of Trios costs are borne locally (and therefore, included in the direct expenses). Trios has local staff who provide accounting services, human resources, billing and other types of services that are often allocated at other larger systems (e.g., Providence). Trios' pro forma financials accurately reflect the overhead assessed to Trios."

Department Evaluation
To evaluate this sub-criterion, the department first reviewed the assumptions used by Trios to determine the projected PCIs. They based their volumes on 2017 actuals. In public comment, Providence questioned the reliability of the 2017 actuals reported to the department.

Outpatient volumes are provided to the department via survey with signed attestation. While the department will not conclude that these volumes were double counted, it is true that 2017 volumes were potentially anomalous, and certainly a departure from the norm. Trios acknowledged in their rebuttal that the 2018 volumes totaled 130, which is a marked decrease from 2017. Because of this, it is unclear whether this pattern would continue into the future, and may not be the most reliable measure for basing need for a new program.

Regardless, there is no numeric need for the program in the planning area (see discussion under WAC 246-310-210). Absent numeric need, the department cannot conclude that there are sufficient volumes to support a new program.

Trios based its revenue and expenses for Trios on the assumptions referenced above. Trios also used its current operations as a base-line for the revenue and expenses projected for the hospital as a whole with the proposed elective PCI program.

To assist in the evaluation of this sub-criterion, the Department of Health's Hospital Finance and Charity Care Program (HFCCP) reviewed the pro forma financial statements submitted by Trios for the hospital. To determine whether Trios would meet its immediate and long range capital costs, HFCCP reviewed the 2018 historical balance sheet for Trios. The information shown in Table 9 below shows both balance sheets. [source: HFCCP analysis, p2]

Department's Table 9
Trios Balance Sheets for Year 2018

Trios FY 2018			
Assets		Liabilities	
Current	28,750,613	Current	16,613,703
Board Designated	736,717	Long Term Debt	19,583,104
Property/Plant/Equipment	15,957,893	Other	576,090
Other	(11,122,111)	Equity	(2,449,784)
Total	34,323,112	Total	34,323,113

Fiscal Year End Financial and Utilization Report to WA ST Dept. of Health

For hospital projects, HFCCP 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. The 2018 balance sheets was used to review applicable ratios and pro forma financial information.

Table 10 compares statewide data for historical year 2018 and projected years 2020 through 2022. [source: HFCCP analysis, p3]

Department's Table 10
Current and Projected Debt Ratios

Trios			2018	2020	2021	2022	2023
Ratio Category	Trend	State 2018	Trios	Partial	CONy1	CON2	CONy3
Long Term Debt to Equity	B	0.460	(7.994)	(2.260)	(2.161)	(2.228)	(2.484)
Current Assets/Current Liabilities	A	2.702	1.731	1.810	1.786	1.764	1.748
Assets Funded by Liabilities	B	0.397	1.055	1.392	1.421	1.391	1.316
Operating Expense/Operating Revenue	B	0.976	1.185	1.023	1.008	0.994	0.984
Debt Service Coverage	A	5.014	(0.596)	1.991	2.874	3.627	4.181
Long Term Debt to Equity	Long Term Debt/Equity						
Current Assets/Current Liabilities	Current Assets/Current Liabilities						
Assets Funded by Liabilities	Current Liabilities+Long term Debt/Assets						
Operating Expense/Operating Revenue	Operating Expense/Operating Revenue						
Debt Service Coverage	Net Profit+Depr and Interest Exp/Current Mat. LTD and Interest Exp						

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

After reviewing the financial ratios above, staff from HFCCP provided the following statements. [source: HFCCP analysis, pp3-4]

"Because Trios already provides diagnostic and emergent PCI services, there is no capital cost for the project. The hospital has adequate resources to initiate this project.

I have also reviewed various ratios' that can give a snapshot of the financial health of Trios as of 2018. Also detailed are the three years following completion of the project. Statewide 2018 ratios are included as a comparison and are calculated from all community hospitals in Washington State whose fiscal year ended in that year. The data is collected by the Washington State Dept. of Health Community Health Systems section of the Health Systems Quality Assurance division. A table showing the results is on the following page.

The A means it is better if the number is above the State number and B means it is better if the number is below the state number.

CON year 3, (third full year following addition of elective PCI services fiscal year end ratios for Trios are either within or nearly within preferred range of the 2018 State average. Each ratio except long term debt to equity is outside the preferred range compared with the statewide average. The value for long term debt to equity is distorted and unreliable because Trios carries a negative balance of goodwill and also negative balance of owner's equity due to the circumstances of the purchase of Trios during its recent bankruptcy proceedings.

Of the remaining ratios, each shows an improving trend, except for current assets to current liabilities (current ratio). 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 Trios' 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. In this case, however, Trios' current ratio is well below and moving further away from the preferred range each year of the projection period.

Only Trios' operating expense to operating revenue and debt service coverage ratios are near the statewide average during the projection period.

Review of the financing and ratios makes it difficult to conclude that the immediate and long range capital needs of the hospital can be met, however the proposed project involves no capital expenditure and will not add to the debt of the facility. Trios is reasonably projecting operating revenue to exceed operating expenses with this project. Were this a project that required significant capital expenditure, approval would be unlikely, however Trios has demonstrated that this project can likely be properly funded and this criterion is met, contingent upon a finding of need for the service."

The Certificate of Need program concurs with the HFCCP analysis – that the financial feasibility of this proposal is largely contingent on need for the project. Based on the lack of numeric need for the project, the department cannot conclude that the immediate and long-range operating costs of the project can be met. **This sub-criterion is not 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

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

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)

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that Trios Health **did not meet** the applicable structure and process of care criteria in WAC 246-310-230.

(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.

Trios Health

Trios Health provided the following table and discussion regarding recruitment of staff necessary for the adult, elective PCI program. [source: Application pdf25]

Applicant's Table

Trios Health Cardiac Catheterization Laboratory
Current and Incremental FTEs by Year

Staff Position	Current FTEs	Year 1	Year 2	Year 3
Technologists	4.0	4.0	4.0	4.0
Nurses	2.0	2.0	2.0	2.0
Management	1.0	1.0	1.0	1.0
Total	7.0	7.0	7.0	7.0

Source: Applicant.

"Table 11 details the current number of FTEs for the existing cardiac catheterization lab. No additional staffing is required during the first three full years of expanded operation." [source: Application pdf25]

Public Comments
None

Rebuttal Comments
None

Department Evaluation

This section of the evaluation focuses on the staffing of the proposed project. Trios is currently licensed for 111 acute care beds, which includes a 10-bed level II intermediate care nursery. The addition of adult, elective PCI program does not require the addition of acute care beds. Trios states that the incremental volume increase does not require additional staff.

Information provided in the application demonstrates that Trios Health is a well-established provider of healthcare services Benton County and surrounding areas. The application demonstrates that Trios Health has the ability and expertise to recruit and retain a sufficient supply of qualified staff for this project. **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.

Trios Health

To demonstrate compliance with this sub-criterion, Trios Health provided the following information and specific line drawings of the catheterization labs at related to the infrastructure of Trios. Trios

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 pdf17, 27-28, Screening 1 Response Attachment 9]

"There will be no construction or alterations to the existing space."

"100% of Trios Health's existing catheterization lab nursing staff have current and direct experience and competencies working in an interventional laboratory. All nursing staff assigned to the cath lab are required to demonstrate competencies in PCI related technologies and have direct coronary care, critical care, or equivalent experience."

"Trios Health's protocol is that 24/7 in-house board-certified emergency room physicians and respiratory therapists be stat called to immediately respond to a respiratory code. If a patient needs ventilator management during transfer, our cath lab nurses and/or respiratory therapists will be available to accompany patients during transfer.

100% of Trios Health's Cath lab RN staff is 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."

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.

Trios Health
Trios Health provided the following information related to this sub-criterion. [source: Application, pdf25-26]

"Trios Health's PCI program is already staffed to perform emergency PCIs twenty-four hours per day, seven days per week. In house staffing of the cath lab happens weekdays from 7:30 a.m. – 5:00 p.m. A call team covers after hours and on weekends. The on-call staff are required to be in-house within 30 minutes of call. Table 12 identifies Trios Health's staffing plan detailing the twenty-four-hour coverage."

Applicant's Table

Current Cardiac Catheterization Lab Staffing

Hours	Staffing
0730 to 03:30 Monday- Friday	2 RNs and 4 Techs
On-Call 15:30-0730 Monday-Friday 24 hours Saturday and Sunday	1 RN and 2 Techs

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.**

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.

Trios Health

Trios provided the following statement related to this sub-criterion:

Trios Health has an agreement with Cardiosolutions for the staffing of the cath lab. Table 4 details the required information on these providers because of our current volumes, each provider can perform elective cases from program.. [source: Application pdf28]

Trios provided a letter from Cardiosolutions documenting physician volumes. [source: screening 1 response Attachment 1]

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. If this project were approvable, the department would attach a condition identifying that only physicians meeting the 50 PCIs per year standard would be permitted to perform PCIs at Trios. With agreement to this condition, the department concludes that **this sub-criterion would be met**.

WAC-246-310-730(1) Employ a sufficient number of properly credentialed physicians so that both emergent and elective PCIs can be performed

Trios Health
Trios Health provided the following information for this sub-criterion. [source: Application, pdf29]

"Trios Health has an agreement with Cardiosolutions for the staffing of the cath lab. Table 4 details the required information on these providers because of our current volumes, each provider can perform elective cases from program". [source: Application pdf28]

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Documentation provided by Trios Health demonstrated Trios will contract with a sufficient number of cardiologists to meet its projected number of PCIs, with net increase of PCIs in the planning area. **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

Trios Health
Trios Health provided job descriptions for their staff, along with the following information. [source: Application pdf27-28]

"100% of Trios Health's existing catheterization lab nursing staff have current and direct experience and competencies working in an interventional laboratory. All nursing staff assigned to the cath lab are required to demonstrate competencies in PCI related technologies and have direct coronary care, critical care, or equivalent experience."

"Trios Health's protocol is that 24/7 in-house board-certified emergency room physicians and respiratory therapists be stat called to immediately respond to a respiratory code. If a patient needs ventilator management during transfer, our cath lab nurses and/or respiratory therapists will be available to accompany patients during transfer.

100% of Trios Health's Cath lab RN staff is 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."

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 at Trios, the 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.
As an operating facility, Trios has 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).

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.

Trios Health
Trios Health provided its executed partnering agreement between Trios Health in Kennewick and Kadlec Regional Medical Center in Richland. [sources: Screening 1 Response pdf12; Application Attachment 2]

"The elective PCI Patient Transfer and Surgical Partnering Agreement (Attachment 2) contains the requested information. Specifically, page 1, #1 states:

Kadlec shall serve as Transferring Facility's back-up cardiac surgery hospital. In furtherance thereof:

- *Kadlec and the Transferring Facility shall:*
  - *i. Ensure that the Transferring Facility only performs elective PCIs during hours that Kadlec is providing cardiac surgery. Kadlec has 24/7 surgery capabilities but will notify the Transferring Facility if there is an unexpected gap in availability. The Transferring Facility is responsible for not scheduling elective PCIs during these gaps.*
  - *ii.* ***Coordinate availability of surgical teams and operating rooms using the Kadlec/St. Mary Transfer Center as the point of coordination.****"*

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided their partnering agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed partnering agreement submitted by Trios Health 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.

Trios Health
Trios Health provided its executed partnering agreement between Trios Health in Kennewick and Kadlec Regional Medical Center in Richland. [sources: Screening 1 Response pdf13; Application Attachment 2]

"The elective PCI Patient Transfer and Surgical Partnering Agreement (Attachment 2) contains the requested information. Specifically, page 1, #1 states:

Kadlec shall serve as Transferring Facility's back-up cardiac surgery hospital. In furtherance thereof:

- *Kadlec and the Transferring Facility shall:*
    - ***i. Ensure that the Transferring Facility only performs elective PCIs during hours that Kadlec is providing cardiac surgery. Kadlec has 24/7 surgery capabilities but will notify the Transferring Facility if there is an unexpected gap in availability. The Transferring Facility is responsible for not scheduling elective PCIs during these gaps.***
    - *ii. Coordinate availability of surgical teams and operating rooms using the Kadlec/St. Mary Transfer Center as the point of coordination."*

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided their partnering agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed partnering agreement submitted by Trios Health 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.

Trios Health
Trios Health provided its executed partnering agreement between Trios Health in Kennewick and Kadlec Regional Medical Center in Richland. [sources: Screening 1 Response pdf13; Application Attachment 2]

The elective PCI Patient Transfer and Surgical Partnering Agreement (Attachment 2) contains the requested information. Specifically, page 1, #4 states:

Clinical Data and Transfer Memorandum. *Transferring Facility will be responsible for the transfer all clinical data, including images and videos, to Kadlec. The Transferring Facility will provide this data to the Kadlec/St. Mary Transfer Center prior to transport if determined necessary for the Provider discussion. The remaining needed information will be sent via fax or with the Emergency Transport agency during transport.*

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided their partnering agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed partnering agreement submitted by Trios Health 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.

Trios Health
Trios Health provided its executed partnering agreement between Trios Health in Kennewick and Kadlec Regional Medical Center in Richland. [sources: Screening 1 Response pdf13; Application Attachment 2]

"The elective PCI Patient Transfer and Surgical Partnering Agreement (Attachment 2) contains the requested information. Specifically, page 1, #3 states:

Acceptance of Patients. *The physician at the Transferring Facility shall immediately notify the Kadlec/St. Mary Transfer Center regarding the clinical reasons for urgent transfer and the patient's clinical condition. The transferring physician and the Transfer Center shall cover and jointly determine the patient's appropriateness for transfer. Kadlec shall accept, as promptly as possible, all appropriate patients referred for transfer under the terms of this Agreement."*

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided their partnering agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed partnering agreement submitted by Trios Health 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.

Trios Health
Trios Health provided its executed partnering agreement between Trios Health in Kennewick and Kadlec Regional Medical Center in Richland. [sources: Screening 1 Response pdf14; Application Attachment 2]

"The elective PCI Patient Transfer and Surgical Partnering Agreement (Attachment 2) contain the requested information. Specifically, page 1, #3 states:

Acceptance of Patients. *The physician at the Transferring Facility shall immediately notify the Kadlec/St. Mary Transfer Center regarding the clinical reasons for urgent transfer and the patient's clinical condition. The transferring physician and the Transfer Center shall cover and jointly determine the patient's appropriateness for transfer. Kadlec shall accept, as promptly as possible, all appropriate patients referred for transfer under the terms of this Agreement."*

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided their partnering agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed partnering agreement submitted by Trios Health 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.

Trios Health
Trios Health provided its executed partnering agreement between Trios Health in Kennewick and Kadlec Regional Medical Center in Richland. [sources: Screening 1 Response pdf14; Application Attachment 2, Attachment 3]

"The elective PCI Patient Transfer and Surgical Partnering Agreement (Attachment 2) contains the requested information. Specifically, page 2, #7 states:

Transportation of Patient. *Transferring Facility is responsible for and shall arrange for transportation of the patient to Kadlec in accordance with the following:*

> *a) Transferring Facility is responsible for establishing 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 Kadlec.*

The Medical Transportation Service Agreement (Attachment 3) contains the requested information. Specifically, page 1, section C states:

KFD is a qualified emergency transport provider and is willing to provide the necessary transportation services as stated herein in order to facilitate the care and timely transport of Elective PCI patients from Trios Health to a hospital providing on- site cardiac surgery."

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided their partnering agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed partnering agreement submitted by Trios Health 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.

Trios Health
Trios Health provided its executed partnering agreement between Trios Health in Kennewick and Kadlec Regional Medical Center in Richland. [sources: Screening 1 Response pdf15; Application Attachment 2, Attachment 3]

"The elective PCI Patient Transfer and Surgical Partnering Agreement (Attachment 2) contains the requested information. Specifically, page 2, #7 states:

Transportation of Patient. *Transferring Facility is responsible for and shall arrange for transportation of the patient to Kadlec in accordance with the following:*

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

The Medical Transportation Service Agreement (Attachment 3) contains the requested information. Specifically, page 1, #1 states:

KFD will make every attempt to meet or exceed the requirements of WAC 246-310-735 to initiate emergency transportation beginning within twenty minutes of the initial notification of complication requiring transport to an open-heart hospital. In the unlikely circumstance that a KFD medic unit is precluded from arriving at Trios Health within the specified timeframe, KFD will immediately notify Trios Health and ensure a transport unit arrives as soon as possible. Additionally, KFD will make every attempt to transport patients experiencing complications during elective PCIs that require transfer to a backup hospital with on-site cardiac surgery, within total transport time of one hundred twenty minutes or less."

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided their partnering agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed partnering agreement submitted by Trios Health 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).

Trios Health
Trios Health provided its executed partnering agreement between Trios Health in Kennewick and Kadlec Regional Medical Center in Richland. [sources: Screening 1 Response pdf15-16; Application Attachment 2, Attachment 3]

"The elective PCI Patient Transfer and Surgical Partnering Agreement (Attachment 2) contains the requested information. Specifically, page 2, #7 states:

Transportation of Patient. *Transferring Facility is responsible for and shall arrange for transportation of the patient to Kadlec in accordance with the following:*

> *d) The Transferring Facility will require documentation and is responsible to ensure that emergency transport staff 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) or the Transferring Facility will be responsible to provide the staff to accompany the patients with these capabilities.*

The Medical Transportation Service Agreement (Attachment 3) contains the requested information. Specifically, page 1, #2 states:

> *KFD will ensure an adequate number of their staffed personnel are advanced cardiac life support (ACLS) certified and possess the skills, experience, and equipment required to transfer Elective PCI patients with complications, and to monitor and treat said patients en-route pursuant to the aforementioned state laws and regulations. Trios Health will also provide ACLS certified staff with the skills, experience and equipment necessary to monitor and treat these types of patients en-route, and to manage an intra-aortic balloon pump (IABP). Trios Health shall provide the IABPs. When available, and as time permits, KFD personnel will transport Trios Health staff back to Trios Health in a timely manner."*

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided their partnering agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed partnering agreement submitted by Trios Health 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.

Trios Health
Trios Health provided its executed partnering agreement between Trios Health in Kennewick and Kadlec Regional Medical Center in Richland. [sources: Screening 1 Response pdf16; Application Attachment 2, Attachment 3]

"The elective PCI Patient Transfer and Surgical Partnering Agreement (Attachment 2) contains the requested information. Specifically, page 2, #7 states:

> ***Transportation of Patient.*** *Transferring Facility is responsible for and shall arrange for transportation of the patient to Kadlec in accordance with the following:*
>
> *c) Transferring Facility is responsible to ensure and will document the transportation time from the decision to transfer the patient with an elective PCI complication to arrival in the operating room of Kadlec and will ensure that transportation time is less than one hundred and twenty minutes.*

The Medical Transportation Service Agreement (Attachment 3), contains the requested information. Specifically, page 1, #1 states:

> *KFD will make every attempt to meet or exceed the requirements of WAC 246- 310-735 to initiate emergency transportation beginning within twenty minutes of the initial notification of complication requiring transport to an open-heart hospital. In the unlikely circumstance that a KFD medic unit is precluded from arriving at Trios Health within the specified timeframe, KFD will immediately notify Trios Health and ensure a transport unit arrives as soon as possible. Additionally, KFD will make every attempt to transport patients experiencing complications during elective PCIs that require transfer to a backup hospital with on-site cardiac surgery, within total transport time of one hundred twenty minutes or less."*

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided their partnering agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed partnering agreement submitted by Trios Health 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.*

Trios Health
Trios Health provided its executed partnering agreement between Trios Health in Kennewick and Kadlec Regional Medical Center in Richland. [sources: Screening 1 Response pdf17; Application Attachment 2, Attachment 3]

"The elective PCI Patient Transfer and Surgical Partnering Agreement (Attachment 2) contains the requested information. Specifically, page 1, #1 states:

> ***On-Site Cardiac Surgery Hospital.*** *Kadlec shall serve as Transferring Facility's back-up cardiac surgery hospital. In furtherance thereof:*
>
> *a) Kadlec and the Transferring Facility shall:*
>
> *ii) Participate in at least two annual timed emergency transportation drills. It is the Transferring Facility's responsibility to coordinate these drills and to report outcomes to their Quality Assurance Program.*

The Medical Transportation Service Agreement (Attachment 3), contains the requested information. Specifically, page 1, #3 states:

> *Trios Health will coordinate two timed emergency transportation drills each year with KFD and the hospital providing on-site cardiac surgery. Trios Health will report the outcomes of each drill to its quality assurance program, the KFD Fire Chief, and to the quality assurance manager of the hospital providing on-site cardiac surgery."*

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided their partnering agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed partnering agreement submitted by Trios Health 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

Trios Health
Trios Health provided its executed partnering agreement between Trios Health in Kennewick and Kadlec Regional Medical Center in Richland. [sources: Screening 1 Response pdf17; Application Attachment 2]

"The elective PCI Patient Transfer and Surgical Partnering Agreement (Attachment 2) contains the requested information. Specifically, page 1, #2 states:

Patient Informed Consent. *Transferring Facility is responsible for informing patients that they will have to be urgently transferred if they have a complication during their PCI. The Transferring Facility agrees to acquire patient signed, informed consent for adult elective (and emergent) PCIs performed at the Transferring Facility. The consent forms will explicitly communicate to the patients that the intervention at the Transferring Facility is being performed without on-site surgery back-up and address risks related to transfer, the risk of urgent surgery, and refer to this established transfer agreement with Kadlec."*

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided their partnering agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed partnering agreement submitted by Trios Health 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.*

Trios Health
Trios Health provided its executed partnering agreement between Trios Health in Kennewick and Kadlec Regional Medical Center in Richland. [sources: Screening 1 Response pdf18; Application Attachment 2]

"The elective PCI Patient Transfer and Surgical Partnering Agreement (Attachment 2) contains the requested information. Specifically, page 1, #1 states:

On-Site Cardiac Surgery Hospital. *Kadlec shall serve as Transferring Facility's back-up cardiac surgery hospital. In furtherance thereof:*

a) *Kadlec and the Transferring Facility shall:*

iii) *Participate in joint quarterly conferences in which a significant number of preoperative and postoperative cases, including all transport cases, are reviewed. These conferences will be the responsibility of the Transferring Facility to coordinate."*

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided their partnering agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed partnering agreement submitted by Trios Health 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.).

Trios Health
Trios Health provided its executed partnering agreement between Trios Health in Kennewick and Kadlec Regional Medical Center in Richland. [sources: Screening 1 Response pdf18; Application Attachment 2]

"The elective PCI Patient Transfer and Surgical Partnering Agreement (Attachment 2) contains the requested information. Specifically, page 2, #1 states:

> ***b)*** *Kadlec shall report peak volume periods to Transferring Facility and the Transferring Facility will be responsible to secure alternate back-up surgical services when necessary."*

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided their partnering agreement to meet many of the PCI standards.

Specific to this sub-criterion, the executed partnering agreement submitted by Trios Health demonstrated compliance with this standard. **This sub-criterion is met**.

(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.

Trios Health

The specific question in the application form related to this sub-criterion requests the applicant to identify if the owner, operator, or physician(s) identified in this application has had any of the following in this state or other states:

a. Decertification from Medicare
b. Decertification from Medicaid
c. Convictions related to the competency to practice medicine or own or operate a hospital.
d. Denial of a license
e. Revocation of a license
f. Voluntary withdrawal from Medicare or Medicaid while decertification processes were pending.

In response to the specific question above, Trios provided the following statement. [source: Application, pdf34]

"Neither Trios Health 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

As a part of this review, the department must conclude that the proposed services provided by an applicant would be provided in a manner that ensures safe and adequate care to the public.[9] To accomplish this task, the department reviewed the quality of care and compliance history for Trios and the facilities associated with their parent corporation

Washington State Survey Data
The four hospitals owned and operated by LifePoint Health include Trios Health, Lourdes Medical Center, Lourdes Counseling Center, and Capital Medical Center.

All of the hospitals listed above are licensed and certified by CMS. [source: ILRS]

The department also reviewed the survey deficiency history for years 2016 through the present for all LifePoint-affiliated hospitals located in Washington State. No enforcement actions have taken place against their facilities during that period.

Other States
In addition to a review of all Washington State facilities owned and operated by LifePoint, the department also examined a sample of LifePoint facilities nationwide. According to information in the application and its website, LifePoint operates healthcare facilities across the United States. The department looked up compliance with federal standards at all 87 LifePoint facilities across the

[9] WAC 246-310-230(5)

United States. The department found that generally LifePoint hospitals operate in compliance with federal standards without noticeable patterns in non-compliance.[10]

In addition to the facility review above, Trios provided the names and credential numbers for all physicians who could perform PCIs at Trios and current staff in the cardiac catheterization lab. A review of each providers credential revealed no sanctions.

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.

Trios Health
In response to this standard, Trios Health provided their PCI Performance Monitoring and Results Reporting Policy. [source: Screening 1 Response pdf19, Application Exhibit 5]

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided a PCI Performance Monitoring and Results Reporting Policy to meet many of the PCI standards.

Specific to this sub-criterion, the draft PCI Continuous Quality Improvement Plan submitted by Trios Health 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

Trios Health
In response to this standard, Trios Health provided their PCI Performance Monitoring and Results Reporting Policy. [source: Screening 1 Response pdf19, Application Exhibit 5]

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided a PCI Performance Monitoring and Results Reporting Policy to meet many of the PCI standards.

Specific to this sub-criterion, the draft PCI Continuous Quality Improvement Plan submitted by Trios Health demonstrated compliance with this standard. **This sub-criterion is met.**

[10] The 87 hospitals averaged 0.25 surveys with condition-level findings over the last five years.

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

Trios Health
In response to this standard, Trios Health provided their PCI Performance Monitoring and Results Reporting Policy. [source: Screening 1 Response pdf19, Application Exhibit 5]

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided a PCI Performance Monitoring and Results Reporting Policy to meet many of the PCI standards.

Specific to this sub-criterion, the draft PCI Continuous Quality Improvement Plan submitted by Trios Health 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.

Trios Health
In response to this standard, Trios Health provided their PCI Performance Monitoring and Results Reporting Policy. [source: Screening 1 Response pdf19, Application Exhibit 5]

Public Comments
None

Rebuttal Comments
None

Department Evaluation
Trios Health provided a PCI Performance Monitoring and Results Reporting Policy to meet many of the PCI standards.

Specific to this sub-criterion, the draft PCI Continuous Quality Improvement Plan submitted by Trios Health demonstrated compliance with this standard. **This sub-criterion is met.**

Based on the above information, the department concludes that Trios demonstrated reasonable assurance that Trios Health would continue to operate in compliance with state and federal requirements if this project is approved. **This sub criterion – WAC 246-310-230(3) – 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.

Trios Health

Trios provided their Patient Transfer Agreement to demonstrate conformance with this sub-criterion. [source: Screening 1 response Attachment 2]

Public Comments

None

Rebuttal Comments

None

Department Evaluation

This evaluation takes into consideration the numeric methodology and rules related to the establishment of a new adult, elective PCI program within a planning area.

However, there is not sufficient need to approve a new PCI program as required under WAC-310-720(2)(a). Therefore, a new provider in planning area #2 cannot be approved. For those reasons, the department concludes that approval of this project during this review cycle may result in unwarranted fragmentation of PCI services in the planning area. **This sub-criterion is not 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.

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 and agreement to the conditions identified in the conclusion section of this evaluation, the department determines that Trios Health **did not meet** the applicable cost containment 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 criteria contained throughout WAC 246-310 related to the specific project type. The adopted superiority criteria are objective measures used to compare competing projects and make the determination between two or more approvable projects which is the best alternative. If WAC 246-310 does not contain any service or facility type superiority criteria as directed by WAC 246-310-200(2)(a)(i), then the department would look to WAC 246-310-240(2)(a)(ii) and (b) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b), then using its experience and expertise, the department would assess the competing projects and determine which project should be approved.

Department Evaluation

Step One:

The department concluded that Trios did **not meet** the applicable review criteria under WAC 246-310-210, 220, and 230. Therefore, the department need not move to step two.

Public Comment

None

Rebuttal

None

Department Evaluation

In earlier portions of this evaluation, the department concluded that the applicant had not demonstrated the project's conformance with WAC 246-310-210, 2230, and 230.

HFCCP provided the following analysis of this sub-criterion:

"In its application, Trios noted that it had not considered any alternative to submitting this application. When asked by the department in screening to explain this lack of alternatives, Trios restated arguments from its application that the department's data for projecting need was incomplete, therefore need was understated. Trios also noted that in 2017, it transferred nearly 40 patients who needed therapeutic PCI services, and that those patients required duplicate procedures, delay in treatment, and higher costs.

In neither its initial application nor in its responses to the screening questions did Trios provide any analysis of alternatives to the project proposed in this application, other than by discussion of the data used in the department's need projection methodology. Without any consideration of alternatives to this project, Trios has failed to document that its proposal can be deemed the superior option for treatment of patients in its planning area.

While the project proposed by Trios carries no capital expenditure, if the project incurs ongoing costs to patients and payors that are not justified by its being the superior alternative, the project would be found non-compliant with this criterion. Because Trios provided no discussion of the costs or benefits of any alternatives, this criterion is not satisfied." [source: HFCCP analysis pp4-5]

Because of this, the department cannot conclude that approval of this facility is the superior alternative to meet the health care needs of the residents of the planning area.

This sub-criterion is **not met**.

(2) In the case of a project involving construction:
(a) The costs, scope, and methods of construction and energy conservation are reasonable;

Department Evaluation
This project does not involve construction – this sub-criterion is not applicable.

(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
This project does not involve construction – this sub-criterion is not applicable.

(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.

Trios Health
"Being able to perform elective PCI will allow our already highly trained and competent cath lab staff to perform more cases which will assure skills while also realizing productivity increases and operating efficiencies. Today, unless a patient is actively having a heart attack or significant chest pain, the interventional cardiologist, cannot, even with the patient already is in the laboratory undertake the therapeutic PCI procedure. Additional costs, frequently involving an ambulance transport, and an additional catheterization procedure as well as additional stress to the patient and his/her family and delays in treatment are too frequent occurrences. Addressing the patient's clinical need at the time of diagnosis holds great promise for reducing total costs of care and improving patient satisfaction." [source: Application, pdf36]

"The current delivery system is costly and adds unnecessary risk for patient s(two groin punctures, two procedures, ambulance transport, etc. This 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." [source: Application, pdf36]

Public Comments
None

Rebuttal Comments
None

Department Evaluation
For this project, Trios did not meet the applicable review criteria under WAC 246-310-210, 220, and 230. HFCCP provided the following statement regarding this sub-criterion:

"Contingent upon a finding of need, this project would improve delivery of PCI services within the service area." [source HFCCP analysis p5]

Based on the lack of numeric need, the department concludes **this sub-criterion is not met**.

Appendix A

Department of Health
Updated 2018-2019 Percutaneous Coronary Intervention Numeric Need Methodology
Using COAP data

Washington State Department of Health

Planning Area	County	2017 15+ Pop	2017 PCI Pop./1000 (1a)	2017 PCIs (COAP ONLY)	WA pts in Oregon	Total PSA PCIs	2017 Use Rate (1b)	2022 15+ Pop	2022 PCI Pop./1000 (1a)	2022 Use Rate	2022 Projected Demand (2a)	Current PCI Capacity (3d)	2022 Projected Net Need (4)	Projected Need/200 (5a)	# of New Programs (5b)
PSA 1	Adams	13,548		13				14,683							
	Asotin	18,439		<10				19,104							
	Ferry	6,604		<10				6,693							
	Grant	73,302		92				80,408							
	Lincoln	8,978		10				9,072							
	Pend Oreille	11,434		20				11,997							
	Spokane	405,615		571	<10			427,280							
	Stevens	37,284		43				39,117							
	Whitman	41,824		28				42,294							
	Total:	**617,028**	**617.03**			**787**	**1.28**	**650,647**	**650.6**	**1.28**	**830**	**1,614**	**-784**	**-3.92**	**0**
PSA 2	Benton	151,893		24	<10			163,011							
	Columbia	3,441		<10				3,375							
	Franklin	66,268		<10				76,448							
	Garfield	1,912		<10				1,902							
	Walla Walla	50,106		70				51,201							
	Total:	**273,620**	**273.62**			**115**	**0.42**	**295,936**	**295.9**	**0.42**	**124**	**678**	**-554**	**-2.77**	**0**
PSA 3	Chelan	61,452		132				64,485							
	Douglas	32,868		64				35,902							
	Okanogan	34,170		82	<10			35,156							
	Total:	**128,490**	**128.49**			**279**	**2.17**	**135,543**	**135.5**	**2.17**	**294**	**310**	**-16**	**-0.08**	**0**
PSA 4	Kittitas	37,588		91				40,284							
	Klickitat East	6,644		<10	<10			6,946							
	Yakima	189,022		402	<10			199,776							
	Total:	**233,254**	**233.25**			**499**	**2.14**	**247,005**	**247.0**	**2.14**	**528**	**260**	**268**	**1.34**	**1**
PSA 5	Clark	377,303		134	131			417,030							
	Cowlitz	86,477		80	57			90,431							
	Klickitat West	11,941		<10	17			12,692							
	Skamania	9,860		<10	<10			10,471							
	Wahkiakum	3,484		<10	<10			3,509							
	Total:	**489,064**	**489.06**			**441**	**0.90**	**534,133**	**534.1**	**0.90**	**482**	**774**	**-292**	**-1.46**	**0**
PSA 6	Grays Harbor	60,899		271				61,848							
	Lewis	64,035		208	<10			66,860							
	Mason	54,211		229				58,910							
	Pacific	18,237		26	19			18,277							
	Thurston	227,712		645	<10			248,976							
	Total:	**425,094**	**425.09**			**1409**	**3.31**	**454,871**	**454.9**	**3.31**	**1,508**	**1,093**	**415**	**2.07**	**2**

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

Planning Area	County	2017 15+ Pop	2017 PCI Pop./1000 (1a)	2017 PCIs (COAP ONLY)	WA pts in Oregon	Total PSA PCIs	2017 Use Rate (1b)	2022 15+ Pop	2022 PCI Pop./1000 (1a)	2022 Use Rate	2022 Projected Demand (2a)	Current PCI Capacity (3d)	2022 Projected Net Need (4)	Projected Need/200 (5a)	# of New Programs (5b)
PSA 7	Pierce East	313,630		708	<10			336,832							
	Total:	**313,630**	**313.63**			**709**	**2.26**	**336,832**	**336.8**	**2.26**	**761**	**313**	**448**	**2.24**	**2**
PSA 8	Pierce West	383,943		911	<10			404,409							
	Total:	**383,943**	**383.94**			**913**	**2.38**	**404,409**	**404.4**	**2.38**	**962**	**1,386**	**-424**	**-2.12**	**0**
PSA 9	King East	987,724		1987	<10			1,063,175							
	Total:	**987,724**	**987.72**			**1993**	**2.02**	**1,063,175**	**1063.2**	**2.02**	**2,145**	**1,767**	**378**	**1.89**	**1**
PSA 10	King West	837,532		1196	<10			895,491							
	Total:	**837,532**	**837.53**			**1198**	**1.43**	**895,491**	**895.5**	**1.43**	**1,281**	**2,651**	**-1,370**	**-6.85**	**0**
PSA 11	Snohomish	639,666		1688	<10			700,169							
	Total:	**639,666**	**639.67**			**1690**	**2.64**	**700,169**	**700.2**	**2.64**	**1,850**	**1,372**	**478**	**2.39**	**2**
PSA 12	Island	68,078		205				71,044							
	San Juan	14,679		24				15,379							
	Skagit	101,557		283				109,554							
	Total:	**184,314**	**184.31**			**512**	**2.78**	**195,978**	**196.0**	**2.78**	**544**	**273**	**271**	**1.36**	**1**
PSA 13	Clallam	62,941		220	<10			64,830							
	Jefferson	28,201		112				29,721							
	Kitsap	218,159		558				231,228							
	Total:	**309,302**	**309.30**			**892**	**2.88**	**325,778**	**325.8**	**2.88**	**940**	**674**	**266**	**1.33**	**1**
PSA 14	Whatcom	181,277		389	<10			195,977							
	Total:	**181,277**	**181.28**			**390**	**2.15**	**195,977**	**196.0**	**2.15**	**422**	**467**	**-45**	**-0.23**	**0**

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 CHARS and DOH survey data

Planning Area	County	2017 15+ Pop	2017 PCI Pop./1000 (1a)	2017 Inpatient PCIs CHARS	2017 Outpatient PCIs SURVEY	WA pts in Oregon	Total PSA PCIs	2017 Use Rate (1b)	2022 15+ Pop	2022 PCI Pop./1000 (1a)	2022 Use Rate	2022 Projected Demand (2a)	Current PCI Capacity (3d)	2022 Projected Net Need (4)	Projected Need/200 (5a)	# of New Programs (5b)
PSA 1	Adams	13,548		10	<10				14,683							
	Asotin	18,439		<10	<10				19,104							
	Ferry	6,604		<10	<10				6,693							
	Grant	73,302		76	26				80,408							
	Lincoln	8,978		14	11				9,072							
	Pend Oreille	11,434		27	12				11,997							
	Spokane	405,615		561	213	<10			427,280							
	Stevens	37,284		62	21				39,117							
	Whitman	41,824		23	10				42,294							
	Total:	**617,028**	**617.03**				**1088**	**1.76**	**650,647**	**650.6**	**1.76**	**1,147**	**1,153**	**-6**	**-0.03**	**0**
PSA 2	Benton	151,893		189	190	<10			163,011							
	Columbia	3,441		<10	<10				3,375							
	Franklin	66,268		64	37				76,448							
	Garfield	1,912							1,902							
	Walla Walla	50,106		73	32				51,201							
	Total:	**273,620**	**273.62**				**598**	**2.19**	**295,936**	**295.9**	**2.19**	**647**	**459**	**188**	**0.94**	**0**
PSA 3	Chelan	61,452		86	25				64,485							
	Douglas	32,868		52	15				35,902							
	Okanogan	34,170		61	21	<10			35,156							
	Total:	**128,490**	**128.49**				**261**	**2.03**	**135,543**	**135.5**	**2.03**	**275**	**291**	**-16**	**-0.08**	**0**
PSA 4	Kittitas	37,588		45	35				40,284							
	Klickitat East	6,644		<10	<10	<10			6,946							
	Yakima	189,022		245	123	<10			199,776							
	Total:	**233,254**	**233.25**				**459**	**1.97**	**247,005**	**247.0**	**1.97**	**486**	**221**	**265**	**1.33**	**1**
PSA 5	Clark	377,303		376	152	131			417,030							
	Cowlitz	86,477		153	87	57			90,431							
	Klickitat West	11,941		<10	<10	17			12,692							
	Skamania	9,860		<10	<10	<10			10,471							
	Wahkiakum	3,484		<10		<10			3,509							
	Total:	**489,064**	**489.06**				**1003**	**2.05**	**534,133**	**534.1**	**2.05**	**1,095**	**802**	**293**	**1.47**	**1**
PSA 6	Grays Harbor	60,899		128	110				61,848							
	Lewis	64,035		119	75	<10			66,860							
	Mason	54,211		114	94				58,910							
	Pacific	18,237		14	12	19			18,277							
	Thurston	227,712		324	231	<10			248,976							
	Total:	**425,094**	**425.09**				**1251**	**2.94**	**454,871**	**454.9**	**2.94**	**1,339**	**941**	**398**	**1.99**	**1**

Source: County_Age Pop. Projections OFM 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

Planning Area	County	2017 15+ Pop	2017 PCI Pop./1000 (1a)	2017 Inpatient PCIs CHARS	2017 Outpatient PCIs SURVEY	WA pts in Oregon	Total PSA PCIs	2017 Use Rate (1b)	2022 15+ Pop	2022 PCI Pop./1000 (1a)	2022 Use Rate	2022 Projected Demand (2a)	Current PCI Capacity (3d)	2022 Projected Net Need (4)	Projected Need/200 (5a)	# of New Programs (5b)
PSA 7	Pierce East	313,630		372	254	<10			336,832							
	Total:	**313,630**	**313.63**				**627**	**2.00**	**336,832**	**336.8**	**2.00**	**673**	**307**	**366**	**1.83**	**1**
PSA 8	Pierce West	383,943		472	264	<10			404,409							
	Total:	**383,943**	**383.94**				**738**	**1.92**	**404,409**	**404.4**	**1.92**	**777**	**1,194**	**-417**	**-2.08**	**0**
PSA 9	King East	987,724		924	919	<10			1,063,175							
	Total:	**987,724**	**987.72**				**1849**	**1.87**	**1,063,175**	**1063.2**	**1.87**	**1,990**	**1,666**	**324**	**1.62**	**1**
PSA 10	King West	837,532		689	478	<10			895,491							
	Total:	**837,532**	**837.53**				**1169**	**1.40**	**895,491**	**895.5**	**1.40**	**1,250**	**2,332**	**-1,082**	**-5.41**	**0**
PSA 11	Snohomish	639,666		945	546	<10			700,169							
	Total:	**639,666**	**639.67**				**1493**	**2.33**	**700,169**	**700.2**	**2.33**	**1,634**	**1,165**	**469**	**2.35**	**2**
PSA 12	Island	68,078		130	48				71,044							
	San Juan	14,679		15	<10				15,379							
	Skagit	101,557		153	47				109,554							
	Total:	**184,314**	**184.31**				**401**	**2.18**	**195,978**	**196.0**	**2.18**	**426**	**162**	**264**	**1.32**	**1**
PSA 13	Clallam	62,941		99	104	<10			64,830							
	Jefferson	28,201		65	30				29,721							
	Kitsap	218,159		247	258				231,228							
	Total:	**309,302**	**309.30**				**805**	**2.60**	**325,778**	**325.8**	**2.60**	**848**	**587**	**261**	**1.30**	**1**
PSA 14	Whatcom	181,277		269	135	<10			195,977							
	Total:	**181,277**	**181.28**				**405**	**2.23**	**195,977**	**196.0**	**2.23**	**438**	**501**	**-63**	**-0.32**	**0**

Source: County_Age Pop. Projections OFM August 2017
Sub county Pop Claritas 2017-2022
PCI Outpatient 2017 Data Survey
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