

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

April 8, 2022

Emily Studebaker, Esq. Studebaker Nault, PLLC e-mail: <u>estudebaker@studebakernault.com</u>

RE: Certificate of Need Application #21-60 Tri-City Orthopaedic Clinic, PSC.

Dear Ms. Studebaker:

We have completed review of the Certificate of Need application submitted by Tri-City Orthopaedic Clinic, P.S.C., proposing to operate the existing Tri-City Orthopaedic Kennewick Surgery Center as a CN-approved, four operating room ambulatory surgical facility within the Benton-Franklin Secondary Health Services Planning Area. Attached is a written evaluation of the application.

For the reasons stated in the enclosed decision, the application is consistent with the applicable criteria of the Certificate of Need Program, provided Tri-City Orthopaedic Clinic, P.S.C. agrees to the following in its entirety.

Project Description

This certificate approves the establishment of an ambulatory surgical facility in the Benton-Franklin Secondary Health Services Planning Area at 6703 West Rio Grande Avenue in Kennewick [99336]. The surgical facility will have four operating rooms and provide orthopedics; pain management; ear, nose and throat surgery; general surgery, maxillofacial surgery; oral surgery; plastic surgery; and vascular surgery. The surgical facility will serve patients who require surgical services, are not expected to require hospitalization, and can be served appropriately in an outpatient setting.

Conditions

- 1. Tri-City Orthopaedic Clinic, PSC., dba Tri-City Orthopaedic Kennewick Surgery Center agrees with the project description as stated above. Tri-City Orthopaedic Clinic, PSC., dba Tri-City Orthopaedic Kennewick Surgery Center further agrees that any change to the project as described in the project description above is a new project that requires a new Certificate of Need.
- 2. Tri-City Orthopaedic Clinic, PSC., dba Tri-City Orthopaedic Kennewick Surgery Center will maintain Medicare and Medicaid certification for the surgery center.
- 3. The surgery center will provide charity care in compliance with its charity care policy reviewed for this project. Tri-City Orthopaedic Clinic, PSC., dba Tri-City Orthopaedic

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Kennewick Surgery Center will use reasonable efforts to provide charity care in the amount consistent with the three-year average of charity care provided by the hospitals in the Benton-Franklin Secondary Health Services Planning Area. The three-year average for years 2017 – 2019 is 1.50% of gross revenue and 4.04% of adjusted revenue.

- 4. Tri-City Orthopaedic Clinic, PSC., dba Tri-City Orthopaedic Kennewick Surgery Center will maintain records of charity care applications received and the dollar amount of charity care discounts granted at the surgery center. The records must be available upon request.
- 5. Tri-City Orthopaedic Clinic, PSC., dba Tri-City Orthopaedic Kennewick Surgery Center will ensure that no staff will perform healthcare services at the surgery center without current credentials.

Approved Costs

The approved capital expenditure is \$192,244.32 and consists of moveable equipment and associated sales tax.

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

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

Send your written response to the Certificate of Need Program at this e-mail address: <u>FSLCON@doh.wa.gov</u>.

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

Sincerely,

Eric Hernandez, Program Manager Certificate of Need Office of Community Health Systems

Attachment

EVALUATION DATED APRIL 8, 2022, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY TRI-CITY ORTHOPAEDIC CLINIC, PSC. PROPOSING TO ESTABLISH AN AMBULATORY SURGICAL FACILITY IN KENNEWICK

APPLICANT DESCRIPTION

Tri-City Orthopaedic Clinic

Tri-City Orthopaedic Clinic, PSC., is a Washington State corporation established in October 1997. It is governed by seven, physicians: Faustin Stevens, MD; Johnathan Perry, MD; Mark Merrell, MD; Janmeet Sahota, MD; Allen Shoham, MD; Uel Hansen, MD; Judd Fitzgerald, MD; and Cathryn Vadala, MD.¹ Tri-City Orthopaedic Clinic owns, operates, and manages two Certificate of Need exempt ambulatory surgical centers, 'The Surgery Center at Tri-City Orthopaedic' in Richland and 'The Surgery Center at Tri-City Orthopaedic Clinic' in Kennewick. The latter, Kennewick, facility is the subject of this evaluation. The applicant will be referenced in this evaluation as 'Tri-City Orthopaedic Clinic' or 'TCO.' The Surgery Center at Tri-City Orthopaedic Clinic' or 'TCO.' The Surgery Center at Tri-City Orthopaedic Clinic' or 'TCO.' The Surgery Center at Tri-City Orthopaedic Clinic' or 'TCO.' The Surgery Center at Tri-City Orthopaedic Clinic will be referenced as 'TCO Kennewick.'

PROJECT DESCRIPTION AND BACKGROUND INFORMATION

Tri-City Orthopaedic Clinic

Within the application, TCO provided the following rationale for submission of this application. [source: Application, p7]

"The establishment of the proposed ASF is being undertaken to provide additional capacity for outpatient surgical services in the Benton-Franklin County secondary health services planning area. The proposed ASF will not duplicate services. Instead, it is necessary in order to expand the services offered at Tri-City Orthopaedic Kennewick Surgery Center to all patients and providers in a health planning area, which has need for additional outpatient ORs.

No CN-approved ASF in the Benton-Franklin County secondary health services planning area offers ear, nose and throat surgery, general surgery, maxillofacial surgery, oral surgery, or vascular surgery. Moreover, only one CN-approved ASF in the planning area that is unaffiliated with a hospital offers orthopedic surgery. Accordingly, the ability of patients in the Benton-Franklin County secondary health services planning area to obtain these services at an ASF, an outpatient surgical setting that is significantly more cost-effective for patients and payors, is currently limited. The proposed ASF would alleviate this access issue."

TCO Kennewick has been operating as a CN-exempt facility under a series of exemption requests, the most recent of which was issued in October 2014. As a result, portions of this review will acknowledge that the surgery center is currently operational, however, under CN statute, this project is reviewed as the establishment of a new healthcare facility.²

The surgery center has four operating rooms (ORs) and is currently located at 6703 West Rio Grande Avenue in Kennewick [99336] within Benton County. This application does not propose to relocate the surgery center or increase the number of ORs. TCO intends to expand the types of services provided at the surgery center from its current offerings of orthopedics and pain management to also include ear, nose and throat; general; maxillofacial; oral; plastic; and vascular surgeries. [source: Application, p4]

¹ UBI 601 824 458

² Revised Code of Washington 70.38.105(4)(a).

TCO has identified a capital cost of \$192,244, which is composed of moveable equipment and associated sales tax. [source: Application, p14] If this project is approved, the applicant anticipates the surgery center will become operational as a Certificate of Need approved facility upon issuance of the approval. Based on an anticipated approval date of August 2021, the first full calendar year of operation is year 2022 and year three is 2024.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This application is subject to Certificate of Need review as the construction, establishment, or other development of a health care facility under RCW 70.38.105(4)(a) and WAC 246-310-020(1)(a).

PIVOTAL UNRESOLVED ISSUE (PUI)

The screening activities in WAC 246-310-090 consist of the department determining whether an application is sufficiently complete to begin review, and "(1)f an application has been found to be incomplete, the notice from the department shall specifically identify the portions of the application where the information provided has been found to be insufficient or indefinite and request supplemental information needed to complete the application.³" An applicant may respond by providing answers to the department's screening questions and request that the department begin review without additional screening, or ask that the department begin review without responding to the screening questions.⁴ The practice of the department is to scrutinize application to "insufficient or indefinite." This practice is intended to reduce reconsideration or appeal of department decisions when clarifying information could have been elicited by the department prior to review.

During the review of this project, the applicant requested that the department conduct a second screening of the application and the applicant's first screening responses. The program analyst did not note any issues requiring additional clarification and placed the application under review. While preparing the written analysis, the analyst determined that the decision not to conduct a second screening had been in error and several issues related to financial feasibility, structure and process of care, and supporting exhibits required clarification. The analyst concluded that several items should have been identified for clarification or correction had not been found in the first screening and would likely have been cited had a second screening been conducted consistent with the program's normal practice

For the reasons stated above, on December 27, 2021, the department declared a pivotal unresolved issue (PUI). The PUI process allows the department to obtain missing information pivotal to its decision and continue with the evaluation.

Consistent with the PUI process historically used, once a PUI is declared, the department allows the applicant one opportunity to provide requested information and documents. Both public and rebuttal comments are allowed on the PUI responsive documents, then the department completes its evaluation of the project. Given that the PUI focused on the financial documents and structure and process of care information provided by the applicant, the PUI documents will be addressed in those sections of this evaluation.

During the PUI process, Kadlec Regional Medical Center provided comments opposing the department's decision to request the additional information. Below is an excerpt of those comments:

³ WAC 246-310-090(2)(a)

⁴ WAC 246-310-090(2)(c)

Kadlec Regional Medical Center PUI Comment

"The purpose of the PUI process is to enable the Department to obtain information about a single or limited number of discrete and specific issues that are critical to the Department's evaluation of a CN application. It is important to recognize that the PUI process is not intended to provide an applicant with the opportunity to rectify a broad range of errors and/or omissions in its application. Nor is the process intended to serve as an additional set of application screening questions which will enable an applicant to revise or supplement its application.

"The limited purpose and scope of the PUI process as articulated in the regulation is, in turn, reflected in the Department's long-standing policy, procedure, and practice. The Department's PUI declarations and information requests have consistently been narrowly focused on a single or limited number of — as the regulation requires — "pivotal" issues. The Department has never used the PUI process as a continuation of the application process.

"With all due respect, we are concerned that, in this case, the broad scope of the Department's PUI information requests is not consistent with either the clear language of the regulation or the Department's long-established policy, procedure, and practice when applying the regulation. The Department's wide-ranging PUI information requests to TCO are essentially a new set of screening questions necessitated by TCO's failure to (1) submit a complete and accurate application and (2) adequately respond to the Department's first set of screening questions. Thus, the PUI information requests do not constitute an attempt to resolve a limited number of narrow "unresolved pivotal issue[s]," as required by the regulation."

TCO Rebuttal

TCO provided the following response to Kadlec's PUI comments:

"WAC 246-310-090(1)(a)(iii) authorizes the Department to request submission of "further information by an applicant" when, during its final review period, the Department finds an unresolved pivotal issue. The regulation specifically states:

Except as provided in WAC 246-310-190, no information regarding a certificate of need application submitted by an applicant after the conclusion of the public comment period shall be considered by the department in reviewing and taking action on a certificate of need application. <u>An exception to this rule shall be made when, during its final review period, the department finds an unresolved pivotal issue requires submission of further information by an applicant and the applicant agrees to an extension of the review period in order to resolve this issue as provided for in WAC 246-310-160 (2)(b), 246-310-150 (2)(c), and 246-310-140(4). The department shall give public notice of such request for additional information through the same newspaper in which the "notification of beginning of review" for the project was published. <u>The notice shall identify the project, the nature of the unresolved issue and the information requested of the applicant</u>, and shall state the period of time allowed for receipt of written comments from interested persons.</u>

"(Emphasis.) See also WAC 246-310-160(2)(b) ("If an issue, which is pivotal to the decision of the secretary's designee remains unresolved, the department may make one request for additional information from the person submitting the application").

"Without citing authority for the proposition, Kadlec appears to argue that the Department has limited authority to request only certain or a certain amount of information. There is no authority to support this proposition. In the absence of such authority, Kadlec makes vague reference to the Department's "longestablished policy, procedure, and practice". But, in fact, a review of past certificate of need evaluations shows the Department often has requested multiple items of "further information" pursuant to WAC 246310-160(2)(b). See e.g., Evaluation dated May 29, 2019 of the Certificate of Need Application Submitted by Providence Health & Services – Washington Proposing to Establish an Ambulatory Surgical Facility in Walla Walla County at pp. 2-3."

Department's Evaluation

Kadlec's observation that PUI processes tend to be limited to a small set of specific items is correct, but CN rules do not contain such a limitation with regard to what issues may be considered "pivotal" or "unresolved." In this case, the department identified that it had not followed its usual practice with regard to thoroughly screening the application. Information necessary to fully evaluate the application was not requested. Rather than deny the application because the applicant did not provide information the department would ordinarily have requested – but did not – the department opted to pause the process and obtain the additional information it could have obtained earlier, but did not. Interested persons were given appropriate opportunity to provide comment on the additional information and did so.

The department concludes that the PUI process was necessary to prevent penalizing an applicant for the department's own deviation from its usual screening process. The information requested by the department, while more extensive than most PUI requests, was both pivotal to the department's decision and unresolved in that it was not in the record to be evaluated.

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.

If 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.

To obtain Certificate of Need approval, an 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). Additionally, WAC 246-310-270 (ambulatory surgery) contains service or facility specific criteria for ambulatory surgical facility (ASF) projects and must be used to make the required determinations for applicable criteria in WAC 246-310-210.

TYPE OF REVIEW

This application was reviewed under a regular review timeline. The table below shows a summary of the timeline used for the project.

Action	Tri-City Orthopaedic Clinic, PSC.		
Letter of Intent Received	August 25, 2020		
Application Received	February 25, 2021		
Department's pre-review activities including:			
DOH First Screening Letter	March 22, 2021		
Applicant's Responses Received	May 3, 2021		
• Second Screening conducted, but no additional			
information requested			
Beginning of Review	June 7, 2021		
End of Public Comment	July 12, 2021		

APPLICATION CHRONOLOGY

Action	Tri-City Orthopaedic Clinic, PSC.		
• Public Comments accepted through the end of			
public comment			
No public hearing requested or conducted			
Rebuttal Comments Deadline	July 26, 2021		
Pivotal Unresolved Issue Declared	December 7, 2021		
 Applicant's Responses Received 	January 7, 2022		
Public Comment Received	January 21, 2022		
Applicant's Rebuttal Comments	January 31, 2022		
Department's Anticipated Decision	March 4, 2022		
Department's Actual Decision	April 8, 2022		

AFFECTED PERSONS

"Affected persons" are defined under WAC 246-310-010(2). In order to qualify as an affected person someone must first qualify as an "interested person" defined under WAC 246-310-010(34). For this project one entity requested affected person status:

<u>Kadlec Regional Medical Center</u> – is a 337-bed acute care hospital located at 888 Swift Boulevard in the city of Richland, within Benton County. [source: DOH internal database] The hospital provides a variety of health care services to residents of the county and surrounding communities. On April 21, 2021, Kadlec Regional Medical Center submitted its request for affected person status. The hospital qualifies as an interested person. Kadlec Regional Medical Center provides public comments; therefore, it qualifies as an affected person for this project.

SOURCE INFORMATION REVIEWED

- Tri-City Orthopaedic Clinic, PSC. Certificate of Need application received on February 25, 2021
- Tri-City Orthopaedic Clinic, PSC.'s screening response received May 3, 2021
- Public comments received on or before July 12, 2021
- Rebuttal comments received on or before July 26, 2021
- Pivotal Unresolved Issue (PUI) response received on January 7, 2022
- PUI Public Comments received on or before January 21, 2022
- PUI Rebuttal comments received on or before January 31, 2022
- Compliance history for credentialed or licensed staff from the Medical Quality Assurance Commission and Nursing Quality Assurance Commission
- Compliance history for facilities and services from the Washington State Department of Health Office of Health Systems Oversight
- DOH Provider Credential Search website: <u>http://www.doh.wa.gov/pcs</u>
- Historical charity care data for years 2017, 2018, and 2019 obtained from the Department of Health Hospital/Finance and Charity Care.
- Years 2018 and 2019 Annual Ambulatory Surgery Provider Surveys for surgical procedures performed during calendar years 2017 and 2018 for hospitals, ambulatory surgery centers, or ambulatory surgical facilities located in Benton-Franklin.⁵
- Department of Health internal database Integrated Licensing & Regulatory Systems (ILRS)
- Washington State Secretary of State website: <u>https://sos.wa.gov</u>

⁵ For Certificate of Need purposes, "Ambulatory Surgery Centers" (ASCs) and "Ambulatory Surgical Facilities" (ASFs) are often used interchangeably – ASCs are Medicare-certified surgery centers, whereas ASFs are licensed facilities in the state of Washington. With limited exceptions, all CN-approved ASFs are also ASCs, and the applicants in this review have self-identified as both.

CONCLUSION

Tri-City Orthopaedic Clinic

For the reasons stated in this evaluation, the application submitted by Tri-City Orthopaedic Clinic, PSC. proposing to establish an ambulatory surgical facility with four operating rooms in Kennewick is consistent with applicable criteria of the Certificate of Need Program, provided Tri-City Orthopaedic Clinic, PSC. agrees to the following in its entirety.

Project Description

This certificate approves the establishment of an ambulatory surgical facility in the Benton-Franklin Secondary Health Services Planning Area at 6703 West Rio Grande Avenue in Kennewick [99336]. The surgical facility will have four operating rooms and provide orthopedics; pain management; ear, nose and throat surgery; general surgery, maxillofacial surgery; oral surgery; plastic surgery; and vascular surgery. The surgical facility will serve patients who require surgical services, are not expected to require hospitalization, and can be served appropriately in an outpatient setting.

Conditions

- 1. Tri-City Orthopaedic Clinic, PSC., dba Tri-City Orthopaedic Kennewick Surgery Center agrees with the project description as stated above. Tri-City Orthopaedic Clinic, PSC., dba Tri-City Orthopaedic Kennewick Surgery Center further agrees that any change to the project as described in the project description above is a new project that requires a new Certificate of Need.
- 2. Tri-City Orthopaedic Clinic, PSC., dba Tri-City Orthopaedic Kennewick Surgery Center will maintain Medicare and Medicaid certification for the surgery center.
- 3. The surgery center will provide charity care in compliance with its charity care policy reviewed for this project. Tri-City Orthopaedic Clinic, PSC., dba Tri-City Orthopaedic Kennewick Surgery Center will use reasonable efforts to provide charity care in the amount consistent with the three-year average of charity care provided by the hospitals in the Benton-Franklin Secondary Health Services Planning Area. The three-year average for years 2017 2019 is 1.50% of gross revenue and 4.04% of adjusted revenue.
- 4. Tri-City Orthopaedic Clinic, PSC., dba Tri-City Orthopaedic Kennewick Surgery Center will maintain records of charity care applications received and the dollar amount of charity care discounts granted at the surgery center. The records must be available upon request.
- 5. Tri-City Orthopaedic Clinic, PSC., dba Tri-City Orthopaedic Kennewick Surgery Center will ensure that no staff will perform healthcare services at the surgery center without current credentials.

Approved Costs

The approved capital expenditure is \$192,244.32 and consists of moveable equipment and associated sales tax.

CRITERIA DETERMINATIONS

A. <u>NEED (WAC 246-310-210)</u>

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that Tri-City Orthopaedic Clinic, PSC. met the applicable need criteria in WAC 246-310-210 and the applicable ambulatory surgery facility criteria in WAC 246-310-270.

(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. To evaluate this sub-criterion, the department uses facility-specific criteria found in WAC 246-310-270.

WAC 246-310-270(6)

WAC 246-310-270(6) requires a minimum of two operating rooms (ORs) in an ASF.

Tri-City Orthopaedic Clinic

The applicant stated that the surgery center currently has four ORs and will continue to operate four ORs. [source: Application p5 and Exhibit 3]

Department Evaluation

The applicant provided documentation and statements to demonstrate the surgical facility will have four ORs. **This sub-criterion is met.**

WAC 246-310-270(9) – Ambulatory Surgery Numeric Need Methodology

The Department of Health's Certificate of Need Program uses the numeric methodology outlined in WAC 246-310-270 for determining the need for additional ASFs in Washington State. The numeric methodology provides a basis of comparison of existing operating room (OR) capacity for both outpatient and inpatient ORs in a planning area using the current utilization of existing providers. The methodology separates Washington State into 54 secondary health services planning areas. TCO Kennewick is located in Kennewick, within the Benton-Franklin secondary health services planning area.

The methodology estimates OR need in a planning area using multiple steps as defined in WAC 246-310-270(9). This methodology relies on a variety of assumptions and initially determines the existing surgical capacity of dedicated outpatient and mixed-use operating rooms in the planning area, subtracts this capacity from the forecasted number of surgeries expected in the planning area in the target year, and examines the difference to determine:

- (a) Whether a surplus or shortage of ORs is anticipated to exist in the target year; and
- (b) If a shortage of ORs is predicted, the shortage of dedicated outpatient and mixed-use rooms is calculated.

Data used to make these projections specifically excludes special purpose and endoscopy rooms and procedures. Dedicated interventional pain management surgical services are also among the excluded rooms and procedures.

Tri-City Orthopaedic Clinic

The applicant provided a discussion of each step of the numeric methodology and applied it to this project. The applicant's methodology concluded need for 13.13 outpatient ORs in the Benton-Franklin planning area. [source: Application, pp6-10 and Exhibit 4]

Public Comment

Kadlec Regional Medical Center

Kadlec Regional Medical Center provided comment in opposition to this project. Excerpts from that comment are provided below. While not all comment is quoted in this evaluation, all provided information was considered.

"1. The TCO Need Model and Data Used Are Incorrect

"The TCO ambulatory surgery need model and the data used in it appear to be incorrect. As discussed below, a corrected need model does not show Planning Area need overall, but instead shows a surplus of operating rooms. In contrast, TCO's need model shows an overall shortage of operating rooms ("ORs"), and a shortage of 13.13 outpatient ORs. Upon investigation, we determined that TCO appears to have used incorrect volumes and minutes for Trios Health ("Trios"), and, additionally, appears to have included pain/endoscopy procedures, which should have been excluded. When corrected, the Benton-Franklin Planning Area ASC need model shows an overall surplus of operating rooms.

"There appear to be two principal errors by TCO which led it to finding overall numeric need for operating rooms in the Benton-Franklin Planning Area. Correcting for these errors shifts overall need for inpatient and outpatient operating rooms from a positive figure to a negative one in the forecast year of 2025. The two principal errors are:

- a) TCO added an endoscopy/pain center into its model that should have been excluded;
- *b) TCO* appears to have used incorrect case volumes and minute figures for Trios.

"Regarding the first error, in terms of the correct facilities to include in the ASC need model, Exhibit 1 (attached hereto) includes the hospitals and ambulatory surgery centers in the Planning Area. There are four hospitals, two CN-approved ASFs, and four non-CN-approved ASCs. TCO included the correct set of hospitals and CN-approved ASFs, but it incorrectly included The Surgery Center at Tri-City Orthopaedic (ASF.FS.605090), with 3,623 cases and 49,602 minutes. As noted in the standard language used by the Department in its evaluation of need: "[A]ll known OR capacity and procedures are included in the methodology calculations for the planning area, with the exception of special procedure room ORs dedicated to endoscopy, pain management, or other specialized dedicated services." While this apparent error has a small impact in terms of overstating TCO's forecasts, The Surgery Center at Tri-City Orthopaedic should not have been included in TCO's need model.

"The second error is more significant in its impact on the need model and relates to the apparent incorrect use of Trios Health historic inpatient cases in mixed use operating rooms. TCO reported Trios' mixed use case count of 7,540, and referenced the DOH Evaluation of CN #17-19 (Kadlec Regional Medical Center) (August 2 2017) and reported the data year as 2017. We could not verify and could not locate the TCO reference to 7,540 cases for Trios in the DOH Evaluation of CN #17-19. In fact, Appendix A of the Evaluation for CN #17-19 shows that the Department reported Trios case volume as 3,435, with total minutes of 319,058, using the 2015 survey for 2014 data. Thus, as best we can determine, the TCO reported volume and minutes figures for Trios are incorrect. Please see Exhibit 2 and Table 1 below.

Commenter's Table

Table 1. Comparison of TCO TRIOS Volume and Minute Figure with Corrected Estimates

TRIOS Health	Number of Cases (Mixed Use)	Number of Minutes (Mixed Use)	Minutes Per case
Tri City Orthopaedic Model	7,540	754,000	100
CN #17-19 Evaluation	3,435	304,288	88.6
Estimated Figures	2,770	276,955	100

Sources:

Tri-City Model: Unknown, to best of our knowledge.

CN #17-19 Evaluation: Appendix A. CN #17-19 evaluation, August 2, 2017 (See Exhibit 2) Estimated Figures: Trios 2019 Year-End Hospital Report. Based on reported surgery minutes: 276,955/100 = 2770⁶ https://www.doh.wa.gov/Portals/1/Documents/2300/HospPatientData/YearEnd/YE039-2019.xlsx

"TCO's apparent use of incorrect figures for Trios led to incorrect model results showing overall numeric need for ORs in the Benton-Franklin Planning Area. A corrected model, excluding endoscopy cases, using corrected Trios' data, and using the most recent available survey and other data, shows a surplus of 2.8 ORs overall, a surplus of 9.5 mixed use ORs, and a need for 9.2 outpatient ORs. This is a dramatic departure from TCO's conclusions. Please see Exhibit 3 hereto, which provides a corrected ASC need model for the Benton-Franklin Planning Area. The Department's ambulatory surgery regulation permits the Department to approve an application in situations in which there is an overall surplus of ORs, as is the case in Benton-Franklin. However, TCO did not discuss alternative measures of need, since its need model incorrectly showed overall need for ORs and need for outpatient ORs.

"2. The TCO Utilization Figures Are Higher Than Actual Survey Data

"The historical utilization figures in the TCO application are very much higher than actual survey data for TCO. There is no discussion or explanation for this variance, but it appears that TCO also included pain management cases in its figures. Please see Table 2 below for historical volumes as provided by TCO in its application.

Commenter's Table

Table 2. TCO Procedure Volumes, 2017-November 2020 Year-to-Date

Historical Utilization	2017	2018	2019	2020 November YTD, Annualized ¹	Average Annual Growth Rate, 2017-2020 (%)
Procedure Volumes	12,176	10,901	11,370	11,581	-1.66%

Source: Table 4, p. 10, TCO Application.

1. Kadlec annualized the TCO data to create an average annual rate from 2017-2020. In the application, TCO provided November YTD volume of 10,616, which when annualized = 11,581.

Tri City Orthopaedics submitted its survey responses over many of the past years for The Surgery Center at TCO Orthopaedic, located at 6703 W. Rio Grande Avenue, Kennewick. It is clear from TCO's application that this location (6703 W. Rio Grande Avenue, Kennewick) is the location of the ASC for which TCO is requesting certificate of need approval. Its survey data is presented in Table 3 below for the years 2013-2019. TCO apparently did not provide survey data for 2016. Based on the information provided, the case counts for the 6703 W. Rio Grande Avenue facility were for surgical cases, and, based on information provided in TCO's application, these cases appear to have been orthopedic cases. Based on this survey data, there has been a decline in total surgical cases over the 2013-2019 period, but an increase in total minutes, likely due to increased case complexity.

"In addition, The Surgery Center at TCO Orthopaedic submitted survey data for pain management cases provided at its facility located at 985 Goethals Drive, in Richland. These case counts are also provided in Table 3 below. It should be noted that the 985 Goethals Drive facility is not the applicant, and its cases should not be included as part of the applicant's historical utilization. Since the Department does not know what was included in the procedures TCO included as "actuals," we include these pain management volumes below in Table 3.

Surgery Center at Tri City Orthopaedic Clinic (The Applicant)	2013	2014	2015	2016	2017	2018	2019
License:							
Cases	2,765	2,112	2,821		2,134	1,964	2,139
Minutes	136,134	154,862	170,430		187,896	130,230	165,298
Minutes per case	49.23	73.32	60.41		88.05	66.31	77.28
Rooms	4.00	4.00	4.00		4.00	4.00	4.00
Room Utilization	49%	56%	62%		68%	47%	60%
Surgery Center at Tri City Orthopaedic (Pain Mgmt Only)	2013	2014	2015	2016	2017	2018	2019
License: ASF.FS.60100090							
Cases	2,110	2,617					3,623
Minutes	31,985	54,762					49,602
Minutes per case	15.16	20.93					13.69
Combined	2013	2014	2015	2016	2017	2018	2019
Cases	4,875	4,729	2,821		2,134	1,964	5,762
Minutes	168,119	209,624	170,430		187,896	130,230	214,900
Minutes per case	34.49	44.33	60.41		88.05	66.31	37.30

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Table 3. TCO Survey Volumes Reported to the Department of Health, 2013-2019

Source: DOH Annual OR Surveys

"What is striking is the disconnect between TCO's historical volumes as reported to the Department in the Annual Operating Room Use Surveys and what TCO provided in its application. While it is impossible to know based on what TCO has submitted in its application, it appears it is including other procedures (very likely pain management cases) in its "actual" procedure figures as reported in Table 4 of the application. Furthermore, since the historical volumes reported by TCO in its application are higher even than the combined volumes in Table 3, we wonder if TCO is including utilization volumes from one or more of its other facilities listed on page 3 of its application.

"The Department's ASF CN application form asks applicants of existing facilities to provide patient origin data, by zip code, for the most recent full year. This allows the Department to validate not only the catchment area of the applicant, but also verify volume figures across the zip code data and the volumes presented in the application text. In its Exhibit 9, TCO did not provide the standard required volume data and only provided percentages of volume by zip code. The Department cannot determine volumes from the reported percentages, which makes Exhibit 9 unusable in terms of the Department's evaluation." [source: Kadlec July 21, 2021, public comment, pp2-6]

Tri-City Orthopaedic Clinic

"A. Tri-City Orthopaedic Clinic Numeric Need Methodology

In Kadlec's Opposition, it claims that Tri-City Orthopaedic Clinic "appears to have used incorrect volumes and minutes for Trios Health" and that it "appears to have included pain/endoscopy procedures" from The Surgery Center at Tri-City Orthopaedic.

"Tri-City Orthopaedic Clinic did not use incorrect volumes and minutes for Trios Health. Because there is no mandatory reporting requirement for utilization of hospital or ASF ORs, the Department sends an annual utilization survey to hospitals and known ASFs in the state, Annual Provider Survey for Surgical Procedures. The survey is designed by the Certificate of Need Program for the purpose of collecting data for conducting numeric need methodologies. Where these surveys are unavailable, WAC 246-310-270(9) requires assumed amounts for annual surgical minutes per OR and surgical minutes per procedure be used. Here, the most recent Annual Provider Survey for Surgical Procedures for Trios Health is from 2014, data nearly a decade old.

"In 2017, the Department evaluated Certificate of Need Application #17-19 ("CN #17-19") submitted by Kadlec and proposing to establish an ASF in Benton County. In its evaluation, the Department used the data in the 2014 Annual Provider Survey for Surgical Procedures for Trios Health. Recognizing the age of that data, Tri-City Orthopaedic Clinic relied on the Department evaluation of CN #17-19 only for the number of Trios Health ORs. Tri-City Orthopaedic Clinic used the assumptions for the annual surgical minutes per OR and surgical minutes per procedure.

"Kadlec disagreed with the use of these assumptions and instead relied on a data source not historically used in numeric need methodology analyses for ASF projects, the Trios Health 2019 Year-End Hospital Report. This is not the approach outlined in WAC 246-310-270(9). If the Department were to agree with Kadlec that the use of the assumptions in WAC 246-310- 270(9) for the annual surgical minutes per OR and surgical minutes per procedure should not have been used, the correct remedy would be to use the same survey data the Department used previously in evaluating CN #17-19. If the minutes and cases used in CN#17-19 were used in the current analysis, the resulting analysis would still indicate a need for more than 12 outpatient operating rooms. This is true even if the minutes and procedures from The Surgery Center at Tri-City Orthopaedic (ASF.FS.60100090) were excluded from the analysis.

"Even in the absence of numeric need, it is clear from the information submitted in the Application that CN approval should be granted. Approval is necessary to provide patients in the health planning area access to a non-hospital owned or controlled ASF for orthopedic surgical care.

"B. Tri-City Orthopaedic Clinic Utilization

In its Opposition, Kadlec attempts to create confusion concerning utilization data provided in the Application. The data in Tables 4 (Tri-City Orthopaedic Kennewick Surgery Center Historical Utilization) and 5 (Tri-City Orthopaedic Kennewick Surgery Center Projected Utilization) of the Application is accurate and reflects procedure data (not case data)." [source: TCO July 26, 2021, rebuttal comment, pp3-4]

Department Numeric Need Methodology and Evaluation

The numeric portion of the methodology requires a calculation of the annual capacity of the existing providers' inpatient and outpatient ORs in a planning area – for this project, Benton-Franklin, which is comprised of the entirety of Benton and Franklin counties.

According to the department's historical records, there are 15 facilities with OR capacity in the planning area. Of the 15, 4 are hospitals and 11 are ASFs.

There is no mandatory reporting requirement for utilization of ASF or hospital ORs, so the department sends an annual utilization survey to all hospitals and known ASFs in the state. When this application was submitted in February 2021, the most recent utilization survey was soliciting data for year 2019. Not all providers submitted responses. The data provided in the utilization survey is used, if available. Otherwise, the department uses utilization survey information from the previous year (2018 data). If the provider did not respond with any survey data, the department relies on its internal database with information each provider updates for licensure.

For Kadlec Regional and PMH Medical Centers, the department used the 2019 data collected in the 2020 utilization survey. For Lourdes Medical Center, the department used the 2017 data collected in the 2018 survey. For Trios, the department determined that the data used in CN Application #17-19 was the most appropriate information. While TCO applied growth assumptions to the Trios volumes, the department concludes that such adjustment is not explained in the application or screening responses and is inappropriate.

For the 11 ASFs, the department considers the services provided at a facility. The numeric methodology deliberately excludes the OR capacity and procedures of certain facilities from the calculations. Facilities that only provide endoscopy services are excluded.⁶ This excludes three CN approved surgery centers and one CN-exempt surgery center.

Kadlec contended, and TCO did not rebut, that The Surgery Center at Tri-City Orthopaedic, a sister facility to the applicant, located in Richland, should not be included because it performs only pain management procedures. The department located an email dated Marcy 5, 2015 from Scott Faringer, then-CEO of Tri-City Orthopaedic Clinic, PSC, to CN staff stating, "*I am writing to you about our ASC located at 985 Goethals in Richland, WA*. *This ASC will be downgrading its OR suites to Procedural Treatment rooms and performing only Pain Medicine in the absence of General Anesthesia*." Based on this information, the department concludes that this facility and its procedures ought to be excluded.

For the remaining six ASFs, two are CN approved facilities, all of these facilities' ORs and cases are counted in the methodology. Of the four remaining surgery centers, one is the applicant (TCO Kennewick) and the other three are CN-exempt facilities. Since none of these four are CN approved facilities, the cases, but not the ORs, are counted in the numeric methodology.

The following table shows a listing of the 15 facilities, the type and number of ORs, and notes specific to the methodology as described above.

⁶ WAC 246-310-270(9)(iv).

Department's Table 2 Benton-Franklin Planning Area Operating Room Capacity

Hospital or ASFs	# of ORs	Type of OR	Department Notes
Kadlec Regional Medical	12	Mixed Use	Hospital
Center	12	WIIXed Use	All ORs are counted in methodology
Lourdes Medical Center	8	Mixed Use	Hospital
Louides Medical Center	0		All ORs are counted in methodology
Trios	8	Mixed Use	Hospital
11105	0	Mixed Use	All ORs are counted in methodology
PMH Medical Center	2	Mixed Use	Hospital
r win wieulear Center	2	witzed Use	All ORs are counted in methodology

High Desert Surgery Center #60101793	2	Outpatient	CN approved Surgery Center All ORs are counted in methodology
Hoyeol Yang MD PS #60292086	1	Outpatient	CN approved Surgery Center Dedicated to Endoscopy Neither ORs nor cases are counted in methodology
Kadlec Ambulatory Surgery Center – Spaulding Campus #60788612	3	Outpatient	CN approved Surgery Center All ORs are counted in methodology
Mid-Columbia Endoscopy Center #60301938	2	Outpatient	CN-Exempt Dedicated to Endoscopy Neither ORs nor cases are counted in methodology
Northwest Ambulatory Physicians #60109656	5	Outpatient	CN approved Surgery Center Dedicated to Endoscopy Neither ORs nor cases are counted in methodology
Northwest Endovascular Surgery #60528629	1	Outpatient	CN Exempt Cases, but not ORs, are counted in methodology
Pacific Cataract and Laser Institute #60340640	4	Outpatient	CN Exempt Cases, but not ORs, are counted in methodology
The Surgery Center at Tri- City Orthopaedic #60100090	2	Outpatient	CN Exempt Dedicated to Pain Management Neither ORs nor cases are counted in methodology
The Surgery Center at Tri- City Orthopaedic Clinic (the applicant) #60509264	4	Outpatient	Under CN Review Cases, but not ORs, are counted in methodology
Tri-Cities Endoscopy Center #60642274	2	Outpatient	CN approved Surgery Center Dedicated to Endoscopy Neither ORs nor cases are counted in methodology

Hospital or ASFs	# of ORs	Type of OR	Department Notes
Tri-City Regional Surgery			CN Exempt
Center	3	Outpatient	Cases, but not ORs, are counted in
#60100019			methodology

The data points used in the department's numeric methodology are identified in the following table. The methodology and supporting data used by the department is provided in the attached Appendix A with this evaluation.

Benton-Franklin Methodology Assumptions and Data Summary				
Assumption Data Used				
Planning area	Benton-Fra	nklin		
	Age Group: A	All ages		
Denvilation estimates and forecasts	OFM Population Data	a, 2017 Growth		
Population estimates and forecasts	Management Act	Projections		
	Year 2019 – 253,273 / Ye	ear 2024 – 278,828		
Use rate	174.511 /1,000 p	oopulation		
Veen 2010 tetal another of annoing	Inpatient or mixed use	Outpatient		
Year 2019 total number of surgical	25,302 cases	18,897 cases		
cases in the planning area	Total cases 44,199			
Percent of surgeries:	57.25%	12 750/		
outpatient vs. inpatient (based on survey)	37.23%	42.75%		
Average minutes per case	97.93 minutes	5 9.01 minutes		
(based on survey)	97.93 minutes	58.91 minutes		
OR annual capacity in minutes	94,250 surgery	68,850 surgery		
(per methodology in rule)	minutes	minutes		
Existing providers/ORs	30 mixed-use ORs	5 dedicated		
(using DOH survey and ILRS database)	50 mixed-use ORs	outpatient ORs		
Department's Methodology Results	Net Need for 12.80 ORs in the planning			
Department 5 Methodology Results	area			

Department's Table 3 Benton-Franklin Methodology Assumptions and Data Summary

As noted in the table above, the department's numeric methodology calculates a need for 12.80 ORs in the Benton-Franklin planning area. This number is rounded down to 12 ORs. The applicant's methodology concluded need for 13.13 outpatient ORs, which is rounded down to 13 ORs.

When comparing the results of the applicant's and department's methodology, they are not significantly different. The two methodologies appear to differ in two ways – first, TCO assumed more than twice the surgical volumes for Trios last reported in the evaluation of CN App #17-19. In that evaluation and its supporting documents, Trios showed 3,535 surgeries and 319,058 minutes. TCO's methodology uses 7,540 surgeries and 754,000 minutes. Second, TCO's population projections differ from those used by the department. TCO used Claritas data for its population projections and appears to have only included ages 15 and older. The department used the most recent available county-level population projections prepared by the Washington State Office of Financial Management (OFM). Because OFM does not produce population projections at the zip-code level, the department does use Claritas projections when a planning area is smaller than an entire county, as is common in areas such as King and Pierce counties. In this case, the planning area is a combination of two entire counties, therefore

OFM data is used. Finally, TCO included the procedures at its Richland facility in creating a use rate, while the department excluded that volume.

TCO proposes to have four ORs at the surgery center. Regardless of the methodology used, TCO does not propose to add more ORs to the planning area than needed. The department concludes that TCO demonstrated numeric need for its project. **This sub-criterion is met**.

WAC 246-310-270(4)

WAC 246-310-270(4) gives the department some flexibility when the numeric methodology does not demonstrate numeric need for operating rooms. It states: "*Outpatient operating rooms should ordinarily not be approved in planning areas where the total number of operating rooms available for both inpatient and outpatient surgery exceeds the area need.*"

The applicant's methodology concluded need for 13.13 outpatient ORs in the Benton-Franklin planning area. [source: Application, pp8-11, and Exhibit 4] As discussed above, the department's methodology concluded need for 12.8 ORs in the planning area. [source: Department's Evaluation, Appendix A] Therefore, TCO was not required to address this specific standard. As a result, information provided by TCO under this standard is included and evaluated under the availability and accessibility sub-criterion immediately below.

WAC 246-310-210

In addition to demonstrating need for services within a planning area, an applicant must also demonstrate that existing services are not sufficiently available and accessible to meet that need.

<u>Tri-City Orthopaedic Clinic</u>

TCO provided the following statements and historical information related to this sub-criterion. [source: Application, pp10-11]

"No CN-approved ASF in Benton-Franklin County secondary health services planning area offers ear, nose and throat surgery, general surgery, maxillofacial surgery, oral surgery, or vascular surgery. Moreover, only one CN-approved ASF in the planning area that is unaffiliated with a hospital offers orthopedic surgery. Therefore, the proposed project is critical for providing patients in the planning area a meaningful choice for outpatient surgical services in a cost-effective setting."

In addition to the statement above, TCO provided its historical surgical volumes for full calendar years 2015 through 2019 and partial year 2020. The applicant's table is recreated below.

1	<u>FCO Kennewick Historical Utilizatio</u>							
	Number of Procedures							
	2020	10,616						
	2020	(through November 2020)						
	2019	11,370						
	2018	10,901						
	2017	12,176						

Applicant's Table 4 Recreated TCO Kennewick Historical Utilization

In addition to numeric need, the department must determine whether other services and facilities for the type proposed are not or will not be sufficiently available and accessible to meet that need.

The applicant provided additional information related to this sub-criterion under WAC 246-310-270(4) which allows the department to approve a new surgery center in a planning area absent numeric need. Given that the numeric methodology resulted in need for at least four ORs in the Benton-Franklin planning area, the information is also considered in the review below.

TCO provided statements related to the availability and accessibility of other providers in the planning area. This project proposes to offer a range of services not otherwise available in an outpatient setting in Benton-Franklin as described in this application. The applicant also asserts that its facility would offer these services at a lower cost to both patients and the healthcare system than those provided in a hospital setting. The department did not receive any public comment to suggest that other providers in the planning area offer the additional surgical services proposed by TCO Kennewick.

In summary, the department previously concluded that the applicant demonstrated numeric need for its project. The existing supply of ORs for surgical services is not sufficiently available and accessible in the Benton-Franklin planning area. Thus, the TCO project meets the standard under WAC 246-310-270(6). **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 aged 65 and over.

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. Specific to ASFs, WAC 246-310-270(7) requires that ASFs shall implement policies to provide access to individuals unable to pay consistent with charity care levels reported by the hospitals affected by the proposed project.

Tri-City Orthopaedic Clinic

TCO provided the following statements directly related to this sub-criterion.

"Tri-City Orthopaedic Kennewick Surgery Center will offer and provide care to patients ages two years to 100 years who require ambulatory surgery, are not expected to require hospitalization, and can be treated appropriately in an outpatient surgery setting." [source: Application, p5] The applicant provided copies of the following policies currently in use, and will continue to be used, at the surgery center. [source: Application, Exhibits 7-10]

- Scope of Services and Patient Admission Criteria
- Charity Care Policy
- Patient Rights and Responsibilities Policy
- Non-Discrimination Policy •

In addition to the policies and statements above, TCO provided its current and projected sources of revenue by payer and patient. The information is summarized in the table below. [source: Application, pp15-16; Applicant's PUI Response, Exhibit A]

Tri-City Orthopaedic Clinic							
Current and Projected Payer MixPayer2017-20202017-2020ProjectedProjectedPercent byPercent byPercent byPercent byPercent byRevenue ⁷ Patient ⁸ RevenuePatient							
Medicare	14.7%	24.5%	14.2%	23.1%			
Medicaid	0.4%	2.8%	0.3%	3.5%			
All Other Payers*	84.9%	72.8%	85.5%	73.4%			
Total	100.0%	100%	100.0%	100%			

Department's Table 4

* All other payers include commercial, HMO, and self-pay

While not explicitly stated by the applicant, the projected percentages by revenue and patient for each payer source are identical to the applicant's stated 2020 payer mix from the initial application. Years 2017-2019 had slightly different payer mixes. The values shown in the first two columns above were calculated by averaging historical years 2017-2019.

Given that the surgery center is operational, TCO provided the following information regarding the basis and assumptions for the payer mix above. [source: May 4, 2021, screening response, p2]

"Tri-City Orthopaedic Clinic has been operational since 1987. The projected number of surgeries for the first three years of operation is conservative and is based on the ASF's historical utilization only. Tri-City Orthopaedic Clinic assumes the three physicians listed in Table 8 (Brian D. Lueth, M.D., Thomas W. Jones, Jr., M.D., and Thomas W. Jones, III, M.D.) will continue to utilize the proposed ASF and with the same or similar patient volumes."

Department Evaluation

As previously stated, TCO Kennewick is currently operational, and all documents are currently in use. Each of the policies provides the necessary information specific to the purpose of the policy.

The surgery center is both Medicare and Medicaid certified and holds an active Washington State license. The information is below.

Medicare Certification	Medicaid Certification	Washington State License
G8935749	2056252	ASF.FS.60509264

⁷ Average of values provided by the applicant in Exhibit A of the PUI Responses

⁸ Average of values provided by the applicant on Exhibit A of the PUI Responses

TCO also provided its projected percentages of revenue by payer for the surgical facility based on its current payer mix. That projected payer mix shows a stated intent to serve Medicare, and Medicaid, patients.

To ensure the surgical facility would be available to all residents of the service area, if this project is approved, the department would condition the approval requiring the applicant to maintain both Medicare and Medicaid certification.

Based on this information, the department concludes that approval of this project has the potential to increase, or maintain, the availability and accessibility of outpatient surgical services to the Medicare and Medicaid populations of Benton-Franklin.

Based on the information reviewed and with TCO's agreement to the conditions identified above, the department concludes **this sub-criterion is met.**

WAC 246-310-270(7) - Charity Care Requirement

WAC 246-310-270(7) requires that ASFs shall implement policies to provide access to individuals unable to pay consistent with charity care levels reported by the hospitals affected by the proposed ASFs.

Tri-City Orthopaedic Clinic

To demonstrate compliance with this sub-criterion, TCO's application provided its projected charity percentages for each of the three full calendar years of operation. The amounts are shown in the table below. [source: Applicant's PUI Response, Exhibit B]

Department's Table 5 Tri-City Orthopaedic Clinic Projected Charity Care Dollars and Percentages

	Year 2022	Year 2023	Year 2024
Dollar Amounts	\$57,418	\$60,288	\$63,301
Percentage of Total Revenue	0.46%	0.46%	0.46%
Percentage of Adjusted Revenue*	0.55%	0.55%	0.55%

*Not provided by applicant. Calculated using stated payer mix

The applicant provided the following basis for the charity care amounts identified in the statements. [source: May 4, 2021, screening response, p4]

"As stated in the Application, consistent with WAC 246-310-270(7), Tri-City Orthopaedic Kennewick Surgery Center will offer charity care in an amount equal to or greater than the average percentage of total patient revenue, other than Medicare or Medicaid, that affected hospitals in the planning area utilized to provide charity care in the last available reporting year."

Public Comment

Kadlec Regional Medical Center

"In its PUI declaration, the Department states that TCO did not provide "charity care dollars" in its "historical financial statements" and requests TCO to "identify the historical amounts of charity care provided" from 2017 through 2020. In response, TCO provides the charity care amounts shown in Table 2 below. In terms of historical charity care rates as a percentage of net revenue, TCO provided 0.16% in 2017, 0.14% in 2018, and 0.09% in 2019 before a sudden, significant increase to 0.20% in 2020, followed by a further significant increase to 0.46% in 2021. While TCO states that these historical "numbers are conservative," it provides no adequate explanation for the significant increase in 2021. This is important given that TCO states that "2021 was the most accurate [year] due to new write off policies, so [TCO] used this year as the base year for projections for the revised financial reports." However, although TCO references "new write off policies," it did not update its charity care policy in its PUI response. Without access to the "new write off policies," the Department cannot determine whether TCO remains committed to providing charity care at its 2021 rate.

"In addition, TCO's modeling of charity care in its "updated" pro forma financial statement and its professed adherence to WAC 246-310-270(7) are open to question given that the charity care rates modeled in the "updated" PUI pro forma statement place TCO's average annual charity care rates at 0.45% for the years 2022 through 2024. In Table 6 of its CN application, TCO notes that the Benton-Franklin Planning Area average annual charity care rates are 1.10% of Total Revenue and 3.03% of Adjusted Revenue. In the application, TCO states:

Consistent with WAC 246-310-270(7), Tri-City Orthopaedic Kennewick Surgery Center will offer charity care in an amount equal to or greater than the average percentage of total patient revenue, other than Medicare or Medicaid, that affected hospitals in the planning area utilized to provide charity care in the last available reporting year.

"However, when examining the projected charity care rates in the "updated" pro forma statement provided by TCO in its PUI response, it appears that, as noted above, TCO commits to providing annual charity care at only 0.45% of net revenue, not 3.03% as stated in its application. This is shown in Table 3 below.

"Finally, TCO does not explain why it substantially changed its total charity care amounts between what was provided in its application and screening responses versus what is provided in its PUI response. As shown in Table 4 below, in its PUI response TCO inexplicably reduces its annual projected charity care between 58% to 60% in the period from 2021 through 2024. TCO provides no explanation for this significant discrepancy between what was provided in its application and screening responses versus what it provides in its "updated" pro forma revenue and expense statement. Given this inconsistency and the inconsistencies noted above, the Department cannot be assured that TCO is committed to providing charity care "at least equal to or greater than" the Benton-Franklin Planning Area annual average." [source: Kadlec's January 21, 2022, PUI comment, pp4-6]

Rebuttal Comment

Tri-City Orthopaedic Clinic

"TCO is a small, physician-owned company and is well respected in the community. Historically, TCO has provided charity care, but it did not record charity care in a consistent or detailed way, as it was not required either by applicable law or regulation or by our certified public accountant. When TCO initiated the certificate of need review process, it learned for the first time of the need for CN-approved ASFs to record and maintain this data, so it began to maintain the data in its business office. The recorded charity care numbers have increased as a result. Additionally, as a result of the pandemic, the patient need for charity care increased; in response, the amount of charity care provided by TCO also increased. TCO has indicated that the charity care numbers provided in the Application are conservative, as the business office staff sometimes inadvertently use the "bad debt" journal code rather than the charity care journal code.

"In the application, TCO stated (and it reiterated in its May 4, 2021 screening responses) that it will comply with WAC 246-310-270(7). It has repeatedly and explicitly stated, "Consistent with WAC 246-310-270(7), Tri-City Orthopaedic Kennewick Surgery Center will offer charity care in an amount equal to or greater than the average percentage of total patient revenue, other than Medicare or Medicaid, that affected hospitals in the planning area utilized to provide charity care in the last available reporting year." If the purpose of Kadlec's response is to argue that TCO calculated the charity care amount incorrectly, TCO reiterates that it will provide charity care in the amount equal to or greater than that 2022, PUI Rebuttal]

Department Evaluation – Charity Care Requirement

For charity care reporting purposes, Washington State is divided into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. Benton and Franklin Counties are included in the Central Region.⁹ Data reviewed includes full years 2017 through 2019. In year 2019, there were 21 hospitals operating within the Central Region. Of the 21 hospitals, two hospitals did not report in year 2019¹⁰, three did not report in 2018¹¹, and one did not report in 2017¹².

Of the 21 hospitals, five are located in the Benton-Franklin planning area and may be affected by approval of this project. Those hospitals are Prosser Memorial Health in Prosser, Kadlec Regional Medical Center and Lourdes Counseling Center in Richland, Trios Health in Kennewick, and Lourdes Medical Center in Pasco. Lourdes Counseling Center, as a psychiatric hospital that would likely not be affected by an ASC, is eliminated from the planning area charity care calculations for this project. The table below compares the three-year historical average of charity care provided by the hospitals operating in the Central Region¹³, the Benton-Franklin planning area, and the applicant's projected charity care percentages.

I failing Area	Training Area Charity Care – Three Tear Average									
	% of Total Revenue	% of Adjusted Revenue								
Central Region	1.62%	3.97%								
Benton-Franklin Hospitals	1.50%	4.04%								
Tri-City Orthopaedic Clinic	0.14%	0.17%								

Department's Table 6
Planning Area Charity Care – Three Year Average

[source: Department of Health's charity care reports for years 2017, 2018, and 2019 and PUI Response, Exhibit B]

As shown above, the projected percentage of charity care proposed by the applicant is lower than the regional average and the average of the four Benton-Franklin hospitals that provide surgical services. A review of the information provided in the application indicates that TCO based its analysis of the area hospitals on 2017 values only, not the average of the three most recent years.

The 2019 Report of Charity Care in Washington Hospitals offers the following analysis of charity care costs across Washington State Hospitals as impacted by the Affordable Care Act (ACA):

⁹ As of the writing of this evaluation, year 2020 charity care data is not yet available.

¹⁰ The two hospitals are Astria Regional Medical Center and Astria Toppenish Community Hospital.

¹¹ Astria Sunnyside Community Hospital, Astria Toppenish Community Hospital, and Astria Regional Medical Center.

¹² Astria Sunnyside Hospital

¹³ With the exception of the hospitals previously identified that did not report.

"In 2013, as a result of the Affordable Care Act, Washington saw the first decline in the amount of charity care reported by hospitals since the department began gathering these data in 1989. That decline, however, has ceased and charity care has been increasing again. Charity care rates in Washington in 2019 have remained similar to levels in 2018, which includes slight increases in revenue and slight increases in charity care. Charity care charges increased 24 percent between 2017 and 2018, but only 9.3 percent between 2018 and 2019, so the rise may be slowing." [source: 2019 Washington State Charity Care in Washington Hospitals]

TCO Kennewick's historical and projected charity care percentages of total and adjusted revenue are less than that of the planning area's hospitals. Because of this, the department recalculated the charity care dollars to be provided at TCO to be consistent with the charity care percentage of adjusted revenues for the other hospitals in the Benton-Franklin planning area.

Department's Table 7								
Charity Care – Three Year Average Comparison								
	Tri-City Orthopaedic	Tri-City Orthopaedic						
	Clinic	Clinic						
	Proposed PUI Response =	Proposed Recalculated =						
	0.45%	1.50%						
Year 1 - 2022	\$57,418	\$191,036						
Year 2 - 2023	\$60,288	\$200,588						
Year 3 - 2024	\$63,301	\$210,618						

When comparing the applicant's projected and recalculated charity care dollars shown above, the increased amounts would affect the net profits of the surgery center. Taking this into account, the department will also apply the increased charity care dollar amounts to the financial feasibility criteria in WAC 246-310-220(1) of this evaluation.

If this project is approved, a charity care condition would be attached to the approval requiring Tri-City Orthopaedic Clinic to provide charity care at the surgery center in an amount at least equal to the four affected hospitals in the Benton-Franklin planning area. **With agreement to a charity care condition, this sub-criterion is met.** The financial implications of this will be discussed under WAC 246-310-220(1).

- (3) The applicant has substantiated any of the following special needs and circumstances the proposed project is to serve.
 - (a) <u>The special needs and circumstances of entities such as medical and other health professions</u> schools, multidisciplinary clinics and specialty centers providing a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.
 - (b) <u>The special needs and circumstances of biomedical and behavioral research projects</u> <u>designed to meet a national need and for which local conditions offer special advantages.</u>
 - (c) <u>The special needs and circumstances of osteopathic hospitals and non-allopathic services.</u>
- (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) <u>The effect of the means proposed for the delivery of health services on the clinical needs of</u> <u>health professional training programs in the area in which the services are to be provided.</u>

- (b) <u>If proposed health services are to be available in a limited number of facilities, the extent to</u> which the health professions schools serving the area will have access to the services for <u>training purposes.</u>
- (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

WAC 246-310-210(3), (4), and (5) do not apply to this project under review.

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 concludes that Tri-City Orthopaedic Clinic meets the applicable financial feasibility criteria in WAC 246-310-220.

(1) The immediate and long-range capital and operating costs of the project can be met.

WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that 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.

To evaluate this sub-criterion, the department reviews the assumptions provided by an applicant, projected revenue and expense (income) statements, and projected balance sheets. The assumptions are the foundation for the projected statements. The income statement is a financial statement that reports a company's financial performance over a specific period—either historical or projected. Projected financial performance is assessed by giving a summary of how the business expects its revenues to cover its expenses for both operating and non-operating activities. It also projects the net profit or loss incurred over a specific accounting period.¹⁴

The purpose of the balance sheet is to review the financial status of company at a specific point in time. The balance sheet shows what the company owns (assets) and how much it owes (liabilities), as well as the amount invested in the business (equity). This information is more valuable when the balance sheets for several consecutive periods are grouped together, so that trends in the different line items can be viewed.

As a part of its review, the department must determine that a project is financially feasible – not just as a stand-alone entity, but also as an addition to its own existing operations, if applicable. To complete its review, the department may request an applicant to provide projected financial information for the parent corporation if the proposed agency would be operated under the parent.

¹⁴ One purpose behind the income statement is to allow key decision makers to evaluate the company's current situation and make changes as needed. Creditors use these statements to decide on loans it might make to the company. Stock investors use these statements to determine whether the company represents a good investment.

<u>Tri-City Orthopaedic Clinic</u>

As explained in the project description section of this evaluation, while the surgery center is currently operational, based on the CN Program's rules, this project is reviewed as the establishment of a new healthcare facility. Given that the surgery center is operational and has been for many years, this portion of the evaluation will rely on historical data in specific sections.

The applicant provided the assumptions used to determine the projected number of cases at the surgery center. [source: May 4, 2021, screening response, p2 and p5]

"Tri-City Orthopaedic Clinic has been operational since 1987. The projected number of surgeries for the first three years of operation is conservative and is based on the ASF's historical utilization only. Tri-City Orthopaedic Clinic assumes the three physicians listed in Table 8 (Brian D. Lueth, M.D., Thomas W. Jones, Jr., M.D., and Thomas W. Jones, III, M.D.) will continue to utilize the proposed ASF and with the same or similar patient volumes."

TCO also provided its historical and projected payer mix for patients and revenue. Based on the assumptions above, TCO provided its historical and projected utilization of the surgery center for years 2017 through 2024. With this data, the department calculated the historical and projected number of cases for TCO Kennewick broken down by patient payer mix. The information is summarized in the two tables on the following page. [source: Application, p14 and pp19-20; May 4, 2021, screening response, p5; January 7, 2022, PUI response, Exhibit A]

Department's Table 8 Historical and Projected Payer Mix

	Percentage of Revenue	Percentage of Patients
Medicare	14.7%	24.5%
Medicaid	0.4%	2.8%
All Other	84.9%	72.8%
Total	100.0%	100.0%

Departments Table 9

Historical and Projected Number of Cases for Tri-City Orthopaedic Clinic

	Year 2017	Year 2018	Year 2019	Year 2020	Year 2021	Year 2022	Year 2023	Year 2024
Medicare	2,977	2,665	2,780	2,596	2,698	2,967	3,116	3,116
Medicaid	335	300	313	292	409	450	472	472
All Other	8,864	7,936	8,277	7,728	8,572	9,428	9,900	9,900
Total Cases	12,176	10,901	11,370	10,616	11,678	12,845	13,488	13,488

TCO also clarified that payers included in the 'All Other' category include private, HMO, and self-pay. [source: Application, pp19-20]

Following are the assumptions TCO used to project revenue, expenses, and net income for the surgery center in Benton-Franklin. [source: January 7, 2022, PUI response, p6]

Assumptions for Revenues and Expenses

"a. When developing the original pro forma, 2019 was the most current completed fiscal year. Tri-City Orthopaedic Clinic anticipated 2019 would provide the best depiction at the time. Procedures are expected to increase due to the addition of new specialties. Expenses are not expected to increase with these new specialties due to lower supply usage.

"b. Procedures are expected to increase due to the addition of new specialties. Expenses are not expected to increase with these new specialties due to lower supply usage.

" c...Tables 4 and 5 were updated with 2020 actual numbers, and 2021 was estimated based on the average of January through November applied to December 2021. The 2022 through 2024 projections were calculated based on 2020 as a correct and completed base year. Tri-City Orthopaedic Clinic anticipates growth by 10% for the first year and 5% in the years thereafter. Its rationale is that recruiting physicians to use the facility will become more difficult after an initial offering the first year.

"d. Tri-City Orthopaedic Clinic is a small independent Christian based company and has traditionally been charitable to our community. As stated in answer to Question #3, Tri-City Orthopaedic Clinic grouped charity care with bad debt and contractual write offs prior to this application. Tri-City Orthopaedic Clinic was able to pull conservative historical numbers for 2017 through 2020, but 2021 was the most accurate due to new write off policies, so it used this year as the base year for projections for the revised financial reports. The projections for 2022 through 2024 are specifically tied to revenue that was projected by Table 5." [source: TCO January 31, 2022, Rebutta]

Within the application, TCO provided a copy of the executed lease agreement for the site at 6703 West Rio Grande Avenue in Kennewick [99336] to demonstrate site control. [source: Application, Exhibit 15]. In its PUI responses, TCO provided a revised lease showing site control through December 2036. [source: PUI responses, Exhibit D] Since TCO Kennewick will continue leasing the site, lease costs were included in pro forma revenue and expense statement.

Given that the medical director is an employee/owner of the TCO Kennewick and is not separately compensated for the services, no medical director cost is included in financial statements. However, TCO provided the job description for the medical director. [source: Application, p18 and Exhibit 13]

Based on the assumptions and information above, TCO provided its projected revenues, expenses, and net income for the surgery center for projected year 2021 and full calendar years 2022 through 2024. The projections are summarized in the table below. [source: January 7, 2022, PUI response, Exhibit C]

Department Table 10

Tri-City Orthopaedic Clinic Revenue and Expense Statement Summary Year 2021 Full Year 1-Full Year 2-Full Year 3-2022 2023 2024 \$13,178,518 \$13,839,390 Total Net Revenue \$11,397,786 \$12,549,172 \$6,984,644 Total Expenses \$6,494,421 \$7,307,269 \$7,646,027 Net Profit / (Loss) \$4,903,365 \$5,564,528 \$5,871,249 \$6,193,363

The "Total Net Revenue" line item is gross patient revenue, minus deductions from revenue for refunds, bad debt, and charity care. The "Total Expenses" line item includes operating expenses, including personnel, marketing, supplies, taxes, IT, fees, utilities, insurance, and depreciation. Because TCO operates on a cash basis, rather than an accrual basis, there are no contractual deductions identified. The "Fees Collected" income line item is net of all contractual deductions.

TCO also provided its projected balance sheets for partial year 2021 and full calendar years 2022 through 2024. The information is summarized in the table below. [source: May 4, 2021, screening response, Exhibit B]

(1) (7) 11 14

	Tri-City Orthopaedic Clinic									
Projected Balance Sheets for Years 2021 through 2024*										
Assets	Year 2021	Year 2022	Year 2023	Year 2024						
Current Assets	\$458,070	\$1,258,070	\$1,108,070	\$758,070						
Property & Equipment	\$1,699,206	\$1,699,206	\$1,699,206	\$1,699,206						
Other Assets	\$0	\$0	\$0	\$0						
Total Assets	\$2,157,276	\$2,957,276	\$2,807,276	\$2,457,276						
Liabilities	Year 2021	Year 2022	Year 2023	Year 2024						
Current Liabilities	\$3,673,932	\$3,673,932	\$3,673,932	\$3,673,932						
Long Term Liabilities	\$0	\$0	\$0	\$0						
Total Equity	\$1,516,656	\$716,656	\$866,656	\$866,656						
Total Liabilities & Equity	\$2,157,276	\$2,957,276	\$2,807,276	\$2,457,276						

* All numbers are rounded to nearest dollar and may not add to exact amounts.

Public Comment

Kadlec Regional Medical Center

"3. TCO Provides No Assumptions for Its Forecasted Utilization Volumes

"Despite its historical volumes falling, TCO in its application projects very aggressive growth. Although TCO was asked in screening to explain its historical and forecast volumes, it did not provide any assumptions related to its projections. It should also be noted that pain procedures are specifically excluded from the Department's ASC need methodology. Given that TCO did not provide any information to explain its "actuals," nor did it provide the assumptions used for its projections, the Department cannot know what TCO included in its projections and why it apparently inflated its forecast as it did.

Forecast Utilization (Procedure Volumes)	2021	2022	2023	2024	Average Annual Growth Rate, 2021-2024 (%)	
Ortho / Pain	11,581	12,739	13,376	13,376	4.92%	
Management	11,561	12,739	13,370	13,370	4.3270	
ENT	20	22	23	23	4.77%	
General	25	28	29	29	5.07%	
Maxillofacial	10	11	12	12	6.27%	
Oral Surgery	10	11	12	12	6.27%	
Plastic Surgery	12	13	14	14	5.27%	
Vascular Surgery	20	22	23	23	4.77%	
Total	11,678	12,846	13,488	13,488	4.92%	

Commenter's Table Table 4. Tri-City Forecast Volumes, 2021-2024

Source, Applicant Screening, p.2.

"Table 4 above provides TCO's projections showing a 4.9% average annual growth rate over the period 2021-2024, while Table 2 above shows the purported historical utilization declining -1.66% over the period 2017-2020. There is no explanation provided for any of these volume forecasts, let alone an explanation on how TCO plans to turn declining volume into a growth scenario. In screening, the Department asked TCO the following question:

Table 5 on page 11 provides the projected number of surgeries for the first three years of operation. Question #7 also requests the basis for all assumptions used for the projections. This information is necessary to determine the reasonableness of the projections shown in the table. Provide the basis for all assumptions used for the projections shown in the table.

"This question from the Department was very clear: provide an explanation for the projections. In response, TCO stated:

The projected number of orthopedic and pain management surgical procedures is conservative and based on historical numbers of surgical procedures performed by Tri-City Orthopaedic Clinic physicians. In addition, Tri-City Orthopaedic Clinic is engaged in recruiting efforts among community physicians who surgeons who [sic] provide services in the following: ear, nose and throat surgery; general surgery; maxillofacial surgery; oral surgery; plastic surgery; and vascular surgery.

"TCO's response does not answer the Department's question. It states that orthopedic and pain management forecasts are "based on historical number of surgical procedures performed by Tri-City Orthopaedic Clinic physicians." However, as seen in Table 2, these volumes have declined. Further, it is unclear if TCO's response refers to all of its locations in the Tri-Cities or only the facility listed as the proposed ASF on page 3 of its application.

"Given the lack of a relevant response from TCO, the Department is left to guess as to how TCO built its utilization forecast. While the Department made it clear that "[t]his information is necessary to determine the reasonableness of the projections shown in the table," TCO has not provided the required assumptions. Without the assumptions, the Department has no way to determine the reasonableness of the forecast and consequently does not have a path to approve the application. "1. TCO Does Not Provide Required Information for the Department to Evaluate its Application As part of the CN application and review process, an applicant is required to provide certain financial information in order for the Department to conduct a valid evaluation. These include the following: (1) three years of historical financial profit and loss statements, including the current year; (2) three full years, after the implementation year, of projected financials; (3) a balance sheet for the current year and three full years post-implementation; (4) a letter of financial commitment from the entity that will finance the project; (5) audited financial statements for the applicant and for the organization that will finance the project (generally, the parent entity); and (6) a list of assumptions that explain the sources and methodology used to prepare the financial forecasts.

"Much of the required information identified in the paragraph immediately above was not provided to the Department in TCO's application, nor was it provided in TCO's screening responses when the Department requested additional information and clarification. Required information not provided by TCO includes the following:

- There was no 2020 financial information provided.
- There was no current year balance sheet provided.
- There was no forecast balance sheet as required.
- There was no letter of financial commitment.
- There were no audited financial statements included. Revenue and expense statements were provided, but these were not audited statements.
- There were no assumptions included, despite direct questions from the Department.

"The omitted information identified above is standard information required by the Department to evaluate an application. Critical to the Department's evaluation is an understanding of the underlying assumptions that drive an applicant's financial pro forma and utilization forecasts. Without this essential information, the Department has no way to assess the accuracy and reliability of an applicant's stated forecast. Fortunately, the CN application process allows the Department to ask questions during the screening process in order to obtain needed information and to seek clarity on key issues.

"2. TCO Provides No Assumptions for its Pro Forma Revenue and Expense Statement

The screening process is an ideal time for an applicant to fill in any information gaps and provide the Department with the necessary information to fully evaluate the merits of its application. In an effort to create a full record and obtain the necessary information to evaluate TCO's application, in screening the Department asked a number of clarifying questions. With respect to understanding the assumptions driving TCO's pro forma financial statements, the Department asked:

In accordance with application guidelines, provide the assumptions used to generate the pro forma revenue and expense projections.

"TCO was presented with an opportunity to provide the required assumptions to the Department, but instead answered as follows:

The projected number of orthopedic and pain management surgical procedures is conservative and based on historical numbers of surgical procedures performed by Tri-City Orthopaedic Clinic physicians. In addition, Tri-City Orthopaedic Clinic is engaged in recruiting efforts among community physicians who surgeons who [sic] provide services in the following: ear, nose and throat surgery; general surgery; maxillofacial surgery; oral surgery; plastic surgery; and vascular surgery "The response by TCO does not include any information about revenue and expense assumptions, but only speaks generally of its utilization projections being based on historical experience. The question was specific to the pro forma, not utilization projections. The Department, with respect to Exhibit 12 of the application (which includes TCO's pro forma revenue and expense statements), requested once again that the pro forma assumptions be provided:

Provide all assumptions used to create the revised Revenue and Expense Statement provided.

"TCO provided the exact same response as it did to screening questions 1 and 3, missing once again an opportunity to provide the Department the required information:

The projected number of orthopedic and pain management surgical procedures is conservative and based on historical numbers of surgical procedures performed by Tri-City Orthopaedic Clinic physicians. In addition, Tri-City Orthopaedic Clinic is engaged in recruiting efforts among community physicians who surgeons who [sic] provide services in the following: ear, nose and throat surgery; general surgery; maxillofacial surgery; oral surgery; plastic surgery; and vascular surgery.

"Thus, TCO missed multiple opportunities to provide the Department the required assumptions that drive its pro forma financial statements so the Department could conduct a fully-informed and meaningful evaluation of its application. TCO's failure to respond places the Department in a position in which it cannot properly evaluate TCO's application. "[source: Kadlec's July 12, 2021, public comment, pp6-10]

Rebuttal Comment

Tri-City Orthopaedic Clinic

"D. Tri-City Orthopaedic Clinic Pro Forma Revenue and Expenses

In Kadlec's Opposition, it expresses concern that Tri-City Orthopaedic Clinic provides no assumptions for its pro forma revenue and expense statement. This is simply incorrect. At Table 11, the Application sets forth a detailed projection of surgical procedure counts for the proposed project through 2024. It details the number of surgical procedures in each of the following categories: orthopedic surgery and pain management; ear, nose and throat surgery; general surgery; maxillofacial surgery; oral surgery; plastic surgery; and vascular surgery. Tri-City Orthopaedic Clinic explains the projected number of orthopedic and pain management surgical procedures is conservative and based on historical numbers of surgical procedures performed by Tri-City Orthopaedic Clinic physicians, and the projections for other specialties is based on discussions from its recruiting efforts among community physicians. It also provides details on its projected outpatient and other revenue as well as deductions from revenue (e.g., bad debt and refunds; billing and collection fees; building rent or lease; charity care; depreciation and amortization; equipment leases and maintenance; insurance; IT expenses; janitorial services; laboratory supplies and services; licensing and accreditation; medical director fees; medical supplies; net revenue salaries; office supplies; personnel costs; pharmacy supplies and services; transcription; utilities; and wages and benefits)." [source: TCO July 26, 2021, rebuttal comment, p5]

Department Evaluation

To evaluate this sub-criterion, the department first reviewed the assumptions used by TCO to determine the projected number of procedures and utilization of the proposed ASF. The utilization assumptions are based on the historical number of procedures performed at the surgery center and includes a modest percentage of increase in the projection years through 2024 to account for the additional specialties expected to be served.. .

TCO based its revenue and expense assumptions on historical figures or contracts currently in place, again focusing historical operations. Some categories were held constant, and others were estimated as a percent of anticipated revenue, this approach is reasonable.

The pro forma financial statements show revenues would cover expenses beginning in partial year one (2021) through full year three (2024).

As discussed in WAC 246-310-210(2), the department recalculated the proposed surgery center's projected charity care dollars to be consistent with the three-year average of the Benton-Franklin hospitals. Those calculations increased the charity care dollars for all three projection years. The table below is a recalculation of the Revenue and Expense Statement Summary with the projected increase in charity care dollars that equal the total amount provided by the Benton-Franklin hospitals. This approach is used because it would include the larger dollar amount for charity care and would show the most impact to the net profit / (loss) line item.

I ri-City Orthopaedic Chinc									
Revenue and Expense Statement Summary Recalculated									
	Full Year 1-	Full Year 2-	Full Year 3-						
	2022	2023	2024						
Total Net Revenue	\$12,415,553	\$13,038,217	\$13,692,073						
Total Expenses	\$5,564,528	\$5,871,249	\$6,193,363						
Net Profit / (Loss)	\$5,430,909	\$5,730,948	\$6,046,046						

Department Table 12 Tri-City Orthopaedic Clinic Revenue and Expense Statement Summary Recalculated

With the increase of charity care for all years shown, the table above shows a smaller net profit, however, the surgery center's revenues would continue to cover expenses.

Based on the information submitted, the department concludes that the immediate and long-range operating costs of the project can be met. If this project is approved, the department would attach a charity care condition consistent with past surgical center projects. **This sub-criterion is met.**

(2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

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

<u>Tri-City Orthopaedic Clinic</u>

The capital cost associated with this project is \$192,244.32, which is entirely comprised of moveable equipment. The applicant states that the required equipment has already been purchased using stimulus money from the U.S. Department of Health & Human Services. [source: PUI Response, p1] There is no construction associated with this project.

Public Comment

Kadlec Regional Medical Center

'The Department requested TCO to "[i]dentify the intended timeline" for TCO's "purchase of \$192,244 of moveable equipment." In response to this request, TCO states: "The moveable equipment has been purchased using stimulus money from U.S. Department of Health & Human Services." Thus, TCO did provide a response to the Department's question regarding the "timeline" for the equipment purchase. However, TCO's response discloses that "[t]he moveable equipment has been purchased." TCO does not provide any explanation as to why it has purchased the equipment absent approval of its CN application. The lack of detail does not provide the Department with sufficient information to understand whether the moveable equipment purchased by TCO is part of, or separate from, the proposed ASF project.' [source: Kadlec PUI Comment, p4]

Rebuttal Comment

Tri-City Orthopaedic Clinic

"TCO proposes to operate Tri-City Orthopaedic Kennewick Surgery Center as a CN-approved, 4-OR ASF. Tri-City Orthopaedic Kennewick Surgery Center has historically operated, and currently operates, as a CN-exempt ASF. The proposed ASF is fully built-out and operational. Since it opened in 2015, TCO has strategically purchased equipment that can be used across locations and specialties. Consistent with its historical approach, TCO has purchased equipment that it will use irrespective of whether the proposed project is approved." [source: TCO PUI rebuttal comments, p3]

Department Evaluation

As noted above, the capital cost associated with this project is \$192,244.32, which is entirely comprised of moveable equipment. The applicant states that the required equipment has already been purchased using stimulus money from the U.S. Department of Health & Human Services.

TCO's rebuttal to Kadlec's criticism of its equipment purchase is persuasive. The department concludes that TCO's use of stimulus funds to purchase the equipment for an existing ASC is reasonable, and it is similarly reasonable to associate those costs with the proposed expansion of services. This sub-criterion is met.

(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)(i) 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.

Tri-City Orthopaedic Clinic

As noted above, the applicant noted that the equipment for this project has already been purchased using stimulus funds from the US government, therefore there is no additional financing necessary. [source: TCO rebuttal comments, p3]

TCO also provided a copy of its historical financial statements for years 2017, 2018, and 2019 to demonstrate sufficient reserves to finance the project. [source: TCO screening responses, Exhibit B]

Department Evaluation

The applicant has already financed the project with COVID-19 pandemic-related stimulus funds and has purchased the necessary equipment. There is no construction associated with the project. The department concludes that this project **meets this sub-criterion**.

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 concludes that Tri-City Orthopaedic Clinic meets the applicable structure and process (quality) 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.

WAC 246-310 does not contain specific WAC 246-310-230(1) 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 specific staffing patterns or numbers of FTEs [full time equivalents] that should be employed for projects of this type or size. Therefore, using its experience and expertise the department concludes that the planning would allow for the required coverage.

Tri-City Orthopaedic Clinic

TCO provided the following information related to this sub-criterion. [source: Application, p18 and May 4, 2021, screening response, p3]

"The above FTEs by classification for the proposed project are based on Tri-City Orthopaedic Clinic's historical staffing, which has remained constant for at least the past three years. Tri-City Orthopaedic Clinic does not anticipate any change in staffing levels.

"Current Tri-City Orthopaedic Clinic staff have sufficient capacity to address the anticipated increase in work associated with the anticipated increase in surgical volume."

In its PUI Responses, the applicant provided its projected number of full-time equivalents (FTEs) for the surgery center. A summary of the information is shown in the table below. [source: Applicant's PUI responses, p3]

Projected FTEs for Current Year 2020 and Projection Years 2021 through 2024										
FTE Туре	Year 2020	Projection Year 2021 Increase	Year 1 2022 Increase	Year 2 2023 Increase	Year 3 2024 Increase	Total				
Administrator	1.00	0.00	0.00	0.00	0.00	1.00				
RN Manager	1.00	0.00	0.00	0.00	0.00	1.00				
Pre/Post RN	12.00	2.00	1.00	0.00	0.00	15.00				
Circulating RN	6.00	1.00	0.00	0.00	0.00	7.00				
X-ray Tech	0.50	0.00	0.00	0.00	0.00	0.50				
CAN	1.00	0.00	0.00	0.00	0.00	1.00				
Scrub Tech	5.00	0.00	1.00	0.00	0.00	6.00				
Central Services	3.00	0.00	1.00	0.00	0.00	4.00				
OR Aide	1.00	1.00	0.00	0.00	0.00	2.00				
Billing Services	4.00	0.00	0.00	0.00	0.00	4.00				
Receptionist	2.00	1.00	0.00	0.00	0.00	3.00				
Materials Manager	1.00	0.00	0.00	0.00	0.00	1.00				
TOTAL FTEs	37.50	5.00	3.00	0.00	0.00	45.50				

Department's Table 13 Tri-City Orthopaedic Clinic Projected FTFs for Current Year 2020 and Projection Years 2021 through 2024

Focusing on recruitment and retention of staff, TCO provided the following information. [source: Application, p21]

"Timely patient care is provided by carefully anticipating the needs of Tri-City Orthopaedic Clinic on a daily, weekly and monthly basis and utilizing agency staff when necessary. Tri-City Orthopaedic Clinic managers are also working managers and participate in patient care as necessary. Tri-City Orthopaedic Clinic also delegates non-nursing tasks to appropriate personnel, utilizing our nursing staff for patient care to the extent possible."

One of the physician owners, Johnathan R. Perry, MD, is the current medical director and will continue providing these services if this project is approved. A copy of the medical director Policy was provided in the application. [source: Application, p21 and Exhibit 13]

Public Comment

Kadlec Regional Medical Center

"In its application, TCO notes that its existing facility at Tri-City Orthopaedic Kennewick Surgery Center currently provides orthopaedics and pain services: "Upon CN approval, it would also offer the following: ear, nose, and throat surgery; general surgery, maxillofacial surgery, oral surgery; plastic surgery; and vascular surgery"

"As noted in our comments above, TCO has very aggressive growth assumptions when compared to its historical volumes. In its application, TCO notes that it has eight existing credentialed physicians, and upon CN approval will have eleven credentialed physicians. While TCO claims that it has been in "discussions with physicians who are not members or employees of Tri-City Orthopaedic who intend to provide services at Tri-City Orthopaedic Kennewick Surgery Center if a CN is granted," it is not clear if TCO can adequately staff its proposed project.

"When reviewing the additional three physicians in Table 9 of the application, it is noteworthy that the specialty of all three physicians is anesthesia, suggesting that they would be providing pain management services. What is not clear, and what TCO does not adequately elaborate in its application, is which credentialed physicians will be providing the services for ear, nose, and throat surgery, general surgery, maxillofacial surgery, oral surgery, plastic surgery, and vascular surgery. When asked in the application form to describe what methods it has in place to adequately recruit and retain the appropriate staff, TCO's response did not provide the Department with any reassurance that it could adequately staff the project. TCO stated:

Timely patient care is provided by carefully anticipating the needs of Tri-City Orthopaedic Kennewick Surgery Center on a daily, weekly and monthly basis and utilizing agency staff when necessary. The Tri-City Orthopaedic Kennewick Surgery Center managers are also working managers and participate in patient care as necessary.

"In summary, TCO provides very aggressive utilization projections with a considerable expansion of surgical services beyond its historical pain management and orthopedic services, but TCO does not provide a staffing model that appears to be adequate to staff the project. [source: Kadlec initial public comment]

"PUI Request No. 4: FTE Staffing

The Department asks TCO to provide a "revised staffing table" for "the last three full years of operation, the current year, and the first three full years of operation." The Department also asks TCO to define "[a]ll staff classifications." In response, TCO provides an "updated Table 8" to its CN application. (The table is replicated below.) The Department's PUI request is prompted by TCO's response to the Department's Screening Questions Nos. 3 and 13, in which TCO provided projected annual FTEs for 2021 through 2024, but did not provide (1) historical annual FTE staffing levels or (2) its underlying assumptions with respect to future FTE staffing. TCO stated in its screening responses: "The FTEs by classification for the proposed project are based on Tri-City Orthopaedic Kennewick Surgery Center's historical staffing, which has remained constant for at least the past five years." While TCO stated in its screening responses that historical staffing "has remained constant," its PUI response shows that historical staffing has increased, with a 6.0% increase between 2018 and 2019, a 10.7% increase between 2019 and 2020, and an 11.8% increase between 2020 and 2021, as shown in Table 5 below. TCO provides no explanation for this discrepancy and, in addition, provides no description of its staffing model.

TABLES OMITTED

"Comparing the two tables reveals a significant and unexplained difference between the two staffing models. Between TCO's screening response and its PUI response the number of staff classifications has increased from four classifications in screening to twelve classifications in the PUI response. No explanation is provided for this large increase. In addition, and most importantly, the total projected FTE staffing rises steeply, increasing by over 15.5 to 17.5 FTEs annually (depending on the year), representing a 52% to 63% annual increase (depending on the year), as shown in Table 7 below. TCO provides no explanation for this significant change, which represents a dramatic departure from the original projected FTE staffing levels.

"Equally striking is that, given this large increase in projected FTE staffing, one would expect to see a commensurate increase in the annual expenses for salaries, wages, and benefits in TCO's "updated" pro forma revenue and expense statement submitted in its PUI response. TCO's original pro forma

statement in its application projected that the annual expenses for salaries, wages, and benefits would be \$2,377,544.08 in 2021, \$2,496,422.04 in 2022, \$2,621,243.14 in 2023, and \$2,752,305.30 in 2024.32 However, these annual expense projections are exactly the same in the "updated" pro forma statement provided by TCO in its PUI Response. It is inconceivable that annual expenses for salaries, wages, and benefits would remain constant, while FTEs increase by over fifty percent. As demonstrated in Table 7, TCO's updated FTE projections show an annual increase in FTE staffing ranging between 52% to 63% in the years from 2021 through 2024. This incongruity renders TCO's "updated" pro forma revenue and expense statement wholly unreliable." [source: Kadlec's January 21, 2022 PUI comment]

Rebuttal Comment

Tri-City Orthopaedic Clinic

"E. Tri-City Orthopaedic Clinic Staffing

In Kadlec's Opposition, it asserts it is "not clear" that Tri-City Orthopaedic Clinic can adequately staff the proposed project. The basis for Kadlec's assertion is unclear. At Table 8, the Application sets forth a detailed projection of staffing levels for the proposed project through 2024. It details the number of staff in each of the following categories: Administrator; RNs; Surgical Technologists; and Receptionist/Scheduler. As indicated in the application, the staffing by category for the proposed project is based on Tri-City Orthopaedic Kennewick Surgery Center's historical staffing, which has remained constant for at least the past five years. As indicated in the Application, the proposed project does not include any increase in the number of ORs at Tri-City Orthopaedic Kennewick Surgery Center are already fully built out and operational. Therefore, the increase in staffing for the proposed project is modest. The staffing information provided by Tri-City Orthopaedic Clinic is complete and unambiguous, evidenced by the fact that the Department posed no screening questions concerning staffing for the proposed project.

"Kadlec expresses concern that Tri-City Orthopaedic Clinic does not identify the additional physicians who will be providing services for certain specialties if the proposed project is approved. Kadlec's concern is disingenuous. It is understood that community and especially hospital affiliated physicians are reluctant to be identified in certificate of need applications for fear of retaliation by local hospitals with which the physicians maintain are unnamed in the Application is not dispositive. [source: TCO July 26, 2021 rebuttal comments]

"The Application asked the following: "Provide a table that shows FTEs [full time equivalents] by classification (e.g. RN, LPN, Manager, Scheduler, etc.) for the proposed facility." See Application at p. 18. In its Application, TCO limited its answer to the staff types indicated in the foregoing question, providing in answer a table showing the following staff classifications: RN, Surgical Technologist (which TCO employs in lieu of LPNs), Manager (i.e., Administrator), and Scheduler. Id. In its PUI response, TCO included all ASF staff (i.e., not only those specifically requested in the text of the Application). The historical and projected wages did not increase when these additional categories of staff were detailed because the complete ASF staff wages were already included in the pro forma (i.e., wages for those classifications provided in the initial Application as well as those classifications added in its PUI response).

"To increase employee satisfaction, in 2020 TCO did create a new position, OR Aid, to assist the nursing staff and help avoid staff burnout. In its PUI Response, TCO provided this staffing information for the last three full years of operation, the current year, and the first three full years of operation following project completion, as requested by the Department. When TCO filed the Application, complete information from 2020 was unavailable. In its PUI Response, TCO was able to provide this actual data." [source: TCO PUI rebuttal comments, pp3-4]

Department Evaluation

As previously stated, the surgery center is currently operational. While TCO provided information regarding recruitment and retention of staff, as shown in the table above the surgery center is currently fully staffed with 37.5 FTEs. TCO Kennewick projects an increase of only eight employees through 2024. The increases are projected to be five FTEs in projection year 2021 and three more in 2022.

The department concludes that TCO's explanation of the differing FTE tables between its initial application materials and its PUI response, including TCO's discussion of staffing costs, is reasonable.

Given that the medical director of the facility is one of the physician owners, the medical director is already in place.

Information provided in the application demonstrates the applicant has the ability to staff the surgery center. Based on the information above, the department concludes that the TCO Kennewick project **meets this 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.

WAC 246-310 does not contain specific WAC 246-310-230(2) 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 relationships, ancillary and support services should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials contained in the application.

Tri-City Orthopaedic Clinic

Given that the surgery center has been operational for many years, TCO provided a listing of ancillary and support services that have been established for the surgery center. [source: May 4, 2021, screening response, p5]

"In addition to the transfer agreement with Tri-City Orthopaedic Clinic¹⁵, P.S.C. has the following ancillary and support services in place:

- Anesthesia services are provided by Robert B. Goldstein, M.D. (MD00039823) and Wade R. Otte, M.D. (MD00029568)
- Laboratory services, e.g., for specimens taken during surgery, are referred to Diagnostics for *Pathology and TriCities Laboratory*.
- Pharmacy consultant services are provided by contractual arrangement with Nathan S. Wende (PH00045533)."

The transfer agreement provided in the application, is between Tri-City Orthopaedic Clinic and Trios Health. The agreement was executed on September 4, 2014, and identifies roles and responsibilities for both entities. There are no costs associated with the agreement and the agreement does not include an expiration date. [source: Application, Exhibit 17]

Department Evaluation

TCO provided appropriate documentation to demonstrate compliance with this sub-criterion. A patient transfer agreement is an integral part of operating a freestanding surgery center and is a required

¹⁵ This is an apparent typographical error. The applicant provided a transfer agreement between itself and Trios Health.

agreement for Certificate of Need approval. TCO's agreement with Trios Health includes all information necessary and demonstrates compliance with this sub-criterion.

TCO also provided information to demonstrate its ancillary and support agreements are appropriate for its ophthalmic surgery center.

Based on the information reviewed in the application, the department concludes that there is reasonable assurance that TCO Kennewick will maintain the necessary relationships with ancillary and support services for the surgery center if this project is approved. **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.

Tri-City Orthopaedic Clinic

The applicant provided the following statements related to this sub-criterion. [source: Application, p24] "*No facility or practitioner associated with Tri-City Orthopaedic Clinic has any history with respect to criminal convictions related to the ownership or operation of a health care facility, license revocation, or other sanction described in WAC 246-310-230(3) or (5).*"

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.¹⁶ For surgery centers, the department reviews two different areas when evaluating this sub-criterion. One is a review of the Centers for Medicare and Medicaid Services (CMS) "Terminated Provider Counts Report" covering years 2018 through 2021. The department uses this report to identify surgery centers that were involuntarily terminated from participation in Medicare reimbursement.

The department also reviews an applicant's conformance with Medicare and Medicaid standards, with a focus on Washington State facilities. The department uses the CMS 'Survey Activity Report' to identify Washington State facilities with a history of condition level findings. For CMS surveys, there are two levels of deficiencies: standard and condition.¹⁷

• <u>Standard Level</u>

A deficiency is at the Standard level when there is noncompliance with any single requirement (or several requirements) within a particular standard that is not of such character as to substantially limit a facility's capacity to furnish adequate care, or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred.

<u>Condition Level</u>

Deficiency at the Condition level may be due to noncompliance with requirements in a single standard that, collectively, represent a severe or critical health or safety breach, or it may be the

¹⁶ WAC 246-310-230(5)

¹⁷ Definitions of standard and condition level surveys: https://www.compass-clinical.com/deciphering-tjc-condition-level-findings/

result of noncompliance with several standards within the condition. Even a seemingly small breach in critical actions, or at critical times, can kill or severely injure a patient, and such breaches would represent a serious or severe health or safety threat.

Below is a summary of the two areas reviewed for TCO Kennewick.

Terminated Provider Counts Report

Focusing on years 2018 through 2021, TCO Kennewick was not involuntarily terminated from participation in Medicare reimbursement.

Conformance with Medicare and Medicaid Standards

For years 2018 through 2021, TCO was surveyed once, on August 29, 2018. The August 5*, 2018, survey resulted in a total of 22 deficiencies, and of those, 4 were condition level and 18 were standard level. The condition level deficiencies focused in the following areas: Governing Body and Management; Nursing Services; Pharmaceutical Services; and Patient Admission, Assessment and Discharge.

TCO submitted its plans of correction and surveyors returned for a follow up survey on October 18, 2018. The follow up survey resulted in no deficiencies.

TCO also provided a listing of 11 physicians associated with the practice and surgery center. Using data from the DOH Office of Customer Service, the department found all are in full compliance with state requirements, hold active state licenses, and have no conditions or limits on their license. One of the physician owners, Johnathan Perry, MD, will continue to provide medical director services.

One physician associated with TCO, Mark R. Merrell, MD, entered into a stipulation to informal disposition related to care of a patient in 1997. Dr. Merrell complied with the terms of the stipulation and was released from the agreement in 2004.

Johnathan Perry, MD, also entered into a stipulation to informal disposition related to care of a patient in 2015. Dr. Perry complied with the terms of the stipulation and was released from the agreement in 2020.

TCO identified 29 registered nurses, 6 surgical technicians, 2 nursing assistants, and 1 radiologic technician associated with the surgery center. Using data from the DOH Office of Customer Service, the department found all staff are in full compliance with state requirements, hold active state licenses, and have no conditions or limits on their license with the exception of one identified nursing assistant, whose credential expired in 2019. That nursing assistant, Ricardo Perez (NC60671011), has not renewed his credential. If this application is approved, the department would attach a condition that no providers would be allowed to perform healthcare services at TCO Kennewick without appropriate credentials.

In review of this sub-criterion, the department considered the total compliance history of the surgery center owned and operated by TCO. The department also considered the compliance history of the medical director and current physician partners or employees of the practice and the surgery center.

Based on the information reviewed, the department concludes that TCO's currently operational ASF is currently compliant with applicable state and federal licensing and certification requirements. The department also concludes there is reasonable assurance that the approval of this project would not have a negative effect on TCO's compliance.

The department concludes that TCO has demonstrated reasonable assurance that the proposed surgery center would operate in compliance with state and federal requirements, subject to the condition discussed above. **This sub-criterion is met.**

(4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

WAC 246-310 does not contain specific WAC 246-310-230(4) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that direct 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.

Tri-City Orthopaedic Clinic

TCO provided the following statements in response to this sub-criterion. [source: Application, p23] "The proposed ASF will improve access to affordable, high-quality ambulatory surgical services to the Benton-Franklin County secondary health services planning area residents. Approval of the proposed ASF will allow Tri-City Orthopaedic Kennewick Surgery Center to offer a more convenient, lower-cost alternative to hospital-based outpatient surgery for the following: ear, nose and throat surgery; general surgery; maxillofacial surgery; oral surgery; orthopedics; pain management; plastic surgery; and vascular surgery. CN approval will also make Tri-City Orthopaedic Kennewick Surgery Center available to all physicians in the community who are credentialed, privileged and in good standing and who perform ambulatory surgical services. Local physicians gaining access to Tri-City Orthopaedic Kennewick Surgery Center will improve Benton-Franklin County secondary health services planning area residents' access to the procedures expected to be performed at the Tri-City Orthopaedic Kennewick Surgery Center. Further, because freestanding ASFs are more efficient and cost-effective in comparison to hospital outpatient surgery departments, the contractual rates for purchasers in the Benton-Franklin County secondary health services planning area can be lower in a freestanding setting, which translates to cost savings to patients."

Department Evaluation

As an existing provider, TCO Kennewick is already part of the healthcare infrastructure for the Benton-Franklin planning area. As a result, any impact this surgery center would have on the existing providers has already occurred. This is further evidenced by the lack of public comment submitted for this project.

The department also considers the conclusions reached in this evaluation regarding need for the surgery center and whether the facility would be available and accessible to residents of Benton-Franklin. The department also considers the conclusions reached in the financial review of the project. TCO provided information within the application materials to demonstrate it meets the review criteria in WAC 246-310-210 and 220.

Based on the information provided in the application, the department concludes there is reasonable assurance that approval of this this project would promote continuity in the provision of health care services in the community. **This sub-criterion is met.**

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

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 concludes that Tri-City Orthopaedic Clinic meets the applicable cost containment criteria in WAC 246-310-240.

(1) <u>Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.</u> To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria, then the project is determined not to be the best alternative and would fail this sub-criterion.

If the project has met the applicable criteria in WAC 246-310-210 through 230 criteria, in step two, the department 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 in step three. Tri-City Orthopaedic Clinic's application is the only application under review to add OR capacity in the Benton-Franklin planning area. Therefore, step three is not applicable to this project.

Tri-City Orthopaedic Clinic met the applicable review criteria under WAC 246-310-210 through 230. Its application will be evaluated further under this sub-criterion.

Tri-City Orthopaedic Clinic

The applicant provided the following statements in response to this sub-criterion. [source: Application, p23-24]

"There is significant need for outpatient surgery ORs in the Benton-Franklin County secondary health services planning area. The proposed ASF will improve access, a key criterion for a CN. The proposed ASF will also provide a low cost, freestanding ambulatory surgical facility in the health planning area to meet the needs of patients and help residents of the planning area avoid wait times for procedures and lower health care costs.

Tri-City Orthopaedic Clinic has a presence in the Benton-Franklin County secondary health services planning area, and the proposed ASF will build upon this presence and offer other patients convenient access to surgical services. Tri-City Orthopaedic Clinic is committed to providing high quality, affordable care in the Benton-Franklin County secondary health services planning area, and the proposed ASF will help accomplish this goal. The proposed project promotes continuity of care with Tri-City Orthopaedic Clinic's other services, and it offers cost containment as well. Making the proposed ASF available to qualified, credentialed and privileged physicians in good standing is significantly less costly than building a new ASF to address the need for surgical services.

Tri-City Orthopaedic Clinic is requesting a CN for the proposed ASF so that other qualified, credentialed and privileged physicians in good standing can use the facility, which is fully built-out and operational. As part of its due diligence, Tri-City Orthopaedic Clinic examined alternatives to the proposed project and evaluated those alternatives. The alternatives are addressed below.

Alternative 1: "Do Nothing"

Tri-City Orthopaedic Clinic rejected a "do nothing" alternative. The Benton-Franklin County secondary health services planning area currently has too few outpatient ORs. Planning area residents are underserved relative to the forecasted demand for surgical services and must travel or wait to obtain care. Tri-City Orthopaedic Clinic has a presence in the Benton-Franklin County secondary health services planning area and can add value to community health services by extending its continuum of care to additional residents of the community and other patients. A "do nothing" alternative strategy is detrimental to the community, in that such a strategy would do nothing to reduce the travel or wait times for surgical services, would further restrict needed health care services within the health planning area, and would not improve the cost effectiveness of care delivery. There is no advantage to the "do nothing" alternative, so it was not considered feasible.

Alternative 2: Request Approval for a Freestanding ASF, i.e., The Proposed Project

In contrast to the "do nothing" approach, the advantages of a CN-approved ASF are clear. A CNapproved ASF would afford increased access and local choice for the health planning area residents and local, independent physicians. It would increase physicians' and patients' ease of access and improve their ability to deliver and receive high quality care. This alternative model reduces the overall cost of care and passes these relative cost and efficiency advantages of a freestanding ambulatory surgical facility to patients and payers.

There are no disadvantages to granting Tri-City Orthopaedic Clinic's request for CN approval. The facility is built out and operational. The data demonstrates there would not be a duplication of services, given a projected net demand of over <u>13.13</u> outpatient ORs in the health planning area.

A CN-approved ASF would better serve the interests of the planning area residents and achieve Benton-Franklin County secondary health services planning area's desire to reduce wait times for outpatient surgical services."

Department Evaluation

The applicant identified sufficient unmet need for OR capacity in the planning area and the department also did not identify any other alternatives that that would be considered superior based on quality, efficiency, and costs that are available or practicable for TCO Kennewick. Further, this project met the review criteria under need, financial feasibility, and structure and process of care. Based on the above information, the department concludes that **this sub-criterion is met**.

(2) *In the case of a project involving construction:*

- (a) <u>The costs, scope, and methods of construction and energy conservation are reasonable;</u>
- *(b)* <u>The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.</u>

Department Evaluation

Given that there is no construction or alternations associated with this project, these two sub-criteria do not apply to this project.

(3) <u>The project will involve appropriate improvements or innovations in the financing and delivery of</u> <u>health services which foster cost containment and which promote quality assurance and cost</u> <u>effectiveness.</u>

Tri-City Orthopaedic Clinic

TCO provided the following statements related to this sub-criterion. [source: Application, p24]

"The primary objective of the proposed project is to provide needed access to a high quality, low cost ASF in the planning area where there is clearly demonstrated need. Patients who need outpatient surgery will have the option to have their procedure in an ASF where they can obtain the same quality surgical experience, but at a lower cost. The proposed ASF will offer care that is both affordable and local. The proposed ASF will be available to Tri-City Orthopaedic Clinic's physicians and their patients as well as to other qualified, credentialed and privileged physicians in good standing and their patients."

Department Evaluation

This project proposes the expansion of services of an existing, CN-approved surgical facility to allow other surgeons to perform procedures there. Since this project has demonstrated need for additional OR capacity in the planning area, has a low capital cost, and has been deemed financially feasible, the project has the potential to improve the delivery of health services in the Benton-Franklin Secondary Health Services Planning Area. In addition, based on information provided within the application, and evaluated under WAC 246-310-210, 220, and 230, the department is satisfied that this project is appropriate. **This sub-criterion is met.**

APPENDIX A



APPENDIX A ASC Need Methodology Benton-Franklin Planning Area

													
Service	Area Pop	ulation: 2024	278,828	OFM	Age 0 - 85	ł							
		901/1,000:	48,659	-	J								
		,	-,										
a.i.	94,250	minutes/year/	mixed-use OR										
		,											
a.ii.	68,850	minutes/year/	dedicated outpatie	nt OR									
a.iii.	5	dedicated out	patient OR's x 68,	850 minute	s =	344,250	minutes de	dicated OR	capacity	5,844	Outpatient	surgeries	
			-								-		
a.iv.	30	mixed-use OF	R's x 94,250 minute	es =		2,827,500	minutes m	xed-use OF	capacity	28,872	Mixed-use	surgeries	
b.i.		d inpatient sure		27,855				patient surg					
	projecte	d outpatient su	rgeries =	20,804	=	1,225,473	minutes ou	itpatient sur	geries				
b.ii.	Forecas		it surgeries - capa										
		20,804	-	5,844	=	14,960	outpatient	surgeries					
b.iii.		time of inpatie			=		minutes						
	average	time of outpati	ent surgeries		=	58.91	minutes						
b.iv.		surgeries*ave			=	2,727,916							
	remainin	g outpatient su	urgeries(b.ii.)*ave t	ime	=	881,223							
						3,609,139	minutes						
c.i.			a.ivb.iv.) by 94,2			lus of mixe	d-use OR's	5					
	Not App		o c.11. and ignore	any value	here.								
		2,827,500											
	-	3,609,139											
	_	-781,639	1	94,250	=	-8.29							
c.ii.			patient part of b.iv	- a.iv.) by 9	94,250 to de	termine sho	ortage of inp	atient OR's					
	USE TH	ESE VALUES											
		2,727,916							-				
	-	2,827,500	,	04.050									
		(99,584)	/	94,250	=	-1.06							
	all scholar			An distant	da a altra	and the state	eted and						
	divide o		of b.iv. By 68,850				ated outpa	tient OR's					
		881,223	1	<mark>68,850</mark>	=	12.80			Г				



APPENDIX A ASC Need Methodology Benton-Franklin Planning Area

	Special Procedure		Dedicated Outpatient	Mixed Use	Mixed Use	2011 Inpatient Cases	Inpatient Mins. In	Outpatient	Outpatient	Outpatient	
Facility	Rooms	ORs	ORs	ORs	min/case	in Mixed Use	Mixed Use ORs	Min/Case	Cases	-	Data Source
Kadlec Regional Medical Center	5			12	103.0	10,023	1,032,766				Year 2019 data from 2020 survey
Lourdes Medical Center	5			8	108.7	3,207	348,447				Year 2017 data from 2018 survey
PMH Medical Center				2	95.1	1,467	139,511				Year 2019 data from 2020 survey
Trios health				8	90.3	3,535	319,058				From CN App 17-19
High Desert Surgery Center			2					82.5	3,144	259,367	Year 2017 data from 2018 survey
Hoyeoul Yang MD PS	1		Dedicated to Endoscopy					Year 2017 data from 2018 survey			
Kadlec Ambulatory Surgery Center			3			7,070	638,116	56.9	2,620	149,017	Year 2019 data from 2020 survey
Northwest Ambulatory Physicians			5			Dedicated to End	doscopy				Data from ILRS database; outpatient minutes calculated
Tri-Cities Endoscopy Center	2			Dedicated to Endoscopy							
Mid-Columbia Endoscopy Center	2		Dedicated to Endoscopy						Year 2018 data from 2019 Survey		
Northwest Endovascular Surgery			1					48.1	640	30,784	Year 2018 data from 2019 Survey
Pacific Cataract and Laser Institute			4					50.0	7,148	357,400	Year 2019 data from 2020 survey
The Surgery Center at Tri-City Orthopaedic (Richland)	2		2 Dedicated to Pain Management					, í	Year 2019 data from 2020 survey		
The Surgery Center at Tri-City Orthopaedic Clinic (Ken	newick)		4				Ŭ	77.3	2,139	165,298	Year 2019 data from 2020 survey
Tri-City Regional Surgery Center	1		3					47.2	3,206	151,291	Year 2019 data from 2020 survey
Totals	15	0	10	30		25,302	2,477,898		18,897	1,113,157	
					Avg min/ca	ise inpatient	97.93	Avg min/cas	e outpatient	58.91	
ORs counted in numeric methodology (in bold)			5	30							
2019 survey collecting 2018 data											
Population data source: OFM released 2017											
Total Cases	44.199										
Area population 2019 [0 - 85+]	253,273		Using 2019 population b/c using 2019 survey data				1				
Use Rate	174.511					,,					
Planning Area projected population Year: 2024	278,828										
0/ October 1 and 1 and 1	42.75%										
% Outpatient of total surgeries	42.75%										
% Inpatient of total surgeries	57.25%										