EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON BEHALF OF MID-COLUMBIA ENDOSCOPY CENTER, LLC PROPOSING TO ESTABLISH AN AMBULATORY SURGERY CENTER IN BENTON COUNTY

APPLICANT DESCRIPTION

On November 9, 1994, Tri-Cities Digestive Health Center (TCDHC), PS was granted an exemption from Certificate of Need review for the establishment of an ambulatory surgery center (ASC). At that time, the practice and ASC were located at 780 Swift Boulevard in the city of Richland within Benton County. The exempt ASC solely provided endoscopy procedures. When the ASC was established, only the owing physician Mathias Lam and his future partners or employees performed surgeries at the ASC. [Source: CN Historical Record]

PROJECT DESCRIPTION

The exempt ASC operated under the Tri-Cities Digestive Health Center practice is currently used by only the owning physician, Somprak Boonpongmanne (Dr. Boon). The practice and ASC remain located at the Swift Boulevard site. This project proposes the following changes:

1. Relocation of the practice and ASC to 8800 West Victoria Avenue in the city of Kennewick within Benton County.
2. Endoscopic physicians not employed by, or partners of TCHDC would have the opportunity to perform endoscopic and GI procedures surgeries at the ASC.
3. The ASC and the practice would be operated under separate LLC's. The practice would remain at TCDHC and the ASC would operate under the name of Mid-Columbia Endoscopy Center (MCEC). [Source: Application, Page 7]

The relocation described in #1 above could be accomplished under the current exemption. The actions described under #2 and #3 above require prior Certificate of Need review and approval.

The estimated capital expenditure for the relocation and establishment of Mid-Columbia Endoscopy Center, LLC is $1,451,220. Of that amount, 47.5% is related to construction and 32.3% is related to fixed and moveable equipment; 15.2% is related fees and taxes and the remaining 5.0% is related to other undisclosed cost. [Source: Application, Page 23]

If this project is approved, Mid-Columbia Endoscopy Center, LLC would have three dedicated operating rooms (ORs) used solely for endoscopic procedures. The ASC would be operational by September 2010. Under this timeline, year 2011 would be the endoscopy center's first year of operation and year 2013 would be the third year of operation. [Source: Application, Page 10] For ease of reference, the department will refer to the proposed Mid-Columbia Endoscopy Center, LLC as "MCEC" and its parent entity, Tri-Cities Digestive Health Center as "TCDHC".

APPLICABILITY OF CERTIFICATE OF NEED LAW

Even though the exempt ASC is operational, this project is subject to Certificate of Need review as the establishment of a new health care facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

CRITERIA EVALUATION

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

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

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

- *(i) The consistency of the proposed project with service or facility standards contained in this chapter;*
- *(ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and*
- *(iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project."*

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

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

- *(i) Nationally recognized standards from professional organizations;*
- *(ii) Standards developed by professional organizations in Washington state;*
- *(iii) Federal Medicare and Medicaid certification requirements;*
- *(iv) State licensing requirements;*
- *(v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and*
- *(vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application."*

To obtain Certificate of Need approval, the applicant must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment)[1]. Additionally, WAC 246-310-270 (ambulatory surgery) contains service or facility specific criteria for ASC projects and must be used to make the required determinations.

[1] Each criterion contains certain sub-criteria. The following sub-criteria are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6).

APPLICATION CHRONOLOGY

June 29, 2009	Letter of Intent Submitted
August 10, 2009	Application Submitted
August 11, 2009 through October 19, 2009	Department's Pre-Review Activities 1st screening activities and responses
October 20, 2009	Department Begins Review of Application • Public comments accepted throughout the review • No public hearing requested or conducted
November 25, 2009	End of Public Comment
December 8, 2009	Rebuttal Documents Received at Department
January 27, 2010	Department's Anticipated Decision Date
November 18, 2010	Department's Actual Decision Date

AFFECTED AND INTERESTED PERSONS

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

"…an "interested person" who:

(a) Is located or resides in the applicant's health service area;

(b) Testified at a public hearing or submitted written evidence; and

(c) Requested in writing to be informed of the department's decision."

Throughout the review of this project, no entity sought ore received affected person status under WAC 246-310-010(2).

SOURCE INFORMATION REVIEWED

- Mid-Columbia Endoscopy Center's LLC Certificate of Need Application received August 10, 2009
- Mid-Columbia Endoscopy Center's LLC supplemental information received September 21, 2009, and October 13, 2009
- Benton/Franklin secondary health services planning area ASC's operating room utilization survey
- Public comments /utilization survey responses received from Kennewick General Hospital, Tri-City Regional Surgery Center and Kadlec Regional Medical Center
- Mid-Columbia Endoscopy Center's LLC rebuttal comments received December 10, 2009
- Office of Financial Management population data for Benton/Franklin secondary health services planning areas
- Licensing and/or survey data provided by the Department of Health's Office of Investigations and Inspections

CONCLUSION

For the reasons stated in this evaluation and with agreement to the following terms and conditions, Mid-Columbia Endoscopy Center's LLC Certificate of Need application proposing to establish a new three room endoscopy ambulatory surgery center within the city of Kennewick in Benton County is approved. Provided that Mid-Columbia Endoscopy Center, LLC agrees to the terms and conditions outlined below, a Certificate of Need would be issued with the following terms and conditions.

Terms

1. Prior to commencement of the project, Mid-Columbia Endoscopy Center, LLC must provide to the Certificate of Need Program for review and approval an admission policy. The adopted policy must be consistent with the draft provided in the application and include admitted criteria that showed no discrimination based on race, creed, color, ethnic origin, nationality, sex, handicap, age, or affiliation with fraternal or religious organization.

2. Prior to commencement of the project Mid-Columbia Endoscopy Center, LLC must provide to the Certificate of Need Program for review and approval a charity care policy. The adopted charity care policy must be consistent with the draft provided in the application.

3. Prior to commencement of the project, Mid-Columbia Endoscopy Center, LLC must provide to the department for review and approval an executed copy of the lease agreement for the proposed site located at 8800 West Victoria Avenue, Kennewick, Washington. The proposed site is also legally known as Lots 3 and 4, Short Plat 2921 records of Benton County, Washington. The executed lease agreement must be consistent with draft lease provided in the application.

4. Prior to providing services, Mid-Columbia Endoscopy Center, LLC must provide an executed copy of the Patient Transfer Agreement for the department's review and approval. The executed agreement must be consistent with draft provided in the application

Conditions

1. Mid-Columbia Endoscopy Center, LLC will provide charity care in compliance with the charity care policies provided in its Certificate of Need application and the requirements of the applicable law. Mid-Columbia Endoscopy Center, LLC will use reasonable efforts to provide charity care in an amount comparable to the average amount of charity care provided by the thee hospitals located in Benton/Franklin secondary health services planning area during the three most recent years. For historical years 2006-2008, these amounts are 2.29% of gross revenue and 5.07% adjusted revenue. Mid-Columbia Endoscopy Center, LLC will maintain records documenting the amount of charity care it provides and demonstrating it compliance with its charity care policies and applicable law**.**

2. Mid-Columbia Endoscopy Center, LLC is limited to only endoscopic/GI type services as described within the application and relied upon by the department in this evaluation

The approved capital expenditure associated with the establishment of Mid-Columbia Endoscopy Center, LLC is $1,451,220.

A. Need (WAC 246-310-210)

Based on the source information reviewed and the applicant's agreement to the terms and conditions identified in the "conclusion section" of this evaluation, the department determines that the applicant has met the need criteria in WAC 246-310-210 and 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

WAC 246-310-270(9) – Ambulatory Surgery Numeric 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 ASCs in Washington State. The numeric methodology provides a basis of comparison of existing operating room (OR) capacity for both outpatient and inpatient OR's in a planning area using the current utilization of existing providers. The methodology separates Washington State into 54 secondary health services planning areas. The proposed ASC would be located in the Benton/Franklin planning area.

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

a) whether a surplus or shortage of OR's is predicted to exist in the target year, and
b) if a shortage of OR's is predicted, the shortage of dedicated outpatient and mixed-use rooms are calculated.
c) Data used to make these projections specifically exclude specialty purpose rooms, such as open heart surgery rooms, delivery rooms, cystoscopic rooms, and endoscopic rooms.[2]

Applicant's Methodology

MCEC does not believe that WAC 243-310-270 is reliable in predicting endoscopy need and therefore did not provide a need methodology. To support its position MCEC states, "*It is the applicant assertion that when applying the need calculation in WAC 246-310-270 (9), the department has historically excluded endoscopy OR's from it numeric methodology. Since it is the intent of this applicant to solely provide endoscopy procedures, we believe the need calculation typically found in a freestanding ASC is not warranted here."* [Source: Application, Page 14] To demonstrate need for a new endoscopy center in the planning area, MCEC provided TCDHC historical patient utilization data and projected the number of endoscopic procedures in the planning area. [Source: Application, Page 19] Table 1 within this evaluation shows the historical number of procedures and Table 2 shows the projected number of procedures.

[2] WAC 246-310-270(9)(a)(iv).

MCEC's need assumptions and projections are based on TCDHC's historical use data and population growth projection data available from the Office of Financial Management. [Source: Application, Page 15] In addition, MCEC states that due to shortages of endoscopy providers and lack of adequate infrastructure such as free-standing ASC's within the planning area, it has been difficult to recruit new providers.

Further, MCEC states, *"Without this facility, the community will continue to experience a critical shortage of this specialty...the applicant currently operates an exempt facility with one procedure room. With over 2,200 procedures performed in one suite there is little surplus capacity. The move to larger facility with three procedure rooms will greatly improve both citizen and physician access."* [Source: Application, Page 13]

In order to show that MCEC application demonstrated adequate patient's utilization in the planning area, the department compared the applicant parent entity historical number of endoscopy procedures against the projected anticipated endoscopy volumes. [Source: Application, Pages 6, 17 and 19] Summarized in Tables 1 and 2 below, are the results of that comparison.

Table 1
TCDHC Historical Number of Procedures

Year	Number of Procedures
2006	1,329[3]
2007	1,980
2008	2,113
2009	1,126[4]

Table 2 below, shows MCEC anticipated volumes from partial year 2010 through the fifth year of operation or year 2015.

Table 2
MCEC Utilization Forecast

Year	Number of Procedures
2010	704[5]
2011	2,113
2012	3,265
2013	4,353
2014	5,441
2015	6,529

The comparison of Tables 1 and 2 above shows that MCEC anticipates it would progressively perform more procedures overtime. MCEC asserted this would be possible with the recruitment of additional gastroenterologists to the practice in the community. MCEC states, that there is no definitive way to foresee when a new physician would be hired.

[3] 2006 Partial year data for—10 months procedures only.
[4] 2009 Annualized partial year data –6 months
[5] 2010 Partial year data from September to December

During the review of this project, Tri-City Regional Surgery Center located in Richland provided public comment related to the need criteria. Tri-City Regional Surgery Center asserted that the applicant's projected numbers of procedures are overstated. Year 2011 procedures are estimated at over 2000 which is equal to about two to four new physicians.

Additionally, Tri-City Regional Surgery Center asserted that the applicant did not take into account the recent opening of Kennewick General Hospital' endoscopy surgery center located in the "Medical Mall".

In response to comments provided to the department regarding this project, MCEC states that it currently operates an exempt facility conducting business as Tri-Cities Digestive Health Center, P.S. and the approval of this project will have minimal impact on the existing volumes in the planning area. [Source: MCEC Rebuttal comments received December 10, 2009]

Department's Methodology

The numeric portion of the methodology requires a calculation of the annual capacity of outpatient and inpatient existing ORs and it excludes specialized dedicated rooms. Examples of 'dedicated' rooms are open heart surgery rooms, delivery rooms, cystoscopic rooms, and endoscopic rooms. Given that endoscopic rooms are specifically excluded from the utilization calculations and this project proposes to establish an ASC dedicated to endoscopic procedures, the numeric methodology is not suitable for projecting need for the ORs specific to this project. The department recognizes that dedicated outpatient endoscopy ASCs are deliberately excluded from the numeric methodology outlined in WAC 246-310-270(9). MCEC proposes to establish a new endoscopy ASC in the Benton/Franklin secondary planning area. There are a total of seventeen providers located within the planning area with OR capacity including the applicant. The seventeen providers are listed below.

Hospital's/City	**ASC/City**
Kennewick General Hospital, Kennewick	High Desert Surgery Center
Kadlec Medical Center, Richland	Tri-Cities Digestive Health Center[6], Richland
Lourdes Medical Center, Pasco	Northwest Ambulatory Physicians, Richland
Prosser Memorial Hospital, Prosser	Pacific Cataract & Laser Institute, Kennewick
	Tri-Cities Endoscopy Center, Kennewick
	Tri-City Orthopedic Center, Richland
	Tri-City Regional Surgery Center, Richland
	Columbia Basin Pediatric Dentistry, Kennewick
	Columbia River Eye Center, Richland
	Retina Laser Eye Center, Kennewick
	Tri-City Anesthesia Management, Richland
	Richard Ehlers, MD—Ehlers Eye Surgery, Kennewick
	Hoyeol Yang MD, PS, Richland

[6] Tri-Cities Digestive Health Center is MCEC's parent company

Since the four hospitals are located in the planning area, all appropriate OR capacity will be used in the numeric methodology calculations under WA 246-310-270. Of the thirteen ASCs shown above, eleven including the applicant are located within a solo or group practice (considered an exempt ASC) and therefore, the use of these ASC's is restricted to the physicians that are employees of members of the clinical practices that operate the facilities.

Therefore, these eleven facilities do not meet the ASC definition found in WAC 246-310-010 and the surgeries and ORs are not included in the methodology for the planning area. The remaining two ASCs High Desert Surgery Center and Northwest Ambulatory Physicians are CN approved and the OR utilization and capacity are included in the calculations for the Benton/Franklin planning area.

To assist in its application of the numeric methodology for this project, on August 12, 2009, the department requested utilization information from the four hospitals and the twelve[7] ASC's in the planning area. Two hospitals Kadlec Regional Medical Center and Kennewick General Hospital and one CN approved provider Tri-City Regional Surgery Center provided responses to the department[8]. Tri-City Regional Center is the only ASC that responded and according to the department's record, Tri-City Regional Center is a CN exempt ASC. The use of the facility is limited to only physicians within the clinical practice and non-physicians members are not allowed usage of the facility. To apply the numeric methodology, the department relied on the following assumptions to apply its methodology.

Assumption	**Data Used**
Planning Area	Benton/Franklin counties
Population Estimates and Forecasts	Office of Financial Management medium series population data for Benton and Franklin counties. Target year 2012 Benton –172,045 Franklin—74,162
Use Rate	Divide 2008 estimated current surgical cases by estimated 2008 populations results in the service area use rate of 37.09/1,000 population
Percent of surgery ambulatory vs. inpatient	Based on DOH survey results, 44.9% ambulatory (outpatient) and 55.1% inpatient
Average minutes per case	Based on DOH survey results, Outpatient cases = 114.58 minutes; inpatient cases 113.48 minutes
OR Annual capacity in minutes	16 mixed-use OR's—1,508,000 mixed-use OR capacity minutes and 13,289 mixed-used surgeries
Existing providers	Based on 2008 listing of Benton/Franklin counties providers. OR capacity: 6 dedicated outpatient and 16 mixed use ORs

[7] The applicant was not sent a utilization survey.
[8] The two hospital's Lourdes Medical Center and Prosser Memorial Hospital and the other eleven CN exempt ASC's did not provide responses.

The department's application of the numeric methodology using available survey responses forecast a surplus of 9.28 mixed used OR's for the Benton/Franklin planning area in year 2012. The department's methodology is Appendix A attached to this evaluation.

In summary, the methodology results in surplus mixed-used OR capacity in the Benton/Franklin counties planning area. However, if this project is approved, the addition of three dedicated ORs providing only endoscopic and GI procedures would not be counted in the OR supply and would have no impact on the need calculations or the future need for additional ORs in the planning area.

Department's Evaluation

Other than raising concerns about the projected number of procedures, Tri-City Regional Surgery Center did not provide any documentation to support its assertion that MCEC's projected utilization is overstated. Tri-City Regional Surgery Center also states that if its own physicians left to join MCEC, it would have to close one OR, but did not provide an evaluation on the impact of this action.

MCEC asserts the new facility will have minimal impact on the existing capacity in the planning area since it currently operates an exempt facility within the same planning area. The department recognizes that MCEC's goal of achieving its anticipated patient's projections is based on the assumption that new gastroenterologists would be recruited to the community who would perform surgeries at the ASC. MCEC anticipates it would recruit new physicians to the planning area rather than draft physicians from existing practices. Therefore, the department expects that MCEC's proposal to establish a new ASC in Benton/Franklin secondary health services planning area would not have an unreasonable impact on the providers in the planning area.

MCEC states that only endoscopic/GI type procedures would be provided at the ASC. To ensure that MCEC operate the proposed facility in accordance with information provided within the application, the department would limit the types of procedures at the ASC with the following condition. As a result, the department concurs with the applicant that numeric methodology outlined in WAC 246-310-270(9) is not predictor of need for the dedicated endoscopic ORs. However, as required by rule the department also applied the numeric methodology to this project. Based on the source information reviewed the department concludes that this sub-criterion is met.

WAC 246-310-270(6)

WAC 246-310-270(6) requires a minimum of two ORs in an ASC. The exempt ASC currently operates with one OR. This project does propose to develop a new three OR endoscopy center to be known as Mid-Columbia Endoscopy center. [Source: Application, Page 7]

Mid-Columbia Endoscopy Center, LLC is limited to providing only those endoscopic and GI type services described within the application and relied upon by the department in this evaluation.

(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.

TCDHC is currently a provider of endoscopy services to residents of Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups.

As a Certificate of Need approved ASC, MCEC must participate in the Medicare and Medicaid programs. To determine whether all residents of the service area would have access to an applicant's proposed services, the department requires applicants to provide a copy of its current or proposed admission policy.

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 any assurances regarding access to treatment.

To demonstrate compliance with this sub-criterion, MCEC provided a copy of its draft admission policy. The draft policy provided the ASC pre-operative guidelines, but did not demonstrate that patients needing care would be admitted for services without regard to race, creed, color, ethnic origin, nationality, sex, handicap, age, or affiliation with fraternal or religious organization. [Source: Application, Page 19, Attachment III-F] If this project is approved, the department would attach a term requiring submission of an executed admission policy. The adopted policy must be consistent with the draft provided in the application.

To determine whether low-income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination.

TCDHC currently provides services to Medicaid eligible patients. Information provided in the application demonstrates that MCEC intends to maintain this status for its existing facilities. A review of the policies and data provided for MCEC reveals the facility's financial pro forma includes both Medicare and Medicaid revenues. [Source: Supplemental Information received September 21, 2009, Attachment SA5-SA8]

To determine whether the elderly would have access or continue to have access to the proposed services, the department uses Medicare certification as the measure to make that determination.

TCDHC currently provides services to Medicare patients. Information provided in the application demonstrates that MCEC intends to maintain this status if this project is approved. A review of the policies and data provided for MCEC reveals the facility's financial pro forma includes both Medicare and Medicaid revenues. [Source: Supplemental Information received September 21, 2009, Attachment SA5-SA8]

A facility's charity care policy should confirm that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups have, or would have, access to healthcare services of the applicant. The policy should also include the process one must use to access charity care at the facility.

MCEC demonstrated its intent to provide charity care to residents by submitting its draft Charity Care/Policy. The policy outlines the process one would use to access charity care. Further, MCEC included a 'charity care' line item as a deduction from revenue within the pro forma financial documents. If this project is approved, the department would attach a term requiring the submission of an executed charity care policy. [Source: Application, Page 21]

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

For charity care reporting purposes, the Department of Health's Hospital and Patient Data Systems (HPDS), divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. MCEC would be located in Benton County within the Central Washington region.

For charity care reporting purposes, there are twenty one hospitals in the Central Washington Region and four affected hospitals located within the Benton/Franklin secondary health services planning area. The four hospitals are Kennewick General Hospital in Kennewick, Kadlec Medical Center in Richland, Lourdes Medical Center in Pasco, and Prosser Memorial Hospital in Prosser. For this project, the department reviewed charity care data for MCEC and the four hospitals currently operating within the Central Washington Region.

According to 2006-2008[9] charity care data obtained from HPDS, the three-year average for the Central Washington Region is 1.94% for gross revenue and 4.46% for adjusted revenue. The combined three year charity care data reported by Kennewick General Hospital, Kadlec Medical Center, Lourdes Medical Center and Prosser Memorial Hospital is 2.29% of gross revenue and 5.07% adjusted revenue. The applicant's pro-forma indicates that the ASC will provide charity care at approximately 2.00% of gross revenue and 3.09% of adjusted revenue. [Source: Application, Page 21 and Supplemental Information received September 21, 2009, Attachment SA5-SA8]

Summarized in the table below is MCEC's projected charity care percentages compared with all of the hospitals located in the Central Washington Regional and the four hospitals within the Benton/Franklin planning area.

[9] Year 2009 charity care data is not available as of the writing of this evaluation.

Charity Care Percentage Comparisons

	% of Total Revenue	% of Adjusted Revenue
MCEC	2.00%	3.09%
Central Washington Region	1.94%	4.46%
Combined Hospitals [10]	2.29%	5.07%

As shown in the table above, MCEC pro forma indicate charity care percentages would be below the regional percentages in the planning area. If this project is approved, the department would attach a condition related to the percentage of charity care to be provided at the ASC.

Based on the documents provided in the application and MCEC's agreement to the condition related to charity care identified in the conclusions section of this evaluation, the department concludes that all residents, including low income, racial and ethnic minorities, handicapped, and other under-served groups would have access to the services provided by the applicant. This sub-criterion is met.

B. Financial Feasibility (WAC 246-310-220)

Based on the source information reviewed, and the applicant's agreement to the terms and conditions identified in the conclusion section of this evaluation, the department determines that the applicant has met the 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.

If this project is approved, MCEC anticipates that it be would be operational by September 2010. Under this timeline, calendar year 2011 would be the first year of operation and years 2012 through 2013 would be the second and third years of operation. [Source: Application, Page 10]

TCDHC is currently operating the ASC under an exemption from Certificate of Need review. To determine whether MCEC would meet its immediate and long range operating costs, the department reviewed its assumptions, projected revenue and expense statement and projected balance sheets for years 2010 through 2013.

[10] The four combined hospital located within the planning area are: Kennewick General Hospital in Kennewick, Kadlec Medical Center in Richland, Lourdes Medical Center in Pasco and Prosser Memorial Hospital in Prosser

MCEC provided the following statements related to the assumptions used as a basis for the projected number of procedure at the proposed ASC. [Source: Application, Page 23]

- Using cost data from several other projects of the same size and scope as well as hard estimates from the project contractor, projects costs were calculated.
- The project consultant has been developing ASC's for over ten years, their experience in all aspects of project development were heavily relied upon

The assumption relied upon by MCEC to project the financial feasibility of the ASC appears to be reasonable. Summarized in Table 3 below, are the projected revenues and expenses for years 2010 to 2013 using financial data from the profit and loss statement provided by MCEC. [Source: Supplemental Information September 21, 2009, Attachment SA-5 through SA-8]

Table 3
MCEC Revenue and Expense Summary

	Partial 2010	FY 2011	FY 2012	FY 2013
# of Procedures	704	2,113	3,265	4,353
Net Revenue*	$389,446	$1,113,352	$1,820,801	$2,566,418
Total Expense	$330,533	$992,593	$1,074,704	$1,315,821
Net Profit or (Loss)	$58,913	$120,759	$746,097	$1,250,597
Net Revenue per Procedure	$553.19	$526.91	$557.67	$589.57
Total Expenses per Procedure	$469.51	$469.76	$329.16	$302.28
Net Profit or (Loss) per Procedure	$83.68	$57.15	$228.51	$287.29

As shown in Table 3 above, at the projected volumes identified, MCEC would be operating at a profit beginning in year 2010 through year 2013. The applicant also included in the expenses above, lease costs for the proposed facility and provided a draft lease agreement between Three Rivers Property, LLC (Landlord) and Mid-Columbia Endoscopy Center, LLC (Tenant). [Source: Application, Attachment II-J]

The agreement outlines the roles and responsibilities for both landlord and tenant. The draft lease costs are consistent with the assumptions used to prepare the financial projections evaluated in Table 3 above. If approved the department would include a term that MCEC provide for review and approval an executed lease agreement consistent with the draft agreement provided within the application.

The 'net revenue' line item in Table 3 is the result of gross revenue minus any deductions for contractual allowances, bad debt, and charity care. The 'total expenses' line item includes staff salaries/wages and the ASC's portion of overhead costs based on the assumptions stated above. In addition to the projected Statement of Operations, MCEC also provided its projected balance sheet for year 2012 through 2013 shown in Table 4 below. [Source: Application, Page 203-205, Attachment IV-H to IV-J]

Table 4
MCEC Projected Balance Sheet Year 2011

Assets		Liabilities	
Current Assets	$ 1,358,206	Current Liabilities	$ 196,902
Fixed Assets	$ 0	Long Term Debt	$ 665,209
Board Designated Assets	$ 0	Other Liabilities	$ 0
Other Assets	$ 0	**Equity**	**$ 496,096**
Total Assets	**$ 1,358,206**	**Total Liabilities and Equity**	**$ 1,358,206**

MCEC Projected Balance Sheet for Year 2012

Assets		Liabilities	
Current Assets	$ 1,016,961	Current Liabilities	$197,322
Fixed Assets	$ 0	Long Term Debt	$ 518,289
Board Designated Assets	$ 0	Other Liabilities	$ 0
Other Assets	$ 0	**Equity**	**$ 301,350**
Total Assets	**$ 1,016,961**	**Total Liabilities and Equity**	**$ 1,016,961**

MCEC Projected Balance Sheet for Year 2013

Assets		Liabilities	
Current Assets	$ 2,263,287	Current Liabilities	$196,423
Fixed Assets	$ 0	Long Term Debt	$ 360,538
Board Designated Assets	$ 0	Other Liabilities	$ 0
Other Assets	$ 0	**Equity**	**$ 1,706,326**
Total Assets	**$ 2,263,287**	**Total Liabilities and Equity**	**$ 2,263,287**

As shown in the balance sheet above, MCEC projected it would operate the ASC in a financially conservative manner. There were no comments submitted to the department related to this sub-criterion. Based on the financial information above, the department concludes that the immediate and long range capital and operating costs of the project can be met. This sub-criterion is met.

Based on the information presented and with Mid-Columbia Endoscopy Center, LLC's agreement to the term related to the lease agreement, the department concludes 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 source of financing criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

MCEC identified the capital expenditure associated with the establishment of the endoscopy center to be $1,451,220. [Source: Application, Page 23]

This project proposes approval of an existing exempt ASC. The proposed project is not expected to have any new impact on the operating costs and charges for ambulatory surgery services because it's already operating and any impact would have occurred when it first opened. MCEC provided the existing and projected percentage of revenue by source. [Source: Application, Page 9 and Supplemental Information September 21, 2009]

Table 5
TCDHC Yearly Revenue Source and Percentages

Source of Revenue	2008-09	2011
Insurance/Health Maintenance Organization (HMO)	67.7%	64.7%
Medicare	32.1%	32.1%
Medicaid /State (DSHS)	0.2%	3.2%
Total	100%	100%

As shown above, the majority of TCDHC's revenue for years 2008 and 2009 is from private/HMO insurance. MCEC projected that in year 2011, it would have 3% more revenue from Medicaid once the ASC was approved. Based on the information reviewed, the department concludes that the costs of this project would probably not result in an unreasonable impact to the costs and charges for health care services within the services area. 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)(ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

To demonstrate compliance with this sub-criterion, MCEC provided the following capital expenditure breakdown for the project**.** [Source: Supplemental Information September 21, 2009]

Table 6
MCEC projected Capital Cost

Item	Cost	% of Total
Building Construction & Tenant Improvements	$688,950	47.5%
Fixed & Moveable Equipment	$468,415	32.3%
Sales Tax and Fees	$191,134	13.2%
Interest and Other	$102,721	7.1%
Total Project Cost	$1,451,220	100%

MCEC states the funding for the project will come from three sources [Source: Application Attachment II-E]

- Member physician capital contribution of $209,220
- Debt financing through a local lending institution –$888,000. Buyers Bank a local lending institution submitted a letter conforming interest in the project. MCEC also provided an amortization schedule for the life of the loan
- Tenant improvement allowance from the landlord—$354,000 the agreed allowance is $60 per square foot of useable area.

A review of TCDHC's historical profit and loss statement for years 2006 through 2008 provided within the application shows this project would not have a significant impact on the overall financial health of the company. [Source: Application, Attachment IV-O through IV-Q]

Based on the information, the department concludes the proposed source of funding for this project is appropriate. This sub-criterion is met.

C. Structure and Process (Quality) of Care (WAC 246-310-230)

Based on the source information reviewed and the applicant agreement to the terms and conditions identified in the conclusion section of this evaluation, the department determines that the applicant has met the structure and process of care criteria in WAC 246-310-230.

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

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 that should be employed for projects of this type or size. Therefore, using its experience and expertise the department assessed the materials contained in the application.

TCDHC is currently operating the ASC under an exemption from Certificate of Need review. As an operational ASC, all staff is already in place and no additional staff is anticipated. Table 6 below summarizes the current staffing**.** [Source: Application, Page 26]

Table 6
MCEC FTE's years 1-3

Type of Staff	Year 1	Year 2	Year 3
RN Nurse Manager	1.0	-	-
RNs	2.0	-	-
LPN's/Tech's	2.0	-	-
Reception	1.0	-	-
Business Office	1.0	-	-
Total FTEs	**7.0**	**-**	**-**

As shown in Table 6 above, MCEC anticipates that it would have all the FTE's needed to operate the proposed ASC during the first year of operation.

The department notes that TCDHC the applicant parent company owns and operates an endoscopy facility located within the same planning area and has demonstrated that it can recruit trained staffs to its facility. Given that the applicant parent entity currently operates a CN exempt facility within the same planning area and has not experienced any difficulty recruiting staff to the ASC to manage the existing volumes, the department concludes that with the additional volumes expected, the applicant can reasonably be expected to hire additional staff as necessary. Based on the source information reviewed, the department concludes that staffing is available for recruitment. This sub-criterion is met.

(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.

MCEC states that it parent company currently operates an endoscopy exempt facility and as a result, has established relationships with the local hospital and healthcare providers. MCEC states these relationships will be maintained as the new facility transitions to a new location. Further, MCEC states it anticipates signing formal patient transfer agreement with Kadlec Medical Center and provided a draft patient transfer agreement. [Source: Application, Attachment V-A]

If this project is approved, the department would include a term requiring MCEC to provide a copy of the executed transfer agreement with a local healthcare provider. Prior to providing services Mid-Columbia Endoscopy Center, LLC will provide an executed copy of the Patient Transfer Agreement for the department's review and approval. The executed agreement must be consistent with draft provided in the application.

Based on this information and with agreement to the term above, the department concludes that Mid-Columbia Endoscopy Center, LLC will have appropriate ancillary and support services relationships with a local healthcare provider. 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.

To demonstrate compliance with this sub-criterion, the applicant stated, *"The applicant currently operates an exempt facility in conformance with all applicable state and federal rules and regulations and intends to comply with them in the future".* [Source: Application, Page 28]

As stated within the application, TCDHC is the applicant parent entity and currently operates a CN exempt ASC in Benton County. Within the most recent six years, the Department of Health's Office of Investigation and Inspections (IIO), which surveys healthcare facilities within Washington State, completed one compliance survey for TCDHC.
The survey revealed minor non-compliance issues and plan of corrections was submitted within the allowable response time. [Source: Office of Health Care Survey 2003 survey data]

Within the application, MCEC identified Dr. Somprak Boonpongmanee as the active medical staff for the parent company TCDHC. Compliance history review of Dr. Boon did not reveal any recorded sanctions. [Source: Licensing and compliance history data provided by DOH-Medical Quality Assurance Commission] Given the compliance history of TCDHC and Dr Boon, the department concludes there is reasonable assurance that MCEC would be operated in conformance with state and federal regulation.

Based on the applicant parent company compliance history and that of the identified active medical staff, the department concludes there is reasonable assurance that MCEC would be operated in conformance with state and federal regulations. This sub-criterion is met.

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

To demonstrate compliance with this sub-criterion, MCEC states that its parent company TCDHC currently operates an endoscopy exempt facility and has established relationships with a local hospital and healthcare providers within the planning area.

MCEC states that those relationships will be maintained as MCEC transition to its new location. MCEC also asserts that, the establishment of the new facility will provide the type of infrastructure necessary to promote the continuity of care in the most efficient and cost-effective manner. [Source: Application, Page 21] Based on the source information reviewed, the department concludes 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 evaluated in sub-section (3) above, and based on that evaluation, the department concludes that this sub-criterion is met.

D. Cost Containment (WAC 246-310-240)

Based on the source information reviewed and the applicant agreement to the terms and conditions identified in the conclusion section of this evaluation, the department determines that the applicant has met the applicable cost containment criteria in WAC 246-310-240.

(1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.

To determine if a proposed project is the best alternative, 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 met WAC 246-310-210 thru 230 criteria, the department would move to step two in the process and assess the other options the applicant or applicants considered prior to submitting the application under review.

If the department determines the proposed project is better or equal to other options the applicant considered before submitting their application, the determination is either made that this criterion is met (regular or expedited reviews), or in the case of projects under concurrent review, move on to step three.

Step three of this assessment is to apply any service or facility specific criteria (tie-breaker) contained in WAC 246-310. The tiebreaker criteria are objective measures used to compare competing projects and make the determination between two or more approvable projects which is the best alternative. If WAC 246-310 does not contain any service or facility criteria as directed by WAC 246-310-200(2)(a)(i), then the department would look to WAC 246-310-240(2) (a)(ii) and (b) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b), then using its experience and expertise, the department would assess the competing projects and determine which project should be approved.

Step One

For this project, MCEC has met the review criteria under WAC 246-310-210, 220, and 230. Additionally, MCEC has met the ambulatory surgery specific review criteria identified in WAC 246-310-270**.** Therefore, the department moves to step two below

Step Two

MCEC states that before submitting an application, it considered maintaining the status quo and establishing a joint venture with a provider. Detailed below are the alternatives considered by MCEC.

Maintaining the status quo

MCEC states it considered maintaining the status quo and rejected it for two reasons. The current exempt facility has limited capacity maintaining the exempt model eliminates the ability of non-member use. [Source: Application, page 29]

Joint Venture

MCEC states that a joint venture option was evaluated but was deemed impractical because there are two CN approved ASC's operating in the planning area. The applicant stated that the model it proposes would allow outside ownership and ASC's are a lower patient cost alternative to that of the hospital base ASC's. [Source: Application, Page 29]

MCEC states that establishing a new facility that allows more GI screening and treatment capacity is attractive. [Source: Application, page 30]

MCEC states there are several advantages to using a free-standing ASC to provide endoscopy services because they promote staff and system efficiencies. Further, MCEC states that additional benefits provided by free-standing ASC's are:

- Freestanding lab facilities are known for their exceptionally high efficiencies and productivity. After a brief start-up period, the facility should meet or exceed industry benchmarks. Typical for this type of facility the average procedures times are about 30 minutes with turnover times of 8-10 minutes.

- In addition to the facility, MCEC has developed work teams who have specialized knowledge in the delivery of routines gastroenterological services. These gastroenterological routine are cost effective and will not jeopardize the quality of patient care.

- System productivity is enhanced and patients will no longer experience delays in scheduling routine screening procedures. Further, the new facility is designed to meet current energy utilization requirements. [Source: Application, Page 30]

Therefore, the department concludes that the project described is the best available alternative for the community.

Step Three

MCEC is the only applicant that submitted an application to provide services for the Benton/Franklin secondary health services planning area. As a result, step three is not evaluated under this sub-criterion.

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

(a) The costs, scope, and methods of construction and energy conservation are reasonable.

As stated in the project description portion of this evaluation, this project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Within that evaluation, the department determined the sub-criterion was met. Therefore, this sub-criterion would also be considered met.

(b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

This sub-criterion is also evaluated within the financial feasibility criterion under WAC 246-310-220(2). Within that evaluation, the department determined the sub-criterion was met. Therefore, this sub-criterion would also be considered met.

APPENDIX A