STATE OF WASHINGTON
DEPARTMENT OF HEALTH

May 29, 2012

CERTIFIED MAIL # 7010 2780 0003 6529 7670

Jan Zemplenyi, MD
Bel-Red Ambulatory Surgical
1260 116th Avenue NE, Ste. 110
Bellevue, Washington 98004

Dear Dr. Zemplenyi:

We have completed review of the Certificate of Need application submitted by Bel-Red Ambulatory Surgical proposing to establish an ambulatory surgery center in Bellevue. Enclosed is a written evaluation of the application.

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

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

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

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

| Mailing Address: | Other Than By Mail |
|---|---|
| Department of Health | Department of Health |
| Certificate of Need Program | Certificate of Need Program |
| Mail Stop 47852 | 111 Israel Road SE |
| Olympia, WA 98504-7852 | Tumwater, WA 98501 |

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

| Mailing Address: | Other Than By Mail |
|---|---|
| Adjudicative Service Unit | Adjudicative Clerk Office |
| Mail Stop 47879 | 111 Israel Road SE |
| Olympia, WA 98504-7879 | Tumwater, WA 98501 |

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

Sincerely,

Steven M. Saxe, FACHE
Director, Health Professions and Facilities

Enclosure

cc: Department of Health, Investigations and Inspections Office

**EVALUATION DATED MAY 29, 2012 OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY BEL-RED CENTER FOR AESTHETIC SURGERY, PS PROPOSING TO ESTABLISH AN AMBULATORY SURGERY CENTER IN EAST KING COUNTY**

## APPLICANT DESCRIPTION

Bel-Red Center for Aesthetic Surgery, PS is a privately held corporation established in 2006. The corporation is governed by its two members, Dr's Jan and Eva Zemplenyi, and operates the Bel-Red Ambulatory Surgical Facility (BRASF). The facility is located at 1260 116th Avenue Northeast, Suite 110 in the city of Bellevue and is operated under an exemption awarded in 2006. [source: Application, p1; Washington Secretary of State web search]

## PROJECT DESCRIPTION

This project proposes the establishment of a new surgery center with two operating rooms. The ASC will allow physicians not employed by BRASF the opportunity to perform surgeries and procedures in Bellevue. This action requires prior Certificate of Need review and approval.

If the project is approved, the location of the ASC would not change. Services offered at the ASC would include otolaryngologic procedures and various forms of cosmetic plastic surgery. [source: Application, p5 & 23]

There is no capital expenditure associated with this project. The ASC is expected to be available to outside physicians upon CoN approval. Based upon the expected release of this evaluation, an approval would result in 2013 being the ASC's first full calendar year of operation. [source: Application, p8]

## APPLICABILITY OF CERTIFICATE OF NEED LAW

This project requires review as the establishment of a new healthcare 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, Bel-Red Center for Aesthetic Surgery, PS must demonstrate compliance with the applicable criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment).[1] Additionally, WAC 246-310-270 contains service or facility specific criteria for ASC projects and must be used to make the required determinations.

**APPLICATION CHRONOLOGY**

| | |
|---|---|
| Letter of Intent Submitted | September 21, 2011 |
| Application Submitted | November 28, 2011 |
| Department's Pre-Review Activities<br>• screening activities and responses | November 29, 2011 through<br>February 16, 2012 |
| Department Begins Review of the Application<br>• No public hearing conducted<br>• public comments accepted throughout the review | February 17, 2012 |
| End of Public Comment/Public Hearing | March 23, 2012 |
| Department's Anticipated Decision Date | May 10, 2012 |
| Department's Updated Decision Date | June 11, 2012 |
| Department's Actual Decision Date | May 29, 2012 |

[1] Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), & (6), WAC 246-310-220(3), and WAC 246-310-240(2) & (3).

## AFFECTED PERSONS

Washington Administrative Code 246-310-010(2) defines "affected person as:
*"…an "interested person" who:*

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

No entities sought or received affected person status for this project.

## SOURCE INFORMATION REVIEWED

- Bel-Red Center for Aesthetic Surgery, PS Certificate of Need Application received November 28, 2011
- Bel-Red Center for Aesthetic Surgery, PS supplemental information received February 14, 2012
- East King County ASC operating room utilization survey responses
- Data reported to the Integrated Licensing and Regulatory System (ILRS)
- Claritas population data for East King County secondary health services planning areas
- Historical charity care data obtained from the Department of Health's Hospital and Patient Data Systems (2008, 2009, and 2010 summaries)
- Washington Secretary of State web site
- Department of Health / Health Systems Quality Assurance Provider Credential Information
- Medicaid/Health Care Authority ASC Procedure Groupings Effective July 1, 2011
- Certificate of Need historical files

## CONCLUSION

For the reasons stated in this evaluation, the application submitted by Bel-Red Center for Aesthetic Surgery, PS proposing to establish a freestanding ambulatory surgery center in East King County is not consistent with the applicable criteria of the Certificate of Need program, and a Certificate of Need is denied.

**A. Need (WAC 246-310-210) and Ambulatory Surgery (WAC 246-310-270)**

Based on the source information reviewed, the department determines that Bel-Red Ambulatory Surgical Facility has not 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 East King County planning area.

Applicant's Methodology

The numeric portion of the methodology requires a calculation of annual capacity of existing ORs, both outpatient and inpatient. To support this application, BRASF relied on a version of a need methodology from a recently released program evaluation. The assumptions applied in the methodology are detailed below. [source: February 14, 2012 Supplemental Information, p2]

| Assumption | Data Used |
|---|---|
| Planning Area | East King County |
| Target Year | 2013 |
| Population-Target Year | 553,278 |
| Use Rate | 141.726/1,000 |
| Average minutes per case | Inpatient cases= 149.08 minutes<br>Outpatient cases = 48.95 minutes |
| OR capacity Counted: | Mixed Use: 20<br>Dedicated outpatient: 30 |

The methodology based on the assumptions described above indicates a surplus of 9 in-patient OR's and need for 20.88 out-patient ORs in 2013.

Department's Methodology

The numeric 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. Preference is given to dedicated outpatient operating rooms.

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]

In the East King planning area there are four hospitals and thirty-five ASCs. The table below lists those hospitals and ASCs.

**Table 1**
**East King County Planning Area Hospitals and ASCs**

| **Hospital's/City** | |
|---|---|
| Evergreen Hospital Medical Center, Kirkland | Snoqualmie Valley Hospital |
| Overlake Hospital Medical Center, Bellevue | Swedish Issaquah Hospital [3] |
| **ASC's** | |
| Allure Laser Center | Northwest Nasal Sinus Center |
| Anderson Cosmetic Surgery | Overlake Surgery Center |
| Ambulatory Surgery Center at the GH Bellevue MC | Pacific Cataract & Laser Institute |
| Aysel Sanderson MD | Plastic Surgery North West Surgery Center |
| Bellevue Spine Specialist | Pratt Plastic Surgery Center |
| Bel Red | Proliance Highlands Surgery Center |
| Bellevue Urology Associates | Remington Plastic Surgery |
| Cosmetic Surgery & Dermatology of Bellevue | Retina Surgery Center, The |
| Eastside Ambulatory Surgery[4] | Seattle Children's-Bellevue ASC[5] |
| Eastside Endoscopy-Bellevue[6] | Sammamish Center for Facial Plastic Surgery |
| Eastside Endoscopy-Issaquah[7] | Sephehr Egrari MD FACS Plastic Surgery Center |
| Evergreen Orthopedic Surgery Center | Skin Surgery Center |
| Evergreen Surgical Center | Swedish Health Services -Bellevue ASC |
| Evergreen Surgical Clinic Ambulatory Surgery Ctr. | Swedish Lakeside Surgery Center[8] |
| La Provence Esthetic Surgery | Stern Center for Aesthetic Surgery, The |

[2] WAC 246-310-270(9)(a)(iv). "…Exclude cystoscopic and other special purpose rooms (e.g., open heart surgery) and delivery rooms.

[3] Swedish Issaquah is a new hospital that recently opened in Issaquah. On July 1, 2011, the department issued CN1264R2A for a change in site for the Swedish-Bellevue ASC. That CN approved moving the ASC's 5 ORs to the outpatient surgery space of the new Issaquah hospital. In this way, the ORs could be used to provide outpatient surgery before the rest of the hospital was operational. Once the hospital became operational, these 5 ORs became the hospital's outpatient surgery within the hospital's license. Since the hospital is now open, these 5 ORs are included in the hospital's count of OR capacity and are not counted as a separate ASC.

[4] Approved with CN1462 in January 2012

[5] Seattle Children's Bellevue ASC is limited to providing services to pediatric patients.

[6] Approved with CN1469 in April 2012

[7] Approved with CN1460 in December 2011

[8] This facility was previously known as Issaquah Surgery Center. On October 10, 2006, CN1338 was issued to Proliance Surgeons, Inc. The Issaquah Surgery Center began offering services in November 2006. In approximately January 2010, Issaquah Surgery Center, LLC was formed to operate the ASC. Swedish Health Services and two physicians were the sole members of the LLC. Under the terms of the LLC agreement, Swedish was required to buy out the interest of the two physicians. This occurred sometime in 2010. [source: DoR11-16]

| | |
|---|---|
| Naficy Plastic Surgery & Rejuvenation Center | Virginia Mason-Bellevue Ambulatory Surgical Ctr. |
| North Pacific Dermatology | Washington Institute Orthopedic Center |
| Northwest Center for Aesthetic Plastic Surgery | |

For the hospitals located in the planning area, their mixed use ORs and dedicated outpatient ORs are counted in the planning area's supply of ORs, if known. Of the thirty-five ASC facilities located within the planning area, 10 have Certificates of Need[9]. Their OR capacity is also counted in the supply of ORs available in the planning area. The remaining 25 ASCs are within solo or group practices. The use of these ASCs is restricted to physician owners or employees of the respective clinical practices. These ASCs are exempt from CoN[10]. The utilization but not the OR capacity of these exempt ASCs is counted in the numeric methodology.

On February 10, 2011, the department requested utilization information from the hospitals and ASCs in the planning area. Seven providers responded. Those were Overlake Hospital Medical Center, Overlake Surgery Center, LLC, Swedish-Issaquah Hospital, Swedish Lakeside ASC, Swedish Health Services-Issaquah ASC, Swedish Health Services-Bellevue ASC, Remington Plastic Surgery Center, and Bellevue Urology Associates. The utilization information obtained from these responses and information obtained from the department's ILRS program was used to determine the planning area's use rate.

The department used the following assumptions in applying its numeric methodology.

| **Assumption** | **Data Used** |
|---|---|
| Planning Area | East King County |
| Target Year | 2013 |
| Population-Target Year | 553,278 |
| Use Rate | 141.726/1,000 |
| Average minutes per case | Inpatient cases= 149.08 minutes<br>Outpatient cases = 48.95 minutes |
| OR capacity counted: | Mixed Use: 20<br>Dedicated outpatient: 36 |

The department's application of the numeric methodology based on the assumptions described above indicates a surplus of 10 in-patient OR's and need for 15.55 out-patient ORs in 2013. With the inclusion of recent department approvals for additional OR's in the planning area[11], need still exists in excess of the 2 OR's requested in this application. The department's methodology is Attachment A of this evaluation.

[9] Evergreen Orthopedic Surgery Center, Evergreen Surgery Center, Northwest Nasal Sinus, Overlake Surgery Center, Seattle Children's Bellevue ASC, Swedish Health Services-Issaquah ASC, Swedish Lakeside Surgery Center, Eastside Ambulatory Surgery approved in January 2012, Eastside Endoscopy-Issaquah approved December 2011, and Eastside Endoscopy-Bellevue approved April 2012.
[10] WAC 246-310-010(5)
[11] 6 new ORs with Applications CN11-15, CN11-16, and CN12-01

When reviewed, each method shows need for out-patient OR capacity beginning in the first full year of operation (2013). This need, if left unmet, may lead to reduced access to the surgery facilities necessary to serve the residents of the planning area. In summary, based solely on the numeric methodology performed as contained in WAC 246-310-270, need of outpatient OR capacity in the East King planning area is demonstrated.

Based on the source information reviewed, the department concludes that need for additional OR capacity has been established. **This sub-criterion is met.**

*WAC 246-310-270(6) (6) An ambulatory surgical facility shall have a minimum of two operating rooms*

This project is to build a new two OR surgical center in Bellevue. BRASF provided single line drawings within the application. Those drawings show the ASC will have the required two ORs. **This sub-criterion is met**. [source: Application, p33]

*(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 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, BRASF provided a copy of the non-discrimination policy. The policy states that services will be provided regardless of race, creed, color, ethnic origin, nationality, sex, handicap, age, or affiliation with fraternal or religious organizations. The policy is comparable to others the department has reviewed. [source: Application, Exhibit L]

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

This sub-criterion requires the applicant to demonstrate the extent to which Medicare, Medicaid, and medically indigent patients would be served by the project [WAC 246-310-210(2)(c)]. Generally, the department reviews the documents provided in the application to determine whether the facility intends to carry a Medicare contract. The Medicare contract ensures that the applicant intends to provide services for elderly patients-which would include women, handicapped, and racial and ethnic minorities. The department also reviews information provided in the application to determine whether the facility intends to carry a Medicaid contract. This contract ensures that the applicant intends to provide services for low-income patients, which may also include women, handicapped, and racial and ethnic minorities.

Documents provided in this application demonstrate that the applicant intends to carry a Medicare contract, however, the application also shows that the applicant does not now, nor does it intend to, carry a Medicaid contract. Although, a review of both the current and proposed additional procedures, shows that many are eligible for Medicaid reimbursement. The table below itemizes the proposed services and the corresponding Medicaid reimbursement categories. [source: Application, p7 & Exhibit D, 2011 Medicaid ASC Fee Schedules]

**Table 2**
**2011 Health Care Authority / Medicaid ASC Groupings and Fees**

| Current BRASF Procedures | CPT | Payment Group | Maximum Reimbursement |
|---|---|---|---|
| Functional Nasal Surgery | 30465 | 9 | $924 |
| | 30520 | 4 | $415 |
| Sinusectomy | 31255 | 5 | $466 |
| UVPP | 42145 | 5 | $466 |
| Tonsillectomy | 42826 | 4 | $415 |
| **Proposed New Procedures** | | | |
| Mastoplexy | 19316 | 4 | $415 |
| Mastectomy | 19300 | 4 | $415 |
| Reduction mammaplasty | 19318 | 4 | $415 |
| Post-mastectomy reconstruction | 19342 | 3 | $366 |
| Areola reconstruction | 19350 | 4 | $415 |

These groupings and rates are based upon the Medicaid fee schedule effective July 1, 2011. This dates approximately 6 months prior to the receipt of this application and is only one of many updates since reimbursements for ASC procedures began in 2008[12].

To determine whether the elderly would have access to the proposed services, the department uses Medicare certification as the measure to make that determination. To demonstrate compliance with this sub-criterion, BRASF demonstrated its intent to continue to be Medicare certified and approximately 2% of BRASF's revenue is expected to be from Medicare patients. [source: Application, p7]

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. To demonstrate compliance with this sub-criterion, BRASF provided a copy of the charity care policy. [source: BRASF Application, Exhibit M]

WAC 246-310-270(7) states "*Ambulatory surgical facilities shall document and provide assurances of implementation of policies to provide access to individuals unable to pay consistent with charity care levels provided by hospitals affected by the proposed ambulatory*

[12] DSHS Health and Recovery Services Administration Memorandum No: 08-14

*surgical facility. The amount of an ambulatory surgical facility's annual revenue utilized to finance charity care shall be at least 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*."

For charity care reporting purposes, the Department of Health's Hospital and Patient Data Systems program (HPDS), divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. BRASF is located in King County. There are 21 hospitals located within the region[13]. According to 2008-2010 charity care data obtained from HPDS, the three-year average for the hospitals affected in the East King County planning area[14] was 1.08% for total revenue and 1.80% of adjusted revenue. The applicant's revenue and expense statement shows the BRASF is projecting a three-year average level of 1.30% of total revenue. The department calculated BRASF's adjusted revenue using the percentages of revenue expected to be received from Medicare and Medicaid and subtracted from gross revenue. [source: Application, p7; February 14, 2012 Supplemental Information, p4]

The table below shows the comparison of BRASF proposed level of charity care to the applicable East King County hospitals.

**Table 3**
**Bel-Red Aesthetic Surgery Facility**
**Charity Care Comparison**

| | 3-Year Average for East King County Hospitals | 3-Year Average for Projected BRASF |
|---|---|---|
| **% of Total Gross Revenue** | 1.08 % | 1.30 % |
| **% of Adjusted Net Revenue** | 1.80 % | 1.33 % |

As shown, BRASF is projecting its charity care below the regional average in the adjusted revenue category. The similarity of the applicant's gross and adjusted calculations is due to the Medicare reimbursements accounting for only 2% of the facilities total revenues.

Based on the information provided, the department cannot conclude there is reasonable assurance that the ASC, if approved, would be available to all residents in the planning area including low-income residents or meet the level of charity care required by WAC 246-310-270(7). As a result, this project **does not meet this sub-criterion**.

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

Based on the source information reviewed, the department concludes Bel-Red Ambulatory Surgical Facility has not met the financial feasibility criteria in WAC 246-310-220.

[13] This number includes Swedish-Issaquah Hospital which recently opened.
[14] Includes both Evergreen and Overlake hospitals.

*(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.

The assumptions relied on by BRASF to project the financial viability of the ASC are based upon BRASF experience and letters from local surgeons expressing a need for access to a fully-equipped facility. The table below is the applicant's projected patient cases for the proposed ASC. [source: Application, p24 & Exhibit F; February 14, 2012 Supplemental Information, p6]

**Table 4**
**Bel-Red Aesthetic Surgery Facility**
**Estimated Surgical Utilization**

| Current Services | 2013 | 2014 | 2015 |
|---|---|---|---|
| Blepharoplasty | 12 | 13 | 14 |
| Rhinoplasty | 17 | 17 | 18 |
| Rhytidectomy | 15 | 16 | 18 |
| Mammaplasty | 17 | 18 | 21 |
| Liposuction | 20 | 21 | 22 |
| Smartskin | 18 | 18 | 19 |
| Other Cosmetic Surgery | 12 | 14 | 16 |
| Functional Nasal Surgery | 28 | 28 | 29 |
| Sinusectomy | 14 | 15 | 15 |
| UVPP | 5 | 5 | 6 |
| Tonsillectomy | 13 | 13 | 13 |
| Other functional surgery | 12 | 12 | 12 |
| **New Services** | | | |
| Mastoplexy | 7 | 10 | 12 |
| Mastectomy | 3 | 4 | 4 |
| Reduction mammaplasty | 6 | 7 | 7 |
| Post-mastectomy reconstruction | 5 | 5 | 8 |
| Areola reconstruction | 3 | 4 | 4 |
| Belt-lipectomy | 4 | 5 | 6 |
| Plasma Injections | 8 | 9 | 9 |
| Breast augmentation | 7 | 14 | 16 |
| **Total** | **226** | **248** | **269** |

Using the projected procedures above, the applicant provided its projected revenue and expense statement for years 2013 to 2015. The table below is a summary of BRASF's projected financials.

**Table 5**
**Bel-Red Aesthetic Surgery Facility**
**Revenue and Expense Summary**

| | Projected FY 2013 | Projected FY 2014 | Projected FY 2015 |
|---|---|---|---|
| Number of Procedures | 226 | 248 | 269 |
| Net Revenue | $ 474,724 | $ 520,936 | $ 675,430 |
| Total Expenses | $ 386,288 | $ 411,076 | $ 420,329 |
| Net Profit or (Loss) | $ 88,436 | $ 109,860 | $ 255,101 |
| Average Revenue per Procedure | $ 2,101 | $ 2,101 | $ 2,511 |
| Average Expenses per Procedure | $ 1,709 | $ 1,658 | $ 1,563 |
| Net Profit or (Loss) per Average Procedure | **$ 391** | **$ 443** | **$ 948** |

The 'net revenue' line item cited above 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 overhead costs based on the assumptions and forecasts outlined above. As shown, BRASF anticipates it would operate at a profit from the beginning in fiscal year 2013.

In addition to the projected Statement of Operations, BRASF provided the projected Balance Sheets for the facility Below is a summary of years 2013 and 2015, which are the first and third full years of operation as a Certificate of Need approved ASC. [source: February 14, 2012 Supplemental Information, p5]

**Tables 6**
**Bel-Red Aesthetic Surgery Facility Forecasted Balance Sheets**
**Year 2013**

| Assets | | Liabilities | |
|---|---|---|---|
| Cash | 172,918 | Current Liabilities | 150,000 |
| Inventory | 14,500 | Long Term Debt | 226,486 |
| Fixed Assets (Equipment) | 544,208 | Other Liabilities | (100,000) |
| Accumulated Depreciation | (366,704) | **Equity** | 88,436 |
| **Total Assets** | **364,922** | **Total Liabilities and Equity** | **364,922** |

**Year 2015**

| Assets | | Liabilities | |
|---|---|---|---|
| Cash | 376,167 | Current Liabilities | 150,000 |
| Inventory | 13,000 | Long Term Debt | 224,781 |
| Fixed Assets (Equipment) | 604,208 | Other Liabilities | (100,000) |
| Accumulated Depreciation | (463,494) | **Equity** | 255,100 |
| **Total Assets** | **529,881** | **Total Liabilities and Equity** | **529,881** |

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**.

*(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.

There are no capital costs associated with this project.

To demonstrate compliance with this sub-criterion, BRASF provided the projected sources of patient revenue for its ASC are shown below. [source: Application, Exhibit H; October 10, 2011 Supplemental Information, p3]

**Table 7**
**Bel-Red Aesthetic Surgery Facility**
**Projected Sources and Percentages of Revenue**

| Source of Revenue | Projected |
|---|---|
| Medicare | 2 % |
| State (Medicaid) | 0 % |
| Commercial | 20 % |
| Private Pay | 78 % |
| **Total** | **100 %** |

As shown above, the majority of revenues are expected to be paid by private and commercial payers due to the historical nature of cosmetic surgery services. These payer sources are not expected to raise fees or reimbursements based on this project.

However, as previously stated in the need portion of this evaluation and shown above, BRASF does not participate in the Medicaid program. As a result, any Medicaid patient in the planning area would have to be served by the planning area hospitals. The result is an unreasonable impact on the costs and charges for health services within the planning area for these facilities. On the basis of this information, the department concludes that **this sub-criterion is not met**.

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

Based on the source information reviewed, the department concludes Bel-Red Ambulatory Surgical Facility has not met the 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 that should be employed for projects of this type or size. Therefore, using its experience and expertise the department reviews whether the planning would allow for the required coverage.

BRASF anticipates having its current part-time staff remain the primary employees. Additional FTEs will be added as the projected procedures are realized. The table below summarizes the projected staffing at the ASC through 2015. [source: Application, p26]

**Table 8**
**Bel-Red Aesthetic Surgery Facility**
**Staffing Totals for Years 2013 through 2015**

| Type of Staff | 2013 FTEs | 2014 FTEs | 2015 FTEs |
|---|---|---|---|
| Med Director | 1.00 | 1.00 | 1.00 |
| RN | 0.75 | 0.75 | 1.00 |
| Scrub Tech | 0.50 | 0.50 | 1.00 |
| Registration/Reception | 0.25 | 0.25 | 0.40 |
| Tech Sterilization | 0.25 | 0.50 | 0.50 |
| **Total FTEs** | **2.75** | **3.0** | **3.9** |

As shown above, BRASF anticipates almost 4 FTEs by year 2015. To demonstrate that staff would be available and accessible for this project, BRASF notes that current staff is available to expand the initial services as necessary. The additional staff will be recruited initially from an internal listing of available RNs who have experience in working with the expected patient base. [source: Application, p16]

BRASF identified Jan Zemplenyi, MD as the Medical Director for the facility. The application includes an outline of the medical director duties and the rules and regulations the medical director will operate. If approved, the department would include a condition that, prior to providing services, BRASF must provide to the department documents showing that Dr. Zemplenyi has accepted the terms and responsibilities outlined in the application materials. [Source: Application, p21; February 14, 2012 Supplemental Information, p8]

Based on the information provided above, and acceptance of the medical director condition, the department concludes that staff is available or can be recruited and retained. **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(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 comply with this sub-criterion BRASF states that it anticipates purchasing ancillary and support services from the vendors available in the community. The applicant provided a listing of the current vendors for services in areas such as biomedical waste, equipment maintenance, pharmacy, and janitorial services. [source: February 14, 2012 Supplemental Information, p8]

Based on the source information reviewed the department concludes that BRASF is likely to maintain the appropriate ancillary and support services and relationships with the local providers. **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.

The ASC has been operating at its current location since 2006, and it does not own or operate any other health care facilities in Washington or any other state. The Department of Health's Investigations and Inspections Office (IIO), which surveys ASCs within Washington State, has completed both compliance and a licensing survey for BRASF.[15] The surveys revealed no substantial non-compliance issues. [Source: IIO compliance data]

The applicant identified Jan Zemplenyi, MD as the Medical Director for the facility. Also included is a list of area MDs that are expected to use the OR space within the facility. The list includes Doctors Michael Novia, Lisa Precht, Rena Wong, Lorne Trimble, E. Antonio Mangubat, Donald Wortham, Russell Paravecchio, and Robert Soloman. There are no recorded sanctions for any of these surgeons. [Source: Licensing and compliance history data provided by DOH-Medical Quality Assurance Commission]

After reviewing the compliance history of the exempt ASC and the medical staff associated with the proposed facility, the department concludes there is reasonable assurance that BRASF would continue to operate in conformance with applicable state and federal licensing and certification requirements. **This sub-criterion is met**.

[15] Initial compliance survey completed in 2006 and a licensing survey in December 2010.

*(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.

BRASF currently operates as an exempt ASC. Any ancillary and support services agreements are not expected to change if this project is approved. [source: February 14, 2012 Supplemental Information, p8]

However, as previously stated, BRASF does not participate in the Medicaid program. The department concluded that approval of this project may have an unreasonable impact on the existing hospitals in the planning area. Based on this information, the department cannot conclude that there is reasonable assurance that this project would promote continuity of care. As a result, the department must also conclude that approval of this project may result in an unwarranted fragmentation of services for the Medicaid patients. **This sub-criterion is not met.**

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

This sub-criterion is 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, the department concludes Bel-Red Ambulatory Surgical Facility has not met the 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 through 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, BRASF's project met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

**Step Two**

Within the application, BRASF identified three options before submitting this application. These are described below. [source: February 14, 2012 Supplemental Information, p8]

Option 1 – Remaining an exempt ASC

This option was rejected because it would not fulfill the need for additional capacity. And the needs of the surgeons that have requested use of the existing OR space but do not constitute a group practice.

Option 2 – Integrating other surgeons into the BRASF practice

This option was rejected because the interested physicians are not interested in becoming partners of BRASF while maintaining independent offices.

Option 3 – Establish a condominium arrangement with separate ownerships

This option was rejected due to BRASF's concern that the process would be more restrictive and onerous in their efforts to more completely utilize the existing facility and its equipment.

BRASF currently operates an exempt ASC. This project proposes to allow physicians not part of the BRASF practice to use the exempt ASC. This action requires prior CoN review and approval. As a result, BRASF had no other option than to submit this application.

Even though the applicant was able to demonstrate need for the ASC, since BRASF has elected not to participate in the Medicaid program, the department cannot conclude that this project is the best available alternative for all the residents and the existing healthcare system in the planning area. As a result, **this sub-criterion is not met**.

**Step Three**

For this project, only BRASF submitted an application to establish an ASC in the East King County planning area. As a result, step three is not evaluated under this sub-criterion.

# APPENDIX A

# APPENDIX A
## ASC Need Methodology
## East King County

Service Area Population: 2013 553,278 Per CN program files
Surgeries @ 141.726/1,000: 78,414

a.i. 94,250 minutes/year/mixed-use OR

a.ii. 68,850 minutes/year/dedicated outpatient OR

a.iii. 36 dedicated outpatient OR's x 68,850 minutes = 2,478,600 minutes dedicated OR capacity 50,636 Outpatient surgeries

a.iv. 20 mixed-use OR's x 94,250 minutes = 1,885,000 minutes mixed-use OR capacity 12,644 Mixed-use surgeries

b.i.
projected inpatient surgeries = 5,905 = 880,305 minutes inpatient surgeries
projected outpatient surgeries = 72,509 = 3,549,255 minutes outpatient surgeries

b.ii. Forecast # of outpatient surgeries - capacity of dedicated outpatient OR's

| | | | | |
|---|---|---|---|---|
| 72,509 | - | 50,636 | = | 21,873 outpatient surgeries |

b.iii.
average time of inpatient surgeries = 149.08 minutes
average time of outpatient surgeries = 48.95 minutes

b.iv.
inpatient surgeries*average time = 880,305 minutes
remaining outpatient surgeries(b.ii.)*ave time = 1,070,655 minutes
1,950,959 minutes

c.i. if b.iv. < a.iv. , divide (a.iv.-b.iv.) by 94,250 to determine surplus of mixed-use OR's
**Not Applicable - Go to c.11. and ignore any value here.**

| | | | | |
|---|---|---|---|---|
| 1,885,000 | | | | |
| - 1,950,959 | | | | |
| -65,959 | / | 94,250 | = | **-0.70** |

c.ii. if b.iv. > a.iv., divide (inpatient part of b.iv - a.iv.) by 94250 to determine shortage of inpatient OR's
**USE THESE VALUES**

| | | | | |
|---|---|---|---|---|
| 880,305 | | | | |
| - 1,885,000 | | | | |
| (1,004,695) | / | 94,250 | = | **-10.66** |

divide outpatient part of b.iv. By 68,850 to determine shortage of dedicated outpatient OR's

| | | | | |
|---|---|---|---|---|
| 1,070,655 | / | 68,850 | = | **15.55** |

Prepared by: Janis Sigman/Mark Thomas

**APPENDIX A**
**ASC Need Methodology**
**East King County**

| Facility | Special rms | Ded. Inpat | Ded. Outp at | Mixed use | closed /not used | op hrs | op wks | ip hrs | ip wks | mixed hrs | mixed wks | ip min/case | ip clean | 2009 ip cases | 2009 ip min | op min/case | op clean | 2009 op case | 2009 op min | Comments |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Evergreen Hospital Medical Center | | | | 8 | | | | | | | | | | | | | | | | Used Applicant reported ORs |
| Overlake Hospital Medical Center | | 15 | 4 | | | 47 | 52 | 143 | 52 | | | 142 | 38 | 6614 | 986025 | 56 | 27 | 7329 | 495328 | |
| Snoqualmie Valley Hospital | | | | 2 | | | | | | | | | | | | | | | | No surgeries reported to CHARS in 2009. Surgeries reported in 2008 and 2007. Used previously Reported ORs |
| Swedish Issaquah Hospital | 4.00 | | | 10 | | | | | | | | | | | | | | | | 14 ORs reported (including 2 endoscopy and 2 caths) Used 10 these other 4 are specical purposes & not counted |
| Allure Laser Center | | | | | | | | | | | | | | | | | | 815 | 40750 | Reported 2 ILRS |
| Aysel Sanderson MD | | | | | | | | | | | | | | | | | | 175 | 8750 | Reported 2 ILRS |
| Ambulatory Sergery Center at the GH Bellevue MC | | | | | | | | | | | | | | | | | | 5070 | 253500 | Reported 2 ILRS |
| Anderson Cosmetic Surgery | | | | | | | | | | | | | | | | | | 160 | 8000 | Reported 2 ILRS |
| Belevue Spine Specialist | | | | | | | | | | | | | | | | | | 2500 | 125000 | Reported 2 ILRS |
| Bellevue Urology Associates | | | | | | 16 | 26 | | | | | | | | | 60 | 30 | 1700 | 85000 | Survey did not ID No. of cases. Number of Cases obtained from ILRS. Minutes calculated using default outpatient #. |
| Bel Red | | | | | | | | | | | | | | | | | | 200 | 10000 | Reported 2 ILRS |
| Cosmetic Surgery & Dermatology of Issaquah | | | | | | | | | | | | | | | | | | 511 | 25550 | Reported 2 ILRS |
| Eastside Endoscopy-Bellevue (Applicant 11-15) | | | 2 | | | 50 | 52 | | | | | | | | | 60 | 30 | 12079 | 603950 | |
| Eastside Endoscopy-Issaquah (Applicant 11-16) | | | 2 | | | | | | | | | | | | | 60 | 30 | 12079 | 603950 | |
| Eastside ASC (Applicant 12-01) | | | 2 | | | | | | | | | | | | | | | | | |
| *Evergreen Orthopedic Surgery Center | | | 3 | | | | | | | | | | | | | | | 2600 | 130000 | Reported 2 ILRS |
| *Evergreen Surgical Center | | | 8 | | | | | | | | | | | | | | | 9000 | 450000 | Reported 2 ILRS |
| Evergreen Surgical Clinic Ambulatory Surgery Center | | | | | | | | | | | | | | | | | | 1550 | 77500 | Reported 2 ILRS |
| La Provence Esthetic Surgery | | | | | | | | | | | | | | | | | | 105 | 5250 | Reported 2 ILRS |
| Naficy Plastic Surgery & Rejuvenation Center | | | | | | | | | | | | | | | | | | 410 | 20500 | Reported 2 ILRS |
| North Pacific Dermatology | | | | | | | | | | | | | | | | | | 625 | 31250 | Reported 2 ILRS |
| Northwest Center for Aesthetic Plastic Surgery | | | | | | | | | | | | | | | | | | 200 | 10000 | Reported 2 ILRS |
| *Northwest Nasal Sinus Center | | | 2 | | | | | | | | | | | | | 92.9 | 15 | 4009 | 85745 | Number of ORs obtained from ILRS |
| *Overlake Surgrey Center | | | 6 | | 1 | 50 | 52 | | | | | | | | | 35 | 15 | 7272 | 253762 | |
| Pacific Cataract & Laser Institute | | | | | | | | | | | | | | | | | | 3749 | 187450 | Reported 2 ILRS |
| Plastic Surgery North West Surgery Center | | | | | | | | | | | | | | | | | | 520 | 26000 | Reported 2 ILRS |
| Pratt Plastic Surgery Ctr | | | | | | | | | | | | | | | | | | 100 | 5000 | Reported 2 ILRS |
| Proliance Highlands Surgery Center | | | | | | | | | | | | | | | | | | 3000 | 150000 | Reported 2 ILRS |
| Remington Plastic Surgery | | | | | | 24 | 48 | | | | | | | | | 180 | 30 | 177 | 31860 | Used survey responses op min/case times # of cases reported in survery to calculate surgery minutes. |
| Retina Surgery Center, The | | | | | | | | | | | | | | | | | | 1500 | 75000 | Reported 2 ILRS |
| *Seattle Children's-Bellevue ASC | | | 2 | | | | | | | | | | | | | | | | | Specialized - limited to pediatric patients |
| Sammamish Center for Facial Plastic Surgery | | | | | | | | | | | | | | | | | | 100 | 5000 | Reported 2 ILRS |
| Sephehr Esrari MD FACS Plastic Surgery Center | | | | | | | | | | | | | | | | | | 326 | 16300 | Reported 2 ILRS |
| Skin Surgery Center | | | | | | | | | | | | | | | | | | 1256 | 62800 | Reported 2 ILRS |
| Swedish Health Services -Bellevue ASC | | | | | | | | | | | | | | | | | | | | On July 1, 2011, the department issued CN1284R2A for a change in site for the Swedish-Bellevue ASC. That CN approved moving the ASC's 5 ORs to the outpatient surgery space of the new Issaquah hospital. In this way, the ORs could be used to provide outpatient surgery before the rest of the hospital was operational. Once the hospital became operational, these 5 ORs became the hospital's outpatient surgery within the hospital's license. Since the hospital is now open, these 5 ORs are included in the hospital's count of OR capacity and are not counted as a separate ASC. |
| *Swedish Health Services-Issaquah ASC | | | 3 | | | | | | | | | | | | | | | | | CN1330R Expires 10.1.12 Est. commencement stated Ulown-June Progress Report |
| *Swedish Lakeside Surgery Center | | | 2 | | | 40 | 52 | | | | | | | | | 90 | 45 | | | This facility was previously known as Issaquah Surgery Center. On October 10, 2006, CN1336 was issued to Proliance Surgeons, Inc. The Issaquah Surgery Center began offering services in November 2006. In approximately January 2010, Issaquah Surgery Center, LLC was formed to operate the ASC. Swedish Health Services and two physicians were the sole members of the LLC. Under the terms of the LLC agreement, Swedish was required to buy out the interest of the two physicians. This occurred sometime in 2010. [Source: DoR11-16] |
| Stern Center for Aesthetic Surgery, The | | | | | | | | | | | | | | | | | | 250 | 12500 | Reported 2 ILRS |
| Virginia Mason-Bellevue Ambulatory Surgical Center | | | | | | | | | | | | | | | | | | 1350 | 67500 | Reported 2 ILRS |
| Washington Institute Orthopedic Center | | | | | | | | | | | | | | | | | | 500 | 25000 | Reported 2 ILRS |
| Totals | 4.00 | 15 | 36 | 20 | 1 | 227 | 282 | 143 | 52 | 0 | 0 | 142 | 38 | 6614 | 986025 | 643.9 | 222 | 81217 | 3988196 | |
| | | | | | | | | | | | | Average min/case | | | 149.08 | Ave min/case | | | 49.10543 | |

*ASCs that have CoNs and are counted in supply for methodology

Outpatient minutes calculated at default 50 minutes/case for those ASCs not responding to survery.
ILRS: Integrated Licensing & Regulatory System
Population data source: Claritas

| | |
|---|---|
| Total Surgeries 2009 | 87,831 |
| Area population 2010 | 534,496 |
| Use Rate 2009 per survey or ILRS | 164.325 |
| Planning Area projected population for 2013 | 553,278 |
| *ASCs that have CoNs and are counted in supply for methodology | |
| % Outpatient of total surgeries | 92.47% |
| % Inpatient of total surgeries | 7.53% |