

STATE OF WASHINGTON DEPARTMENT OF HEALTH

December 13, 2013

CERTIFIED MAIL # 7011 1570 0002 7802 6326

Jennifer Graves, RN MSN Chief Executive Swedish Medical Center-Ballard 5300 Tallman Avenue Northwest Seattle, Washington 98107

RE: CN 13-43

Dear Ms. Graves:

We have completed review of the Certificate of Need (CN) application submitted by Swedish Health Services proposing to establish an 8-bed level II intermediate care nursery and obstetric services at the Ballard campus. For the reasons stated in the enclosed decision, the application is consistent with the applicable criteria of the Certificate of Need Program, provided Swedish Health Services agrees to the following in its entirety:

Project Description:

This certificate approves the establishment of an 8-bed intermediate care nursery and level II obstetric services at the Ballard Campus. Once the intermediate care nursery is operational, the breakdown of beds by use is shown below.

Bed Type	# of Licensed Beds		
General Medical/ Surgical	125		
Level II ICN	8		
Total Number of Licensed Beds	133		

Condition:

Approval of the project description as stated above. Swedish Health Services further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.

Approved Costs:

The approved capital expenditure for this project is \$3,603,658.

Jennifer Graves, RN MSN Chief Executive Swedish Medical Center-Ballard December 13, 2013 Page 2 of 2

You have two options, either accept or reject the above in its entirety. If you accept the above in its entirety, your application will be approved and a Certificate of Need sent to you. If you reject any provision of the above, you must identify that provision, and your application will be denied because approval would not be consistent with applicable Certificate of Need review criteria. Please notify the Department of Health within 20 days of the date of this letter whether you accept the above in its entirety.

Your written response should be sent to the Certificate of Need Program, at one of the following addresses.

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

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

Sincerely.

Steven M. Saxe, FACHÉ Director, Community Health Systems

Enclosure

EVALUATION DATED DECEMBER 13, 2013 OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY SWEDISH HEALTH SERVICES PROPOSING ESTABLISH AN EIGHT-BED INTERMEDIATE CARE NURSERY WITHIN SPACE AT THE BALLARD HOSPITAL CAMPUS

APPLICANT DESCRIPTION

Swedish Health Services (SHS) is a not-for-profit corporation and a 501(c)(3) exempt organization with 100% ownership of Swedish Medical Center.¹ Swedish Medical Center is also a Washington private, not-for-profit corporation and a 501(c)(3) exempt organization. Swedish Medical Center provides Medicare and Medicaid acute care services at the following five campuses.

SHS-First Hill	747 Broadway, Seattle	King County
SHS-Ballard	5300 Tallman Avenue Northwest, Seattle	King County
SHS-Cherry Hill	500 – 17 th Avenue, Seattle	King County
SHS Edmonds	21601 76th Avenue West, Edmonds	Snohomish County
SHS-Issaquah	751 Northeast Blakely Drive, Issaquah	King County

PROJECT DESCRIPTION

This project focuses on SHS-Ballard identified in bold above. SHS-Ballard is licensed under SHS-First Hill. The combined license is 860 acute care beds, and of those, 133 are located at SHS-Ballard.²

Services currently provided at SHS-Ballard include general medical surgical services and obstetric services. This project proposes the establishment of an 8-bed intermediate care nursery (ICN) and level II obstetric services at the hospital. The 8-bed ICN bassinettes would be licensed within the 133 acute care beds located at SHS-Ballard. [source: Application, p15; August 22, 2013, supplemental information, pp2; and CN historical files.]

The capital expenditure associated with the establishment of the 8-bed ICN is \$3,603,658. Of that amount 51% is related to construction costs; 32% for fixed/moveable equipment; and the remaining 17% is related to fees, permits, and state taxes. [source: Application, p49]

SHS anticipates the 8-bed ICN would become operational by mid-year 2014. At that time, SHS-Ballard would have 125 general medical surgical beds and 8 beds dedicated to its ICN. For this project, full year one is 2015 and year three is 2017. [source: Application, pp24-25]

¹ Swedish Health Services also has ownership percentages in a variety of other healthcare entities, such as home health, ambulatory surgery, and urgent care clinics. Since these entities are not pertinent to this project, they will not be discussed in this evaluation.

 $^{^2}$ The 133 licensed beds do NOT include the 30 dedicated nursing home beds that are banked under the full facility closure provisions of RCW 70.38.115(13)(b). During a September 2013 survey by the department's Construction Review Services staff, the Ballard campus had 75 set up beds and 49 acute care beds available, but not set up, for a total of 124 beds.

APPLICABILITY OF CERTIFICATE OF NEED LAW

SHS's application is subject to Certificate of Need review as the establishment of a new tertiary service under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(f) and Washington Administrative Code (WAC) 246-310-020(1)(d)(B).

EVALUATION CRITERIA

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

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

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

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

In the event 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).³ Where applicable, meeting the February 2013 Perinatal Level of Care Guidelines established by the Washington State Perinatal Advisory Committee assists in demonstrating compliance with the criteria.

 $^{^{3}}$ 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), and (6).

TYPE OF REVIEW

This application was reviewed under the regular review timeline outlined in WAC 246-310-160, which is summarized below.

APPLICATION CHRONOLOGY

Action	Swedish Health Services-Ballard
Letter of Intent Submitted	February 12, 2013
Application Submitted	June 25, 2013
Department's pre-review activities	June 26, 2013 through
including screening and responses	September 12, 2013
Beginning of Review	September 13, 2013
End of Public Comment	
• public comments accepted through the end of public comment	October 18, 2013
• No public hearing requested or conducted	
Rebuttal Comments ⁴	November 4, 2013
Department's Anticipated Decision Date	December 19, 2013
Department's Actual Decision Date	December 13, 2013

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."

For this project, no entities sought and received affected person status under WAC 246-310-010(2).

SOURCE INFORMATION REVIEWED

- Swedish Health Service's Certificate of Need application submitted June 25, 2013
- Swedish Health Service's supplemental information received August 22, 2013
- Public comment received during the review
- February 2013 Statewide Perinatal Advisory Committee Washington State Perinatal Level of Care Guidelines
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Licensing data provided by the Medical Quality Assurance Commission

⁴ The only comments submitted for this project were letters of support. The applicant chose not to provide rebuttal comments on these documents.

SOURCE INFORMATION REVIEWED (continued)

- Swedish Health Service's website [www.swedish.org/services/addiction-recovery/treatment-for-pregnant-or-postpartum-women]
- Pediatrix Medical Group website [www.pediatrix.com]
- Certificate of Need historical files

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Swedish Health Services proposing to establish an 8-bed intermediate care nursery and level II obstetric services within space at the Ballard Campus is consistent with the applicable review criteria, provided Swedish Health Services agrees to the following in its entirety.

Project Description:

This certificate approves the establishment of an 8-bed intermediate care nursery and level II obstetric services at the Ballard Campus. Once the intermediate care nursery is operational, the breakdown of beds by use is shown below.

Bed Type	# of Licensed Beds
General Medical/ Surgical	125
Level II ICN	8
Total Number of Licensed Beds	133

Condition:

1. Approval of the project description as stated above. Swedish Health Services further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.

Approved Costs:

The approved capital expenditure associated with this project is \$3,603,658.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed and the applicant's agreement to the conditions identified in the conclusion section of this evaluation, the department determines that Swedish Health Services' project has met the need criteria in WAC 246-310-210(1) and (2).

(1) <u>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.</u> WAC 246-310 does not contain an ICN need methodology. As a result, the evaluation of the need criterion for ICN projects begins with an evaluation of the methodology provided by the applicant. For its application, SHS relied on historical Comprehensive Hospital Abstract Reporting System (CHARS) data as a foundation for the numeric methodology. CHARS data is reported annually by each Washington State hospital to the department's Hospital and Patient Data Systems program (HPDS). The CHARS data provides historical trends in discharges and lengths of stay for newborn patients for the major diagnostic category (MDC) #15 - NEWBORNS AND OTHER NEONATES WITH CONDITIONS ORIGINATING IN THE PERINATAL PERIOD. MDC #15 is made up of seven diagnosis related groups (DRGs). For years 2003 through 2006, those DRGS were identified as 385 through 391. Beginning in year 2007, the DRGs are identified as 789 through 795. The chart below provides the DRG and corresponding definition for MDC #15.⁵

DRG	Definition	Level of Care
385 / 789	NEONATES, DIED OR TRANSFERRED TO ANOTHER ACUTE CARE FACILITY	Level III
386 / 790	EXTREME IMMATURITY OR RESPIRATORY DISTRESS SYNDROME, NEONATE	Level III
387 / 791	PREMATURITY WITH MAJOR PROBLEMS	Level II or III
388 / 792	PREMATURITY WITHOUT MAJOR PROBLEMS	Level II
389 / 793	FULL TERM NEONATE WITH MAJOR PROBLEMS	Level II
390 / 794	NEONATE WITH OTHER SIGNIFICANT PROBLEMS	Level II
391 / 795	NORMAL NEWBORN	Level I

For ease of reference, the remainder of this evaluation will refer to the DRGs above using the current 700 series number, rather than the former 300 series number.

As shown in the chart above, of the DRGs included in MDC #15, some do not correspond exactly with the level of care definitions. However, the majority of level III patients are included in DRGs 789 and 790, with a few level III patients in DRG 791. The majority of level II patients are included in DRGs 791, 792, 793, and 794.

SHS used data from DRGs 791, 792, 793, and 794 for its level II calculations and focused on a 'north King' planning area, which includes the following zip codes and cities. [source: 1980 State Health Plan]

⁵ Each DRGs corresponding level of care is based on October 3, 2001, testimony provided by Louis Pollack, MD, a board certified neonatologist and member of Washington State Perinatal Advisory Committee, and the October 16, 2007, testimony provided by Linda Wallen, MD, also a board certified neonatologist.

Zip	Preferred City	Location/Area
98103	Seattle	Greenwood or Wallingford
98105	Seattle	University
98107	Seattle	Ballard
98115	Seattle	Wedgwood
98117	Seattle	Crown Hill
98125	Seattle	Lake City or Northgate
98133	Seattle	Shoreline
98155	Seattle	Lake Forest Park or Shoreline
98160	Seattle	Richmond Beach
98177	Seattle	Shoreline
98185	Seattle	SafeCo Plaza
98195	Seattle	University of Washington

Based on 2003 through 2012 historical CHARS data, SHS provided a 4-step numeric methodology that projected to year 2022. SHS's application and this evaluation focus on projection years 2013 to 2017. Below is a summary of the numeric methodology. [source: August 22, 2013, supplemental information, Exhibit 22]

<u>Step 1 – Identify 10-year historic planning area resident days, discharges, and use rates</u> SHS used the following data points for this step.

- Patient day statistics obtained from years 2003-2012 CHARS data for the DRGs identified above.
- Average length of stay (ALOS) was calculated by dividing patient days by discharges, for each of the years 2003 through 2012. ALOS was calculated separately for each year. The resulting ALOS was held constant when applied in step 3 below.
- The number of females within the age cohort of 15-44 (childbearing age) were compiled from Claritas population data for the north King planning area for each year 2003-2012.
- A level II use rate was calculated based on discharges per 1,000 women of childbearing age for each year 2003-2012.
- Using the same rate estimates for years 2003 2012, a use rate trend adjustment factor of 0.55 was calculated. SHS noted that the use rate had generally increased from years 2003 through 20012.

Based on the factors above, SHS calculated a projected ALOS of 5.1 days. The projected use rates for years 2013 through 2022 shown below.

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Use Rate	13.9	14.4	15.0	15.5	16.1	16.6	17.2	17.7	18.3	18.8

<u>Step 2 – Calculate planning area provider level II patient origin, in-migration ratio, and planning</u> <u>area provider market share</u>

• Based on year 2012 CHARS data, approximately 28% of the north King planning area level II discharges are north King residents. However, planning area providers provided care to only 39% of these resident level II discharges. This means that 61% of these resident

discharges receive care outside the planning area. SHS First Hill provided care to 34% of these discharges.

- Upon opening in 2014, SHS expects the Ballard campus to recapture approximately one quarter of the north King residents who currently choose First Hill for level II services. In 2015, SHS expects to recapture approximately one half of these level II discharges.
- With the addition of Ballard as a level II provider, SHS anticipates north King providers would increase their market share of north King residents. In 2012, the market share is 39%; SHS expects the market share to increase to 46% in 2014, and 56% in 2015.
- Since approximately 28% of the north King planning area level II discharges are north King residents, the remaining 72% of the level II discharges reside outside the north King planning area. This results in an in-migration ratio of 2.5.

Using the factors described above, the results of SHS's calculations are shown below.

Planning area provider level II patient origin	North King Residents - 416 Outside North King Residents - 1,048 Total 2011 level II discharges 1,464
In-migration ratio	2.5192
Planning area provider market share	Year 2012 – Current 39.4% Year 2014 – 46.4% Year 2015 through 2022– 56.3%

<u>Step 3 – Calculate future total discharges based on forecast use rates and forecast population of</u> women of childbearing age. Apply the market share figures and in-migration ratio from step 2 to calculate future total level II discharges to planning area providers. Apply base year ALOS to forecast discharges to calculate planning area patient days

- The projected use rate trend of 0.55 calculated in step 1 was applied to the forecast years.
- The number of women of childbearing age (15-44) were projected using Claritas projections for each year of the forecast period.
- Planning area resident level II discharges were forecast by multiplying the projected use rates (from step 1) by the forecast number of women of childbearing age for each year of the forecast period.
- The total number of planning area resident level II discharges for planning area hospitals was determined using the market share forecast calculated in step 2.
- The in-migration ratio of 2.5192 calculated in step 2 was applied to the projected nonplanning area residents.
- A level II discharge market share shift was assumed. Based on 2012, First Hill had a 34% market share of north King level II discharges. In year 2014, the projections assume 1/5 of the 34% would continue to receive services at First Hill, and 4/5 would stay in the north King planning area. For year 2015 and beyond, the projections assume ½ would stay at First Hill and ½ would stay in the north King planning area.

- The projections then added together the following calculations:
 - the number of north King planning area providers' level II discharges for residents of north King;
 - the number of north King planning area providers' level II discharges for residents outside of north King; and
 - the number of SHS-Ballard level II patients that were transferred to SHS-First Hill that were expected to remain at SHS Ballard.
- The sum from above was multiplied by the 2012 average length of stay of the two North King planning area providers—Northwest Hospital and University of Washington Medical Center. The product is projected total level II patient days for North King planning area hospitals.

The table below shows the total level II patient days SHS projected for north King providers.

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Total Level II Patient Davs	7,750	8,422	9,285	9,578	9,869	10,158	10,442	10,725	11,004	11,281

<u>Step 4 – Use total patient days projected in step 3 to determine forecast gross and net level II bed</u> <u>need</u>

- The average daily census (ADC) was calculated for each year of the forecast period by dividing the level II days by 365.
- The forecast ADC was adjusted to reflect the occupancy standards for the level II ICN of 65%. These forecasts represent gross bed need for level II bassinettes.
- SHS identified the total level II capacity of existing providers in the planning area at 23 as shown in the breakdown below:
 - > Northwest Hospital with 8 level II bassinettes; and
 - University of Washington Medical Center with 15 level II bassinettes.
- Net need for level II bassinettes was calculated by subtracting current planning area supply from gross bed need.
- The table below summarizes the results of the calculations described above and shows years 2013 through 2018. In summary, based on the factors and assumptions described, SHS projected a need for 9 level II beds in current year 2013, which increases to 18 level II beds in year 2017, the projected third year of operation of SHS-Ballard's level II services.

	2013	2014	2015	2016	2017	2018
Total Level II Patient Days	7,750	8,422	9,285	9,578	9,869	10,158
Average Daily Census (ADC)	21.2	23.1	25.4	26.2	27.0	27.8
Gross Bed Need at 65% occp'y	32.7	35.5	39.1	40.4	41.6	42.8
Minus Current Level II Supply	23.0	23.0	23.0	23.0	23.0	23.0
Net Level II Bed Need	9.7	12.5	16.1	17.4	18.6	19.8

In past level II applications, the department has accepted this methodology as a reasonable projection of need for level II beds in a planning area. The department concludes that numeric need for 8 level II ICN beds in the north King planning area is demonstrated.

Within this application, SHS provided information to demonstrate that projected level II bed capacity in step 4 should be located at SHS-Ballard. SHS provided information related to the number of SHS-Ballard's transfers of level II patients and an overview of the chemical dependency program located at SHS-Ballard. Below is a summary of each issue.

Number of SHS-Ballard transfers of level II patients

[source: August 22, 2013, supplemental information, Exhibit 22]]

Using 2012 CHARS data, SHS provided a table showing the level I [normal newborn] and level II discharges by hospitals in King County in year 2012. Because SHS-First Hill and Ballard are licensed under the First Hill hospital license, data is reported to CHARS for the combined campuses. While SHS-First Hill is currently a provider of both level II and level III services, SHS-Ballard is not. The table showed SHS-First Hill and Ballard birth the largest number of level I and level II infants in the county. The data showed that the combined number of births at SHS-First Hill and Ballard equate to approximately one-half of all level I and level II births in the county at 49.8%--equating to 3,909 level I and 1,947 level II births. Since data for the two facilities is reported to the department under one license, the department is unable to verify the number of SHS-Ballard transfers of level II patients. Since SHS-Ballard does not have a level II program, level II births must either occur at, or be transferred to, SHS-First Hill.

SHS-Ballard Chemical Dependency Program

[source: Application, pp15-18; SHS-Ballard website]

SHS established a chemical dependency program at its Ballard campus. The program includes:

- Evaluation and diagnosis;
- Medical detoxification; and
- Treatment for pregnant and postpartum women.

Specific to the treatment for pregnant and postpartum women, the program is known as 'Chemical Using Pregnant Women' or CUPW [pronounced 'cup W']. This program provides the following women services on-site:

- Detoxification and stabilization;
- Chemical dependency treatment and support;
- Education about pregnancy, parenting, and infant care; and
- Referrals to support services in the community.

Women in the CUPW program are enrolled for 26 days, however a team of caregivers close to the patient determines the length of stay for each patient, as well as the overall treatment plan. Treatment includes individual and group counseling, which helps patients plan for their continued recovery. Patients also participate in behavior groups to understand substance use and the associated problems. Community support groups are also an important part of the treatment process. After patients are in recovery, continued care through an outpatient program is usually recommended.

Often these CUPW patients birth higher risk, or level II, infants. At this time, SHS-Ballard cannot retain the level II infants, so they are transferred to SHS-First Hill. Mothers of these infants are encouraged to continue treatment at SHS-Ballard, however, a very large number of these new mothers 'follow' their infants to SHS First Hill, resulting in the loss of continuity of their recovery treatment in the CUPW program.

During the review of this application, the department received 24 letters of support and no letters in opposition. Of the 24 letters of support, nine letters were submitted by the mothers, or mothers-tobe, currently enrolled CUPW program at SHS-Ballard. All of these letters stated that much of the success of their recovery would hinge on mother-baby contact. This mother-baby bonding is nearly impossible if the infant is at SHS-First Hill and the mother stays in the CUPW program at SHS-Ballard. All letters stated that being able to care for their infants while participating in the CUPW program was imperative to the success of their own recovery. These nine letters were most compelling. Three of the letters of support were from community physicians/providers. These letters also recognized the importance of the CUPW program at SHS-Ballard and demonstrated full support of level II services at that site. The remaining 12 letters were from SHS staff and also fully supported the proposed level II ICN at SHS-Ballard.

There was no public comment submitted related to this sub-criterion.

Based on the above evaluation, numeric need for additional level II bed capacity in the north King planning area is demonstrated. Need for a number of the level II beds to be located at SHS-Ballard was also demonstrated. The department concludes that the 8-bed intermediate care nursery and level II obstetric services at SHS-Ballard is demonstrated and reasonable. This sub-criterion is met.

(2) <u>All residents of the service area, including low-income persons, racial and ethnic minorities,</u> women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

SHS-Ballard has been an acute care hospital in north King County for many years and currently provides health care services to residents of Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. As a provider of acute care services, SHS-Ballard currently participates in the Medicare and Medicaid programs. For this project, SHS-Ballard must demonstrate a commitment to maintain its Medicare and Medicaid participation and provide a percentage of charity care in the planning area.

Admission Policy

To determine whether all residents of the north King County planning area would have access to the 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. The admission policy must also include language to ensure all residents of the planning area would have access to the proposed services. This is accomplished by providing an admission policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status. To demonstrate compliance with this sub-criterion, SHS provided a copy of the Admission Policy currently used at all five SHS campuses. The Admission Policy outlines the process/criteria that SHS uses to admit patients for treatment, and ensures that patients will receive appropriate care at any of the SHS hospitals. The Admission Policy also states that SHS admits any patient without regard to race, color, national origin, disability, sexual orientation, age, payer source, or ability to pay. [source: August 22, 2013, supplemental information, Revised Exhibit 12]

Medicare and Medicaid Programs

The department uses Medicare certification to determine whether the elderly would have access or continue to have access to the proposed services. To demonstrate compliance with this subcriterion SHS provided its current and projected source of revenues by payer at SHS-Ballard. Medicare revenues are, and would continue to be 27.8% of total revenues at the hospital. Additionally, the financial data provided in the application shows Medicare revenues.

Level II obstetric services are not typically used by elderly patients. While the hospital as a whole will not change its Medicare status or percentages, the proposed level II cost center appropriately did not project revenues from the Medicare payer source. [source: Application p22 and p55; August 22, 2013, supplemental information, Revised Exhibit 17]

The department uses the facility's Medicaid eligibility or contracting with Medicaid to determine whether low-income residents would have access to the proposed services. To demonstrate compliance with this sub-criterion, SHS also provided its current and projected percentage of Medicaid revenues at 14.41% for SHS-Ballard. Additionally, the financial data provided in the application shows Medicare revenues. For the proposed level II cost center, SHS anticipated 41.7% of its revenues would be from the Medicaid payer source. This percentage was based on the current revenue percentages of patients enrolled in the CUPW recovery program. [source: Application p22 and p55; August 22, 2013, supplemental information, Revised Exhibit 17]

Charity Care Policy

A facility's charity care policy should confirm that all residents of the service area including lowincome, 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, SHS provided a copy of its current charity care policy currently in use at SHS-First Hill and Ballard. The policy includes the appropriate non-discrimination language and outlines the process one must follow to obtain charity care. The policy was also recently reviewed and approved by the Department of Health's Hospital and Patient Data Systems office. The pro forma financial documents provided in the application also include a charity care 'line item.' [source: August 22, 2013, supplemental information, Revised Exhibit 12]

For charity care reporting purposes, HPDS divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. SHS-Ballard is located in King County within the King County Region. Currently there are 21 hospitals located within the region, including SHS-Ballard. According to 2009 - 2011 charity care data obtained from HPDS,⁶

⁶ As of the writing of this evaluation, 2012 charity care data is not available.

SHS has historically provided slightly more than the average charity care provided in the region, however, the charity care data is reported for the combined First Hill and Ballard campuses. The table below is a comparison of the average charity care for the King County region, less Harborview⁷, the historical combined charity care for the First Hill and Ballard campuses, and the projected charity care for Ballard separately. [source: August 22, 2013, supplemental information, Revised Exhibit 17 and HPDS 2009-2011 charity care summaries]

Charity	y Care Percentage Co	omparisons
	% of Total Revenue	% of Adjusted Revenue
King County Region	1.67%	3.05%
SHS Combined	1.85%	3.37%
SHS-Ballard Projected	2.73%	4.72%

Table 1
Charity Care Percentage Comparisons

As shown in the table above, SHS's pro forma revenue and expense statements for the Ballard campus indicate that the hospital will provide charity care at approximately 2.73% of gross revenue and 4.72% of adjusted revenue. RCW 70.38.115(2)(j) requires hospitals to meet or exceed the regional average level of charity care. Since SHS's historical charity care is currently greater than the average for the region, the department concludes a charity care condition is not necessary to ensure continued compliance with this sub-criterion.

There was no public comment submitted related to this sub-criterion.

The department concludes that all residents of the service area would have access to the services proposed by SHS. **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 conditions in the conclusion section of this evaluation, the department determines that Swedish Health Services' project has met the financial feasibility criteria in WAC 246-310-220.

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

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, SHS expects to begin providing level II ICN services at the Ballard campus within eight months, or approximately July 2014. [source: Application, p25] Based on this

⁷ Harborview Medical Center is subsidized by the state legislature to provide charity care services. Charity care percentages for Harborview make up almost 50% of the total percentages provided in the King County Region. Therefore, for comparison purposes, the department excluded Harborview Medical Center's percentages.

timeline, year 2015 would be the facility's first full calendar year of operation with an 8-bed level II ICN and 2017 would be year three.

To evaluate this sub-criterion, the department first reviewed the assumptions used by SHS to determine the projected number of patients for its level II ICN. The assumptions are summarized below. [source: Application, pp37-38]

- The projected number of <u>recaptured</u> level II neonates relies on two groups: 1) the CUPW neonates whose mothers are currently referred to SHS-First Hill for birth; and 2) the north King planning area neonates whose mothers are currently admitted to SHS-First Hill. SHS assumed the majority of its patients would be from these two groups.
- SHS also assumed some patient <u>in-migration</u>. SHS expects to serve neonates whose mothers reside outside of the north King planning area.

Using the assumptions stated above, SHS projected the number of level II discharges and percentage of occupancy for the 8-bed level II ICN for years 2015 through 2021. The table below shows the projections for the first three full years of operation. [source: August 22, 2013, supplemental information, Revised Exhibit 17]

SHS-Ballard Level II ICN Projections				
	Year 2015	Year 2016	Year 2017	
CUPW Neonate Discharges	50	55	60	
Non-CUPW Neonate Discharges	244	257	271	
Total Neonate Discharges	294	312	331	
Total Patient Days	2,199	2,367	2,534	
Average Daily Census [ADC]	6.02	6.48	6.95	
Average Length of Stay [ALOS]	7.5	7.6	7.7	
% Occupancy with 8 beds	75.3%	81.0%	86.8%	

Table 2SHS-Ballard Level II ICN Projections

Based on the assumptions above and taking into consideration the results of the numeric need methodology, the projections shown above are considered reasonable.

SHS provided three separate pro forma revenue and expense statements.

- 1) Level II ICN cost center only;
- 2) SHS-Ballard as a whole, with the proposed 8-bed level II ICN; and
- 3) SHS-Ballard as a whole, <u>without</u> the proposed 8-bed level II ICN.

[source: August 22, 2013, supplemental information, Revised Exhibit 17]

For the ICN cost center statement, SHS relied on the assumptions summarized below. [source: Application, p55]

- Gross and net revenues were calculated from SHS-First Hill 2012 actuals for level II neonates.
- Payer mix is 41.7% Medicaid, 58.0% commercial/other, and 0.3% self-pay.
- All operating expenses, except for wages, salaries and benefits, were calculated from SHS-First Hill 2012 actuals for level II neonates.

- Wages, salaries, and benefits were calculated using the forecast SHS-Ballard level II cost center staffing model.
- Medical director fees are included separately within the expenses.
- Expense inflations are not included.

Using the assumptions above, the table below illustrates the projected revenue, expenses, and net income for CY 2015 through 2017 for SHS-Ballard's ICN cost center. [source: August 22, 2013, supplemental information, Revised Exhibit 17]

SHS-Ballard Level II ICN Cost Center Only Projected Revenue and Expenses Calendar Years 2015 - 2017						
CY 1 2015 CY 2 2016 CY 3 201						
Net Patient Revenue [1]	\$ 2,742,045	\$ 3,008,085	\$3,273,887			
Total Operating Expense [2]	\$ 3,256,095	\$ 3,477,024	\$3,699,769			
Net Profit or (Loss).	(\$ 514.050)	(\$ 468,939)	(\$ 425.882)			

Table 3

[1] includes deductions for bad debt, charity care and contractual allowances

[2] includes allocated costs

As shown in the table above, even with a projected occupancy averaging more than 75%, SHS projects the 8-bed ICN would be operating at a loss in the first three calendar years of operation. SHS states the annual loss is mostly attributed to the allocated costs included in the expenses.

For SHS-Ballard as a whole, SHS relied on the assumptions summarized below. [source: Application, pp54-55]

- Aggregate gross and net revenues were based on SHS-Ballard 2012 actuals where actual gross and net revenue figures by payer, per patient day were calculated.
- No revenue inflation is included.
- Reimbursement percentages were assumed to remain constant from 2012.
- Charity care is forecast at 2.8% of gross revenue.
- Bad debt is expected to be 2.9% of gross revenues.
- Operating expenses were estimated using SHS-Ballard 2012 operating expenses.
- Annual depreciation expenses were estimated using the capital expenditure and included in each of the forecast years. Life assumptions are 15 years for the facility and fixed equipment and 7.5 years for moveable equipment
- Corporate allocated costs were included by type.
- 'Healthcare taxes' are taxes paid to Washington State so it can receive additional federal funds for the care of Medicaid patients.

Using the assumptions above, the table on the following page illustrate the projected revenue, expenses, and net income for CY 2015 through 2017 for SHS-Ballard with and without the proposed 8-bed ICN. [source: August 22, 2013, supplemental information, Revised Exhibit 17]

	CY 1 2015	CY 2 2016	CY 3 2017
Net Patient Revenue [1]	\$ 98,318,809	\$ 100,393,720	\$ 102,538,748
Total Operating Expenses	\$ 74,980,534	\$ 76,310,802	\$ 78,514,878
Net Profit or (Loss) .	\$ 23,338,275	\$ 24,082,918	\$ 24,023,870
Minus Allocated Costs	\$ 3,627,757	\$ 4,306,393	\$ 4,185,318
Net Profit or (Loss) [2]	\$ 19,710,518	\$ 19,776,525	\$ 19,838,552

Table 4SHS-Ballard WITHOUT Level II ICNProjected Revenue and Expenses Calendar Years 2015 - 2017

[1] includes deductions for bad debt, charity care and contractual allowances

[2] includes allocated costs

Projected Revenue and Expenses Calendar Years 2015 - 2017				
	CY 1 2015	CY 2 2016	CY 3 2017	
Net Patient Revenue [1]	\$ 101,060,856	\$ 103,401,807	\$ 105,812,635	
Total Operating Expenses	\$ 78,054,473	\$ 79,601,259	\$ 82,023,578	
Net Profit or (Loss).	\$ 23,006,383	\$ 23,800,548	\$ 23,789,057	
Minus Allocated Costs	\$ 3,627,757	\$ 4,306,393	\$ 4,185,318	
Net Profit or (Loss) [2]	\$ 19,378,626	\$ 19,494,155	\$ 19,603,739	

Table 5 SHS-Ballard WITH Level II ICN Projected Revenue and Expenses Calendar Years 2015 - 2017

[1] includes deductions for bad debt, charity care and contractual allowances

[2] includes allocated costs

When comparing the Tables 4 and 5 above, it is clear that SHS-Ballard is financially capable of covering the financial loss of the 8-bed level II ICN cost center shown in Table 3. While the ICN cost center does not add to the financial health of SHS-Ballard, by submission of this application, SHS demonstrates its commitment to these services in the planning area. Further, related to the ICN cost center losses, the tables above substantiate SHS's assertion that the allocated costs are attributed to SHS-Ballard regardless of whether the 8-bed level II ICN is approved.

There was no public comment submitted related to this sub-criterion. Based on the above information, the department concludes that SHS's projected revenues and expenses for SHS-Ballard are reasonable and the immediate and long range capital and operating costs of project can be met. **This sub-criterion is met.**

(2) <u>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.</u>
 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

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.

Item	Cost	% of Total
Construction Costs	\$ 1,840,006	51.1%
Fixed & Moveable Equipment	\$ 1,144,850	31.8%
Architect & Engineering Fees	\$ 238,241	6.6%
Supervision & Inspection	\$ 41,800	1.2%
Permit Fees	\$ 55,200	1.5%
Washington State Sales Tax	\$ 283,561	7.9%
Total Estimated Capital Costs	\$ 3,603,658	100.0%

The capital expenditure associated with the establishment of the 8-bed ICN is \$3,603,658. A breakdown of the costs is shown below. [source: Application, p49]

To establish the 8-bed level II ICN, SHS elected to convert and renovate existing space at SHS-Ballard in the area known as '5 North.' Currently, the space is used for staff classrooms, offices, bathroom/locker room, and an outpatient WIC clinic.⁸ Staff space will be relocated to other floors and the WIC clinic will be relocated to other existing space within SHS-Ballard. All relocation costs are included in the estimated capital costs identified above. [source: Application, p15 and August 22, 2013, supplemental information, p3]

To demonstrate compliance with this sub-criterion, SHS provided the following documents:

- a non-binding construction cost estimate from its contractor;
- current and proposed line drawings of the space;
- proposed functional plan for the level II ICN; and
- a listing of recent construction projects SHS has completed for its five campuses. [source: Application, p16; Exhibits 7 and 15; and August 22, 2013, supplemental information, Revised Exhibit 9]

SHS also provided a table showing the costs of the project per gross square foot. The breakdown is replicated below. [source: Application, p50]

Table 6			
SHS ICN Cost Center Construction Cost Breakdown			
Estimated Gross Square Footage (GSF)	3,868		
Number of Level II ICN Beds	8		
Construction Cost per GSF	\$771.68		
Total cost per GSF	\$931.71		
Total Cost per Bed	\$931.71 \$450,457.25		

The department recognizes that the majority of the costs are for construction and planning for ICN space. While the calculated cost per bed appears to be high, the department recognizes that a retro-

⁸ Established as a pilot program in 1972 and made permanent in 1974, WIC [Women, Infants, and Children] is administered at the Federal level by the Food and Nutrition Service of the US Department of Agriculture. WIC provides food, nutrition counseling, and access to health services. [source: WIC website]

fit project is typically the most costly when compared to construction of new space in an existing facility. In the case of SHS-Ballard, since it has been operational at the site for many years, a retrofit is the only option available to SHS if these additional services are to be provided.

There was no public comment submitted related to this sub-criterion.

Based on the above information, the department that 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. **This sub-criterion is met.**

(3) <u>The project can be appropriately financed.</u>

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.

SHS proposes the establishment of an 8-bed level II ICN within space at SHS-Ballard at an estimated cost of \$3,603,658. SHS states it would fund the project with a combination of money from its Private Foundation⁹ and accumulated reserves. These two funding sources do not include any outside loans or interest costs. SHS provided a letter of financial commitment for the project from its chief financial officer. [source: Application, Exhibit 16]

SHS also provided the following information related to a cost comparison review for the funding sources.

"Swedish evaluates each capital expenditure in terms of what capital is required and the size of the proposed expenditure. In this case, the majority of the proposed capital costs would be space renovation costs, which would either need to be cash or debt-financed. These build-out costs would include construction and fixed equipment costs, much of which typically could not be leased. ...In terms of cash vs. debt finance decision, Swedish evaluates the capital expenditure in terms of its timing, its relative cost, its effect on cash reserves, and the organization's opportunity costs of capital at that time. In the case of this project, given its size and the availability of cash reserves to fund it, it was determined to be most prudent, i.e. most cost effective, to finance the building out and the fixed and moveable equipment with cash and investment reserves." [source: Application, p53]

There was no public comment submitted related to this sub-criterion.

Based on the above information, the department concludes that SHS's project can be appropriately financed. **This sub-criterion is met.**

⁹ The Swedish Medical Center Foundation launched The Campaign for Swedish in January 2007 in conjunction with the Swedish Medical Center Foundation board and a 17-person volunteer Campaign Leadership Council lead by co-chairs Janet True, Kirby McDonald, and Dave Sabey. [source: <u>www.campaignforswedish.org</u>]

C. Structure and Process (Quality) of Care (WAC 246-310-230) and the Washington State **Perinatal Levels of Care Guidelines**

Based on the source information reviewed and the applicant's agreement to the conditions in the conclusion section of this evaluation, the department concludes Swedish Health Services' project has met the structure and process of care criteria in WAC 246-310-230 and the February 2013 Washington State Perinatal Levels of Care Guidelines.

(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). The department uses the recognized standards as identified in the most recent Washington State Perinatal Levels of Care Guidelines. For this project, the most recent guidelines were released in February 2013.

To demonstrate that staff is available or can be recruited for the level II ICN, SHS provided a staff table showing calendar years 2014 through 2017 specific to its level II ICN staff. [source: August 22, 2013, supplemental information, Exhibit 17A] The table below shows that information.

SHS-Ballard Level II ICN Projected FTEs					
	2014	2015	2016	2017	Total FTEs
Staff/FTEs	Partial Year	Increase	Increase	Increase	
Medical Director*		Professior	al Services C	Contract	
Management	0.10	0.20	0.00	0.00	0.30
Nursing	4.00	6.00	0.70	0.80	11.50
Support	2.10	2.90	0.00	0.00	5.00
Pharmacists	3.20	0.00	0.00	0.00	3.20
Other FTEs*	0.64	1.53	1.53	1.53	5.23
Total FTE's	10.04	10.63	2.23	2.33	25.23

Table 7

*Contracted positions

SHS clarified that the table above shows direct level II ICN employees and non-employee contract FTEs, including the medical director. The table does not include neonatologists, anesthesiologists, OB/GYN, pediatricians, radiologists, ophthalmologists, or neurodevelopmental physicians. While this staff is currently staff of SHS-Ballard and would be available for the level II ICN, they are not directly allocated to only the SHS-Ballard ICN. [source: August 22, 2013, supplemental information, Exhibit 17A]

As shown in the table above, SHS already has most of the necessary staff for the ICN and projects an increase in FTEs based on the projected increase in patients and patient days from year 2015 to 2015.

SHS states it expects no difficulty in recruiting staff for its ICN at SHS-Ballard because of its relationship with SHS-First Hill, which is the largest provider of neonatal care in the state. Further, a strong core of experienced level II nursing staff at the First Hill campus will support and augment staff at the proposed ICN at the Ballard campus. SHS also maintains strong relationships with schools of nursing in the Puget Sound region and supports over 700 nursing student placements each year. In the nursing students' senior year of school, they are offered the opportunity to work in the specialty of their choice. Each quarter, the requests to work in the neonatal intensive care unit and infant special care are more than there are open positions. SHS-First Hill offers on site neonatal training program through its Center of Education and Practice. This is a 12 week training program that combines didactic learning, simulation, and 1:1 preceptorship on the neonatal unit. [source: Application, p57]

Washington State Perinatal Levels of Care Guidelines

The department also uses the standards of care guidelines outlined in the Washington State Perinatal Levels of Care Guidelines in evaluating this project. The guidelines, adopted by the Perinatal Advisory Committee in February 2013, offer recommendations on facility and staffing standards for level II services.¹⁰

The Perinatal Levels of Care Guidelines recommend that an applicant be providing the previous level of services before applying for the next higher level. For this application, SHS-Ballard should already be providing level I, or basic OB services before applying for level II services. Documentation provided in the application demonstrates that SHS-Ballard meets this recommendation. SHS also provided a comparison chart as verification and documentation that its proposed level II services meet or exceed the advisory committee's recommended guidelines. [source: Application, Exhibit 6] The comparison chart is provided in Appendix A attached to this evaluation.

There was no public comment related to this sub-criterion. Based on the above information, the department concludes that SHS demonstrated adequate staffing for the 8-bed level II ICN at SHS-Ballard is available or can be recruited. **This sub criterion is met.**

(2) <u>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.</u>
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 no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's

history in meeting these standards at other facilities owned or operated by the applicant.

As an existing provider of both level II ICN and level III NICU services at SHS-First Hill, and level II ICN services at SHS-Issaquah and SHS-Edmonds, SHS has many ancillary and support services in place. Specific to this project, SHS-Ballard will work closely with SHS-First Hill to ensure neonates are stabilized, treated, or transferred appropriately. Since SHS intends that its level III neonates would be transferred to SHS-First Hill, no internal transfer agreement is necessary.

¹⁰ The guidelines were initially developed in 1988, and revised in years 1993, 2001, 2005, 2010, and 2013. [source: Washington State Perinatal and Neonatal Level of Care Guidelines, February 2013, p1]

SHS provided a copy of its current Medical Director Agreement with Pediatrix Medical Group of Washington.¹¹ The agreement was initially created in July 2000 for the First Hill campus. In June 2013, the agreement was revised to include SHS-Ballard. The agreement identifies roles and responsibilities for both SHS and the medical group, and includes all costs associated with the services. The agreement is reviewed and renewed annually.

There was no public comment submitted related to this sub-criterion. Based on the above information, the department concludes that SHS demonstrated appropriate relationships and ancillary services are in place or would be established. **This sub criterion is met**.

(3) <u>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.</u> 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 no 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.¹² 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.

SHS provides healthcare services to the residents of Washington State through its various healthcare facilities, including five operational hospitals. SHS does not operate any healthcare facilities outside of Washington State.

As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public.

Since January 2010, the Department of Health's Investigations and Inspections Office has completed at least eleven compliance surveys for SHS or its related healthcare providers.¹³ Of the compliance surveys completed, all revealed minor non-compliance issues related to the care and management at the SHS healthcare facilities. These non-compliance issues were typical of the specific type of facility and SHS submitted and implemented acceptable plans of correction. [source: facility survey data provided by the Investigations and Inspections Office]

SHS provided names and professional license numbers for its current and proposed staff for the level II ICN. A review of the compliance history for all staff, including the physicians and medical

¹¹ Pediatrix Medical Group is a national provider of maternal-fetal, newborn and pediatric subspecialty physician services. The company is also one of the nation's largest providers of newborn hearing screens. Pediatrix Medical Group, an operating unit of MEDNAX, was founded in 1979. Combined, Pediatrix and its affiliated professional corporations employ more than 1,675 neonatal, maternal-fetal and pediatric subspecialists and over 700 advanced practitioners in 34 states and Puerto Rico. [source: Pediatrix Medical Group website] ¹² Also pertains to WAC 246-310-230(5).

¹³ Compliance surveys completed for SHS-Cherry Hill [2011 & 2013], SHS First Hill and Ballard [2010, 2011, & 2013], SHS Edmonds [2011 & 2013], SHS Issaquah [2011 & 2013], and SHS's home care agency [2010]. On February 2012, SHS elected to close its home care agency. The closure was not related to quality of care or non-compliance issues.

directors associated with Pediatrix Medical Group, revealed no recorded sanctions. [source: Compliance history provided by Medical Quality Assurance Commission]

There was no public comment submitted related to this sub-criterion. Based on the above information, the department concludes that SHS demonstrated reasonable assurance that the proposed level II ICN would be operated in compliance with state and federal requirements. **This sub criterion is met.**

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

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, SHS provided discussion related to the continuity of care for mothers enrolled in the CUPW program and their high-risk neonates that are currently being transferred to SHS-First Hill. SHS also provided documentation related to the costs of transfer for the families of these neonates, and the disruption of care sometimes caused by transferring high risk neonates. [source: Application, p59]

The department recognizes that SHS is a long-time provider of health care services in Washington State, and as such, has already established long term relationships within the healthcare system. [source: CN historical files] In the need section of this evaluation, the department concluded that level II ICN beds located at SHS-Ballard is reasonable.

There was no public comment submitted related to this sub-criterion. Based on the above information, the department concludes that the proposed project would promote continuity and not result in unwarranted fragmentation of services if approved. Further, SHS demonstrated it would have appropriate relationships to the service area's existing health care system. **This sub criterion is met.**

 (5) <u>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.</u> This sub-criterion is addressed in sub-section (3) above and is **not met**.

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

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

 <u>Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable</u>. To determine if a proposed project is the best alternative, the department takes a multi-step approach. <u>Step one</u> 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 <u>step two</u> 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.

<u>Step three</u> of this assessment is to apply any service or facility specific (tie-breaker) criteria contained in WAC 246-310. The tie-breaker 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.

<u>Step One</u>

For this project, SHS's project has 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, SHS explored and evaluated the advantages and disadvantages of three alternatives before submitting this project. Each alternative was evaluated using the specific criteria below. [source: Application, pp62-64]

- promoting access to healthcare services
- promoting quality of care
- promoting cost and operating efficiency
- legal restrictions

The three alternatives and SHS's rationale for rejecting each is summarized on the following page.

Alternative 1-Do Nothing

This alternative was quickly rejected by SHS because it does not address the projected need for level II beds in the planning area or promote access to the needed healthcare services for north King residents. This alternative would also require CUPW mothers to continue to be transferred to other facilities for birth and continue to separate the neonate and mother during the important bonding time.

Alternative 2-Establish a 5-bed level II ICN

While this alternative would alleviate some north King planning area need, a 5-bed ICN would still require many transfers of mothers and babies to facilities outside the planning area. A 5-bed ICN would be less efficient than a larger unit when considering that the space in SHS-Ballard could accommodate a larger unit.

Alternative 3-Establish a 15-bed level II ICN

This alternative would meet more future growth in the planning area than the proposed 8-bed ICN, however, it would also create a surplus capacity at SHS-Ballard for the immediate future. The costs to establish a larger unit would be greater because of current space constraints at SHS-Ballard. While a larger unit may be pursued in the future, this alternative was not considered the best one at this time.

Once SHS determined that the establishment of a level II ICN at the Ballard campus was the best alternative, the only option is to submit a Certificate of Need application. Based on the current women/infant and obstetric services provided at SHS-Ballard, establishment of an ICN at the Ballard campus is both reasonable and appropriate. The department did not identify any other alternatives that should have been considered by SHS. The department concludes that SHS chose the best alternative to meet the need in the planning area.

Step Three

This step is used to determine between two or more approvable projects which is the best alternative. Since SHS is the only applicant requesting to establish an ICN in the north King planning area, this step does not apply.

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

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

WAC 246-310 does not contain specific WAC 246-310-240(2)(a) criteria as identified in WAC 246-310-200(2)(a)(i). There are known minimum building and engergy standards that healthcare facilities must meet to be licensed or certified to provide care. If built to only the minimum stanardards all construction projects could be determined to be resonable. The department, through its experience knows that construction projects are usually built to exceed these minimum standards. Therefore, the department considered information in the application that addressed the reasonableness of the construction projects that exceeded the minimum standards.

This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that **this sub-criterion is met**.

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

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). Based on that evaluation, the department concludes that **this sub-criterion is met**.

	GUIDELINE	SHS-BALLARD	PASS/FAIL
	Definitions, Capabilities, and Provider Types		
 Provide Evalution Stability Stability Stability Stability Stability Stability Stability Stability Provide Stability Weight 	bernitions, capabilities, and T born Nursery [Level I] : ide neonatal resuscitation at every delivery late and provide postnatal care to stable term born infants lize and provide care for infants born 35-37 wk tion who remain physiologically stable lize newborn infants who are ill and those born 5 wk gestation until transfer to a higher level of are Nursery [Level II] : pabilities plus: ide care for infants born ≥ 32 week gestation weighing ≥ 1500 grams who have physiologic aturity or who are moderately ill with problems are expected to resolve rapidly and are not ipated to need subspecialty services on an ant basis ide care for infants convalescing after intensive ide mechanical ventilation for brief duration hrs) or continuous positive airway pressure or lize infants born before 32 wk gestation and hting less than 1500 grams until transfer to a atal intensive care facility	SHS Ballard is an acute care hospital with well newborn [level I] services	Pass

GUIDELINE	SHS-BALLARD	PASS/FAIL
Neonatal Patients: Additional Details of	f Service Capabilities	Pass
 Service capabilities of Level I plus: If services are limited to ≥ 34 week and ≥2000 grams and for newborns whose problems are expected to resolving rapidly and without need for CPAP, assisted ventilation, or arterial catheter: Space designated for care of sick/convalescing neonates Cardiorespiratory monitor for continuous observation Peripheral IV insertion, maintenance, and monitoring for fluids, glucose, antibiotics Neonatal blood gas monitoring ADC of at least 1-2 level II patients If caring for 32-33 week gestation or moderately-ill infants, add: Umbilical or peripheral arterial catheter insertion, maintenance and monitoring Peripheral or central administration and monitoring of total parenteral nutrition and/or medication and fluids High flow nasal cannula Nasal CPAP ADC of at least 2-4 level II patients 	Intend to care for 32-34 week infants or moderately ill infants. Currently meeting level I guidelines, and with level II designation, services will include: All RN staff, neonatal practitioners and anesthesia providers are AHA NRP providers. RNs start IV on newborns, RT will provide support for CPAP and ventilator therapy. Neonatal NNP and or neonatologist will be providing care, including arterial line placement and drawing of blood gases. All standard equipment will be presents. RN staff will maintain and monitor umbilical and peripheral lines. SHS-First Hill will provide access to a neonatal pharmacist Access to parenteral nutrition resources will be supplied by SHS- First Hill. ADC is estimated to be at least 2 level	
	II patients daily	
Obstetrical Patients: Services a		Pass
 Level I patients and services plus: For hospitals prepared to care for newborns > 34 weeks gestation and estimated birthweight > 2000 grams, OB capabilities include: management consistent with ACOG guidelines of selected high risk pregnancy conditions such as: Complications not requiring invasive maternal monitoring or maternal intensive care Preterm labor or other complications of pregnancy judged unlikely to deliver before 34 weeks gestation 	Intend to care for 32-34 week infants. Currently meeting level I guidelines, and with level II designation: OB/GYNs will manage patients with high risk complications starting at 32 weeks. Appropriate triaging and referral to SHS-First Hill as needed. Guidelines for family practitioner and midwife transfer already exist.	
 For hospitals prepared to care for newborns ≥32 0/7 weeks gestation and estimated birthweight > 1500 grams, OB capabilities include: management consistent with ACOG guidelines of selected high risk pregnancy conditions such as: Preterm labor or other complications of pregnancy judged unlikely to deliver before 32 weeks gestation 	Nursing staff will be trained on common antepartum conditions that require hospitalization and preterm delivery. Conditions such as, but no limited to, preterm labor, pre- eclampsia, PROM, and IUGR.	

GUIDELINE	SHS-BALLARD	PASS/FAIL
Medical Director		Pass
Obstetrics: board certified in OB/GYN or family medicine	Intend to care for 32-34 week infants.	
<u>Nursery:</u> board-certified in pediatrics	Currently 5 board certified OB/GYN providers are on staff and available for consultation.	
If caring for 32-34 week infants: <u>Obstetrics:</u> board certified in OB/GYN <u>Nursery:</u> board-certified in neonatology	Medical Director is board certified in OB/GYN. Board certified neonatologist will be directing medical care.	
Healthcare Provide		Pass
 Level I coverage plus: Every high-risk delivery is attended by at least two people one of whom is a pediatrician, family practice physician, or advanced practice nurse capable of a complete resuscitation, including chest compressions, intubation, and administering medications <u>If providing HFNC or CPAP</u> Continuous in-house availability of personnel experienced in airway management and the diagnosis and treatment of pneumothorax when a patient is being treated with high flow nasal cannula or nasal CPAP. Radiologist on staff with daily availability who can interpret neonatal studies such as chest and abdominal radiographs, and cranial ultrasound 	Intend to provide HFNC or CPAP Currently meeting level I and level II guidelines for attendance at a high-risk delivery. Neonatologist and neonatal nurse practitioner will be on site. Respiratory therapist in house 24/7 Radiology available 24/7 Ophthalmologist with pediatric experience available from SHS-First Hill	
Ophthalmologist with pediatric experience available to do eye exams for neonates who are at high risk for retinopathy of prematurity (ROP) if accepting back transport of such infants; written protocol for referral or treatment Arrangement for neurodevelopmental follow-up or referral per written protocol.	Neurodevelopment follow up SHS- First Hill resources	

GUIDELINE	SHS-BALLARD	PASS/FAIL
Nurse:Patient Rat		Pass
 Staffing parameters should be clearly delineated in a policy that reflects (a) staff mix and ability levels; (b) patient census, intensity, and acuity; and (c) plans for delegation of selected, clearly defined tasks to competent assistive personnel. It is an expectation that allocation of personnel provides for safe care of all patients in a setting where census and acuity are dynamic. Newborns 1:6-8 neonates requiring only routine care* 1:4 recently born neonates and those requiring close observation 1:3-4 neonates requiring continuing care 1:2-3 neonates requiring intermediate care 1:1-2 neonates requiring multisystem support 1:1 or greater for unstable neonates requiring complex critical care *Reflects traditional newborn nursery care. A nurse should be available at all times, but only one may be necessary, as most healthy neonates will not be physically present in the nursery. Direct care of neonates in the nursery may be provided by ancillary personnel under the 	io Staffing will be consistent with identified staffing guidelines. SHS provided names and professional license number of all patient care staff.	Pass
nurse's direct supervision. Additional staff is needed to respond to acute and emergency situations. The use of		
assistive personnel is not considered in the nurse: patient ratios noted here.		
Nursing Manageme	ant	Pass
Same as Level I (see below) plus:	Currently meet all guidelines.	1 855
 Advanced degree is desirable Level I: *nurse manager of perinatal and nursery services Maintains RN licensure Directs perinatal and/or nursery services Guides perinatal and/or nursery policies and procedures Collaborates with medical staff Consults with higher level of care units as necessary *=One RN may manage both services, but additional managers may be necessary based on number of births, average daily census, or number of full-time equivalents (FTEs) 	Current manager has an advanced degree and will manage both labor/delivery and level II nursery	

GUIDELINE	SHS-BALLARD	PASS/FAIL
Pharmacy, Nutrition/Lactation and OT/PT		Pass
Pharmacy Services	Pharmacy Services	
Level I:	Currently meeting level I guidelines	
Registered pharmacist immediately available for	Pharmacist will be available 24/7	
telephone consultation, 24 hrs/day and 7 days/wk;		
Provision for 24 hrs/day and 7 days/wk access to	Will use SHS-First Hill as a resource	
emergency drugs	when caring for 32-33 week infants	
Level II	Nutrition/Lactation	
Registered pharmacist available 24 hrs/day and 7 days/wk	Currently meeting level I and level II	
	guidelines	
If caring for 32-33 week infants:	1.0 lactation FTE currently in place	
Registered pharmacist with experience in		
neonatal/perinatal pharmacology available 24 hrs/day and		
7 days/wk	OT/PT	
	SHS-First Hill will be used as the	
Nutrition/Lactation	resource	
Level I:		
Dietary and lactation services and consultation available		
Level II		
One healthcare professional knowledgeable in		
management of special maternal and neonatal dietary needs.		
Lactation services and consultation available		
Diabetic educator for inpatient and outpatient services		
Diabetic educator for inpatient and outpatient services		
If caring for 32-33 week infants:		
Registered dietician knowledgeable in parenteral nutrition		
of low birthweight and other high-risk neonates.		
OT/PT		
Provide for inpatient consultation and outpatient follow-		
up- services		

GUIDELINE	SHS-BALLARD	PASS/FAIL	
Social Services/Case Management, R	espiratory Therapy,	Pass	
Nurse Educator/Clinical Specialist			
Social Services/Case Management Level I services plus: Personnel with relevant experience whose responsibilities include perinatal patients; specific personnel for discharge planning and education, community follow-up, referral process and home care arrangements. If caring for a 32-33 week infants: At least one MSW with relevant experience Nurse Educator/Clinical Nurse Specialist A nursing educator with appropriate training in special care nursery or perinatal care to coordinate staff education and development. If caring for full spectrum of level II patients, a clinical nurse specialist with graduate education is recommended for staff development and to effect system-wide changes to improve programs of care.	Social Services/Case Management Currently meeting level I and level II guidelines Nurse Educator/Clinical Specialist Currently meeting level I and level II guidelines RT is in house 224/7 currently Competency and validation will be a part of the training to open the level II nursery Educator open the level II		
Level I: The role of a respiratory care practitioner is prescribed by the medial director and clearly delineated per written protocol. If attending deliveries or providing neonatal respiratory care, should have current NRP provider status.			
Level II Same as Level I plus: When CPAP in use, in-house and immediately available Respiratory Care Practitioner (RCP) with documented competence and experience in the management of neonates with cardiopulmonary disease			
X-Ray Ultrasound		Pass	
Level I services plus Ultrasound equipment immediately accessible and available to the labor and delivery unit 24 hrs/day and 7 days/wk	Currently meeting level I and level II guidelines		

GUIDELINE	SHS-BALLARD	
Laboratory and Blood Bank Services		Pass
Laboratory	Laboratory	
Same as level I plus;	Currently meeting level I and level II	
• Lab technician in-house 24 hrs/day and 7 days/wk	guidelines	
• Personnel skilled in phlebotomy and IV placement in		
the newborn immediately available 24 hrs/day and 7	Blood Bank	
days/wk	Currently meeting guidelines	
• Microtechnique for hematocrit and blood gasses		
within 15 minutes		
Blood Bank		
Level I through Level IV		
Blood bank technician on-call and available w/n 30		
minutes for performance of routine blood banking		
procedures		
Provision for emergent availability of blood and blood		
products		