

EVALUATION OF THE APPLICATION SUBMITTED BY PROVIDENCE REGIONAL MEDICAL CENTER EVERETT PROPOSING:

- 1) A RECONCILIATION OF UN-LICENSED BASSINETTES AT THE HOSPITAL;**
- 2) REDUCTION OF INTERMEDIATE LEVEL II BASSINETTES; AND**
- 3) EXPANSION OF LEVEL III NICU BASSINETTES**

APPLICANT DESCRIPTION

Providence Regional Medical Center-Everett (PRMCE) is a private non-profit, acute care hospital located at 1321 Colby Avenue in the city of Everett, within Snohomish County. PRMCE is owned and operated by the Washington State Corporation known as Providence Health System-Washington. PRMCE is currently a provider of Medicare and Medicaid services to the residents of Snohomish, Skagit, Island, Whatcom, and San Juan counties.

The hospital is currently licensed for 372 acute care beds, and has Certificate of Need approval for 106 additional beds.¹ Approval of the neonatal application would increase the total number of licensed beds from 372 to 395. Completion and licensing of the 106 bed patient care tower would increase the total number of licensed beds from 395 to 501.

The hospital currently has a 23-bed intermediate care nursery and level II obstetric services (level II) and a 6-bed neonatal intensive care nursery and level III obstetric services (level III) located in the their Women and Children’s Pavilion since 2002. Since 2000, PRMCE has contracted with Providence-Children’s Neonatal Services, LLC to provide management and oversight of care in the combined level II/level III unit. The hospital also holds a three-year accreditation from the Joint Commission. [Source: Application, p10, CN historical files; Joint Commission website]

PROJECT DESCRIPTION

This application proposes to expand the number of beds in its combined level II/ level III nursery at its existing site in the Women and Children’s Pavilion. Currently, PRMCE operates 29 beds in the nursery. PRMCE proposes to reallocate ten level II beds to level III services. Additionally, PRMCE has not included a 23 of its level II and level III beds in its total licensed bed capacity of 372. If this project is approved the number of licensed beds will increase from 372 to 395.² Table 1 below is a breakdown of the current and proposed bassinette configuration. [Source: Application, p8]

**Table 1
PRMCE’s Current and Proposed Bassinette Configuration**

Current status	Bassinettes	Proposed status	Bassinettes
Unlicensed/Non CN approved Level II	14	Licensed Level II	13
Unlicensed/CN approved Level II	9		
Licensed & CN approved Level III	6	Licensed Level III	16
Totals	29	Totals	29

¹ Certificate of Need #1344 issued on December 18, 2006.

² This figure does not include the 106 beds approved by CN #1344

As shown in Table 1, PRMCE has been operating a 29 bed combined level II/level III nursery. Of the 29 beds, only six level III beds have been counted by PRMCE as part of the licensed bed capacity. Of the remaining 23 level II beds, 9 received CN approval, but have not been included in the hospital's license. The remaining 14 level II beds have never received CN approval, and therefore, have also not been included in the hospital's license. With this application, PRMCE proposes: 1) recognition of all 23 level II bassinets, bringing the total level II/level III bassinets to 29 licensed; and 2) reconfigure the 29 bed special care nursery to 13 level II and 16 level III. If this project is approved, the licensed capacity of PRMCE will increase by 23 beds total 395 beds (372 medical/surgical, 13 level II and 10 level III).³

The capital expenditure associated with the project is \$3,933,590, and of that amount 42.0% is related to construction costs; 33.6% is related to fixed and moveable equipment; and the remaining 24.4% is related to fees, tax, and other miscellaneous costs. [Source: Application, p32] The capital expenditure was incurred in 2002. The applicant expended the funds as part of a CN approved project for 6 level III beds. The new combined unit was built to accommodate 29 beds. The applicant submitted the CN to add the additional 23 beds to their license and to get CN approval for the additional 14 beds.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the change in bed capacity of a health care facility the provisions of Revised Code of Washington (RCW) 70.38.105(4)(e) and Washington Administrative Code (WAC) 246-310-020(1)(c).

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*

³ If this project is approved, PRMCE's total licensed bed capacity will increase to 395. Once CN #1344 is complete and the additional 106 acute care beds are included in the hospital's license, PRMCE's total licensed beds will increase to 501.

- 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, PRMCE 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); and 246-310-240 (cost containment).⁴ Where applicable, meeting the 2005 Perinatal Level of Care Guidelines established by the Washington State Perinatal Advisory Committee assists in demonstrating compliance with the criteria.

APPLICATION CHRONOLOGY

March 3, 2010	Letter of Intent Submitted
April 15, 2010	Application Submitted
April 16 through June 15, 2010	Department’s Pre-Review Activities & Extension • 1 st screening activities and responses
June 16, 2010	Beginning of Review
July 21, 2010	Public Hearing Conducted / End of Public Comment
August 4, 2010	Rebuttal Documents Submitted to Department
September 20, 2010	Department's Anticipated Decision Date
January 5, 2011	Department's Actual Decision Date

⁴ 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 (3b & c); (4), (5), and (6); and WAC 246-310-220(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.”

During the review of this application, one entity sought, but did not receive, affected person status under WAC 246-310-010. MultiCare Health System — a healthcare delivery system that operates a variety of healthcare facilities within Pierce County. MultiCare Health System requested affected person status but did not submit comment during the public comment period.

SOURCE INFORMATION REVIEWED

- Providence Regional Medical Center-Everett's Certificate of Need application received March 3, 2010
- Providence Regional Medical Center-Everett's supplemental information dated June 7, 2010
- Public comments submitted throughout the review of the project
- Comprehensive Hospital Abstract Reporting System (CHARS) data obtained from the Department of Health's Hospital and Patient Data Systems
- Financial feasibility and cost containment evaluation prepared by the Department of Health's Hospital and Patient Data Systems dated October 13, 2010.
- Joint Commission website [www.jointcommission.org]
- Certificate of Need Historical files

No rebuttal documents were submitted by the applicant or other parties.

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of Providence Regional Medical Center-Everett proposing a combined 29 bed level II/level III nursery is consistent with applicable criteria. The configuration of the 29 bed nursery is 13 level II bassinets and 16 level III bassinets. With approval of this project the approved bed supply for the Providence Regional Medical Center will be as shown in the table below:

**Providence Regional Medical Center
CN Approved Bed Supply**

General Medical/Surgical Licensed	366
Level II ICN	13
Level III Neonatal ICU	16
General Medical/Surgical CN approved Not Licensed	106
Total	501

A Certificate of Need should be issued provided that the applicant agrees to the terms below.

Terms

1. Within 90 days of issuing the Certificate of Need for this project, Providence Regional Medical Center Everett will provide a copy of the adopted written policies and procedures specific to neonatal transport as recommended by the Washington State Perinatal Levels of Care guidelines.
2. Within 90 days of issuing the Certificate of Need for this project, Providence Regional Medical Center Everett will provide a copy of the adopted guidelines for continued care during transport as recommended by the Washington State Perinatal Levels of Care guidelines.
3. Within 90 days of issuing the Certificate of Need for this project, Providence Regional Medical Center Everett will provide a copy of the adopted written policies for participating in case reviews at hospitals referring infants to Providence Regional Medical Center Everett for higher level care.
4. With in 90 days of issuing the Certificate of Need for this project, Providence Regional Medical Center Everett will provide a copy of the Department of Health approved charity care policy.

The approved capital expenditure for this project is \$3,933,590.

A. Need (WAC 246-310-210)

Based on the source information reviewed and agreement with the terms identified in the “conclusion” section of this evaluation, the department determines that the applicant has met the need criteria in WAC 246-310-210(1) and (2).

- (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 246-310-020 states (in summary) that level II services are to be in an area designed, organized, equipped, and staffed to provide a full range of maternal and neonatal services for uncomplicated patients and for the majority of complicated obstetrical problems. It further states that level III services are to be in an area designed, organized, equipped, and staffed to provide services to the few woman and infants requiring full intensive care services for the most serious type of maternal-fetal and neonatal illnesses and abnormalities. Level III services also provide coordination of care, communications, transfer, and transportation for a given region, as well as the provision of leadership in preparatory and continuing education in prenatal and perinatal care. A level III provider may be involved in clinical and basic research.

Both level II and level III services are considered tertiary services as defined by WAC 246-310-010. For some tertiary services, such as open heart surgery, the department uses an established methodology to assist in its evaluation of need for the services. For other tertiary services, including level II or level III services, no such methodology exists. Given that the department has not developed an established methodology for these services, an evaluation of the need criterion begins with an evaluation of the methodology provided by the applicant.

Level II Intermediate Care Nursery and Level III Neonatal Intensive Care Unit

PRMCE received approval in 1980 to provide level II services and has been actively providing this care, though with a greater number of bassinets than originally proposed⁵. The hospital expanded the level II service over time and moved it to the Women and Children’s Pavilion at the time it received certificate of need approval to establish its 6-bed level III NICU in 2002. Data reported to the Department of Health’s Hospital and Patient Data Program demonstrates that PRMCE’s level II service has been in continuous operation since its inception. With this application PRMCE is not requesting the addition of a new tertiary service, rather, PRMCE requests reconfiguration or expansion of dedicated beds within its existing tertiary services. This portion of the proposed project is to add 13 level II bassinets to the hospital’s licensed bed capacity. This action would correct the hospital’s total licensed beds to equal 385 [372 + 13]. The review will consist of the applicant’s reported planning area and the current utilization of the PRMCE level II service. Patient origin data for 2008 provided in the application shows an Average Daily Census (ADC) of 17.7 for its level II service. [Source: June 7, 2010 Screening Question Response, p3]

⁵ The 1980 decision allowed for the expansion of 15 Level II bassinets to a total of 27. Current records indicate the hospital never fully executed the previous CN.

PRMCE is also proposing to increase the number of level III bassinets from 6 to 16. Patient origin data for 2008 provided in the application shows an ADC of 8.3 for its level III service. [Source: Application, p21] Data reported to the Department of Health's Hospital and Patient Data Program also demonstrates that PRMCE's level III service have been in continuous operation since its inception. PRMCE provided its need projections for the level II and level III projects together.

Comprehensive Hospital Abstract Reporting System (CHARS) data is used to assist in demonstrating need for a level III service. CHARS data is reported by each Washington State hospital to the department's Hospital and Patient Data Systems office (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 #15.⁶

DRG	Definition	Level of Care
385 / 789	NEONATES, DIED OR TRANSFERRED TO ANOTHER ACUTE CARE FACILITY	Level 3
386 / 790	EXTREME IMMATURETY OR RESPIRATORY DISTRESS SYNDROME, NEONATE	Level 3
387 / 791	PREMATURITY WITH MAJOR PROBLEMS	Levels 2 or 3
388 / 792	PREMATURITY WITHOUT MAJOR PROBLEMS	Level 2
389 / 793	FULL TERM NEONATE WITH MAJOR PROBLEMS	Level 2
390 / 794	NEONATE WITH OTHER SIGNIFICANT PROBLEMS	Levels 1 or 2
391 / 795	NORMAL NEWBORN	Level 1

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 II patients are included in DRGs 791, 792, and 793, with a few patients in 794. The majority of level III patients are included in DRGs 789 and 790, with a few patients in DRG 791.

To justify the 13 level II bassinets and 16 level III bassinets, PRMCE applied a 4-step forecast methodology using the hospital's primary service area for neonatal services of Snohomish, Whatcom, Skagit, and Island counties. Below is a discussion of PRMCE's numeric methodology and the assumptions/data used by PRMCE in each step. Throughout the methodology and calculations, PRMCE used six years of historical data (2003-2008) from DRGs 789 and 790 for level 3 calculations; and DRGs 791, 792, and 793 for level II calculations. [Source: Application: pgs 19-23] The applicant also provided historical and projected

⁶ Each DRG 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 October 16, 2007 testimony by Dr. Linda Wallen, MD, also a board certified neonatologist.

ADC for the same data, and included DRG 794 in level II data. [Source: June 7, 2010 Screening Question Response, p3]

PRMCE’s Need Methodology

PRMCE provided the following steps and assumptions used in their methodology:

1. Average annual growth rates were calculated for level II and level III patient days for Island, Skagit, Snohomish, and Whatcom counties.
2. Projections by year and by level of care were developed from a baseline 2008 actual using annual growth rates calculated as described above.
3. Annual average daily census (ADC) was calculated by dividing total patient days by 365.
4. Adjusted average daily census (AADC) was calculated by dividing ADC by 0.65, the target occupancy factor. [Source: Application, p22]

Step 1 – Average annual growth rates were calculated for level II and level III patient days for Snohomish, Skagit, Island, and Whatcom counties in the period 2003-2008.

In this step, the applicant totaled patient days within PRMCE’s neonatal program for the DRG’s associated with level II and level III from 2003 through 2008. The values are based upon CHARS reporting data for the corresponding years and an average annual growth rate is calculated over a six year period. The values are summarized in Table 2. [Source: Application pg19]

**Table 2
2003-2008 Total Patient Days Level II and Level III Neonates
Island, Skagit, Snohomish, and Whatcom Counties**

	2003	2004	2005	2006	2007	2008	Avg.*
Level II							
Total Pt. Days	10,892	11,162	11,916	11,163	10,919	13,297	4.0%
ADC	29.8	30.6	32.6	30.6	29.9	36.4	
AADC (65%)	45.9	47.0	50.2	47.1	46.0	56.0	
Level III							
Total Pt. Days	7,230	8,505	7,690	6,930	7,924	8,677	3.6%
ADC	19.8	23.3	21.1	19.0	21.7	23.8	
AADC (65%)	30.5	35.9	32.4	29.2	33.4	36.6	
Combined Level II & Level III							
Total Pt. Days	18,122	19,670-	19,606	18,093	18,843	21,974	3.9%
ADC	49.6	53.9	53.7	49.6	51.6	60.2	
AADC (65%)	76.38	83.91	82.64	76.26	79.42	79.42	

*Average Annual Growth 2003 to 2008

PRMCE states that the data demonstrates a demand for at least 56 level II bassinets and 36 level III bassinets in year 2008. This demand is based on an adjusted average daily census of 65%.

PRMCE’s level II and level III historical patient days for the same time frame—2003 through 2008—is shown in Table 3 below. These are all level II and level III patient days, regardless of location, rather than the four-county planning area identified above. [Source: Application pg 20 & 21]

**Table 3
PRMCE Historical Level II and Level III Patient Days
Excluding DRG794**

	2003	2004	2005	2006	2007	2008	Avg.*
Level II							
Total Pt. Days	4,358	3,845	4,253	3,841	3,603	5,227	3.6%
ADC	11.9	10.5	11.7	10.5	9.9	14.3	
AADC (65%)	18.4	16.2	17.9	16.2	15.2	22.0	
Level III							
Total Pt. Days	2,233	2,640	2,351	2,106	2,721	3,028	6.1%
ADC	6.1	7.2	6.4	5.8	7.5	8.3	
AADC (65%)	9.4	11.1	9.9	8.9	11.5	12.8	
Combined Level II & Level III							
Total Pt. Days	6,591	6,485	6,604	5,947	6,324	8,255	4.5%
ADC	18.06	17.77	18.09	16.29	17.33	22.62	
AADC (65%)	27.78	27.33	27.84	25.07	26.66	34.79	

*Average Annual Growth 2003 to 2008

PRMCE states that a comparison of Table 2 and Table 3 above demonstrates shows that the historical patient days for PRMCE are increasing faster than the historical patient days for the planning area. The major growth in these patient days was in the level II patient days. There are other level II and level III providers and beds in this planning area, therefore if this increase continues; there are additional resources to absorb this growth. Based on historical data, there is a reasonable possibility that this trend will not continue in a linear trend. There was a substantial increase between 2007 and 2008 and the applicant does not discuss whether they anticipate this trend to continue. The applicant does indicate that they are making some improvements to the program that seems to be increasing their market share of the planning area days.

Step 2 – Projections, by year, were developed from 2008 actuals using growth rates calculated as described above.

PRMCE provided the projected patient days for 2009 through 2018 as shown in Table 4 below. It should be noted that the level II patient days for 2007 are substantially higher than the patient days in the previous five years. This will have an effect on the projected patient days of possibly overestimating the number of future patient days generated in the planning area.

Table 4
2009 – 2018 Forecast Level II and Level III Total Patient Days
Island, Skagit, Snohomish and Whatcom Counties

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Avg.*
Level II											
Total Pt. Days	13,828	14,379	14,953	15,550	16,170	16,815	17,486	18,,184	18,910	19,664	3.9%
Avg. Daily Census	37.9	39.4	41.0	42.6	44.3	46.1	47.9	49.8	51.8	53.9	
AADC	58.3	60.6	63.0	65.5	68.2	70.9	73.7	76.6	79.7	82.9	
Level III											
Total Pt. Days	8,994	9,322	9,662	10,014	10,380	10,759	11,151	11,558	11,980	12,417	3.6%
Avg. Daily Census	24.6	25.5	26.5	27.4	28.4	29.5	30.6	31.7	32.8	34.0	
AADC	37.9	39.3	40.7	42.2	43.8	45.3	47.0	48.7	50.5	52.3	
Combined Level II & Level III											
Total Pt. Days	22,821	23,701	24,615	25,564	26,550	27,574	28,638	29,742	30,889	32,081	3.8%
Avg. Daily Census	62.5	64.9	67.4	70.0	72.7	75.5	78.5	81.5	84.6	87.9	
AADC	96.19	99.90	103.75	107.75	111.91	116.22	120.71	125.36	130.20	135.22	

Average Annual Growth 2009-2018
DRGs 791, 792, & 793

As shown in Table 4 above in 2013, PRMCE shows a total need for at least 68 level II bassinets, 44 level III bassinets, and a combined total of 112 bassinets using the applicant's adjusted ADC of 65% for projected year 2013.

In additional to the population increase, the applicant provided data to demonstrate that its level II and level III market shares have increased. Those statistics are shown in table 5 below.

Table 5
Total PRMCE Planning Area Market Share
Level II and Level III [DRGs 789-793] Inpatient Discharges

Year	Level II & III Combined	% Market Share	Total Market
2008	750	38.32%	1,957
2007	650	35.62%	1,825
2006	643	34.70%	1,853
2005	710	37.02%	1,918
2004	546	31.60%	1,728

As shown in Table 5 above, PRMCE level II and level III market shares have increased more than 6% in the five year span between 2004 and 2008. In addition to the information in Table 5 above, PRMCE provided data on referrals and transfers from other hospitals to PRMCE. This data is contained in Table 6 below.

Table 6
Referrals/Transfers in to PRMCE by Other Hospitals

Year	Number of Transfers to PRMCE
2009	106
2008	99
2007	62

PRMCE states it is working with other hospitals in the planning area to build collaborative relationships and is also developing a Hospitalist program with an expected completion date for 24/7 coverage of June 2010. The OB/GYN Hospitalists provide high-risk obstetric care to hospitalized mothers identified as high risk. The OB/GYN Hospitalists will accept maternal transports from regional OB services (Cascade Valley Hospital located in Arlington; Skagit Valley Hospital located in Mount Vernon; and St. Joseph Hospital located in Bellingham) and provide high risk obstetric care to those hospitalized mothers. In addition, the OB/GYN Hospitalists will be partnering with Community Health Center of Snohomish County to provide delivery services for their patients.

Step 3 – Average Daily Census (ADC) was calculated by dividing total patient days by 365.

In this step, PRMCE calculated the ADC for the program projected out to year 2018. The results are detailed in Table 4. [Source: Application, pg22] The ADC calculations in Table 4 do not include DRG 794; however, PRMCE provided revised ADC calculation with DRG 794 included and current occupancy using 29 bassinets... This data is summarized in Table7. [Source: June 10 Response to Screening Questions, p5]

Table 7
PRMCE Historical ADC with DRG794

Actual	2003	2004	2005	2006	2007	2008
ADC	18.1	17.8	18.1	16.3	17.3	22.6
Occupancy	62%	61%	62	56%	60%	76%

As shown in Table 7 above, PREMC has been operating around 60% occupancy for 4 out of 5 of the most recent years with data available. In 2008, the 76% occupancy was a substantial increase from previous years. This will tend to make the projections higher than a more conservative projection such as one based on a 5 year average of ADC and occupancy. This may result in the applicant not reaching full occupancy of the unit as soon as they have projected.

The applicant also provided projections for the period 2009 through 2018 which includes DRG 794. These projections are shown in Table 8 below. [Source: June 10 Response to Screening Questions, pg5]

Table 8
PRMCE Projected ADC with DRG 794

Projected	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
ADC	23.5	24.4	25.3	26.3	27.3	28.4	29.5	30.6	31.8	33.1
Occupancy	81%	84%	87%	91%	94%	98%	101%	105%	110%	114%

As shown in Table 8 above, PRMCE projects that it's combined level II/level III services would be operating at 94% occupancy in year 2013 and above 100% occupancy in year 2015.

Step 4 – Adjusted Average Daily Census (AADC) was calculated by dividing ADC by 0.65, the target occupancy factor.

In this step, the applicant references a study commissioned at Sacred Heart Medical Center in Spokane, Washington, which reportedly reviewed the appropriate occupancy standard that Sacred Heart Medical Center should apply to the Spokane NICU program. According to the conclusions of that report, the optimal occupancy rate for Sacred Heart Medical Center is 65% of the current total occupancy. PRMCE applied this conclusion to compute an Adjusted Average Daily Census (AADC) for the neonatal program at PRMCE from the data outlined in Table 4. [Source: Application, p 24 & 25]

Based upon these modified calculations, PRMCE produced a 10 year forecast of need for additional neonate demand. The applicant applied the medium-series OFM population projections to establish the planning area population for females aged 15 to 44. Applying the historical growth rate with the population forecast, PRMCE projected that need would exceed the current PREMC operational capacity of 29 by 2015, when a standard ADC is calculated. The current capacity was exceeded in 2009 when PRMCE applied its AADC adjustment. The results, through 2018, are summarized below in Table 9. [Source: Application, p24 & 25]

Table 9
PRMCE's Patient Day Projections for Level II & Level III Neonate Care

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
	Level II									
Pt. Days	5,436	5,652	5,878	6,113	6,356	6,610	6,874	7,148	7,433	7,730
ADC	14.89	15.49	16.10	16.75	17.41	18.11	18.83	19.58	20.37	21.18
AADC	22.91	23.82	24.78	25.76	26.79	27.86	28.79	30.13	31.33	32.58
	Level III									
Pt. Days	3,138	3,253	3,372	3,495	3,622	3,754	3,891	4,033	4,181	4,333
ADC	8.60	8.91	9.24	9.57	9.92	10.29	10.66	11.05	11.45	11.87
AADC	13.23	13.71	14.21	14.73	15.27	15.82	16.40	17.00	17.62	18.26
	Combined Level II & Level III									
Pt. Days	8,574	8,005	9250	9,607	9,979	10,364	10,765	11,181	11,614	12,063
ADC	23.5	24.40	25.34	26.32	27.34	28.40	29.49	30.63	31.82	33.05
AADC	36.14	37.54	38.99	40.49	42.06	43.69	45.38	47.13	48.96	50.85

Department’s Review

The department’s need review begins with consideration of the underlying assumptions used by PRMCE in its need methodology. The main assumptions used by PRMCE are: 1) service area; 2) population projections; 3); current capacity at the hospital; and 4) use of an adjusted occupancy standard.

PRMCE Service Area

PRMCE defines its primary service area to be Snohomish, Skagit, Island, and Whatcom counties. Table 10 identifies the counties in PRMCE’s defined service area and the corresponding percentage of patient days classified as level II or level III care being provided at PRMCE. [Source: Application, p17]

**Table 10
Year 2008 Reported Level II & Level III
Patient Days for PRMCE**

County	Level II Percentage⁷	Level III Percentage
Snohomish	46.5%	39.8%
Skagit	16.8%	27.5%
Island	33.2%	13.1%
Whatcom	7.3%	21.0%

PRMCE is located in Snohomish County and the hospital has a very high percentage of patient days coming from this county for both level II and level III services. Skagit and Island counties also provide enough patient days to confirm their inclusion as part of the service area. Stevens Healthcare located in Snohomish County and Skagit Valley Hospital located in Skagit County both provide level II services.

Whatcom County provides more level III patient days but also provides some level II patient days. St. Joseph Hospital located in Whatcom County provides level II services.

The applicant has appropriately identified Snohomish, Skagit, Island, and Whatcom counties as their service area for neonatal services.

There is no level II service provider located in Island County.

Population Projections

PRMCE projected the female aged 15-44 population based upon the Medium series projections produced by OFM for Snohomish, Skagit, Island, and Whatcom counties. The department relies upon the intermediate/medium series in projecting population for this age. This approach is reasonable.

⁷ Includes reported days for DRG 794

Current Capacity

PRMCE is currently CN approved for 9 level II bassinets and 6 level III bassinets, for an approved total of 15 Level II/III bassinets. PRMCE is currently operating a combined total of 29 level II and level III bassinets. Table 11 below shows the historical ADC of the bassinets at PRMCE based upon data reported to the department for the defined planning area. [CHARS Historical Reports]

**Table 11
PRMCE’s Historical ADC for Planning Area**

	2003	2004	2005	2006	2007	2008
Level II Patient Days	5,189	5,020	5,429	5,247	4,681	6,252
Level III Patient Days	2,241	2,629	2,310	2,072	2,668	2,976
Combined Patient Days	7,430	7,649	7,739	7,319	7,349	9,228
Level II ADC	14.22	13.75	14.87	14.38	12.82	17.13
Level III ADC	6.14	7.20	6.33	5.68	7.31	8.15
Combined ADC	20.36	20.95	21.20	20.06	20.13	25.28
PRMCE Bassinets	29	29	29	29	29	29
Per Cent Occupancy	70.2	72.2	73.1	69.2	69.4	87.1

Source: CHARS

As shown in Table 11 above, PRMCE has been operating at 69 to 73 percent occupancy until 2008. With the increase in patient days the occupancy of the Level II/Level III services increased to 87 percent. As discussed previously, PRMCE has been making improvements to the neonatal services to increase their market share. The market share increase increases the projected patient days beyond the increase expected by normal population growth.

Table 12 below is a capacity summary for the existing providers in the four county planning area with level II or level III capacity. [Source: Application, p6]

**Table 12
Reported Neonate Capacity in the Planning Area**

	County	Level II	Level III
PRMCE	Snohomish	23	6
Skagit Valley Hospital	Skagit	3	0
St. Joseph’s Hospital	Whatcom	14	0
Stevens Hospital	Snohomish	10	0
Planning Area Total		50	6

Table 12 shows that there are additional level II beds in the planning area giving the applicant flexibility in accepting or transferring level II patients. In addition, the applicant has flexibility in assigning the level II patients to Level III bassinets at its own facility, if the level III bed space is available. Since PRMCE only operates 6 level III bassinets, this type of flexibility is typically unavailable. The applicant exceeds the minimum of 10 ADC recommended by the Level of Care Guidelines for combined Level II/III units.

As stated by the applicant, and supported by department records, PRMCE is the only approved provider of level III services in the planning area. There are three other providers of level II services in the planning area. Table 12 lists the providers and the number of bassinettes in each facility.

Since there are 3 other providers of level II services with 27 other level II bassinettes in the planning area, it would be logical for PRMCE to decrease its number of level II bassinettes and increase its level III bassinettes. This approach is also reasonable since the bassinettes were initially built to level III standards and can be converted without any additional capital expenditure.

Use of an adjusted occupancy of 65%

The applicant's use the term *Adjusted Average Daily Census (AADC)* seems to be confusing and the department is interpreting that to actually be the number of bassinettes the applicant is projecting as needed for their facility based on the projected number of patient days.

Table 13 contains the projected patient days provided by the applicant and the projected number of bassinettes projected as needed by the applicant to operate at a level of 65 percent average annual occupancy.

**Table 13
Effects of AADC upon Actual Program ADC**

	2008	2009	2010	2011	2012	2013
Level II						
Total Pt. Days	5,227	5,436	5,652	5,878	6,356	6,610
ADC	14.3	14.89	15.49	16.10	16.75	17.41
AADC (65%)	22.0	22.91	23.82	24.78	25.76	26.79
Level III						
Total Pt. Days	3,028	3,138	3,253	3,372	3,495	3,622
ADC	8.3	8.6	8.91	9.24	9.57	9.92
AADC (65%)	12.8	13.23	13.71	14.21	14.73	15.27
Level II & III						
Total Pt. Days	8,255	8,574	8,905	9,250	9,607	9,979
ADC	22.62	23.49	24.40	25.34	26.32	27.34
AADC (65%)/	34.79	36.14	37.54	38.99	40.49	42.06
Bassinettes Needed	35	36	38	39	41	42

As shown in Table 13, the number of level II/Level III bassinettes projected as needed range from 35 in 2008 to 42 in 2013. PRMCE is proposing to have a total of 29 Level II/III bassinettes. The number of level II/level III bassinettes proposed by PRMCE is less than the number they project as needed for their facility. However, there are other level II bassinettes located in this planning area.

The ADC currently experienced by PRMCE's level II/level III service exceeds the Perinatal Levels of Care guidelines, which recommends level II/III nurseries to have a combined ADC of at least 10, rather than focusing on a program's occupancy rate. Using the applicant's

projections, PRMCE exceeded this standard in 2008. [Application: p7; Washington State Perinatal Levels of Care guidelines, p4]

Department Conclusion

Upon review of the applicant's historical data and the projections both with and without DRG 794, the department concludes that the applicant currently exceeds the recommendation for ADC in level II and level III units. The initial calculations submitted by the applicant, and the revised forecast including DRG 794 both identify a growing need for level III service in the community. Each show differing, but comparable, census calculations that approach or exceed levels that support the applicant's project.

The department has identified the substantial growth in level II patient days for the applicant between 2007 and 2008. There are other level II providers and beds in the four county planning area, therefore if this increase continues; there are additional resources to absorb this growth. Further, level III bassinets are equipped to appropriately care for patients requiring Level II care.

Based on the need methodology results and supporting information, PRMCE's proposed bed addition of 23 (13 level II and 10 level III) has been demonstrated.

Based on the above information, the department concludes that request for 13 level II and 16 level III bassinets can be supported. This sub-criterion is met.

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

PRMCE is currently a provider of health care services to residents of Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. As an acute care hospital, PRMCE also currently participates in the Medicare and Medicaid programs. To determine whether all residents of the service area would continue to have access to a hospital'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, PRMCE provided a copy of its current Patient Rights and Responsibilities Policy and its scope of services policy. The policies outline the process/criteria that PRMCE uses to admit patients for treatment or care at the hospital. The policies also state that any patient requiring care is accepted for treatment at PRMCE without regard to race, religion, sex, age, or ability to pay. These policies are consistent with Certificate of Need requirements. [Source: Application, pgs 123-127; 219-224]

To determine whether low income residents would have access to the proposed services, the department uses the facility's Medicare eligibility or contracting with Medicaid as the measure to make that determination. PRMCE currently provides services to Medicaid eligible patients. Documents provided in the application demonstrate that it intends to maintain this status. For this project, a review of the policies and data provided for PRMCE

identifies the facility’s financial resources as including Medicaid revenues. [Source: Application, p11; Appendix 16

For this project, it is unlikely that residents with Medicare will need access to neonatal services. However, nothing in the application suggests that this project will impact the services provided to Medicare patients.

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.

PRMCE also provided a copy of its current Financial Assistance Program that would continue to be used if this project is approved. This version of the program has not been reviewed and approved by the department’s Hospital and Patient Data Systems⁸. Before this application can be approved and a Certificate of Need issued, the applicant must get the most recent version of the Charity Care Policy approved by HPDS. Further, PRMCE included a ‘charity care’ line item as a deduction from revenue within the pro forma financial documents for the hospital. [Source: Application, p 140]

For charity care reporting purposes, the Department of Health’s Hospital and Patient Data Systems (HPDS), divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. Located in Snohomish County, PRMCE is one of 18 hospitals in the Puget Sound Region. According to 2006-2008 charity care data obtained from HPDS, PRMCE has historically provided more than the average charity care provided in the region. PRMCE’s most recent three years (2006-2008) percentages of charity care for gross and adjusted revenues are 3.20% and 7.03%, respectively. The 2006-2008 average for the Puget Sound Region is 1.95% for gross revenue and 4.23% for adjusted revenue. [Source: HPDS 2006-2008 charity care summaries]

Table 14 contains the 3 year average for Puget Sound and the projected 3 year average for PRMCE. [Source: Application p140, HPDS 2006-2008 charity care summaries

Table 14
PRMCE Charity Care Comparison

	3-Year Average for Puget Sound Region	3-Year Average for PRMCE
% of Gross Revenue	1.95%	3.43%
% of Adjusted Revenue	4.23%	5.97%

PRMCE’s pro forma revenue and expense statements indicate that the hospital will provide charity care at approximately 3.43% of gross revenue and 5.97% of adjusted revenue. RCW

⁸ www.doh.wa.gov/ehsphi/hospdata/charitycare/charitypolicies

70.38.115(2)(j) requires hospitals to meet or exceed the regional average level of charity care. Given that the amount of charity care historically provided by PRMCE is above the regional averages and PRMCE proposes to provide charity care above the three-year historical gross and adjusted revenue averages for the region, the department concludes that this sub-criterion has been met provided PRMCE submits its most recent Department of Health approved Charity Care Policy. [Source: Application, p99 & HPDS Charity Care Reports 2006, 2007 & 2008]

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

Based on the source information reviewed and the applicant’s agreement to the terms identified in the ‘conclusion’, section of this evaluation, the department determines that the applicant has met the financial feasibility criteria in WAC 246-310-220(1), (2), and (3).

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

WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2) (a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what the operating revenues and expenses should be for a project of this type and size. Therefore, using its experience and expertise the department evaluates if the applicant’s pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

To demonstrate compliance with this sub-criterion, PRMCE provided its pro forma financial statements for the neonatal unit alone and the hospital, as a whole, with the proposed project. These reports provided the figures necessary to isolate the projections for the Level II/III services. A summary of the financial projections for the neonatal project alone is shown in Table 15 below. [Source: June 7, 2010 Response to Screening Questions, Attachment 1]

Table 15
Years 2011 through 2013
Level II and Level III Combined Cost Center
Projected Statement of Operations Summary

	Projected Year 1 (2011)	Projected Year 2 (2012)	Projected Year 3 (2013)
Total Operating Revenue	\$15,244,389	\$16,066,605	\$16,457,677
Total Operating Expenses	\$9,406,383	\$9,751,104	\$10,108,359
Net Profit or (Loss)	\$5,838,006	\$6,315,501	\$6,349,318

The ‘total operating revenue’ line item in Table 15 is the result of gross revenue minus any deductions for contractual allowances, bad debt, and charity care directly related to the combined level II level III cost center. The ‘total operating expenses’ line item includes staff salaries/wages and all direct expenses related to the cost center. As shown, the neonate program is currently meeting its direct expenses with sufficient excess to contribute to the hospital’s indirect expenses.

A summary of the financial projections for the hospital, including the proposed neonatal project, is shown in Table 16 below.

Table 16
Years 2011 through 2013
PRMCE with Level II and Level III Project
Projected Statement of Operations Summary

	Projected Year 1 (2011)	Projected Year 2 (2012)	Projected Year 3 (2013)
Total Operating Revenue	\$536,323,000	\$556,968,000	\$573,071,000
Total Operating Expenses	\$513,560,000	\$537,405,000	\$548,981,000
Net Profit or (Loss)	\$22,763,000	\$19,563,000	\$24,090,000

As shown in Table 16 above, when the forecasts for the hospital as a whole are reviewed, the hospital as a whole is meeting its total financial needs.

To assist the department in its evaluation of this sub-criterion, the department's Hospital and Patient Data Systems (HPDS) provided a summary of the short and long-term financial feasibility of the project, which includes a financial ratio analysis. The analysis assesses the financial position of an applicant, both historically and prospectively. The financial ratios typically analyzed are: **1)** long-term debt to equity; **2)** current assets to current liabilities; **3)** assets financed by liabilities; **4)** total operating expense to total operating revenue; and **5)** debt service coverage. If a project's ratios are within the expected value range, the project can be expected to be financially feasible. Additionally, HPDS reviews a project's three-year projected statement of operations to evaluate the applicant's immediate ability to finance provide the service and long term ability to sustain the service.

HPDS compared the financial health of PRMCE to the statewide 2008 financial ratio guidelines for hospital operations. HPDS also included the financial ratios for the proposed project for years 2011-2013, or three years after project completion. Table 17 summarizes the comparison provided by HPDS. [Source: HPDS analysis, p2]

Table 17
Current and Projected HPDS Debt Ratios for PRMCE and NICU Expansion Project

Category	Trend ⁹	State 2008	PRMCE 2009	Application Project Only		
				Projected 2013	Projected 2014	Projected 2015
Long Term Debt to Equity	B	0.527	1.442	0.500	0.451	0.405
Current Assets/Current Liabilities	A	1.877	1.107	1.483	1.588	1.592
Assets Funded by Liabilities	B	0.436	0.649	0.427	0.403	0.382
Operating Exp/Operating Rev	B	0.949	0.926	0.958	0.965	0.958
Debt Service Coverage	A	4.701	7.628	1.928	1.644	1.718
Definitions:	Formula					
Long Term Debt to Equity	Long Term Debt/Equity					
Current Assets/Current Liabilities	Current Assets/Current Liabilities					
Assets Funded by Liabilities	Current Liabilities + Long term Debt/Assets					
Operating Expense/Operating Rev	Operating expenses / operating revenue					
Debt Service Coverage	Net Profit+Depr and Interest Exp/Current Mat. LTD and Interest Exp					

Comparing PRMCE's most current (2009) ratios with the statewide ratios (2008) revealed that the hospital is outside the normal range in three of five ratios. After evaluating the hospital's projected ratios and statement of operations for years 2013-2015, staff from HPDS provided the following analysis. [Source: HPDS analysis, p3]

"PRMCE is in the middle of a \$500 million plus construction project. The ratios are affected by this project as during the CON years the increase in depreciation, interest expense and debt payment compared to 2009 are significant. The hospital is still operating with a profit and the financial ratios are improving over the pro-forma period. The hospital has had an above average financial foundation in the past."

The capital expenditure for this project was \$3,933,590 and was incurred in 2002. The project is already completed and no further funds will be expended. HPDS provides a summary of the balance sheets from the application in Table 18 below.

Table 18
PRMCE Regional Medical Center Balance Sheet for Current Year 2009

Assets		Liabilities	
Current	\$ 83,105,782	Current	\$ 75,070,816
Board Designated	\$ 3,752,734	Long Term Debt	\$265,732,573
Property/Plant/Equip	\$ 406,452,406	Total Liabilities	\$340,803,389
Other	\$ 31,767,062	Equity	\$184,274,595
Total Assets	\$525,077,984	Total Liabilities and Equity	\$ 525,077,984

This project will not adversely impact reserves, or total assets, total liability or the general health of the hospital in a significant way. Based on the information above, the department

⁹ A is better if above the ratio, and B is better if below the ratio.

concludes that the immediate and long-range 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.

PRMCE identified a capital expenditure for this project of \$3,933, 590. The costs are broken down in Table 19 below.

**Table 19
PRMCE’s Capital Cost Breakdown**

Breakdown Of Costs	Total	% Of Total
Construction Costs	\$1,538,645	39.3 %
Moveable Equipment	\$1,249,391	31.8%
Fixed Equipment	\$71,264	1.8%
Architect / Consulting Fees	\$399,967	10.2%
Site Preparation	\$73,653	1.9%
Consulting Fees	\$10,661	0.3%
Supervision & Inspection of Site	\$36,879	0.9%
Washington State Sales Tax	\$468,100	11.9%
Other	\$85,030	2.2%
Total	\$3,933,590	100.00%

To further assist the department in its evaluation of this sub-criterion, HPDS reviewed the financial data reported by the hospital. Staff from HPDS provided the following analysis.

[Source: HPDS analysis, p3]

“There are several ways to review hospital newborn cost information. Hospitals report data to DOH through the financial format and the hospital inpatient format. In the financial reporting system, hospitals can report all newborn revenue and expense for delivery and post partum care under account 6100 Alternative Birth Center or they can report it under 6170 Nursery for the baby only and 6070 Acute Care for the mom. Newborns that need intensive care are reported under 6010 Intensive Care, which also includes Adult and Pediatric patients. PRMCE currently uses 6100 Alternative Birth Center when it reports its year end data to DOH. This applications projected revenue and expense is in the middle for those hospitals that report only using 6100 Alternative Birth Center.”

HPDS also notes those newborn days in the intensive care unit are usually a small percent of the total. HPDS reviewed the hospital inpatient database (CHARS) for comparison data.

Revenue Code 0172 is level II care and 0173 is level III care in the CHARS database. HPDS calculated the average charges per day for those discharges that included Revenue Code 0172 and those for 0173. The average charge per day in 2009 in CHARS was similar to the projections in the applicant’s individual level II and level III pro-forma. [Source: HPDS analysis, p3] Based on that review, HPDS determined that the project costs to the patient and community appears to be comparable to current providers.

Based on the information above, the department concludes that the costs of the project will probably not result in an unreasonable impact on the costs and charges for health services. This sub-criterion is met.

C. Structure and Process (Quality) of Care (WAC 246-310-230) and the Year 2005 Washington State Perinatal Level of Care Guidelines.

Based on the source information reviewed and the applicant’s agreement to the terms identified in the “Conclusion” section of this evaluation, the department determines that the applicant has met the structure and process (quality) of care criteria in WAC 246-310-230 and is consistent with the 2005 Washington State Perinatal Level 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.

As stated in the project description portion of this evaluation, PRMCE is currently offering level II and level III services. PRMCE staffs according to acuity the neonatal patients currently in the unit. The applicant is not anticipating any change in staffing or facility resources with this project. Any impact on staffing as a direct result of increased patient volumes and staffing would be adjusted as appropriate to meet the needs of the neonatal patients. The total FTE counts shown in Table 20 reflect the current staffing levels for the neonatal unit as a whole. The ancillary departments adjust their staffing ratios appropriately to meet the needs of the units they are serving. [Source: Application, p40]

**Table 20
PRMCE’s Current FTE’s Neonatal Unit**

PRMCE's Newborn	Current # of FTE's
Direct Staff (RN/LPN)	41.00
Management	4.75
Clerical	4.20
Vacation, Holiday, Sick	12.44
Staffing Totals	62.39

Source: Application, p40

PRMCE states that it expects no difficulty in retaining FTEs for a variety of reasons. The applicant offers a competitive wage scale and benefits package. In addition they offer internal residency programs to provide specific skills needed for staffing the neonatal unit. [Application, p39 &40]

PRMCE has a contract with Seattle Children's Hospital to manage and staff their neonatal unit. In addition to the staff identified in Table 19 above, PRMCE identified their key medical staff for the neonatal unit. The physicians, Frank Anderson, MD, and Donald Barford, MC are both board certified in maternal-fetal medicine, and Michael Neufeld, MD is board certified in neonatology.

The applicant further describes their neonatal unit staffing as follows:

"Since 2000, PRMCE has contracted with Providence-Children's Neonatal Services, LLC to provide management and oversight of care in the Level II/III Unit. The partners of Neonatal Services, LLC are Seattle Children's Hospital (Children's) and Providence Regional Medical Center Everett. Children's manages the unit. Neonatologists are available by contract from the Children's Hospital University Medical Group. Neonatal nurse practitioners are provided by contract with Children's. We also contract with the University of Washington Medical Group for Maternal Fetal Medicine physicians." [Source: Application, p10 & Appendix 6]

These key medical staff positions are further evaluated in conjunction with the department's evaluation of the project's conformance with the Washington State Perinatal Levels of Care guidelines shown below. These guidelines detail the requirements for the services supporting the neonatal units.

Washington State Perinatal Levels of Care Guidelines

As part of its evaluation of structure and process of care criteria found under WAC 246-310-230, the department uses the standards of care guidelines outlined in the Washington State Perinatal Levels of Care Criteria as guidance in evaluating this project. The guidelines, adopted by the Perinatal Advisory Committee on February 2005, offer recommendations on facility and staffing standards for level II and level III services. Within the guidelines, level II services are separated into A and B categories, and level III services are separated into A, B, and C -- with A being the least intensive and C as the most intensive. The Perinatal Levels of Care Criteria recommend that an applicant be providing the previous level of services before applying for the next higher level. PRMCE is already providing level I, level II, and level III care. PRMCE has CN approval to provide level III services (both A and B) with 6 bassinets and is proposing to increase to 16 bassinets.

PRMCE provided a comparison chart as verification and documentation that its proposed level IIIB services currently meet or exceed the advisory committee's recommended guidelines. The department will compare this project using level IIIB guidelines. The applicant is not requesting, and will not be evaluated, on standards for level 3C services which require separate approval. If the department approves this project, that approval would not include level IIIC care. [Source: June 7, 2010 Response to Screening Questions, Attachment 2] The chart outlined on the following pages shows the comparison.

PRMCE and Perinatal Levels of Care Criteria Comparison

GUIDELINE	PRMCE	Pass/Fail
General Function		Pass
<p><u>All Level IIIA functions plus:</u> Diagnosis and management of all complicated pregnancies and neonates at all gestational ages.</p> <p>Advanced respirator support (such as high frequency ventilation and inhaled nitric oxide)</p> <p>Immediate consultation from pediatric surgical sub-specialists for diagnosis of complications of prematurity and capabilities to perform surgery on-site or at a closely related institution, which would ideally be in geographic proximity and share coordinated care, such as physician staff.</p>	<p>PRMCE’s NICU is staffed to accept and care for most complicated pregnancies of all gestational ages. We provide mechanical ventilation and perform procedures for central venous catheters.</p> <p>Advanced respiratory support including high frequency ventilation and inhaled nitric oxide</p> <p>PRMCE’s NICU, through its relationship with Seattle Children’s, provides immediate consultation from pediatric surgical subspecialists</p> <p>Regional Perinatal Center</p> <p>Perinatal data base for QI and outcomes monitoring</p> <p>Developmental follow-up of high risk neonates</p>	
Neonatal Patients: Services and Capabilities		Pass
<p><u>All Level IIIA patients and services plus:</u> <u>Level IIIB-</u> Infants of all gestational ages</p> <p>Capabilities to perform surgery to treat acute surgical complications of prematurity on-site or at a closely related institution, which would ideally be in geographic proximity and share, coordinated care, such as physician staff.</p> <p>Capabilities for advanced respirator support (such as high frequency ventilation and inhales nitric oxide, are of severely ill neonates requiring mechanical ventilation</p> <p>Capabilities for advanced imaging with interpretation on an urgent basis, including CT, MRI, and echocardiography</p> <p>Average daily census of at least 10 Level II /level III patients</p>	<p>PRMCE can provide care to the neonates of all gestational ages.</p> <p>Capabilities perform surgery at a closely related institute located 28 miles away that shares coordinated care including physician staff</p> <p>PRMCE’s NICU provides advanced respiratory support and advanced imaging</p> <p>Advanced imaging with interpretation on an urgent basis including CT, MRI, and echocardiography</p> <p>PRMCE reports that 2009 CHARS data demonstrates a current ADC of 22 (when combining level II and level III data)</p>	

GUIDELINE	PRMCE	Pass/Fail
Obstetrical Patients: Services and Capabilities		Pass
<u>Level IIIA patients and services plus:</u> <u>Level IIIB</u> Pregnancies at all gestational ages Capabilities include diagnosis and treatment of all perinatal problems	<u>Level IIIA patients and services plus</u> PRMCE treats pregnancies of all gestational ages and has the capability to diagnose and treat all Perinatal problems.	

GUIDELINE	PRMCE	PASS/FAIL
Patient Transport		Fail
<p>All hospitals demonstrate capabilities to stabilize and initiate transport of patients in the event of unanticipated maternal-fetal newborn problems that require care outside the scope of the designated level of care. Access to return transport services may be a necessary capability for Level IIIA and Level IIIB intensive care nurseries.</p> <p>Transport patients:</p> <p>Who are anticipated to deliver a neonate of earlier gestational age than appropriate for the facility's designated level of care in accordance with the law and should not transport if the fetus or mother is unstable or delivery is imminent.</p> <p>Whose illness or complexity requires services with a higher level of care than provided at the admitting facility. For neonatal transport, refer to AAP reference titled, "Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients."</p> <p>A hospital that transports patients to a higher level of care should:</p> <p>Demonstrate on-going relationships with referral hospital(s) for education, immediate consultation, urgent transport facilitation, and quality assurance</p> <p>Establish a written policy and procedure for maternal and neonatal transport that includes an established triage system for identifying patients at risk who should be transferred to a</p>	<p>Level IIIB with ability to stabilize and initiate transport of patients needing care beyond Level IIIB and provide return transport services.</p> <p>Transport services are currently contracted. PRMCE is in the process of developing an internal transport team with an anticipated implementation date of Fall 2010. No written policies and procedures for this proposed transport team were provided by PRMCE</p> <p>PRMCE provided a transportation contract with Seattle Children's Hospital.</p> <p>PRMCE provided a copy of the transportation agreement with their contractor. This agreement does not contain the written transport policies and procedures.</p>	<p>PRMCE did not provide a written policies and procedures for maternal and neonatal transport. Therefore, a term is necessary to ensure this guideline is met</p>

<p>facility that provides the appropriate level of care</p> <p>Establish guidelines that ensure a provider's continuing responsibility for and care of the patient until transport team personnel or receiving hospital personnel assume full responsibility for the patient.</p> <p>A hospital that accepts maternal or neonatal transports in order to provide a higher level of care than is offered at the referral hospital, should:</p> <p>Participate in perinatal and /or neonatal case reviews at the referral hospital</p> <p>Collaborate with state contracted Perinatal center for coordinating outreach education</p> <p>Maintain a 24 hr/day system for reliable, comprehensive communication between hospitals for immediate consultation, initiation, and approval of maternal and newborn transports</p> <p>Provide referring physicians with ongoing communication and recommendations for ongoing patient care at discharge.</p>	<p>PRMCE provided a utilization review policy that did not address this issue</p> <p>Policy to be requested as a term by the department if approved</p> <p>PRMCE is a Regional Perinatal Center</p>	
Medical Director		Pass
<p><u>Obstetrics:</u> board certified in maternal-fetal medicine</p> <p><u>Nursery:</u> board-certified in neonatology</p>	<p>Obstetrics: Board-certified in maternal-fetal medicine</p> <p>Nursery: Board certified in neonatology</p>	

GUIDELINE	PRMCE	Pass/Fail
Medical Providers		Pass
<p><u>Level IIIA staff plus:</u> <u>Obstetrics</u> Immediate availability of an obstetrician with demonstrated competence in the management of complicated labor and delivery patients.</p> <p><u>Newborn:</u> Immediate availability of neonatologist, pediatrician, or neonatal nurse practitioner with demonstrated competence in the management of severely ill neonates, including those requiring mechanical ventilation</p>	<p>Obstetrics: immediate availability of an obstetrician with demonstrated competence in the management of complicated labor and delivery patients.</p> <p>Newborn: immediate availability of neonatologists, pediatrician, or neonatal nurse practitioner with demonstrated competence in the management severely ill neonates, including those requiring mechanical ventilation</p>	
<p><u>Level IIIA staff plus:</u> Anesthesiologist skilled in pediatric anesthesia on call</p> <p>Pediatric imaging, including CT, MRI, and echocardiography services and consultation with interpretation available on an urgent basis</p>	<p>Level IIIA staff plus:</p> <p>Anesthesiologist skilled in pediatric anesthesia on-call</p> <p>Pediatric imaging including CT, MRI, and echocardiography services and consultation with interpretation available on an urgent basis</p>	
Nurse: Patient Ratio		PASS
<p>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 assertive 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 (ref 3)</p> <p><u>Intrapartum:</u> 1:2 patients in labor 1:2 induction or augmentation of labor 1:1 patients in second stage labor 1:1 patients with medical or obstetric complications 1:1 coverage for initiating epidural anesthesia 1:1 circulation for cesarean delivery</p> <p><u>Antepartum/postpartum</u> 1:6 patients without complications</p>	<p>PRMCE adheres to these staffing parameters for intrapartum, antepartum, postpartum, newborns, and neonates requiring all levels of care</p>	

GUIDELINE	PRMCE	Pass/Fail
<p>1:4 recently born neonates and those requiring close observation</p> <p>1:3-4 normal mother-baby couplet care</p> <p>1:3 antepartum/postpartum patients with complications but in stable condition</p> <p>1:2 patients in post-op recovery</p> <p>Newborns</p> <p>1:6-8 neonates requiring only routine care*</p> <p>1:4 recently born neonates and those requiring close observation</p> <p>1:3-4 neonates requiring continuing care</p> <p>1:2-3 neonates requiring intermediate care</p> <p>1:1-2 neonates requiring intensive care</p> <p>1:1 neonates requiring multisystem support</p> <p>1:1 or greater unstable neonates requiring complex critical care</p> <p>*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 nurse's direct supervision. Adequate 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.</p>		

GUIDELINE	PRMCE	Pass/Fail
<i>Nursing Management</i>		
<p><u>Level IIB through Level IIIC</u></p> <p>Same as Level I plus:</p> <p>Advanced degree is desirable</p>	<p>Level 1 plus advanced degrees as follows:</p> <p>Nurse manager of the ICU: RN license, BSN, MS. Directs nursery services, guides nursery policies (with NICU CNS), collaborates with medical staff, and consults with higher level of care as necessary.</p> <p>Nurse manager of Family Maternity Center. RN license, BSN. Directs perinatal/nursery services, guides perinatal/nursery policies (with Family Maternity Center and NICU/CNS); consults with higher level of care as necessary</p>	<p>Pass</p>

GUIDELINE	PRMCE	Pass/Fail
<i>Support Providers: Pharmacy, Nutrition/Lactation and OT/PT</i>		Pass
<p><u>Level IIIB</u> <u>Pharmacy services</u> - same as Level IIIB</p> <p><u>Nutrition/Lactation</u> At least one registered dietitian/nutritionist who has special training in perinatal nutrition and can plan diets that meet the special needs of high-risk mothers and neonates</p> <p><u>OT/PT</u> Provide for inpatient consultation and outpatient follow-up- services</p>	<p><u>Pharmacy services</u> A registered pharmacist with experience in neonatal/Perinatal pharmacology is available 24/7</p> <p><u>Nutrition/Lactation</u> A registered dietician who has special training in perinatal nutrition and plans diets that meet the special needs of high-risk mothers and neonates is on staff 7 days per week.</p> <p>IBCLC certified lactation consultant rounds in unit 6 days a week and available 7 days per week.</p> <p><u>OT/PT</u> Inpatient consultation and outpatient follow-up services available 5 days per week</p>	
<i>Support Providers: Social Services/Case Management, Respiratory Therapy, Nurse Educator/Clinical Specialist</i>		Pass
<p><u>Social Services/case management</u> Level IIB services plus: At least one full-time licensed MSW (for every 30 beds) who has experience with socioeconomic and psychosocial problems of high-risk mothers and babies, available 7 days/wk and 24 hrs/day</p> <p><u>Nurse Educator/Clinical Nurse Specialist</u> A nurse educator or clinical nurse specialist with appropriate training in intensive neonatal or perinatal care to coordinate staff education and development. Those educators already in this position should be grandfathered in until post-graduate education is completed.</p> <p><u>Respiratory Therapy</u> Level IIB plus: Ratio of one Respiratory Care Practitioner to six or fewer ventilated neonates with additional staff for procedures [1:6]</p>	<p><u>Social Services/case management</u> Level IIB services plus: Licensed MSW with experience with socioeconomic and psychosocial problems of high risk mothers and babies on staff and available 7/24.</p> <p><u>Nurse Educator/Clinical Nurse Specialist</u> 24 hour neonatal nurse practitioner services available to function as resources and education support for staff in increasing skills and knowledge base.</p> <p>A 0.75 FTE nurse education and 1.0 FTE CNS are available to staff</p> <p><u>Respiratory Therapy</u> Level IIB plus a minimum of 2 respiratory care practitioners are available in the unit 24/7.</p>	

GUIDELINE	PRMCE	Pass/Fail
<i>X-Ray Ultrasound</i>		Pass
Level IIB services plus: Advanced level ultrasound available to Labor & Delivery and Nursery on-site and on a daily basis	Level IIB services plus advanced level ultrasound available 24/7.	
<i>Laboratory and Blood Bank Services</i>		Pass
<u>Laboratory</u> Comprehensive services available 24 hrs/7days	Comprehensive services 24/7	
<u>Blood Bank</u> 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	Technician on staff and blood/blood products available on an emergent basis 24/7.	

In addition to the comparison chart provided on the previous pages, PRMCE also provided the following documents to further demonstrate that it meets the existing standards of care with its level IIB services:

- Neonatal Program Management Services Agreement between Providence-Children’s Neonatal Services, LLC and PRMCE;
- PRMCE Medical Center Utilization Review Policy
This policy is designed to determine whether a patient meets the criteria for admission and continued stay criteria for the hospital and to assist in the patients needs at discharge.
[Source: Application, pg226 &227]

PRMCE also offers the following related services:

- Midwifery Services
- Providence Everett Healthcare clinic
- Providence Intervention Center for Assault and Abuse
- Camp Prov
- Camp Erin
- Providence Children’s Center
- Providence International Missions Program

Based on the information provided by PRMCE in its application and supplemental documentation, and acceptance of the terms related to the policies, guidelines and collaborations outlined above, the department concludes that, if approved, PRMCE’s level II and level III project would be consistent with the Washington State Perinatal Levels of Care guidelines. As a result, 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.

This sub-criterion was extensively evaluated within the sub-criterion above, and is determined to be 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.*

PRMCE will continue to provide Medicare and Medicaid services to the residents of Snohomish County and surrounding communities. The hospital contracts with the Joint Commission to survey and accredit the quality of service provided. The Joint Commission lists PRMCE in full compliance with all applicable standards following the most recent on-site survey in April 2010.¹⁰

Complementing reviews performed by the Joint Commission are the surveys conducted by the department's Investigation and Inspection's Office (IIO). For the most recent two years, IIO completed one licensing survey at the hospital.¹¹ There were no adverse licensing actions as a result of the survey. [Facility survey data provided by DOH Investigations and Inspections Office]

The majority of PRMCE's level II staff is already in place for the existing level II service. PRMCE provided names and professional license number for all credentialed staff. Quality of care for PRMCE's staff is verified through the Department of Health's Medical Quality Assurance Commission. The commission credentials medical staff in Washington State and is used to review the compliance history for all medical staff, including physicians, RNs, and licensed technicians. A compliance history review of all medical staff associated with PRMCE's family birth center and special care nursery reveals no recorded sanctions. [Compliance history provided by Medical Quality Assurance Commission]

Based on PRMCE's compliance history and the compliance history of the licensed staff associated with the neonatal unit, the department concludes that there is reasonable assurance that the hospital would continue to operate in conformance with state and federal regulations with the addition of level III services. This sub-criterion is met.

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

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

¹⁰ <http://www.qualitycheck.org>

¹¹ Survey completed October 24, 2008.

In response to this sub-criterion, PRMCE restates that it is the only recognized level III provider in the four county planning area. The redistribution of level II and level III bassinets proposed in this project will enable PRMCE to retain mothers and infants rather than having to transfer them to level III units in other planning areas. This will also allow PRMCE to accept more infants needing level III care from other level II units located in this planning area. Thus the program promotes continuity and lack of fragmentation.

The above response provided by PRMCE addresses continuity of care for PRMCE, however, continuity of care is not limited by a facility. Depending on the patient's needs, continuity of care may include transport of the patient to the most appropriate provider. For tertiary services, continuity of care means a hospital's ability and willingness to triage and transport as necessary to the most appropriate tertiary provider. For level III patients, this could mean that the patient would be transported to a physician or physician group who has not previously seen the patient. In this case, continuity of care also means that the referring hospital provides specific patient information and documentation to the receiving facility.

Additionally, continuity of care also includes the communication and sharing of patient information between physicians in different facilities or physicians within the same facility. With a tertiary program, where there is a direct connection among sufficient patient volumes and provider effectiveness, quality of service, and improved outcomes of care, the department concludes that the establishment of a quality provider in this health care service is far more critical than patient, family, or physician convenience.

Information provided in PRMCE's application also addresses this concept of continuity of care. The working relation formed with Seattle Children's Hospital directly addresses some of these complications and minimizes the need to transport of critically ill neonates from the hospital. PRMCE also contacts with Seattle Children's Hospital to provide neonatal nurse practitioners. In addition, PRMCE contracts with the University of Washington Medical Group for maternal fetal medicine physicians. [Source: Application, p10] Transfers from PRMCE would often be made to Seattle Children's Hospital or the University Of Washington Medical Center.

The department concludes that there is reasonable assurance that approval of this project would allow residents access to approved quality level III service. Further, PRMCE's relationships within the existing health care system would continue and are not likely to result in an unwarranted fragmentation of services. This sub-criterion is met.

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

This sub-criterion is also addressed in sub-section 3 above. This sub-criterion is met

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

Based on the source information reviewed and the applicant's agreement to the terms identified in the 'conclusion' section of this evaluation, the department determines that the applicant has met the cost containment criteria in WAC 246-310-240(1), (2), and (3).

(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, PRMCE has met the review criteria under WAC 246-310-210, 220, and 230. Additionally, PRMCE has met the service specific review criteria identified in the Washington State Perinatal Levels of Care Criteria adopted by the Perinatal Advisory Committee on February 2005. Therefore, the department moves to step two below.

Step Two

Before submitting this application, PRMCE considered two alternatives to the application that was submitted. Below is a summary of PRMCE's alternatives and the rationale for rejecting them. [Source: Application p45]

Do nothing and continue operating as presently with 23 Level II and 6 Level III bassinets.

This option was considered unacceptable by PRMCE from a patient access, continuity of care and regulatory perspective. The option does not address the issue of improving access and flexibility by increasing the number of level III bassinets. This alternative also does not have any requirements for additional capital or space. However, this alternative also

leaves the operation of the majority of PRMCE's bassinets unlicensed and subject to regulatory action. PRMCE rejected this alternative.

Increase the number of level II and level III bassinets.

The need calculations performed by the applicant indicate that PRMCE could be approaching a high level of occupancy for its existing unit by 2014. If the applicant achieves the growth of patient days projected in the need calculations, they could experience a need for additional level III bassinets. While level II services could be provided by other providers in the four-county planning area, PRMCE is the only provider of level III services in the planning area. This option was rejected by the applicant since it would require capital funding and space for the additional neonatal services. PRMCE currently does not have the financial and space resources for this.

Taking into account the results of the numeric need methodology and the availability of other providers of level II services in the planning area, the department concurs with PRMCE's rejection of the two alternatives above.

Step Three

This step is used to determine between two or more approvable projects which is the best alternative. There was no other projected submitted requesting to establish a level II or level III services within the four-county planning area. As a result, this step is not applicable to this project.

Based on the information above, the department concludes this project is the best available alternative for this planning area. This sub-criterion is met.

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

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

This project does not require construction of level II or level III space at PRMCE. This sub-criterion is primarily 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) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

This project does not require construction of level II or level III space at PRMCE. This sub-criterion is primarily 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.

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

This project has the potential to improve delivery of level II and level III services to the residents in Snohomish, Skagit, Island, and Whatcom counties by reducing the number of transfers allowing for minimal interruptions of treatment and staffing continuity. This sub-criterion is met.